Self-Care and Chronic Disease
Self-Care and Chronic Disease

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Editorial
Self-Care and Chronic Disease

Victoria Vaughan Dickson,¹ Robyn A. Clark,² Eneida Rejane Rabelo-Silva,³ and Harleah G. Buck⁴

¹ College of Nursing, New York University, 726 Broadway, 10th Floor, New York, NY 10003, USA
² Flinders University, Bedford Park, SA 5042, Australia
³ School of Nursing at Federal University of Rio Grande do Sul, Porto Alegre, RS, 90620-110, Brazil
⁴ School of Nursing, Pennsylvania State University, University Park, PA 16802, USA

Correspondence should be addressed to Victoria Vaughan Dickson; vdickson@nyu.edu

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Chronic diseases are the leading cause of death and disability worldwide. They account for almost 60% of all deaths and 43% of the global burden of disease [1]. This is expected to markedly increase with chronic disease contributing 73% of all deaths and 60% of the global burden of disease by 2020 [1]. The most prevalent chronic diseases—cardiovascular diseases, cancer, and type 2 diabetes—are linked by common and preventable biological risk factors (i.e., high blood pressure, dyslipidemia, and obesity) as well as major behavioral risk factors including unhealthy diet, physical inactivity, and tobacco use. Patient centered care, which includes self-care or self-management, is a fundamental concern for nursing and essential to the prevention and management of chronic diseases [2]. In fact, leading agencies across the globe currently emphasize the importance of patients’ self-management of chronic illness symptoms and treatment. This is an international problem requiring international collaboration to address the needs of this at-risk group [3].

In this issue, the international community of nurse scientists and clinicians has contributed to an increased understanding of the multidimensional influences on self-care in chronic disease by describing predictors of self-care and related outcomes and effective strategies to help people with chronic illness improve their health and quality of life. In addition the ongoing gaps in the science of self-care are highlighted.

We are pleased to include the findings of studies from nurse scientists in Australia, Brazil, Iran, Republic of Korea, Portugal, and the United States in the three most common chronic disease populations—cardiovascular disease, cancer, and type 2 diabetes. Topics covered in this special issue include predictors of self-care in Brazilian patients with heart failure following six months of home visits; the influence of health literacy on heart failure knowledge and self-care in the USA; a supportive educational program that improved self-care among Iranian adults with chronic heart failure; and the cross-cultural adaptation and psychometric testing of the Brazilian version of the Self-Care of Heart Failure Index version 6.2. As heart failure reaches epidemic proportions in all parts of the world [4], these papers add to our understanding of the influences of heart failure self-care and help to advance the science by addressing the need for culturally appropriate measurement and interventions.

The importance of providing holistic nursing care to Portuguese patients with cancer is highlighted by S. M. O. Pinto et al. In this study, authors described the importance of religious beliefs, optimism, and being well-informed as contributing to quality of life among patients undergoing chemotherapy and the essential role of nurses throughout the process.

Another global chronic disease on the rise is diabetes. The number of adults with diabetes is expected to increase from 366 million in 2011 to 552 million by 2030 [5]. A. Thomas and A. Ashcroft address an important and understudied population, individuals who undergo acculturation from traditional to modern life style with resulting increased risk
for type 2 diabetes. As the global population becomes increasingly mobile, understanding increased risk from changes in lifestyle behaviors like physical activity and dietary choices is increasingly important for all nurses.

Finally, despite the advances in nursing research of self-care and chronic disease over the past few decades, the literature reviews in this special edition remind us that there is still a great deal of conceptual and psychometric work to be done. Self-care in chronic disease is complex and there are significant limitations in the science including issues with precise yet pragmatic measurement of multiple chronic conditions, the need for rigorous scientific methodology, and, most importantly, addressing health equity issues by ensuring adequate representation of diverse populations in our research.

This special edition reminds us that the global nursing community shares common concerns and challenges as well as overarching, common goals. As the number of individuals with chronic diseases like cardiovascular disease, cancer, and diabetes continues to increase, it is imperative that we as nurse scientists and nurse clinicians collaborate to improve the health and quality of life of patients with chronic disease worldwide.

Victoria Vaughan Dickson
Robyn A. Clark
Eneida Rejane Rabelo-Silva
Harleah G. Buck

References


Research Article

Health Literacy and Global Cognitive Function Predict E-Mail but Not Internet Use in Heart Failure Patients

Jared P. Schprechman,1 Emily C. Gathright,2,3 Carly M. Goldstein,2,3 Kate A. Guerini,2 Mary A. Dolansky,4 Joseph Redle,3 and Joel W. Hughes2,3

1 Department of Biology, University of Akron, 302 East Buchtel Avenue, Akron, OH 44304, USA
2 Department of Psychology, Kent State University, P.O. Box 5190, Kent, OH 44224, USA
3 Summa Health System, 525 East Market Street, Akron, OH 44309, USA
4 Frances Payne Bolton School of Nursing, Case Western Reserve University, 10900 Euclid Avenue, Cleveland, OH 44106, USA

Correspondence should be addressed to Joel W. Hughes; jhughes1@kent.edu

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Background. The internet offers a potential for improving patient knowledge, and e-mail may be used in patient communication with providers. However, barriers to internet and e-mail use, such as low health literacy and cognitive impairment, may prevent patients from using technological resources. Purpose. We investigated whether health literacy, heart failure knowledge, and cognitive function were related to internet and e-mail use in older adults with heart failure (HF). Methods. Older adults (N = 119) with heart failure (69.84 ± 9.09 years) completed measures of health literacy, heart failure knowledge, cognitive functioning, and internet use in a cross-sectional study. Results. Internet and e-mail use were reported in 78.2% and 71.4% of this sample of patients with HF, respectively. Controlling for age and education, logistic regression analyses indicated that higher health literacy predicted e-mail (P < .05) but not internet use. Global cognitive function predicted e-mail (P < .05) but not internet use. Only 45% used the Internet to obtain information on HF and internet use was not associated with greater HF knowledge. Conclusions. The majority of HF patients use the internet and e-mail, but poor health literacy and cognitive impairment may prevent some patients from accessing these resources. Future studies that examine specific internet and email interventions to increase HF knowledge are needed.

1. Introduction

Healthcare is experiencing a push towards the increasing use of electronic communication. The Health Information Technology for Economic and Clinical Health Act enables providers to receive incentive payments for transitioning to electronic medical records [1]. Allowing patient access to medical records electronically offers the potential to improve health outcomes [2, 3]. For example, electronic portals enable patients to securely communicate with their physician, request medication refills, and view lab results [4]. Electronic resources such as patient portals may even assist patients in disease self-management by tracking refill history and changes in health status. However, adoption has been limited. Although growing in popularity, only 7% of Americans utilize patient portals [5].

However, internet use among older adults is increasing. In 2005, approximately 30% of adults aged 65 and older reported ever using internet or e-mail, and only 46% of those who used the internet reported daily internet use [6]. More recent estimates suggest that 53% of American adults aged 65 and older report internet or e-mail use and that 70% of those regularly use the internet [7]. As internet use increases, older adults will be better suited to take advantage of electronic resources for healthcare purposes. However, previous estimates of internet use in older adults have not focused on individuals with chronic diseases such as heart failure. As patient portals increase in popularity, patients with chronic conditions requiring considerable symptom monitoring, such as heart failure, may be more likely to access electronic resources for disease self-care. These electronic resources may provide
the tools needed to reduce the burden of extensive self-management.

The prevalence of internet and email use among patients with heart failure is not currently known, and heart failure patients may have barriers limiting their ability to successfully navigate electronic resources and apply information. Barriers known to be prevalent in heart failure patients include low health literacy, poor heart failure self-management knowledge, and cognitive impairment. These barriers are associated with decreased compliance [8], increased rehospitalization [9], and increased mortality [10, 11]. Low health literacy is associated with poorer condition-related knowledge [12–14] including worse heart failure knowledge [15]. Adults with limited health literacy struggle to search for pertinent health information on the internet [16]. Heart failure patients with cognitive impairment may also have difficulty navigating the internet. Although cognitive impairment is prevalent in heart failure [17–19], no studies have explored whether cognitive impairment impacts electronic resource use and electronic communication in heart failure patients. Finally, whether patients who use the internet and e-mail have used these resources to gain disease-specific knowledge has not been investigated.

Despite increasing internet use among older adults, it is unclear whether internet and e-mail use among heart failure patients are influenced by health literacy or cognitive impairment and whether internet use relates to increased heart failure knowledge. The current study sought to investigate patterns of electronic resource use among older adults with heart failure and whether heart failure patients who report internet and e-mail use have higher health literacy and less cognitive impairment than heart failure patients who do not use internet or e-mail. Additionally, the present study explored whether heart failure patients who use the internet demonstrate more heart failure-related knowledge than individuals who do not use the internet.

2. Methods

2.1. Participants. The sample consisted of 119 English-speaking older adults with systolic heart failure who were participating in an NIH-funded study examining cognitive function and self-management in older adults with heart failure. The participants were community-dwelling adults living independently, often with a spouse. Participants were 50 to 85 years of age diagnosed as New York Heart Association (NYHA) heart failure class II or III with documented left ventricular ejection fraction less than 40% confirmed by a medical chart review. Participants were excluded if they had untreated sleep apnea, renal failure requiring dialysis, developmental disability impacting functions of daily living, history of substance abuse, neurological disorder (e.g., dementia, stroke), psychotic disorder (e.g., schizophrenia), terminal illness, CABG surgery within the previous 3 months, or head injury with greater than 10 minutes loss of consciousness according to their self-report. See Table 1 for participant demographics.

<table>
<thead>
<tr>
<th>Table 1: Demographic characteristics (n = 124).</th>
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<tbody>
<tr>
<td>Age (years)</td>
</tr>
<tr>
<td>69.85 (9.20)</td>
</tr>
<tr>
<td>Sex</td>
</tr>
<tr>
<td>Male</td>
</tr>
<tr>
<td>Female</td>
</tr>
<tr>
<td>Race</td>
</tr>
<tr>
<td>Caucasian</td>
</tr>
<tr>
<td>Non-Caucasian</td>
</tr>
<tr>
<td>Education level</td>
</tr>
<tr>
<td>8th grade or less</td>
</tr>
<tr>
<td>9th to 11th</td>
</tr>
<tr>
<td>High school</td>
</tr>
<tr>
<td>Technical or trade</td>
</tr>
<tr>
<td>Some college</td>
</tr>
<tr>
<td>Bachelor’s degree</td>
</tr>
<tr>
<td>Master’s degree</td>
</tr>
<tr>
<td>Employment status</td>
</tr>
<tr>
<td>Retired</td>
</tr>
<tr>
<td>Retired but work part time</td>
</tr>
<tr>
<td>Retired but work full time</td>
</tr>
<tr>
<td>Work part time</td>
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<tr>
<td>Work full time</td>
</tr>
<tr>
<td>Homemaker</td>
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<tr>
<td>Marital status</td>
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<tr>
<td>Never married</td>
</tr>
<tr>
<td>Married</td>
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<tr>
<td>Widowed</td>
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<tr>
<td>Separated</td>
</tr>
<tr>
<td>Divorced</td>
</tr>
<tr>
<td>Current living arrangements</td>
</tr>
<tr>
<td>Live alone</td>
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<tr>
<td>Live w/a spouse</td>
</tr>
<tr>
<td>Live w/a friend permanently</td>
</tr>
<tr>
<td>Live w/a family member temporarily</td>
</tr>
<tr>
<td>Live w/a family member permanently</td>
</tr>
</tbody>
</table>

2.2. Procedures. At baseline, participants completed demographic, medical, and psychosocial self-report measures. A brief neuropsychological battery was administered to assess multiple domains of cognitive functioning, including tests of global cognitive function, executive function, attention, and memory.

2.3. Measures

Heart Failure Connectivity. The Heart Failure Connectivity Questionnaire was created for this study to measure computer and internet use and patterns. This questionnaire was developed by adapting questions from a survey in the Kaiser Family Foundation 2005 Report e-Health and the Elderly: How Seniors Use the Internet for Health Information [6]. Fifteen questions were taken from the survey and altered to apply to heart failure patients. The questions assessed the
following: internet access and use, e-mail use, internet-related communication with healthcare professionals, reasons for not using a computer or internet, and heart-failure-related internet use.

METER. Health literacy was assessed using the Medical Term Recognition Test (METER) [20]. METER scores range from 0 to 40 with higher scores reflecting higher health literacy. Scores from 0 to 20 represent low health literacy. Scores from 21 to 34 represent marginal health literacy. Scores from 35 to 40 represent functional health literacy. The METER demonstrates high internal consistency (i.e., Cronbach's alpha = 0.93).

Dutch Heart Failure Knowledge Scale. The Dutch Heart Failure Knowledge Scale was used to assess general heart failure knowledge as well as knowledge related to symptoms, symptom recognition, and treatment (e.g., diet and fluid restriction) [21]. Scores range from 0 to 15, with higher scores indicating more heart failure knowledge.

3MS. The Modified Mini-mental State Examination is a short screening measure of global cognitive function, tapping aspects of memory, spatial abilities, and attention [22]. The 3MS includes a variety of short tasks such as letter sequencing, animal naming, mental reversal, and temporal orientation. This test takes approximately 7 minutes to complete and is sensitive to a range of cognitive impairments including Alzheimer's disease and other forms of dementia. Scores below 90 indicated cognitive impairment.

2.4. Analytic Strategy. Participant e-mail and internet use were described using descriptive statistics (%). Logistic regression was conducted to examine the relationship between health literacy and cognitive function and the dichotomous variables of internet use (0 = no internet use; 1 = internet use) and e-mail use (0 = no e-mail use; 1 = e-mail use). Analysis of covariance (ANCOVA) was used to determine whether heart failure knowledge differed between internet users and nonusers. Age and education were included as covariates. Statistical analyses were performed using SPSS for windows (version 20).

3. Results

Sample characteristics are presented in Table 1. Most participants reported internet access at home or work (82.4%), using the internet (78.2%) and using e-mail (71.4%). 23.5% of the sample were cognitively impaired. Few participants reported communication with a healthcare provider via the internet. Forty-five percent of the sample reported looking up heart failure on the internet (see Table 2). Most participants demonstrated “functional” health literacy (see Table 3). With regard to the Dutch Heart Failure Knowledge Scale, 79.8% of the patients had scores in the 11–15 range, and 20.2% of the patients had lower to marginal scores in the 7–10 range.

| Table 2: How connected are heart failure patients? |
|-----------------------------------------------|------|
| Has a doctor ever asked if you have internet access? | 28 (23.5) |
| Have you ever communicated with a doctor or another provider through e-mail? | 16 (13.4) |
| Has a doctor ever recommended a particular health/medical website? | 11 (9.2) |
| Have you ever looked up information about heart failure on the internet? | 54 (45.4) |

| Table 3: METER scores. |
|------------------------|------|
| Low health literacy (0–20) | 5 (4.2) |
| Marginal health literacy (21–34) | 17 (14.3) |
| Functional health literacy (35–40) | 97 (81.5) |

3.1. Health Literacy. Two separate logistic regression analyses were conducted to investigate whether METER scores predicted internet use and e-mail use after controlling for age and education. The results of the logistic regression for internet and e-mail use are presented in Tables 4 and 5, respectively.

3.2. Cognitive Function. Controlling for age and education, logistic regression indicated that individuals with higher 3MS scores were more likely to report e-mail use ($B = .08, P < .05$). METER scores did not predict internet use ($P = .06$).

3.3. Is Internet Use Related to Heart Failure Knowledge? ANCOVA between internet use and heart failure knowledge, controlling for age and education, revealed no effect of internet use on the Dutch Heart Failure Knowledge Survey, $F(1,116) = .089, P = .77$. Scores were similar in participants who reported internet use ($M = 12.24, SD = 1.89$) and those who reported no internet use ($M = 11.92, SD = 2.40$).

4. Discussion

Here we report that the majority of heart failure patients surveyed have internet access and use both the internet and e-mail. However, higher health literacy and better cognitive function predicted e-mail use but not internet use. Eventually, internet use may become ubiquitous among heart failure patients, which would limit the ability of patient characteristics to predict use. Of course, our patients were not randomly selected and may not be representative of all patients with heart failure. However, they were recruited from two large medical centers in the Midwest and were typically over 65 years of age. What was striking was the contrast between access and use of the internet and e-mail for heart failure-related purposes; few patients reported having discussed the
use of these resources with their physicians, and less than half reported using the internet to find information on heart failure.

Although there is little literature on use of the internet and e-mail by patients with heart failure, use of these resources will only increase and may hold promise for educating patients regarding heart failure and facilitating communication with healthcare providers. For example, a randomized trial of providing an online medical record to patients with heart failure reported that patients were able to use the system and that self-reported adherence to medications improved [23]. Furthermore, the American College of Cardiology has created a website (https://www.cardiosmart.org/) for patient education that includes many conditions including heart failure. Thus, thought leaders are anticipating a need for interventions using the internet should capture usage statistics to demonstrate an adequate “dose,” as mere access and use of available resources is important given that patients are expected to appropriately manage their health and respond to changes in symptoms [24].

In this sample, heart failure knowledge did not differ between internet users and individuals who do not use the internet. Many medical websites exist to provide heart failure-related information, but less than half (45.4%) of the sample reported having looked up heart failure on the internet. Whether information obtained on the internet can help to address poor self-care requires further study. Toward that end, a review of information regarding heart failure on the internet suggested that many websites provide primarily biomedical information as opposed to information designed to be useful to patients and recommended that healthcare providers carefully consider the content of websites prior to recommending them to patients [25]. We are unaware of any trials of internet-delivered patient education for heart failure.

However, there are many cases where the patients themselves are not solely in charge of their medical needs. It may be a family member, friend, or even a nurse who is in charge of making sure they take their medication or even bathing them. The internet could be a reliable tool for these caregivers if they have questions about the patient’s medications or notice some unusual symptoms. In fact, Fox and Brenner of the Pew Research Center [26] stated that “eight in ten caregivers (79%) have access to the internet. Of those, 88% look online for health information” (page 2). They also found that some of the searches that these caregivers made on the internet were for reviews of drugs, treatments, doctor, and even hospital facility ratings [26]. This Pew Report reflects that the internet can be a reliable tool for health information, even if it is not the patients themselves directly going online.

### 4.1. Limitations

Convenience sampling may limit the generalizability of these findings, and we did not intend for this to be an epidemiological investigation of rates of internet and e-mail use. Rates of use of electronic resources change rapidly, and we suspect that increasing numbers of patients with heart failure will be using the internet and e-mail. Although the Heart Failure Connectivity Questionnaire was a simple survey, the reliability is admittedly not known and the questions do not lend themselves to evaluation of internal consistency as they do not total up to create a score. Furthermore, the small sample may have limited power to find associations.

### 5. Conclusions

In sum, the current findings suggest that many heart failure patients can access and use the internet and that higher health literacy and cognitive functioning predict e-mail use, although this sample generally had functional health literacy and dementia was an exclusion criteria. Finally, less than half of the participants used the internet to obtain heart failure knowledge and use of the internet was not related to more heart failure knowledge when compared with individuals who did not report internet use. Electronic health educational resources, including patient portals and medical websites, may represent an untapped resource for bridging the gap between the healthcare team and patient self-management. Interventions using the internet should capture usage statistics to demonstrate an adequate “dose,” as mere access and

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**Table 4**: Logistic regression analysis predicting internet use from age, education, and health literacy (METER).

<table>
<thead>
<tr>
<th></th>
<th>B</th>
<th>SE B</th>
<th>e^b</th>
<th>95% C.I. for e^b</th>
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<tbody>
<tr>
<td>Age</td>
<td>−.03</td>
<td>.03</td>
<td>.97</td>
<td>.92–1.02</td>
</tr>
<tr>
<td>Education</td>
<td>.38*</td>
<td>.16</td>
<td>1.46</td>
<td>1.06–2.01</td>
</tr>
<tr>
<td>METER</td>
<td>.07</td>
<td>.04</td>
<td>1.08</td>
<td>.99–1.16</td>
</tr>
<tr>
<td>Constant</td>
<td>−1.07</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>χ²</td>
<td>10.92*</td>
<td></td>
<td></td>
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<tr>
<td>df</td>
<td>3</td>
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</table>

*P < .05.

**Table 5**: Logistic regression analysis predicting e-mail use from age, education, and health literacy (METER).

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<th>e^b</th>
<th>95% C.I. for e^b</th>
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</thead>
<tbody>
<tr>
<td>Age</td>
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<td>.02</td>
<td>.97</td>
<td>.92–1.01</td>
</tr>
<tr>
<td>Education</td>
<td>.45**</td>
<td>.16</td>
<td>1.56</td>
<td>1.16–2.12</td>
</tr>
<tr>
<td>METER</td>
<td>.08*</td>
<td>.04</td>
<td>1.09</td>
<td>1.01–1.17</td>
</tr>
<tr>
<td>Constant</td>
<td>−2.10</td>
<td></td>
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<tr>
<td>χ²</td>
<td>16.27**</td>
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<tr>
<td>df</td>
<td>3</td>
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*P < .05, **P < .01.

**Table 6**: Logistic regression analysis predicting e-mail use from age, education, and cognitive function (3MS).

<table>
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<tr>
<th></th>
<th>B</th>
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<th>e^b</th>
<th>95% C.I. for e^b</th>
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<tbody>
<tr>
<td>Age</td>
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<td>.98</td>
<td>.94–1.03</td>
</tr>
<tr>
<td>Education</td>
<td>.35*</td>
<td>.16</td>
<td>1.42</td>
<td>1.04–1.95</td>
</tr>
<tr>
<td>3MS</td>
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<td>.04</td>
<td>1.09</td>
<td>1.00–1.19</td>
</tr>
<tr>
<td>Constant</td>
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<td></td>
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<tr>
<td>χ²</td>
<td>15.20***</td>
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<tr>
<td>df</td>
<td>3</td>
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</tbody>
</table>

*P < .05, **P < .001.

Note: 3MS Modified Minimental State.
availability does not ensure use and patient learning. Future studies are needed to investigate the use of health care portal use among heart failure patients and methods to enhance their use.

Acknowledgment

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References

Review Article

Cardiovascular Disease Self-Care Interventions

Victoria Vaughan Dickson, 1 Jill Nocella, 2 Hye-Won Yoon, 1 Marilyn Hammer, 1 Gail D’Eramo Melkus, 1 and Deborah Chyun 1

1 College of Nursing, New York University, 726 Broadway, 10th Floor, New York, NY 10003, USA
2 Department of Nursing, William Paterson University, Wayne, NY 07470, USA

Correspondence should be addressed to Victoria Vaughan Dickson; vdickson@nyu.edu

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Background. Cardiovascular disease (CVD) is a major cause of increased morbidity and mortality globally. Clinical practice guidelines recommend that individuals with CVD are routinely instructed to engage in self-care including diet restrictions, medication adherence, and symptom monitoring. Objectives. To describe the nature of nurse-led CVD self-care interventions, identify limitations in current nurse-led CVD self-care interventions, and make recommendations for addressing them in future research. Design. Integrative review of nurse-led CVD self-care intervention studies from PubMed, MEDLINE, ISI Web of Science, and CINAHL. Primary studies (n = 34) that met the inclusion criteria of nurse-led RCT or quasiexperimental CVD self-care intervention studies (years 2000 to 2012) were retained and appraised. Quality of the review was assured by having at least two reviewers screen and extract all data. Results. A variety of self-care intervention strategies were studied among the male (57%) and Caucasian (67%) dominated samples. Combined interventions were common, and quality of life was the most frequent outcome evaluated. Effectiveness of interventions was inconclusive, and in general results were not sustained over time. Conclusions. Research is needed to develop and test tailored and inclusive CVD self-care interventions. Attention to rigorous study designs and methods including consistent outcomes and measurement is essential.

1. Introduction

Cardiovascular disease (CVD) is a major cause of morbidity and mortality worldwide [1]. It is estimated that 1 in 3 American adults have CVD. After age of 40, the lifetime risk of developing CVD is 49% for men and 32% for women [2]. Although advances in medical and surgical management of CVD have substantially reduced cardiac mortality rates in the United States (US), individuals with CVD remain at increased risk for further cardiac events, including unstable angina, myocardial infarction, and heart failure [1]. Cardiovascular disease in the US costs more than $108 billion each year [3], which includes the cost of health care services, medications, and lost productivity.

Individuals with CVD are routinely instructed to engage in self-care behaviors as part of daily disease management. Numerous terms are used interchangeably with self-care including self-management, self-regulation, self-monitoring, adherence, and compliance to describe the behaviors or activities in which patients are asked to engage in to promote health and well-being [4]. In the cardiovascular literature, self-care refers to adherence to treatment recommendations, symptom response, and adoption of healthy lifestyles like smoking cessation and weight management [5]. Education aimed at promoting these self-care behaviors is incorporated into all major clinical practice guidelines for CVD [6].

Self-care is a fundamental concern for nursing and a nursing research priority. In fact, the National Institute of Nursing Research (NINR) strategic plan [7] emphasizes patients’ self-management of chronic illness symptoms and treatment. To that end, there has been an increase in research efforts that seek to evaluate strategies that help people live with chronic
illness and maintain or improve their quality of life, develop self-management strategies to increase support systems and improve the patient’s and the family’s understanding of the chronic illness, and focus on coping with symptoms associated with chronic illness.

Generally, self-care interventions take place in several ways: on a one-to-one basis between the patient and health care provider; in disease-specific group education programs; in settings including clinical locations or at home; delivered by either peer leaders or health providers; and through interactive technology [8]. According to NINR, the primary goal of self-care including self-management interventions is to improve health and quality of life outcomes in patients with chronic conditions [7]. One way that interventions are hypothesized to be effective is by empowering patients to increase their understanding of their condition and take responsibility for their health; increasing self-efficacy is another common mechanism [8]. Researches targeting specific chronic conditions (e.g., diabetes, cancer, arthritis, HIV/AIDS) have found that self-care interventions are associated with condition-specific, patient-centered outcomes like improved glycemic control [9, 10], improved sleep [11], better pain control [12], and better functional status [13]. Less is known about the effects of self-care interventions on economic outcomes such as healthcare utilization in these conditions. Research to identify effective strategies are essential to developing evidence-based recommendations that can be translated into clinical practice.

Although self-care of chronic conditions has been a nursing research priority for over a decade, recent improvements in CVD outcomes have accelerated the need to develop and test CVD self-care interventions that improve patient-centered outcomes. In 2009, the American Heart Association (AHA) published a scientific statement on self-care as integral to management of heart failure [14], which has been echoed in the 2013 guidelines from the interdisciplinary American College of Cardiology Foundation/American Heart Association Task Force [15]. These recommendations as well as other CVD practice guidelines [6] provide suggestions for what should be included in self-care interventions. Although there has been an increase in the number of self-care studies, there remains a lack of clarity on the impact of CVD self-care interventions. To date, few CVD self-care interventions have been adopted as evidence-based practice.

Therefore, the purpose of this integrative review was to describe the nature of nurse-led CVD self-care interventions. Specifically, we answer 3 questions: (1) what are the CVD self-care intervention strategies and how are they deployed?, (2) what populations are targeted?, and (3) what are the outcomes studied in CVD self-care interventions? We also identify limitations in current nurse-led CVD self-care interventions and make recommendations for addressing them in future research. An integrative review approach was appropriate for this analysis because it allowed for the inclusion of diverse methodologies, specifically varied intervention approaches, as well as inclusion of a range of CVD diagnoses in order to generate a comprehensive description of the “nature” of nurse-led CVD self-care interventions [16].

2. Methods

2.1. Eligibility Criteria. Cardiovascular disease (CVD) was defined as disorders of the heart and blood vessels [1, 17] inclusive of coronary heart disease, cerebral vascular disease, peripheral vascular disease, heart failure, arrhythmias, and heart valve disease. Consistent with the conceptual definition of self-care as a set of behaviors or activities that patients are asked to engage in to promote health and well-being [4], interventions that focused on self-care including adherence, compliance, self-care maintenance, self-care management, symptom monitoring, and self-management were selected. Since self-care is a fundamental concern of nursing and focus of increased research efforts [7], only nurse-led studies defined as studies conducted by a nurse primary investigator (PI) were included in this review. We acknowledge that there are many self-care interventions that include a nursing component or are directed by nurses. However, given the aims of this review, we limited the search to only those studies conducted by a nurse PI.

The search was limited to the dates of 2000 through 2012 primarily because advances in CVD treatment have led to improved survival rates in the past decade [1] resulting in an increased emphasis on patient self-care after a cardiac event or illness. The search was restricted to intervention studies that were randomized controlled trials (RCTs) or quasiexperimental studies in which there was a control group.

2.2. Information Sources. A comprehensive search of the literature was conducted using PubMed, MEDLINE, ISI Web of Science, and Cumulative Index of Nursing and Allied Health Literature (CINAHL). Hand searching of references was also conducted.

2.3. Search. Search terms were selected based on definitions of CVD [1, 17] and self-care [16]. Search terms and strategies were developed in consultation with the research team who are experts in self-care research and with a medical librarian. The search strategy used the National Library of Medicine’s Medical Subject Headings (MeSH) key word nomenclature. All related terms and combinations of terms related to self-care and CVD were used in the initial search. The literature search was then refined to identify intervention studies that were RCTs or quasiexperimental studies with a control group. Finally, the literature was reviewed and filtered to select studies with nurse as PI.

2.4. Study Selection. Selected studies were limited to those with adult populations (age ≥ 19) with CVD diagnosis (“coronary heart disease,” “coronary artery disease,” “heart failure,” “cardiomyopathy,” “hypertension,” “cardiovascular disease,” “peripheral vascular disease,” “cerebral vascular disease,” “stroke,” “arrhythmia,” and “valve disease”).

Only nurse-led self-care interventions were included in this review. Studies had to identify a self-care component to the intervention, for example, self-care, self-care maintenance, self-care management, adherence, symptom-monitoring, symptom management, and self-management.
Nurse as PI was determined by (1) reference as PI status, (2) first author was nurse, or (3) senior author was nurse. This review included RCTs and quasiexperimental studies. Only studies that reported original data and had a comparison or control group were included.

After the initial search of the literature, each title and abstract were examined independently by two reviewers. Initially, 95% agreement on relevance was achieved. In cases where reviewers disagreed (5%), articles were discussed with the review team in order to gain consensus. All articles identified as relevant were then screened for eligibility by two reviewers and if criteria were met advanced to data abstraction.

2.5. Data Collection Process. The data extraction process was conducted by 3 investigators. First, a data extraction form was created based on the aims of the review and piloted on the first 3 studies by 2 of the investigators. Data were compared and confirmed by team members, and data extraction form was refined. Subsequently all studies under went a dual review for data abstraction (i.e., 2 of 3 investigators reviewed each article). In this way, quality measures used throughout the process of screening through data abstraction support protection against bias and enhanced consistency and accuracy of findings reported in this review.

2.6. Data Abstraction Process. Abstracted data elements included first and last author name and discipline, discipline of PI if designated, country of study, purpose, study design, sample characteristics (CVD diagnosis, gender, age, ethnicity/race), sample size, theoretical framework, intervention (type, description), measurement timeframe, main study outcomes, reported outcomes/results, stated key findings, stated or reviewer observed limitations, and attrition rate (number and reason, if reported).

2.7. Synthesis of Results. Data were summarized across studies to describe the nature of nurse-led interventions including the type of intervention (content, mode of delivery, dose, frequency, and theory-based), population studied (gender, and race), methods (randomization process, instruments, psychometrics), outcomes (measurement intervals and results), and limitations; and then by CVD diagnosis. Then data were analyzed to identify common limitations and generate recommendations for future research.

3. Results

3.1. Study Selection and Characteristics. The search initially produced 1424 studies; 34 met the inclusion criteria (Figure 1) and were analyzed (Table 1). Of these 34 studies, 24 were from USA, 10 studies were international studies, and 1 study was a multicenter international study (i.e., Australia and USA); 30 were RCTs and 4 were quasiexperimental studies. The majority (n = 23) focused on heart failure diagnosis, 8 targeted coronary heart disease and/or acute coronary syndrome, and 3 examined interventions for persons with other CVD conditions—arrhythmia, hypertension, and vascular disease.

3.2. Synthesis of Results

Question Number 1. What Are the CVD Self-Care Intervention Strategies and How Are They Deployed? There were a myriad of strategies described in this literature including individualized interventions in which the content was tailored to the needs of the patient or behaviorally focused, structured education, telemonitoring intended to support self-care behaviors (e.g., medication reminders, blood pressure checks), and disease management that integrated case management, monitoring, and education. Most of the studies in this review (18 of 34) were combined interventions and consisted of multiple strategies, including combinations of education, behavioral component, and individualized care through multiple modalities (e.g., in-person and telephone follow-up), or were part of a disease management approach (n = 4).

The delivery method of interventions included telephonic [22, 24, 25, 39], multimedia/computer [31, 36, 42, 44], group based [10], and in-person (one-on-one) [31, 35–38, 40, 45, 51].

In addition, the setting, in which interventions were conducted varied and included in-hospital or predischARGE after a cardiac event [41], outpatient or clinical setting and in-home. Commonly, interventions were initiated in the hospital or clinical setting with follow-up contacts in the home environment. This approach leveraged hospital resources to facilitate transition from hospital to home [28], a vulnerable point in CVD self-care, or augmented existing services like home health care with innovative interventions [20, 21, 32].

Intervention lengths ranged from 3 days to 17 months (mean 14 weeks SD 16.12 weeks, median 8 weeks). The frequency of intervention contact varied and was not reported in several of the studies, making it difficult to assess dose.

Seventeen of the 34 studies described a theoretical framework or conceptual model, either nursing or behavioral, as guiding the development, implementation, or evaluation of the intervention. Five studies were guided by nursing theories: (1) Rogers’ science of unitary human being [42], (2) Orem’s self-care deficit theory [19, 22], and (3) Riegel’s self-care of heart failure conceptual model [32, 39]. However, the most commonly used conceptual framework used was Bandura’s cognitive social theory and theory of self-efficacy [10, 25, 26, 44, 45]. Other behavioral theories used were the health belief model [41], transtheoretical model of stages of change [37], health promotion model [51], and theory of self-regulation [27]. The importance of a theoretical framework to clearly describe the theoretical relationships and measurement of self-care is highlighted by Jaarsma et al. who examined the effects of a theoretically derived supportive educational nursing intervention on self-care abilities, self-care behaviors, and quality of life in patients with HF [30]. Their results that self-care only contributed partially to quality of life indicated that in some populations a more intensive self-care intervention is needed. That is, self-care interventions need to be tailored as to content and dose in order to be effective.

Question Number 2. What Are the Populations Targeted? As noted, heart failure was the most common CVD diagnosis addressed by the self-care interventions. Across the 34 studies
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<tr>
<th>Study and location</th>
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</table>
| **Albert et al. (2007); USA** [18] | N = 112  
Gender: males n = 86  
Ethnicity: Caucasian n = 93  
CVD diagnosis: HF  
Attrition not reported | IG: multimedia (video education)  
CG: standard education by physician and/or nurse | Healthcare resource utilization: hospitalization, emergency care, office visits, and laboratory tests medical records  
Self-care/adherence: adapted from SCHF1  
Functional class: NYHA status change  
Timeframe: baseline, 3 m | (1) 3-month healthcare utilization (P = NS)  
(2) IG had greater sign/symptom recognition (P < .04) and higher mean self-care behavior/adherence (P < .01) |
| **Artinian et al. (2003); USA** [19] | N = 18  
Gender: males n = 17  
Ethnicity: Black n = 11  
Caucasian n = 6  
CVD diagnosis: HF  
Attrition not reported | IG: web-based monitoring  
CG: usual care | Self-care: HFSCBS  
Medication adherence: pill counts  
QOL: MLHF  
Timeframes: baseline, 3 months | (1) Improved QOL in IG (F = 10.0, P = .006), (P = .002); not CG (P = .113)  
(2) Better adherence in IG versus CG (P = NS) |
| **Barnason et al. (2006); USA** [20] | N = total 50  
Gender: males n = 28  
Ethnicity: not reported  
CVD diagnosis: CHD  
Attrition not reported | IG: combined intervention of telemonitoring and home visit  
CG: usual care | QOL: SF-36  
Healthcare utilization: emergency care  
Timeframe: baseline, 6 weeks, 3 m | (1) IG had higher QOL general health functioning (F = 8.41, P < .01)  
(2) Significant time effects in QOL physical (F = 9.42, P < .01), role-physical functioning (F = 5.74, P < .05) in both groups  
(3) CG had more ER visits (NS) |
| **Barnason et al. (2009); USA** [21] | N = 55  
Gender: males n = 46  
Ethnicity: White n = 54, nonwhite n = 1  
CVD diagnosis: CHD  
Attrition not reported | IG: telehealth intervention  
CG: usual care | QOL: SF-36  
Physical activity/energy expenditure: RT3 accelerometer  
Timeframe: baseline, 3 w, 6 w, 3 m, 6 m | (1) Significant main effect by group in energy expenditure/physical activity (F = 4.66, P < .05)  
(2) Both groups had significantly improved QOL (P < .05) |
| **Brandon et al. (2009); USA** [22] | N = 20  
Gender: males = 9  
Ethnicity: Caucasian n = 8, African American n = 12  
CVD diagnosis: CHD  
Attrition not reported | IG: nurse-led telephone intervention (7 telephone calls, 5–30 minutes in length)  
CG: usual care with standard education by physician and/or nurse | QOL: MLHF  
Self-care: Self-Care Behavior scale  
Healthcare utilization: self-report hospitalizations  
Timeframe: baseline, 3 m | (1) IG improved self-care behaviors (F = 21.853, P < .001) and reduced hospital readmissions (F = 7.63, P = .013)  
(2) QOL in IG improved P = NS; no change in UC |
| **Caldwell et al. (2005); USA** [23] | N = 36  
Gender: males n = 25  
Ethnicity: white n = 34, other = 2  
CVD diagnosis: HF  
Attrition n = II | IG: combined intervention: focused education and counseling with telephone follow-up  
CG: usual care | Self-care: EHFScBS  
Biomarkers: BNP  
Timeframe: baseline, 3 m | (1) Self-care improved significantly in IG (P = .03)  
(2) No significant difference in BNP levels (P = .21) |
| **DeBusk et al. (2004); USA** [24] | N = 462  
Gender: males n = 236  
Ethnicity: white n = 386, Black n = 27, Hispanic n = 14, American Indian n = 27, Asian n = 8  
CVD diagnosis: HF  
Attrition n = 72 | IG: telephonic case management  
CG: usual care | Healthcare utilization: HF and all-cause hospitalizations medical claims  
Timeframe: baseline, 12 m | (1) HF rehospitalization similar in both groups (NS) (proportional hazard, 0.85 (95% CI = 0.46, 1.57))  
(2) All-cause rehospitalization NS (proportional hazard, 0.98 (95% CI = 0.76, 1.27)) |
Table 1: Continued.

<table>
<thead>
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<td>Dougherty et al. (2005); USA [25]</td>
<td>N = 168 Gender: males n = 139 Ethnicity: Caucasian n = 150, American Indian/Alaska n = 3, Asian/Pacific Islander n = 4 CVD diagnosis: arrhythmia Attrition n = 18</td>
<td>IG: combined intervention: self-care management patient education, telephone, and clinical support CG: usual care</td>
<td>QOL: SF-36 Depression: CES-D Healthcare utilization: outpatient visits, hospitalizations, and emergency care Timeframe: baseline, 6 m, 12 m</td>
<td>(1) Improved mood in IG (P = .04) compared to CG (2) No statistically significant differences between the groups on total outpatient visits, hospitalizations, or ER visits over 12 months</td>
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<td>Gallagher et al. (2003); Australia [26]</td>
<td>N = 196 Gender: 196 females Ethnicity not reported CVD diagnosis: CHD Attrition not reported</td>
<td>IG: combined intervention: telephone intervention with behavioral focus CG: usual care</td>
<td>Depression: Hospital Anxiety and Depression Scale Timeframe: baseline, 12 w</td>
<td>(1) No significant differences in anxiety (F = 0.15, P = .69) or depression (F = 0.11, P = .74) between groups</td>
</tr>
<tr>
<td>Gould (2011); USA [27]</td>
<td>N = 154 Gender not reported Ethnicity not reported CVD diagnosis: CHD Attrition n = 25</td>
<td>IG: combined intervention: discharge nursing intervention with telephone follow up (IG, n = 64) CG: usual care</td>
<td>Adherence: Morisky adherence Healthcare utilization: urgent care Timeframe: baseline, 3 days</td>
<td>(1) No significant group differences were found on medication adherence, or use of urgent care</td>
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<td>Harrison et al. (2002); Canada [28]</td>
<td>N = 192 Gender: males n = 105 Ethnicity not reported CVD diagnosis: HF Attrition n = 8</td>
<td>IG: combined intervention: transition/discharge care: educational materials, telephone, and home visits CG: usual care included home visits</td>
<td>QOL: MLHF, SF-36 Healthcare utilization: emergency care, readmission rates (medical records) Timeframe: baseline, 6 weeks, 12 weeks</td>
<td>(1) IG: improvement in QOL (27.2 ± 19.1) compared to the CG (37.5 ± 20.3; P = .002) (2) Less emergency room use in transitions group compared to CG (P = .03) but no change in readmission rates</td>
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<td>Holmes-Rovner et al. (2008); USA [29]</td>
<td>N = 525 Gender: males n = 191 Ethnicity: Non-Hispanic white n = 443, African American n = 60, Hispanic White n = 12 CVD diagnosis: CHD/acute coronary syndrome Attrition n = 152</td>
<td>IG: telephonic intervention with behavioral focus CG: usual care</td>
<td>Functional status/physical activity: Duke Activity Status Index BP Timeframe: baseline, 3 m, 8 m</td>
<td>(1) IG showed higher physical activity (OR = 1.53, P = .01) during the first three months (2) No significant differences in functional status or QOL</td>
</tr>
<tr>
<td>Jaarsma et al. (2000); the Netherlands [30]</td>
<td>N = 179 Gender: males n = 79 Ethnicity not reported CVD diagnosis: HF Attrition n = 47</td>
<td>IG: combined intervention of education, telephone, and home visits (6 encounters) CG: usual care</td>
<td>Self-Care: HFSCBS QOL: Cantrill's Ladder Timeframe: baseline, 1 m, 3 m, 9 m</td>
<td>(1) Self-care behaviors improved in IG (1 m (t = 3.3, P &lt; .001), 3 m (t = 2.9, P &lt; .005) but not sustained at 9 m (t = 0.7, P = .47)) (2) QOL in both groups at 3 m not sustained at 9 m (3) Limited effect of self-care on QOL (r = 0.24, P &lt; .05)</td>
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| **Kutzleb and Reiner (2006); USA [31]** | N = 23  
Gender: males = 8  
Ethnicity not reported  
CVD diagnosis: HF  
Attrition not reported | IG: combined intervention: individualized education and counseling with telephone follow-up  
CG: usual care: protocol driven medical care | QOL: Ferrans and Powers QOL Index  
Functional status: 6-minute walk test  
*Timeframe: baseline, 12 m* | (1) IG: improved QOL ($F = 3.569, P < .000$)  
(2) IG: functional capacity NS ($F = 0.228, P = .949$)  
(3) Between-group NS |
| **LaFramboise et al. (2003); USA [32]** | N = 90  
Gender: males = 45  
Ethnicity: Caucasian n = 75, African American n = 12, other n = 3  
CVD diagnosis: HF  
Attrition not reported | Combined intervention  
Group 1: Telephonic only  
Group 2: Home visit only  
Group 3: Telemonitoring  
Group 4: Home visit and Telemonitoring  
*All groups also received structured HF disease management 5 encounters* | Functional status: 6-minute walk test  
Self-efficacy: BEES-HF  
Depression: Geriatric Depression Scale  
QOL: SF-36  
*Timeframe: baseline, 2 m:* | (1) Group by time effect significant ($P = .0027$) in self-efficacy only  
(2) Improved functional status ($P < .01$), HRQL ($P < .05$), and depression (NS) in all groups |
| **Lorig et al. (2003); USA [10]** | N = 551  
Gender: males n = 113  
Ethnicity: U.S. born n = 31  
Mexican born n = 353, Central American born n = 121, South American born n = 36  
CVD diagnosis: CHD  
Attrition not reported | IG: group-based, peer-led community-based program  
CG: usual care | Healthcare utilization: emergency care, hospitalizations,  
*Timeframe: baseline, 6 w, 4 m, 12 m* | (1) IG had fewer emergency room visits ($P < .05$) at 4 m and 1 year ($P < .001$) |
| **Maric et al. (2010); Canada [33]** | N = 20  
Gender: males n = 11  
Ethnicity not reported  
CVD diagnosis: HF  
Attrition n = 3 | IG: combined intervention: web-based education and monitoring with telephone follow-up  
BG: usual care | Self-care: SCHFI  
Functional status: 6-minute walk test  
Biomarkers: BNP  
*Timeframe: baseline, 6 m* | (1) Improved self-care ($P = .039$)  
(2) 6-minute walk test ($P = .124$), and BNP ($P = .210$) |
| **Mårtensson et al. (2005); Sweden [34]** | N = 153  
Gender: males n = 83  
Ethnicity not reported  
CVD diagnosis: HF  
Attrition not reported | IG: combined intervention: individualized education and counseling with telephone follow-up  
CG: usual care | QOL: MLHF, SF-36  
Depression: Zung self-rated depression scale  
*Timeframe: baseline, 3 m* | (1) No significant difference in QOL; but IG preserved QOL while UC deteriorated in QOL ($P = .035$), vitality ($P = .029$)  
(2) No significant differences in depression |
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| McKinley et al. (2008); Australia and USA [35] | N = 3522  
Gender: males n = 2,393  
Ethnicity: white n = 3,207, other n = 315  
CVD diagnosis: CHD  
Attrition n = 386 | IG: combined intervention: individual one-on-one education provided with structured education with counseling  
CG: usual care | Mood: Multiple Affect Adjective Check List  
Timeframe: baseline, 3 m, 12 m  
(1) Knowledge increased significantly from baseline in IG compared to CG at 3 months and sustained at 12 months (P = .0005 for all)  
(2) Higher state anxiety was associated with lower levels of knowledge (P < .05) |
| Otsu and Moriyama (2009); Japan [36] | N = 96  
Gender: males n = 61  
Ethnicity not reported (Japanese study)  
CVD diagnosis: HF  
Attrition n = 3 | IG: individualized (face-to-face) case management  
CG: usual care | QOL: Macnew health-related quality of life  
Functional status: NYHA Biomarkers; BNP  
Mortality: records  
Timeframe: baseline, 3 m, 6 m, 9 m, 12 m  
(1) Statistically significant differences between groups: BNP at 3 m (P = .032) and 6 m (P = .002)  
(2) IG: improved QOL in IG improved (F = 26.157, P < .000)  
(3) No significant difference in NYHA but deterioration in symptom in the UC group (NS) |
| Paradis et al. (2010); Canada [37] | N = 30  
Gender: males n = 22  
Ethnicity not reported  
CVD diagnosis: HF  
Attrition n = 5 | IG: combined intervention: motivational interview (3 encounters—1 in person; 2 telephone)  
CG: usual care | Self-care: SCHFI  
Timeframe: baseline, 1 m  
(1) No significant results in self-care behaviors  
(2) IG: improved self-care confidence (P = .005) |
| Prasun et al. (2005); USA [38] | N = 66  
Gender: males n = 43  
Ethnicity: white n = 58, African American n = 7, other n = 1  
CVD diagnosis: HF  
Attrition not reported | IG: supportive education about flexible diuretic titration  
CG: usual care | QOL: MLHF  
Functional status: 6-minute walk test  
Biomarkers: BNP, norepinephrine  
Healthcare utilization: emergency care, hospitalizations, mortality  
Timeframe: baseline, 3 m, 6 m, 9 m, 12 m  
(1) IG: improved 6-minute walk test (646 ± 60 ft versus 761 ± 61 ft, P = .01) and total QOL score (53 ± 5 versus 38 ± 5, P = .001), no change in CG group  
(2) Significantly fewer emergency care in the IG compared to CG (3% versus 23%, P = .015)  
(3) No differences in hospitalizations or mortality  
(4) No differences were found between baseline and 3-month biomarkers |
| Riegel et al. (2006); USA [39] | N = 134  
Gender: males n = 62  
Ethnicity: Hispanics n = 134 (109 Spanish-speaking)  
CVD diagnosis: HF | IG: telephonic case management with self-care education  
CG: usual care | Self-care: SCHFI  
Depression: Patient Health Questionnaire-9  
Healthcare utilization: hospitalizations, cost, mortality—medical records  
Timeframe: baseline, 3 m, 6 m  
(1) No significant group differences were found in HF readmission rate, HF days in the hospital, HF cost of care, all-cause hospitalizations or cost, mortality, or depression |
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<td>Scott et al. (2004); USA [40]</td>
<td>N = 88 Gender: males n = 39 Ethnicity not reported CVD diagnosis: HF Attrition n = 22</td>
<td>Group 1: individualized counseling and usual care Group 2: supportive-educative and usual care Group 3: usual care and placebo</td>
<td>QOL: SF-36 Depression: Mental Health Inventory Timeframe: baseline, 6 m</td>
<td>(1) IG (groups 1 and 2) improved QOL ($F = 4.632, P = .01$) and depression ($F = 6.27$, $P = .003$) and over a 6-month period (2) between-group comparisons (NS)</td>
</tr>
<tr>
<td>Sethares and Elliott (2004); USA [41]</td>
<td>N = 70 Gender: males n = 33 Ethnicity: white n = 63, black n = 6 CVD diagnosis: HF</td>
<td>IG: combined intervention, individualized/tailored message intervention CG: usual care</td>
<td>QOL: MLHF Healthcare utilization: hospitalizations Timeframe: baseline, 1 w, 1 m</td>
<td>(1) No significant differences in HF readmission rates or QOL</td>
</tr>
<tr>
<td>Shearer (2007); USA [42]</td>
<td>N = 90 Gender: males n = 56 Ethnicity: white n = 81, black n = 2, Hispanic n = 3, Native American n = 1 CVD diagnosis: HF Attrition n = 18</td>
<td>IG: telephonic intervention with behavioral focus CG: usual care</td>
<td>Self-care: self-management heart failure QOL: SF-36 Timeframe: baseline, 3 m</td>
<td>(1) IG improved self-care compared to CG ($F = 6.19$, $P &lt; .001$) (2) QOL NS</td>
</tr>
<tr>
<td>Shivdy et al. (2005); USA [43]</td>
<td>N = 116 Gender: males n = 110 Ethnicity: Caucasian n = 87, African American n = 11, Hispanic n = 9, Asian/Pacific Islander n = 6, mixed n = 3 CVD diagnosis: HF Attrition = 15</td>
<td>IG: combined intervention; behavioral management with telephone follow up CG: usual care</td>
<td>QOL: SF-36, MLHF Functional status/exercise capacity: 6-minute walk test Timeframe: baseline, 4 m, 10 m, 16 m</td>
<td>(1) IG improved QOL compared to UG ($F = 7.04$, $P = .009$) (2) No group differences in exercise capacity</td>
</tr>
<tr>
<td>Smeulders et al. (2010); the Netherlands [44]</td>
<td>N = 317 Gender: males n = 230 Ethnicity not reported CVD diagnosis: HF Attrition n = 42</td>
<td>IG: group-based structured education CG: usual care</td>
<td>Self-care: EHFScBS QOL: SF36, Kansas City Cardiomyopathy Questionnaire Depression: HADS Timeframe: baseline, 26 weeks, 52 weeks</td>
<td>(1) IG improved in self-care ($P &lt; .01$) and QOL ($P = .005$) (2) results not sustained at 6 and 12 months</td>
</tr>
<tr>
<td>Sol et al. (2010); the Netherlands [45]</td>
<td>N = 314 Gender: male n = 242 Ethnicity not reported CVD diagnosis: vascular disease Attrition n = 91</td>
<td>IG: tailored behavioral self-care intervention CG: usual care</td>
<td>QOL: SF-36 Biomarkers: lipids, BP, waist circumference, BMI Timeframe: baseline, 1 yr</td>
<td>(1) IG achieved treatment goals for LDL-cholesterol (difference 13%, 95% CI = 1, 26) and HDL-cholesterol (difference 9%, 95% CI = 0, 19) compared to CG (2) Mean SBP decreased significantly by 5 mm Hg (95% CI = −9, 0) in IG (3) BMI increased significantly by 0.4 kg/m² (95% CI = −0.8, −0.1) in CG (4) No significant differences were seen in waist circumference, smoking, or triglycerides or QOL</td>
</tr>
<tr>
<td>Study and location</td>
<td>Sample (as reported)</td>
<td>Intervention/control</td>
<td>Primary outcomes and measurement</td>
<td>Key findings</td>
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| **Stafford and Berra (2007); USA [50]** | N = 419  
Gender not reported  
Ethnicity not reported  
CVD diagnosis: CHD  
Attrition n = 122 | IG: combined intervention: individualized case management with follow-up meetings, telephone call, home visits  
CG: primary care | Framingham risk score  
Timeframe: baseline, 17 m | (1) IG had statistically significant reduction in mean Framingham risk probability compared to CG (1.6% decrease in 10-year CHD risk, *P* = .007) |
| **Strömberg et al. (2003); Sweden [47]** | N = 106  
Gender: males n = 65  
Ethnicity not reported  
CVD diagnosis: HF  
Attrition n = 43 | IG: combined intervention: group based intervention focused on self-care education and support to patient and family  
CG: usual care | Self-care: HFSCBS  
Healthcare utilization: hospitalizations, length of stay, mortality  
Timeframe: baseline, 12 m | (1) IG had fewer patients with events (death or admission) after 12 months compared to CG (29 versus 40, *P* = .03) and fewer deaths after 12 months (7 versus 20, *P* = .005)  
(2) IG had fewer admissions (33 versus 56, *P* = .047) and days in hospital (350 versus 592, *P* = .045) during the first 3 months  
(3) At 12 months, there was a 55% decrease in admissions/patient/month (0.18 versus 0.40, *P* = .06) and fewer days in hospital/patient/month (1.4 versus 3.9, *P* = .02)  
(4) IG improved in self-care at 3 and 12 months compared to CG (*P* = .02 and *P* = .01) |
| **Strömberg et al. (2006); Sweden [48]** | N = 154  
Gender: males n = 109  
Ethnicity not reported  
CVD diagnosis: HF  
Attrition n = 24 | IG: multimedia intervention  
CG: usual care | QOL: EuroQol  
Adherence: study-specific survey  
Timeframe: baseline, 1 m, 6 m | (1) NS difference between groups in adherence or QOL |
| **Tonstad et al. (2007); Norway [49]** | N = 51  
Gender: males n = 36  
Ethnicity not reported  
CVD diagnosis: hypertension  
Attrition n = 4 | IG: combined intervention: behavioral intervention with telephone follow up focuses on lifestyle counseling  
CG: primary care | Biomarkers: lipids, triglycerides  
BP, Waist circumference  
Timeframe: baseline, 6 m | (1) Waist circumference increased significantly between baseline and 6 m in CG but not in IG (mean difference 3.1 cm (95% CI 1.2–5.0), *P* = .04)  
(2) Reduced serum triglyceride in IG compared with CG (mean difference 0.56 mmol/L (95% CI 0.22–0.90), *P* = .03) |
| **Westlake et al. (2007); USA [46]** | N = 80  
Gender: males n = 57  
Ethnicity: white n = 58, black n = 8, Hispanic n = 3 other n = 11  
CVD diagnosis: HF  
Attrition not reported | IG: web-based education (n = 40)  
CG: standard education | QOL: SF-36  
Timeframe: baseline, 3 m | (1) Between-group improvement in QOL (*P* < .001) |

BMI: body mass index; BNP: B-Natriuretic Peptide; BP: blood pressure; CG: control group; CHD: coronary heart disease; CVD: cardiovascular disease; EHFScBS: European Heart Failure Self-Care Behavior Scale; HF: heart failure; HFSCBS: Heart Failure Self-Care Behavior Scale IG: intervention group; MLHF: Minnesota Living with Heart Failure Questionnaire; NS: not significant; NYHA: New York Heart Association; QOL: quality of life; SCHFI: Self-Care of Heart Failure Index.
reviewed, pooled demographic statistics show 57% male and 67% Caucasian. It is important to note that 19 studies did not report race. Only 2 studies focused on ethnic minority populations [10, 39]. Lorig and colleagues evaluated the health and utilization outcomes of a 6-week community-based peer-led program for Spanish speakers with heart disease [10]. At 4 months, the intervention group (n = 327), as compared with usual-care control subjects (n = 224), demonstrated improved health status, health behavior, and self-efficacy, as well as fewer emergency room visits (P < 0.05). At 1 year, the improvements were maintained and remained significantly different from baseline status.

Riegel et al. examined the effectiveness of telephonic disease management that included a focused self-care intervention in decreasing hospitalizations and improving health-related quality of life (HRQL) and depression in Hispanics of Mexican origin with HF [39]. Although they used bilingual nurses to adapt the intervention, there were no significant group differences in HF hospitalizations, the primary outcome variable (usual care: 0.49 ± 0.81 (CI 0.25–0.73); intervention: 0.55 ± 1.1 (CI 0.32–0.78) at 6 months, or other outcomes of HF readmission rate, HF days in the hospital, HF cost of care, all-cause hospitalizations or cost, mortality, HRQL, or depression. Collectively, the results from these two rigorously designed and conducted studies stress the importance of ensuring adequate diversity in sample populations and continued research to address the unique needs of ethnically diverse populations.

Unfortunately, the proportion of ethnic minorities represented in other studies of this review was very small and subgroup analysis was not performed by any of the studies.

**Question Number 3. What Are the Outcomes Studied in CVD Self-Care Interventions?** The most common outcomes reported in this literature were quality of life, reported by 19 studies while healthcare utilization outcomes including emergency room use, hospital days, were studied in 12 studies. Measurement of these outcomes varied across studies; for example, there were 9 different quality of life measures used including general quality of life measures (e.g., Medical Outcome Study Short Form-36 [52]) and condition specific measures (e.g., Minnesota Living with Heart Failure [53],
MacNew Heart Disease Health-related Quality of Life [54]). Interestingly, few \( (n = 10) \) reported a self-care result; yet measures of self-care either objective or subjective were reported in 16 of the 34 studies. Measurement of physical as well as psychosocial outcomes varied widely throughout the studies. Cardiac-related outcomes were measured by the 6-minute walk test \((n = 5)\), blood pressure \((n = 3)\), cholesterol \((n = 2)\), and B-Natriuretic Peptide (BNP) levels \((n = 4)\). Mood (i.e., depression and anxiety) was measured \((n = 9)\) using 7 different scales. Most studies measured outcomes at multiple intervals, commonly at 3–6 months.

3.3. Limitations of Current Nurse-Led CVD Self-Care Interventions. This integrative review highlighted three overarching limitations in the current nurse-led CVD self-care intervention research: (1) lack of sample diversity, (2) inconclusive results within studies, and (3) methodological weaknesses in study design.

3.3.1. Lack of Sample Diversity. As noted earlier, the studies in this review were predominately male and Caucasian; only 2 studies focused on ethnic minority populations [10, 39]. The lack of sample diversity is a significant limitation and demonstrates the continued need for increased participation in research by women and ethnic minority populations, who continue to experience poorer CVD outcomes [1].

3.3.2. Inconclusive Results within Studies. Only 11 studies reported statistically significant between-group improvement in at least one primary outcome measured; 13 studies reported improvement in one or more primary outcome in the intervention group but not between groups. Only 3 studies reported sustained positive results over time [10, 35, 47]. Inconclusive findings are a significant limitation in that they confuse interpretation of results and impedes the translation of relevant findings into practice.

There are several potential explanations for inconclusive findings: lack of self-care measurement; inadequate measurement of outcomes; and combined interventions that make it difficult to parcel out the effective intervention component. First, although all of the studies in this review were self-care interventions, self-care was only measured in 16 of the studies. Therefore, studies that did not measure self-care were limited in their ability to link the intervention to the primary outcome, which may have contributed to mixed findings within a single study.

Use of subjective measures also confounded the results even in well-designed RCTs. For example, Prasun et al. (2005) tested a self-directed diuretic titration intervention compared to usual care in a sample of 66 adults with HF [38] and measured physiological outcomes (i.e., B-Natriuretic Peptide), behavioral outcomes, and healthcare utilization and mortality at baseline and at 3 months. There was a significant difference between groups in healthcare utilization and exercise capacity. The intervention group who self-titrated diuretics better (60% compared to 40% in control group) had fewer self-reported HF-related emergency visits (2.8% [1] versus 22.7% [7], \( P = 0.15 \)) compared to the usual care group and improved significantly in exercise capacity (646 ± 60 ft versus 761 ± 61 ft, \( P = 0.01 \)) measured by the 6-minute walk test. Since ER visits are common in HF patients and mostly due to symptom exacerbation of fluid overload [55], these results suggest that a diuretic titration intervention may be feasible in promoting self-care, specifically symptom management. Although assessment of physiological markers of fluid overload and myocardial stress [56], along with the 6-minute walk test, are significant strengths of this study, researchers relied on self-report of HF-related healthcare utilization without verification by medical records, which weakens results. It is also not clear if those in the usual care group were instructed to use the ER as the venue for diuretic titration, which could introduce bias into the study and contribute to the inconclusive results within the study.

Also, many studies reported combined interventions making it difficult to ascertain the effective component of an intervention which was a limitation when findings were inconclusive. Brandon et al. reported positive outcomes including improved hospital readmissions, quality of life and self-care behaviors when comparing intervention group who received the advanced practice nurse-led telephonic enhanced disease management and self-care education to the usual care group [22]. Self-care behaviors were measured by the Self-Care Behavior scale and improved significantly in the intervention group compared to the usual care group \((F[1,18] = 21.8, P = 0.001)\) thereby linking the self-care outcome to the specific intervention component that focused on self-care adherence (e.g., medication). However, it was less clear if the effect on the primary outcomes of interest (hospital readmission decreased in intervention group \((F[1,18] = 7.63, P = 0.013)\) and improvement in quality of life \((F[1,18] = 5.80, P = 0.026)\) can be attributed to the self-care intervention or perhaps the clinical care or disease management delivered by the physician and nurse, respectively.

3.3.3. Methodological Weaknesses. There were several common methodological weaknesses found in this integrative review that may also help explain the equivocal results. A number of the studies were pilot studies and/or had small sample sizes [19–21, 23, 33, 37]; thus they were underpowered to detect potentially important differences. Many studies used inappropriate statistical techniques to assess changes over time, using pairwise comparisons between groups at each timepoint or comparing within group changes. Several studies did appropriately use survival analyses when looking at time to first event between groups [22, 24, 25, 48]; analysis of covariance [10] or mixed methods modeling [32, 33]/repeated measures analysis of variance [20, 21, 33, 35, 38, 41, 46] to detect changes interaction effects of time by group changes.

Weak fidelity of treatment monitoring was another methodological weakness. Few studies described a method whereby they monitored or documented the delivery of the intervention. An example of gold standard in treatment fidelity was use of objective assessment via tape-recording of the intervention adherence to a protocol [43]. Other less objective methods included self-appraisal and observer
4. Discussion

4.1. Summary of Evidence. The purpose of this integrative review was to describe the nature of nurse-led CVD self-care interventions and identify limitations of this literature in order to generate recommendations for future research. We found that a range of strategies including a variety of modes of delivery have been tested in this population with varying results. We found a glaring lack of subject diversity in this body of research. This finding is of particular concern because cardiovascular disease is a leading cause of morbidity and mortality worldwide and ethnic minority groups experience disproportionate burden and poorer outcomes, as do women. In addition, inconclusive results and combined interventions make it difficult to identify effective program attributes or pose recommendations for clinical use based on the current findings. Further, we found methodological weaknesses in many of the studies included in this review that threaten both external validity (i.e., small sample sizes skew results and decrease ability to generalize findings of the study) and internal validity (i.e., selection bias, attrition, and combined intervention decrease ability to make an inference that the independent variable is truly influencing the dependent variable).

In the following section, the limitations in our review and how we minimized these challenges are discussed. Then implications for future research that includes recommendations for addressing the current limitations in nurse-led CVD self-care intervention research are presented.

4.2. Limitations of the Review. There are several limitations to this review. As described above, the studies in this review included RCTs and quasiexperimental and varied methodological approaches that preempted ability to conduct any meta-analyses. There was variation in how studies reported ethnicity/race which affected our pooled results of demographics. Numerous instruments were used to study common outcomes (e.g., quality of life) without consistency across interventions or outcomes. Therefore, it was difficult to compare results across studies especially when psychometrics were not reported. Further, the lack of description about the intervention and control group treatments was a significant limitation in reporting the results of this analysis. It may be that the lack of clarity in the descriptions resulted in miscategorization of the study intervention in this analysis. Statistical methods in the analysis of several studies were often either not adequately described or not appropriate, which may have contributed to nonsignificant results as well as influenced our assessment of study. We addressed these challenges by following a rigorous review process in which each study was reviewed by at least two investigators. Statistical methods for each included study were also reviewed independently by an expert on our team. Definitions for categorization of type of intervention were developed and used during data abstraction. Ambiguity in studies was discussed by the entire team until a consensus was reached and in the case where interventions were inadequately described referenced materials were reviewed (e.g., methods papers describing the intervention).

A second limitation in our integrative review may be our a priori decision to define nurse-led CVD self-care intervention studies as those in which the PI was a nurse. Our purpose was expressly to describe the nature of nurse-led interventions, and therefore we included only studies where the PI was a nurse rather than studies led by other disciplines with a nurse as a research team member. It is possible that our search may have missed studies where a nurse was PI but not credited as such in the paper or listed as the first or last author of the study. We made every effort to identify the discipline of the PI by checking funding sources where PI and discipline would be identified, checking academic and department affiliation, and contacting authors. Interestingly, we did not find any cost-effective analyses or comparative effective studies in this review. It may be that by excluding studies where the nurse was not the PI, these studies were missed in this review.

Finally, since the lines between self-care interventions and other CVD patient education interventions sometimes can be unclear [4], we may have missed interventions that had a self-care component. We minimized this limitation by conducting a rigorous search with quality-monitoring in each phase that included careful review of the description of each intervention prior to inclusion.

4.3. Recommendations for Future Research Based on Findings. The 34 studies examined in this review represent a significant body of CVD self-care intervention research conducted over the past 10 years. The results of this integrative review are important because they highlight ongoing limitations in this area and inform recommendations to address the gaps in future CVD self-care intervention research.

Unfortunately, our results regarding the lack of sample diversity are not new [57–60]; but they highlight the need for renewed focus on recruitment strategies to enroll an adequate representation of women and minorities as well as retention strategies to minimize attrition [61]. Such efforts should include outreach to communities and community leaders to facilitate engagement of ethnic minority populations and incorporate culturally appropriate interventions [62, 63]. In addition, strategies to reduce attrition need to be integrated into study design up front [61].

Addressing the significant limitation of lack of sample diversity in future research is paramount and has implications for overcoming health disparities in the CVD population. In 2012, the Department of Health and Human Services developed a formal Action Plan to Reduce Racial and Ethnic Health Disparities [64] that placed emphasis on the conduct of health disparities research. A key part of the action plan...
is to target patient-centered outcomes research among racial and ethnic minority populations; CVD was a priority area. The national initiative, in conjunction with Healthy People 2020, aims to achieve health equity and eliminate disparities such as those that exist in CVD for subpopulations (i.e., race, ethnicity, and gender). Our results suggest more work is needed in the areas of adequate representation of women and minorities in research and culturally appropriate CVD self-care interventions.

Future research must also employ rigorous study design and methods in order to establish effectiveness of interventions for translation into clinical practice [58, 65, 66]. Recommendations to address the common methodological weaknesses include enlisting an interdisciplinary team of experts led by a nurse scientist. Collaborating with a statistician as well as experts in content area to strengthen initial study design stage may help overcome some of the common methodological weaknesses [66] like inadequate power or statistical methods and fidelity monitoring. Further, consistent use of reliable and precise measures such as those included in the Patient Reported Outcomes Measurement Information System (PROMIS) toolbox [67] would facilitate integration and assessment of effectiveness of CVD self-care intervention research in the future. Consistent measurement will also facilitate collaboration among nurse scientists working in similar programs of research and help move this science forward.

Results of this integrative review suggest that incorporation of a theoretical framework may strengthen CVD self-care intervention research [30], a finding advocated by others [57, 68]. Self-care is a fundamental nursing phenomenon, the focus of nursing theorists and a nursing sensitive outcome identified by the American Academy of Nursing. Use of theoretical frameworks has utility in CVD self-care intervention research by delineating factors to address in an intervention as well as linking self-care to desired outcomes [69]. In clinical practice, a theoretically derived intervention can help nurses identify individuals vulnerable to poor self-care and guide a plan of care that incorporates self-care.

Finally, consistent with other reviews [66, 68, 70, 71], we found that the use of combined interventions was very common and led to questions about variance in dose of intervention as well as content. For example, Chodosh et al’s meta-analysis of 53 chronic disease self-management studies (including 19 hypertension studies) concluded that interventions “probably” were beneficial but the elements of the programs that were effective could not be determined [71]. That is, what is it about a combined intervention that makes it effective? Research is needed that rigorously tests the structure, process, and outcomes of an intervention in order to identify the mechanism of effectiveness [66, 72]. In complex combined interventions, evaluation should include fidelity monitoring, calculation of intervention dose, and precise outcome measurement. Qualitative methods can help identify the mechanism of effectiveness and support treatment fidelity especially when interventions are “tailored” [73].

5. Conclusions

This integrative review identified significant shortcomings in the existing nurse-led linebreak CVD self-care intervention research. Research is needed to develop and test tailored and inclusive CVD self-care interventions that are guided by an appropriate theoretical framework. Attention to rigorous study designs and methods is critical. This review reinforces the continued importance of adequate representation in CVD self-care intervention research by diverse populations and the need to develop and test culturally appropriate interventions. As the number of patients with CVD continues to increase worldwide, improving self-care in this population takes on added importance. Nursing research has a critical role to play in advancing the science of CVD self-care.

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References


Review Article

The Conceptualization and Measurement of Comorbidity: A Review of the Interprofessional Discourse

Salimah H. Meghani,¹ Harleah G. Buck,² Victoria Vaughan Dickson,³ Marilyn J. Hammer,³ Eneida Rejane Rabelo-Silva,⁴ Robyn Clark,⁵ and Mary D. Naylor⁶

¹ Department of Biobehavioral Health Sciences, NewCourtland Center for Transitions & Health, University of Pennsylvania, Room 337 Fagin Hall, 418 Carie Boulevard, Philadelphia, PA 19104-4217, USA
² NewCourtland Center for Transitions & Health, University of Pennsylvania, The Pennsylvania State University, University Park, PA 16802, USA
³ New York University, New York, NY 10003, USA
⁴ Federal University of Rio Grande do Sul, School of Nursing, 90040-060 Porto Alegre, RS, Brazil
⁵ School of Nursing & Midwifery, Flinders University, Adelaide, South Australia, SA 5001, Australia
⁶ NewCourtland Center for Transitions and Health, University of Pennsylvania, Philadelphia, PA 19109-4217, USA

Correspondence should be addressed to Salimah H. Meghani; meghanis@nursing.upenn.edu

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Background. Chronic medical conditions often occur in combination. Understanding underlying mechanisms causing diseases and their interactions may make it possible to address multiple complex conditions with single or consolidated treatment approaches and improve patients’ health outcomes while reducing costs. Objectives. We present a synthesis of the current interprofessional discourse on the issues surrounding comorbidities. Methods. A targeted review of the literature was conducted using published editorials, commentaries, and review articles. Results. Errors in conceptualization and measurement plague our current understanding of comorbidities. Two potential paths to generating knowledge involve the use of etiological or epidemiological approach. A etiological approach investigates the risk factors and underlying mechanisms potentially leading to consolidation of diagnosis and treatments. Because of the rudimentary stage of knowledge development in this area, this approach will require time and significant research investments. In contrast, the epidemiological approach relies on statistical identification of disease entities that cooccur beyond random chance; this approach carries an accompanying risk of diagnostic and treatment proliferation. Discussion. The concept of comorbidity, its nature, and measurement is in need of meaningful debate by the scientific and clinical communities. Recommendations in the domains of conceptualization, research, and measurement are discussed.

1. Introduction

Chronic medical conditions rarely occur in isolation but rather in combination, as comorbidities. Successful management of chronic conditions is associated with complex treatment regimens and requires adequate self-care by the patient of all comorbid conditions. Improving self-care among patients with chronic illness therefore necessitates a better understanding of the complexities of comorbidity.

While the concept of comorbidity was introduced in medicine almost four decades ago [1], its scientific underpinnings remain underdeveloped with consequent uncritical use and application of this concept in research and practice [2, 3]. The difficult issue of comorbidities has been appropriately referred to in the literature as a “puzzle,” “tapestry” [4], “Gordian Knot” [5], and something that embodies “dizzying” levels of complexity [6]. Thus the concept of comorbidity remains in continued need of discourse and development. Recently, both research and clinical communities have begun to pay close attention to the complexity of comorbidities in an attempt to appreciate its scope and utility for enhancing practice and patient outcomes [7–9]. Specific calls have been made for changes for the multimorbid in (1) how quality
is measured, (2) how health care is delivered and paid for, and (3) informed clinical decision making [10, 11]. But comorbidity continues to be plagued by two critical errors rooted in the conceptualization and measurement of the concept. Because of these errors, any current definition of comorbidity should be endorsed carefully. Furthermore, the science cannot advance until they are addressed.

To better understand and delineate these conceptualization and measurement issues, an integrative review of the current interprofessional discourse surrounding comorbidity was conducted using published editorials, commentaries, and review articles. A literature search was carried out using ISI Web of Science (Science Citation Index Expanded and Social Sciences Citation Index). Review and editorial materials published in the English language between 1999 and 2012 were searched using the terms “comorbid,” “comorbidity,” and “comorbidities” in the title, resulting in 1,354 titles. Meeting abstracts \((n = 526)\) and proceeding papers \(n = 47\) were excluded, yielding 781 articles. Pediatric \(n = 44\) and empiric, disease-specific articles were excluded, yielding a final set of 29 articles. This resulted in a synthesis of the current conceptual and measurement issues surrounding comorbidities and an offering of recommendations with potential to address these issues. Future directions were identified in the conceptual, measurement, and analytical domains.

2. Errors of Conceptualization

Correct conceptualization of comorbidity is a necessary precondition for knowledge development. The correct ascertainment of comorbidity inevitably depends upon the correct identification of the underlying etiology. The etiological science is constantly evolving and will always remain imperfect. In the absence of sound etiological grounding, the science of comorbidity has been criticized for being atheoretical or without a theoretical base [12, 13]. Four problems currently confound the advancement of comorbidity conceptualization— the presence of heterogeneous definitions, an inadequate nosological system, a lack of modeling of the dynamic patterns of relationships between chronic conditions, and an atheoretical understanding of the causes and predictors of comorbidity.

2.1. Problem Number 1—Heterogeneous Definitions. The term comorbidity was introduced by Feinstein in 1970 to signify a “distinct additional clinical entity” occurring in the setting of an index disease [1]. The term has been used loosely in the literature to imply either “coexisting” diseases or “cooccurring” diseases (Figure 1). Although often used interchangeably, important distinctions exist; for instance, the simultaneous presence of multiple health conditions is also termed “coexisting diseases,” “multiple pathology,” and “multimorbidity” when no single condition can be identified as an index disease [4, 14]. On the other hand, comorbidities are termed “cooccurring diseases,” “concomitant diseases,” and “disease clustering” when diseases cooccur at a significantly higher rate than expected by chance alone [14]. Thus, the existing terms used to denote comorbidities have distinct conceptualizations and scientific implications while still being used interchangeably.

2.2. Problem Number 2—Inadequate Nosological System. The bulk of debate on the nature of comorbidities lies in the domain of nosology or disease classification. This discourse centers on the teasing part of real or true comorbidities from artifacts or spurious comorbidities. To qualify as a comorbid condition, Feinstein argued that each disease must represent a “distinct” disease/clinical entity with unique pathophysiology, course, and response to treatment while sharing a common diathesis/etiology [15]. This is where the conceptualization of comorbidity gets murky, as limited nosological systems challenge the very foundation of the comorbidity designation.

The designation of a valid clinical entity (or taxon disease) assumes that the diagnostic nosology is a concrete science, which is far from the case. There have been several iterations of both the Diagnostic and Statistical Manual of Mental Disorders (DSM) and International Statistical Classification of Diseases (ICD) with earlier versions differing significantly from current ones. This is epitomized in the recognition of depression and mania as “two distinct” clinical entities until late 19th century to a “single” disease, bipolar disorder, in the DSM-III (see Figure 2). Further, the “operational rules” used in the construction of the DSM creates a clinical scenario of diagnostic proliferation when diseases may actually be an extension of the same underlying process [10, 12, 13]. For instance, anxiety is frequently present in individuals with depression; however, the rule in the DSM does not allow occurrence of the same symptom in more than one disorder, resulting in the creation of additional DSM diagnostic categories such as “mixed depressive-anxiety” [12, 13]. Thus, concomitance of two or more diagnoses may indicate either the presence of distinct clinical entities or point to multiple manifestations of a single clinical entity [12, 13, 16, 17]. Contrary to the DSM, the ICD classification
allows for similar symptoms or indicator patterns to appear in more than one disorder. Diseases with different etiologies that produce similar pathology and symptoms are defined as two separate diseases in the ICD classification. However, the knowledge of diseases with shared etiologies, but disparate clinical symptoms, is limited. Further, physical and psychological conditions remain in silos based on an oversimplified approach to studying diseases that dichotomize the mind and body [12, 13, 17]. The 22 chapters of the ICD-10 are organized according to organ systems, and one chapter is devoted to mental and behavioral disorders [18]. Thus, the nosologies are destined to remain arbitrary within the limitations of the existing science and are based on operational rather than theory-based diagnostic criteria [6, 10, 12, 13].

Consequently, some authors have advocated for an epidemiological approach to identifying common patterns of cooccurrence that will offer directions for further rigorous investigation of etiology [19]. The idea is to employ an *a fortiori* approach using observed morbidities and estimate if these conditions cooccur beyond random chance or expected rates of overlap [11, 19]. Other authors warn that *a fortiori* categorization or use of observational variables to arrive at taxon disease entities is unlikely to be useful or may even be harmful [2] and advocate for a more direct investigation of etiological factors that can distinguish taxon disease entities from regions of artifact [2]. Specifically, Drake warns that too much reliance on manifest symptoms can lead to “confused and confusing attempts” to classify and treat diseases [20] resulting in diagnostic proliferation and unnecessary polypharmacy.

2.3. Problem Number 3—Dynamic Patterns of Relationships. As noted earlier, the simultaneous presence of multiple health conditions is termed as comorbidity when there is an index condition as well as other distinct conditions and as multimorbidity when no single condition is identified as an index disease [4, 14]. An index disease refers to a condition or core mechanisms with relatively large impact on the development of comorbidity, its course and outcomes [21]. While operationally appropriate, the above conceptualizations undermine the dynamic and heterogeneous nature of comorbidities.

C. van Weel and Schellevis [22] proposed four categories to capture the complex relationships among disease entities: (1) causal (diseases with a common pathophysiology), (2) complicating (disease-specific complicating morbidity), (3) concurrent (coexisting chronic morbidity without any known causal relation to the index disease), and (4) intercurrent (referring to interacting acute illness, usually limited in time). Based on evidence, additional levels of complexities can be introduced in the above categorization (see Figure 3). The *antecedent-consequent* (Figure 3(B)) category may be further confounded by the evidence of *reciprocal* (Figure 3(C)) and bidirectional association between diseases [23, 24]. For instance, heart disease and diabetes may increase risk for depression and depression may in turn increase the risk for cardiovascular disease and diabetes [19, 21]. Further, several antidepressants have anti-inflammatory properties and anti-inflammatory agents such that cyclooxygenase-2-selective inhibitors have been found to offer mood stabilizing benefits [21] suggesting presence of a *principal or causal* (Figure 3(D))
underlying mechanism responsible for multiple clinical conditions. Similarly, complicating morbidity, as proposed by van Weel and Schellevis, assumes an antecedent temporal relationship of an index disease to a consequent disease which may be arbitrary. This is because a latent-manifest (Figure 3(E)) relation among diseases is plausible; often clinical diagnoses are based on manifest indicators whereas an assumed consequent disease may have been present for years below the threshold level for clinical diagnosis [2]. Further, the relationship among diseases is complicated by other variables often neglected in comorbidity conceptualization and measurement such as stage, severity, complexity [6], health status, frailty, disability [25], and differences across socioeconomic, racial, gender, and age groups [8]. The specific interactions among risk factors and diseases may have synergistic, additive, or multiplicative effects on outcomes [14, 19].

Adding further levels of complexity in the understanding of patterns of relationships between diseases is the classification of diseases as distinct entities when in fact they may share underlying genetic homogeneity. Our human genome (the composite total of all of our chromosomes) is 99.9% identical within each individual; however, the genome is so large that there are about 3 million ways in which we can differ from one another [26]. Some of these differences predispose individuals to disease susceptibility. This is compounded by epigenetic factors, or our risk exposures in life, in which genetic expression can be altered [27, 28]. In effect, the impact of these genetic alterations can lead to health aberrations that manifest throughout multiple body systems, thus contributing to underlying comorbid pathophysiological processes.

2.4. Problem Number 4—Atheoretical Understanding of Causes and Predictors. An understanding of the causes encompassing both the mechanisms and explanations of those mechanisms and predictors of unique patterns of comorbidities is the least developed area in the comorbidity literature. In an empirical review of causes and consequences of comorbidity, only 4 of 82 studies were concerned with the predictors of comorbidity [14]. This finding was supported by a more recent review of empiric comorbidity studies which found a similar lack of measurement of predictors of comorbidity [29]. Studies of social, environmental, and lifestyle risk factors are particularly lacking in the literature [14, 23, 30]. The paucity of research on antecedents versus consequences is understandable since consequences are relatively more straightforward to investigate and more rewarded in the prevailing culture of outcome-based medicine. In contrast, understanding etiologies represents a nearly insurmountable task of understanding a complex interplay of
genetic, epigenetic, biological, neurochemical, structural, social, environmental, and situational risk factors with other intervening mediating and moderating variables [2, 4, 12, 16, 23]. Nevertheless, the predictor-based approach to understanding comorbidities is important since the risk factors for comorbidities are not randomly distributed in the population [4].

Further, there is a lack of critical use of certain variables as predictors of comorbidities. The variable of age is a case in point. Epidemiological and registry data for various incident diseases suggest that a number of comorbidities increase with age [4, 14, 31, 32]. It has been suggested that aging is related to increased burden of comorbidity and that comorbidity will only increase in the face of increasing life expectancy [4, 9]. Others have taken a more critical approach to understanding the effect of age and have argued that the disproportionate representation of certain age groups may result in conflicting conclusions on the relationships between age and comorbidity outcomes. For instance, Firat et al. [31] note that selection bias based on age in clinical trials precludes an understanding of the influence of age on comorbidity-related outcomes. Using an example from Dajczman et al. (as cited in Firat et al.), illustrated that patients 70 years or older are systematically excluded from cancer clinical trials. Only 1 of 81 patients older than 70 years of age was treated as part of an investigational protocol for small-cell lung cancer despite the evidence that a number of “fit elderly” can tolerate cancer treatment protocols. Nonetheless the protocol developed based on the age discrepancy is often accepted as the standard of care for all age groups [31].

In contrast, a Radiation Therapy Oncology Group (RTOG) study of concurrent chemotherapy and radiation therapy among “fit elderly” patients demonstrated greater survival benefits in older persons when compared to younger patients, illustrating that age may not be categorically associated with comorbidities and outcomes [31].

The quandary of age as an antecedent to comorbidity and outcomes remains. Most authors have used an aging society to underscore the significance of comorbidity work, and others have explicitly described age as an independent risk factor for comorbidities and multimorbidities [4, 6]. Stochastic risk factors that contribute to diseases increase with age (e.g., environmental exposure to toxins, passive smoking, and acquired genetic changes). Nevertheless, most studies have investigated the “on-average” effect of age and the risk may be different for subgroups of healthy-aged patients.

3. Errors in Measurement

Measurement influences everything currently known about comorbidity. The presence of comorbidity causes two related difficulties: one statistical and one clinical. The statistical problem arises from a failure to classify and analyze patients and their multiple diseases correctly resulting in misleading, therapy-related, mortality data in populations and individuals [1]. Clinically, comorbidity creates difficulties for both patients and clinicians. For the patient, anticipated outcomes from the index disease may differ based on the amount or type of comorbidities present. For the clinician, diagnosis becomes problematic as the index disease and comorbid disease may share signs and symptom patterns [33] complicating the evaluation of treatments [1].

The statistical difficulties, however, have driven comorbidity measurement from the beginning [1] and continue to exert an undue influence to today [3, 8, 34]. In clinical research the focus has been on controlling for comorbidity rather than understanding the particular condition and the implications for the patient. In the mid-1970s, Kaplan and Feinstein [33] grappled with taxonomic problems in classifying diabetes as a disease entity. In the 1980s, Charlson and colleagues [35] developed a comorbidity index to prospectively identify patients at greater risk of death during clinical trials. This focus on controlling for comorbidity continues on into the digital age with the development of measures utilizing ICD-10 codes [36–38] to aggregate large amounts of administrative data to analyze mortality and resource utilization patterns. For example, de Groot and colleagues [34], in a widely cited critical review of comorbidity measurement methods, listed four key reasons for careful measurement—confounding, effect modification, prediction, and efficiency. All four reasons are statistical rather than clinical and none are patient centered. But despite this focus on statistical precision there remain critical problems which result in errors in the measurement of comorbidity, primarily related to the presence of heterogeneous data sources, atheoretical summary measures, and outcome selection bias.

3.1. Problem Number 1—Heterogeneous Data Sources. The current identification of comorbidities is generally based on multiple data sources (administrative data sources, medical record review, clinician judgment, and patient interview) [29], each with advantages and limitations [8]. For instance, there are known limitations in using diagnostic data from ICD-10 codes, Current Procedural Terminology (CPT) codes, and discharge diagnoses as they pertain mainly to intensity and currency of services used which may exclude chronic diseases that are self-managed or pharmacologically managed. Other challenges in using ICD codes include “upcoding” (assigning a disease code associated with better payment) [36], underreporting (including only the number of secondary disease codes allowed by the database) [37], and failing to distinguish comorbidities from complications of care or severity indicators for the index disease [38]. Similarly, the use of pharmacy databases to ascertain comorbidities suffers from limitations, since participants may not have uniform access to drugs or may fill their prescriptions at pharmacies other than the one housing the database [8]. Using medical records as a data source requires the availability of longitudinal data to assure accurate construction of a comorbidity index. Even when available, the quality of data may vary by setting (inpatient versus outpatient) [8], format (electronic or paper-based), and quality of documentation across providers. Further, certain populations such as minorities, poor, uninsured/underinsured, elderly, and cognitively impaired are at higher risk for poor quality of diagnosis and documentation [4, 8]. Similarly, self-reported measures are
limited due to risk of recall bias and may yield heterogeneous data due to variability in patient reporting.

3.2. Problem Number 2—Atheoretical Summary Measures. Regardless of the data source, the majority of comorbidity measures are summary or aggregate measures. Although summary measures are important in quantifying the effect of an overall disease burden on outcomes, the greatest liability of summary measures is that they do little to advance the science underpinning comorbidities. Diseases occur on a continuum from presence of risk factors, subclinical disease to clinically detectable disease, progressing to multiple stages of advancement. Some elements of this disease continuum may not be amenable to direct observation or measurement. The “dynamic” component of disease progression, including the severity and rate of progress is beyond what most comorbidity instruments are able to capture. The operationalization of a principal or index disease is often based on investigator’s lens and serves the purpose of contextualization. Thus the majority of the existing comorbidity measures are atheoretical and consequently limited in their ability to prognosticate [9] and advance science on diagnostic consolidation or common treatment approaches.

Further, the existing measures and data sources may have varying levels of sensitivity for specific outcomes. For example in a study involving adults with lung cancer, comorbidity was related to survival outcomes when measured with the Cumulative Index Rating Scale. However, no association was found when the same outcome was measured using the Charlson Comorbidity Index [31]. It is also important to note that the most frequently used comorbidity measures are generic and often measure “multimorbidity” or “coexisting diseases” rather than comorbidities. Such measures may be appropriate for and sensitive to generic endpoints but not necessarily useful for disease- or treatment-specific outcomes.

3.3. Problem Number 3—Outcome Selection Bias. The outcome of comorbidities can be classified as generic (e.g., functional status, mortality) or disease-specific. Similar to the designation of an index disease, outcomes of comorbidities depend directly upon how they are identified, operationalized, and measured in a given study. Unlike generic outcomes that cut across diseases and comorbidities, disease-specific outcomes typically necessitate specific operationalization and tailored measurement. Disease- and treatment-specific outcomes have been noted to affect course and progression of illness [19], tolerance and response to treatment and treatment-related complications [19, 31], and behavioral outcomes [23]. It should be noted that outcomes in treatment-specific “efficacy” trials are known to be influenced by patient selection [31]. The presence of multimorbidity or certain types of morbidities is frequently exclusion criteria in efficacy trials [4, 11], which in turn may affect the study of treatment response, tolerance, and survival outcomes in the multimorbid.

A further example of potential selection bias was illustrated in the comprehensive review conducted by Gijsen and colleagues [14] which concluded that while comorbidity typically affected health outcomes across study designs, settings, and outcomes with the effect remaining after adjustment of relevant confounders; that mortality, functional status, and quality of life were disproportionately reported as consequences of comorbidity. Interestingly, psychiatric comorbidities were found to be significantly associated with poor functional status or quality of life, whereas physiologic morbidities were associated with mortality. This may be artifact as effects of psychiatric comorbidities on outcomes such as mortality and health care utilization were seldom studied. In the few studies that investigated mortality outcomes in psychiatric comorbidities, mental disorders increased the risk for mortality both from suicide and having a comorbid disease [14]. The strong link of mental illness to worsening of physical health, illness burden, and premature mortality continues to be documented [19, 39].

From a health service perspective, comorbidities have been found to be consistently related to healthcare utilization and fiscal outcomes including cost, length of hospital stays, and number of physician visits [4, 14, 29]. In addition, there is evidence of interaction between age and patterns of utilization [4, 14] such that higher numbers of comorbidities in older adults are associated with more visits to both specialists and primary care providers (PCPs). In contrast, in the populations under 65 years, a greater number of specialist visits than PCPs visits were observed across all morbidity burden groups [4, 14].

4. Discussion

Despite accumulating literature, effective models for understanding, measuring, and addressing comorbidities are lacking. The two major approaches in the literature to address comorbidities are epidemiological and etiological (Figure 4). The epidemiological approach requires identifying disease entities that cooccur beyond random chance. This approach is purported to be “atheoretical” with accompanying risk of polypharmacy and diagnostic proliferation [4, 12, 13, 15, 40]. However, the etiological approach is in its rudimentary stages of development possibly due to intractability of identifying risk factors, shared mechanisms, interactions, and outcomes around any combination of diseases. New conceptual models are needed informed by an understanding of patterns of relationships among clinical and subclinical disease entities and mechanisms.

Further, current barriers to moving towards a theoretical conceptualization of comorbidity need to be addressed. For instance, while many studies have been conducted to understand the consequences of comorbidities and multimorbidities, little research exists on common etiology and combined risk factors [14]. Specifically lacking are studies of psychological, environmental, and life-style risk factors [11, 14]. Some authors have cautioned that the debate around comorbidities should not be framed such that it leads to overvaluing of physiologic and pharmacological theories at the risk of undervaluing social etiologies [19, 20]. For instance, conceptualizing comorbid mental illness and substance use disorder as merely physiological may undermine
the sociohistorical etiology of this relationship brought about by the closing and downsizing of mental health facilities [20].

Another barrier precluding research advancement relates to operationalizing comorbidities based on historical disease classification systems. Despite considerable evidence that psychiatric diseases are frequently accompanied by physical morbidities [41], researchers studying comorbid mental illnesses frequently fail to employ measures of physical morbidity and vice versa.

Furthermore, failure to investigate comorbidities in a manner that captures patient’s clinical complexity is another factor precluding advancement of comorbidity science. Investigators frequently exclude patients with complex comorbidities from clinical trials and fail to identify, report, and account for comorbidities in research even when they are present [4]. These research limitations may help to explain the clinical variability observed when protocols based on disease-specific clinical trials are applied to people with complex comorbidities [4]. Starfield [4] urged that rather than excluding patients with complex morbidities, participants in clinical trials should be characterized according to their total morbidity burden including patterns and types of illnesses followed by subgroup analysis to understand variability in outcomes based on morbidity burden.

4.1. Recommendations for Addressing Conceptual and Measurement Errors. Rigorous studies that capture the complexity of comorbidities and its etiology from social, psychological, and biological perspectives are needed (Table 1). Researchers should carefully consider potential design and measurement issues in designing studies. For instance, the ascertainment of comorbidities depends upon both correctly applying diagnostic algorithms and accurately recording diagnostic data. This, in turn, depends upon factors including clinician’s judgment, diagnostic skills, as well as accurate and complete documentation in the medical records. Special attention should be paid to inclusion of vulnerable populations such as minorities, poor, uninsured/underinsured, elderly, and cognitively impaired people who are disproportionately affected by ascertainment bias [4, 8].

While correct ascertainment of comorbidities and minimizing sources of errors are important, these corrections do not address the problems related to measurement. An area in need of critical debate is the scientific approach to addressing measurement gaps. The classical psychometric approaches seek to identify consistency and homogeneity in a phenomenon while “dehumanizing” clinical data to make it amenable for statistical analysis [11, 42]. Psychometric models alone may not be appropriate for a heterogeneous and dynamic concept like comorbidities.

5. Limitations

Certain limitations should be acknowledged in this paper. This review was not meant to be systematic and exhaustive; rather the purpose of this paper was to understand the current fluid discourse and directions on comorbidities, which research literature often misses due to focusing on a narrow set of (often disease-specific) variables under study. Thus nonempirical literature (reviews, editorials, and commentaries) was deliberately selected to allow a more inclusive understanding of this topic. Also, we limited our literature search terms to the words “comorbid,” “comorbidity,” and “comorbidities” in the title, which defined the pool of included papers. Use of different search terms in different databases may have resulted in the identification of additional papers not included here. This should be kept in mind when examining the findings. However, based on our experience with an earlier systematic review conducted by members of this group [29], we are confident that this search captured the salient papers related to current interprofessional discourse surrounding comorbidity.

6. Conclusions

Extant literature suggests that the nature of comorbidities is defined by an evolving nosology, dynamic and heterogeneous interactions between and among disease entities that may not follow a clear antecedent-consequent relationship nor linear-temporal progression. The index designation may be
Table 1: Recommendations for improving comorbidity conceptualization and measurement.

<table>
<thead>
<tr>
<th>Domain</th>
<th>Directions</th>
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<tbody>
<tr>
<td>Conceptual</td>
<td>(i) Carve valid next steps with integrated input from clinicians, researchers, taxometricians, psychometricians, and patients.</td>
</tr>
<tr>
<td></td>
<td>(ii) Develop complex conceptual models that capture the complexity of comorbidities while moving away from mind-body, organ system dichotomies.</td>
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<tr>
<td></td>
<td>(iii) Conceptualize comorbidities in a manner that encourages investigation of both biological and social etiologies of comorbidities and outcomes.</td>
</tr>
<tr>
<td></td>
<td>(iv) Keep the patient at the center of all conceptualization endeavors.</td>
</tr>
<tr>
<td></td>
<td>(v) Build the science from both epidemiological and etiological perspectives in tandem.</td>
</tr>
<tr>
<td>Research</td>
<td>(i) Design rigorous longitudinal comorbidity mapping projects that also collect comprehensive data on sociodemographics, lifestyle factors, environmental factors, biomarkers, and outcomes.</td>
</tr>
<tr>
<td></td>
<td>(ii) Commit resources and funding (directed RFAs and supplements from major research agencies and across institutes).</td>
</tr>
<tr>
<td></td>
<td>(iii) Bridge gaps in understanding of physical and psychiatric morbidities.</td>
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<td></td>
<td>(iv) Leverage epidemiological and statistical approaches to move comorbidity science from atheoretical to theoretical; that is, model various sources of uncertainty (e.g., multiple bias modeling), amplify data through simulation (Monte Carlo techniques), and improve understanding of relationships among variables (e.g., using Hybrid Structural Equation modeling techniques combining observed and latent variable analysis).</td>
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<tr>
<td></td>
<td>(v) Interpret carefully findings within the limitations of an emerging science rather than as biological realities or &quot;scientific givens&quot;.</td>
</tr>
<tr>
<td></td>
<td>(vi) Educate clinicians, researchers, and policymakers about the risks of atheoretical approaches to understanding comorbidities including diagnostic proliferation, polypharmacy, and cost.</td>
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<tr>
<td></td>
<td>(vii) Include populations such as minorities, poor, uninsured/underinsured, elderly, cognitively impaired, and those with complex morbidities who are disproportionately excluded from comorbidity research.</td>
</tr>
<tr>
<td>Measurement</td>
<td>(i) Characterize and minimize potential sources of erroneous inference.</td>
</tr>
<tr>
<td></td>
<td>(ii) Develop measures that capture complex and dynamic nature of comorbidities beyond numbers and severity of diseases.</td>
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<tr>
<td></td>
<td>(iii) Incorporate a discussion on nontraditional measurement approaches such as clinimetrics in conceptualizing measurement (e.g., approaching comorbidities using a battery of psychometric and clinimetric instruments that address different dimensions of the phenomenon such as types, severity, trajectory of diseases or symptoms, and rates of progression, clinical states such as functional capacity, and other aspects of health such as well-being and distress).</td>
</tr>
<tr>
<td></td>
<td>(iv) Develop measures that combine physical and psychological morbidities.</td>
</tr>
</tbody>
</table>

The concept of comorbidities and its measurement is in need of meaningful debate by the scientific and clinical communities. In the meantime, comorbidities should be contextualized as an emerging science rather than biological realities or "scientific givens" [20]. It is important to be aware of the real risks of overtreatment and overemphasis of medical interventions while underutilization of social and behavioral interventions towards prevention and disease management [20]. Researchers, clinicians, and policy makers are urged to draw careful conclusions and implications in interpreting comorbidity research findings.

**Conflict of Interests**

There is no conflict of interests to report.

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Research Article

A Supportive-Educational Intervention for Heart Failure Patients in Iran: The Effect on Self-Care Behaviours

Vahid Zamanzadeh,1 Leila Valizadeh,2 A. Fuchsia Howard,3 and Fatemeh Jamshidi4

1 Department of Medical-Surgical Nursing, Faculty of Nursing and Midwifery, Tabriz University of Medical Sciences, Tabriz, Iran
2 Department of Pediatric Nursing, Faculty of Nursing and Midwifery, Tabriz University of Medical Sciences, Tabriz, Iran
3 School of Population and Public Health, Faculty of Medicine, University of British Columbia, Vancouver, Canada
4 Cardiovascular Research Center, Tabriz University of Medical Sciences, Tabriz, Iran

Correspondence should be addressed to Fatemeh Jamshidi; jam_fa@yahoo.com

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Background. Chronic heart failure is a major health and social problem. The promotion of self-care behaviours can potentially assist patients to effectively manage this chronic condition and prevent worsening of the disease. Formal personalized educational interventions that provide support and take into consideration the cultural context are needed. Objective. The objective of this research was to evaluate the effect of a supportive-educational intervention on self-care behaviours of heart failure patients in Iran. Methods. This research was a prospective, randomized trial of a supportive-educational intervention. Eighty heart failure patients were randomly assigned to receive the supportive-educational intervention or usual care. The intervention consisted of a one-hour, nurse-led, in-person education session and postdischarge followup by telephone over three months. Data were collected at baseline, one, two, and three months. Results. The control and intervention groups did not differ in self-care scores at baseline (P > 0.05). Each of the self-care scores was significantly higher in the intervention group than the control group at 1, 2, and 3 months (P < 0.001). There were significant differences in self-care behaviours over the three months, among participants in the intervention group. Conclusion. This study provides support for the effectiveness of a supportive-educational intervention to increase self-care behaviours among Iranian patients suffering from chronic heart failure.

1. Introduction

Chronic heart failure (HF) is a significant health and social problem [1]. In the United States alone, nearly 6 million people suffered from HF in 2008, and this disease is becoming increasingly prevalent [2] with more than 550,000 new cases diagnosed each year [3]. Half of HF patients die within 5 years of the first onset of symptoms, and half (50%–60%) of the patients diagnosed with severe HF do not live longer than a year [4]. HF is the most common cause of hospitalization in those over the age of 65 years [5], and 54% of the patients are readmitted to hospital within 6 months of discharge [6]. HF also results in significant morbidity and disability, thereby generating permanent and high health care costs [7]. Heart disease is the leading cause of mortality in Iran [8]; unfortunately, further accurate statistics describing the burden of HF are not available.

Optimal medical management following a cardiovascular event remains underprescribed, and even more so in developing countries [8]. Similarly, nonpharmacological management and interventions are infrequently recommended, and patient adherence to lifestyle modifications remains poor. Recent European research suggests that the control of cardiovascular risk factors, including tobacco use, obesity, hypertension, hypercholesterolemia, and diabetes, is far below an acceptable level [9, 10].

The nature and severity of HF symptoms greatly depend on the patient’s knowledge, cooperation, and active participation in their health management. However, improving health and preventing HF from progressing by adopting self-care skills, adhering to complex treatment regimens, and changing lifestyle behaviours is particularly challenging [3].

According to orem’s self-Care theory, effective self-care activities can reduce the need for hospitalization [11]. This
theory postulates that nurses interact with patients in three ways according to the patient's ability to participate in their care: total compensation, partial compensation, and supportive-educational systems. Patients in the supportive-educational system are capable of engaging in self-care but require education about the different aspects of therapeutic self-care behaviours [12]. Nurses are optimally positioned to identify existing and potential health issues and to provide supportive-educational interventions where appropriate [13].

Postdischarge support in the form of patient education is one of the most effective interventions to improve self-care abilities and behaviours among HF patients, which ultimately improves prognosis and reduces hospital readmission rates [13]. The main objective of education for HF patients is to improve the patient's management of their disease, thereby reducing the onset of complications and morbidity [14]. Patient education is generally delivered within the framework of a comprehensive discharge program and covers information about fluid and sodium intake restriction, diet, exercise, adherence to pharmaceutical treatment, monitoring symptoms, and seeking health care when symptoms worsen [15]. According to a recent systematic review [14], large studies have demonstrated the efficacy of therapeutic education programs in changing cardiac patients' lifestyles and ultimately improving morbidity and cost-effectiveness. Yet, there are no recommendations or standardized guidelines about methods to deliver information and education.

Str"o{}mberg [5] found that most HF patients do not have a clear understanding of recommended self-care behaviours despite receiving related education. Rather, HF patients require further assistance to learn self-care behaviours and adapt to living with a chronic illness. Providing education and training based on individual patient needs and desires is an essential principle in adult education. Therefore, a thorough assessment of HF patients' educational needs and preferences, as well as their beliefs and abilities related to medical and lifestyle recommendations, can provide the foundation for personalizing educational efforts [16].

Interventions to promote self-care behaviours among HF patients, and corresponding research, must take into account culture, which greatly influences diet, exercise, lifestyle, and attitudes toward medical therapy [13]. The few intervention studies conducted in Iran did not evaluate supportive-educational interventions nor did they measure self-care behaviours [17–19]. The purpose of this research was to evaluate the effect of a supportive-educational intervention on self-care behaviours of Iranian HF patients.

2. Methods

2.1. Design and Setting. The Research Council of the Tabriz University of Medical Sciences gave ethical approval for this randomized control trial. Written informed consent was obtained for all participants prior to study enrollment. All participants were recruited from the Shahid Madani Hospital, located in Eastern Iran.

2.2. Sample and Randomization. Consecutive patients admitted to Shahid Madani Hospital with a diagnosis of HF and who met the inclusion criteria were recruited into the study. A sample size of 80 (40 individuals in the intervention group and 40 in the control group) was deemed sufficient based on a preliminary analysis of self-care scores of 5 HF patients. The following parameters guided the present study; the optimal self-care behaviour score in the study was 70, the mean and standard deviation of self-care behaviours scores were estimated (Mean = 25, SD = 6.15), α = 0.05 and power = 0.9 were chosen, and no attrition during followup was anticipated. The participants were randomized into the control and experimental groups using random number software (Figure 1).

2.3. Inclusion Criteria. Participants who were included were of 18 years age and older, diagnosed with New York Heart Association class III or IV HF, had an ejection fraction less than 40%, agreed to predischarge education and follow-up care, and would be available by phone after discharge.

2.4. Exclusion Criteria. Participants who were excluded were those who experienced significant worsening of their disease and transfer to the intensive care unit, were hospitalized for greater than 1 month, had a chronic disease other than HF, or were diagnosed with a mental illness.

2.5. Study Intervention. According to orem's self-care theory, the supportive-educational system is the only system in which patients require assistance in relation to decision-making, behaviour control, and acquiring knowledge and skills. However, the level and type of assistance/care required can vary. Some patients are capable of carrying out self-care behaviours but are in need of guidance and support, while others only require education. Still, others adequately engage in self-care and only require periodic guidance [12]. The supportive-educational intervention in the present study was tailored to address the appropriate level and type of assistance/care as per the participant's need. Those who needed guidance and support were encouraged to continue to carry out current self-care behaviours, and additional information and support were provided related to reducing salt in the diet, restricting fluids, and increasing physical activity for example. Participants requiring education were given information about how to create new self-care behaviours. Participants only requiring periodic guidance were given frequent tips and advice via telephone.

HF participants randomized to the intervention group received a two-part intervention aimed at improving self-care behaviours. The first phase consisted of a one-hour, nurse-led, in-person HF education session that was customized by the nurse according to the participant's level of education. An individualized education booklet was reviewed with literate patients, while for illiterate patients this booklet was reviewed with the participant as well as a family member. The intervention was also customized according to the participant's prior knowledge and learning needs, which was assessed with a learning need inventory. Participants and their family members attended this session. During the education session the following information was reviewed: the definition and symptoms of HF, strategies to prevent the worsening of HF
80 patients eligible for inclusion

First month of followup
- Control = 40
- Experimental = 40

Second month of followup
- Control = 40
- Experimental = 38

Third month of followup
- Control = 40
- Experimental = 38

40 data were analyzed
- Experimental = 40
- Control = 40

38 data were analyzed
- Experimental = 38
- Control = 40

2 were excluded, one patient due to prolonged hospitalization for pacemaker implantation and one for being a candidate for heart transplantation.

Figure 1: Randomization flow chart.

Symptoms, explanations about medications, and recommendations about dietary changes (i.e., reducing salt intake), exercise, and smoking cessation. These participants were given a booklet at the time of discharge that was based on Heart Failure Society of America (HFSA) 2010 Guideline Executive Summary.

The second phase of the intervention included postdischarge telephone followup. The objective of this phase was to reiterate and review information covered during the initial education session and improve the participant’s ability to cope with the disease, as well as enhance self-care behaviors. The first followup telephone call was made by a nurse two days after hospital discharge to verify participant information and determine the next date of contact. The nurse then contacted the participant by phone every two weeks for 3 months. During these phone calls the nurse asked the participant whether they were experiencing any signs or symptoms that would suggest worsening HF. The nurse also reviewed the recommended self-care behaviours and provided support in the form of advice and encouragement when deemed necessary. These follow-up telephone calls typically lasted 15 minutes. The participants were also advised to contact the nurse if any question or an acute medical issue arose related to preventing or managing their HF.

Participants who were randomized to the control group received usual care provided by the hospital and attending physician (nonsystematic and informal teaching).

2.6. Assessment Tools. Sociodemographic characteristics were gathered through individual interviews and medical data were extracted from medical records.

The educational needs of participants in the intervention group were assessed with a self-report questionnaire, which was filled out independently with pen and paper or with the assistance of a nurse during a face-to-face interview. The education needs assessment instrument [20] is specific to HF patients and consists of 42 items, with 7 subscales to assess learning needs in the areas of anatomy, physiology, diet, activity, cognitive factors, risk factors, and pharmaceutical information. This instrument uses a five-point Likert scale (ranging from least important to know = 1 to most important to know = 5).

Baseline self-care behaviour data were collected with the pen and paper method or during face-to-face interviews using the self-care of heart failure index (SCHFI) [21]. Subsequent self-care behaviour data were collected with this instrument by telephone at 1, 2, and 3 months following hospital discharge. Completion of the SCHFI took 15 minutes. The SCHFI consists of 22 items in three subscales. The maintenance self-care behaviours scores includes 10 questions, the self-care management the scores includes six items, and the self-care confidence the scores includes seven questions. All items are scored on a four-point Likert scale from 1 (poor self-care behaviour) to 4 (optimal self-care behaviour), and summative scores are standardized on a scale of 0 to 100. A cutoff point of ≥70 on each SCHFI scale is used to judge self-care adequacy [21].

To ensure the accuracy of the Farsi translation of these instruments, they were reviewed by three professors (two with English language M.A. degrees and one with an M.S. degree in nursing) and revised accordingly. The instruments were reviewed for content validity by 12 faculty members of Tabriz University of Medical Sciences (9 with an M.S. and 2 with a Ph.D. in nursing, one of whom specializes in cardiovascular care). The reliability was determined through test-retest methods, wherein the instruments were given to 10 HF patients twice, 2 days apart. The correlation coefficient
between these two time points was 96%. These patients were not participants in the current study.

2.7 Statistical Analysis. Measures of central tendency mean, standard deviation, and percentage were used to describe participant characteristics at baseline. The control and intervention groups’ self-care behaviours were compared at baseline, 1, 2, and 3 months using t-tests. A repeated-measures ANOVA was used to determine time effects and the impact of group on different aspects of self-care behaviours. The significance level was set at $P < 0.05$.

### Table 1: Patient demographics.

<table>
<thead>
<tr>
<th></th>
<th>Intervention group ($n = 38$)</th>
<th>Control group ($n = 40$)</th>
<th>Statistics</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean ± SD or $n$ (%)</td>
<td>Mean ± SD or $n$ (%)</td>
<td></td>
</tr>
<tr>
<td>Age in years</td>
<td>65.82 ± 9.87</td>
<td>61.63 ± 12.47</td>
<td>$t = 1.63$</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>$df = 76$</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>$P = 0.10$</td>
</tr>
<tr>
<td>Gender</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>24 (57.9)</td>
<td>19 (47.5)</td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>16 (42.1)</td>
<td>21 (52.5)</td>
<td>$x^2 = 1.63$</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>$df = 1$</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>$P = 0.38$</td>
</tr>
<tr>
<td>Educational level</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Illiterate</td>
<td>20 (52.6)</td>
<td>26 (65)</td>
<td>$x^2 = 6.44$</td>
</tr>
<tr>
<td>Primary</td>
<td>12 (31.6)</td>
<td>5 (12.5)</td>
<td>$df = 5$</td>
</tr>
<tr>
<td>High school</td>
<td>6 (19.4)</td>
<td>6 (15)</td>
<td>$P = 0.26$</td>
</tr>
<tr>
<td>University</td>
<td>0</td>
<td>1 (2.5)</td>
<td></td>
</tr>
<tr>
<td>Marital status</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Single</td>
<td>0</td>
<td>2 (5)</td>
<td>$X^2 = 4.19$</td>
</tr>
<tr>
<td>Married</td>
<td>31 (81.6)</td>
<td>35 (87.5)</td>
<td>$df = 3$</td>
</tr>
<tr>
<td>Widowed, divorced</td>
<td>7 (18.2)</td>
<td>3 (7.5)</td>
<td>$P = 0.24$</td>
</tr>
<tr>
<td>Occupation</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Housewife</td>
<td>16 (42.1)</td>
<td>21 (52.5)</td>
<td>$X^2 = 2.61$</td>
</tr>
<tr>
<td>Employee</td>
<td>1 (2.6)</td>
<td>2 (5)</td>
<td>$df = 3$</td>
</tr>
<tr>
<td>Private</td>
<td>12 (31.6)</td>
<td>7 (17.5)</td>
<td>$P = 0.24$</td>
</tr>
<tr>
<td>Unemployed, and so forth</td>
<td>9 (22.7)</td>
<td>10 (25)</td>
<td></td>
</tr>
<tr>
<td>Heart failure illness and treatment characteristics</td>
<td>$X^2 = 0.05$</td>
<td>$df = 1$</td>
<td>$P = 0.82$</td>
</tr>
<tr>
<td>NYHA functional class</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>III</td>
<td>20 (52.6)</td>
<td>18 (45)</td>
<td></td>
</tr>
<tr>
<td>IV</td>
<td>18 (47.4)</td>
<td>22 (55)</td>
<td>$P = 0.82$</td>
</tr>
<tr>
<td>Ejection fraction</td>
<td>25.73 ± 9.20</td>
<td>24.05 ± 8.94</td>
<td>$df = 75$</td>
</tr>
<tr>
<td>Aetiology</td>
<td></td>
<td></td>
<td>$P = 0.61$</td>
</tr>
<tr>
<td>Ischaemic</td>
<td>11 (28.9)</td>
<td>15 (37.5)</td>
<td>$X^2 = 5.01$</td>
</tr>
<tr>
<td>Hypertensive &amp; dilated</td>
<td>18 (47.4)</td>
<td>12 (20)</td>
<td>$df = 6$</td>
</tr>
<tr>
<td>Cardiomyopathy &amp; valvular</td>
<td>8 (21)</td>
<td>8 (20)</td>
<td>$P = 0.54$</td>
</tr>
<tr>
<td>Medication</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diuretic</td>
<td>6 (15)</td>
<td>4 (10)</td>
<td>$X^2 = 0.92$</td>
</tr>
<tr>
<td>Beta blockers and diuretic</td>
<td>11 (28.9)</td>
<td>9 (22.5)</td>
<td>$df = 2$</td>
</tr>
<tr>
<td>Digoxin and diuretic</td>
<td>21 (55.3)</td>
<td>27 (67.5)</td>
<td>$P = 0.63$</td>
</tr>
</tbody>
</table>

3. Results

3.1 Sample Characteristics. A total of 200 HF patients were screened for inclusion from July to September 2011. 80 HF patients with an ejection fraction above 40% were excluded, 20 patients with severe HF were transferred to another hospital unit, and 20 patients declined to participate. The 80 remaining patients were enrolled in the study and randomized into the control ($n = 40$) or intervention ($n = 40$) groups. Of the 40 individuals assigned to the intervention group, two did not complete the study; one participant required pacemaker implantation, and another became a heart transplant.
Table 2: Comparison of self-care scores (maintenance, management, and confidence) by group and time.

<table>
<thead>
<tr>
<th></th>
<th>Intervention</th>
<th>Control</th>
<th>Student’s t-test, P value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Self-care maintenance</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline</td>
<td>18.5 (12)</td>
<td>21.9 (14.6)</td>
<td>–1, &gt;0.05</td>
</tr>
<tr>
<td>1st month</td>
<td>56.6 (25)</td>
<td>23.8 (15)</td>
<td>6.9, &lt;0.001</td>
</tr>
<tr>
<td>2nd month</td>
<td>70.2 (21.3)</td>
<td>30.5 (16.4)</td>
<td>9.2, &lt;0.001</td>
</tr>
<tr>
<td>3rd month</td>
<td>75.1 (20.7)</td>
<td>31.9 (15.5)</td>
<td>10.4, &lt;0.001</td>
</tr>
<tr>
<td><strong>Self-care management</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline</td>
<td>11.9 (11.9)</td>
<td>16.7 (16.7)</td>
<td>–1.4, &gt;0.05</td>
</tr>
<tr>
<td>1st month</td>
<td>48.9 (20.5)</td>
<td>21.5 (16.7)</td>
<td>6.4, &lt;0.001</td>
</tr>
<tr>
<td>2nd month</td>
<td>61.1 (18.5)</td>
<td>28.2 (17.4)</td>
<td>8, &lt;0.001</td>
</tr>
<tr>
<td>3rd month</td>
<td>66.5 (15.3)</td>
<td>30.3 (17.6)</td>
<td>9.6, &lt;0.001</td>
</tr>
<tr>
<td><strong>Self-care confidence</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline</td>
<td>10.6 (13.3)</td>
<td>16.8 (14.4)</td>
<td>–1.9, &gt;0.05</td>
</tr>
<tr>
<td>1st month</td>
<td>53.5 (24.6)</td>
<td>18.3 (16.5)</td>
<td>7.3, &lt;0.001</td>
</tr>
<tr>
<td>2nd month</td>
<td>66.1 (23.2)</td>
<td>23.6 (17)</td>
<td>9.1, &lt;0.001</td>
</tr>
<tr>
<td>3rd month</td>
<td>69.6 (25.3)</td>
<td>27.6 (18.6)</td>
<td>8.3, &lt;0.001</td>
</tr>
</tbody>
</table>

Table 3: ANOVA test for comparisons of changes in self-care before the intervention and during the first, second, and third months after the intervention in the intervention and control groups.

<table>
<thead>
<tr>
<th>Change source</th>
<th>Type III sum of squares</th>
<th>df</th>
<th>Mean square</th>
<th>F</th>
<th>Sig.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Month effect</td>
<td>54786.96</td>
<td>2.13</td>
<td>25687.18</td>
<td>228.02</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Group effect</td>
<td>54610.00</td>
<td>1</td>
<td>54610.00</td>
<td>61.166</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Within-subjects contrasts</td>
<td>26148.27</td>
<td>2.13</td>
<td>12259.77</td>
<td>108.82</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Within-subjects errors</td>
<td>18260.55</td>
<td>162.09</td>
<td>112.65</td>
<td>228.02</td>
<td>61.16</td>
</tr>
<tr>
<td>Between-subjects errors</td>
<td>67854.36</td>
<td>76</td>
<td>892.82</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Table 4: Bonferroni post hoc test for pairwise comparisons of changes in self-care before the intervention and during the first, second, and third months after intervention.

<table>
<thead>
<tr>
<th>(I) Month</th>
<th>(J) Month</th>
<th>Mean difference (I-J)</th>
<th>Std. error</th>
<th>Sig.</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>1</td>
<td>–21 (*)</td>
<td>1.59</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>2</td>
<td>–30.53 (*)</td>
<td>1.72</td>
<td>&lt;0.001</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>–34.10 (*)</td>
<td>1.78</td>
<td>&lt;0.001</td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>2</td>
<td>–9.53 (*)</td>
<td>0.97</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>3</td>
<td>–13.09 (*)</td>
<td>1.30</td>
<td>&lt;0.001</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>3</td>
<td>–3.56 (*)</td>
<td>0.98</td>
<td>0.003</td>
</tr>
</tbody>
</table>

*The mean difference is significant at the 0.05 level.

Table 5: Bonferroni post hoc test for comparison of two groups for self-care change.

<table>
<thead>
<tr>
<th>(I) Group</th>
<th>(J) Group</th>
<th>Mean difference (I-J)</th>
<th>Std. error</th>
<th>Sig.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intervention Control</td>
<td>26.46 (*)</td>
<td>3.28</td>
<td>&lt;0.001</td>
<td></td>
</tr>
</tbody>
</table>

3.2. Self-Care Behaviours. The control and intervention groups did not differ in self-care scores at baseline, prior to delivery of the intervention. Each of the self-care scores was significantly higher in the intervention group than the control group at 1, 2, and 3 months (Table 2). The ANOVA results showed significant differences in self-care between the control and intervention groups (Tables 3 and 5). The results also showed significant difference in self-care behaviours over the three months, such that as time progressed self-care scores among participants in the intervention group continued to increase (Table 4).

4. Discussion

This study provides evidence that a supportive-educational intervention can strengthen and establish new self-care behaviours among HF patients in Iran. This intervention,
informed by Orem’s self-care theory, provided patient education about self-care behaviours to assist in the management of HF, as well as support in the form of telephone follow-ups. This improvement in self-care behaviours is consistent with previous research, wherein self-care skills among HF patients were improved following one educational session and an eight-month followup with a nurse educator [1]. Additional advances of educational interventions have been documented. Strömberg and colleagues [4] found that the readmission rate and healthcare costs also decreased with educational interventions that included follow-up support for HF patients. This provides support for including education about self-care activities, including nonpharmaceutical interventions, as a part of standard management of hospitalized HF patients. This educational training ought to begin when patients are initially hospitalized and continue following discharge.

In the present study, improvements in self-care among participants in the intervention group were not only maintained, but continued to improve over the three months. This finding lends support to comments made by Evangelista [10] that education alone does not lead to positive outcomes, and that using behavioural strategies, such as reinforcing behaviours through a follow-up program, can help optimize self-care. However, it is unknown how long beyond the 3-month followup the improvements made in self-care in the present study lasted among participants in the intervention group. There is evidence that the effect of educational interventions on self-care behaviours is not maintained over time [22–24].

5. Limitations and Suggestions

It was likely that the participants gave incorrect answers to the self-report questions. However, by gaining their trust and explaining the confidential nature of the study, we attempted to control false reporting. Patient education is currently an essential part of treating chronic diseases such as HF; but, in the busy day-to-day practice of caring for HF patients, education often is not a priority. We recommend that time and resources are to be allocated to enable health care professionals to adequately promote patients’ self-care behaviours through supportive-educational interventions. The present research also suggests that further knowledge about factors that limit or promote effective patient education is needed to improve their quality and effectiveness.

6. Conclusion

Findings of this study indicated that patients with HF not only need pharmaceutical management by physicians and nurses, but they also require support to enhance their self-care behaviours and non-pharmaceutical management (e.g., reducing salt in the diet, restricting fluid intake, daily weighing, and monitoring the symptoms). According to the results of the present study, implementing personalized, theoretically driven, supportive-educational programs based on non-pharmaceutical management strategies might be a useful tool to develop, maintain, and change self-care behaviours of HF patients. This study confirmed that postdischarge supports are very effective in improving self-care activities and reaching optimal behaviours.

Acknowledgments

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References


Research Article

Cross-Cultural Adaptation and Psychometric Testing of the Brazilian Version of the Self-Care of Heart Failure Index Version 6.2

Christiane Wahast Ávila,1,2 Barbara Riegel,3 Simoni Chiarelli Pokorski,1,2 Suzi Camey,4,5 Luana Claudia Jacoby Silveira,2 and Eneida Rejane Rabelo-Silva1,2

1 Graduate Program, School of Nursing, Federal University of Rio Grande do Sul, Rua São Manoel 963, Bairro Rio Branco, 90620-110 Porto Alegre, RS, Brazil
2 Cardiology Division, Heart Failure Clinic, Hospital de Clínicas de Porto Alegre, Porto Alegre, RS, Brazil
3 University of Pennsylvania School of Nursing, Philadelphia, PA, USA
4 Statistics Department, Mathematics Institute, Federal University of Rio Grande do Sul, Porto Alegre, RS, Brazil
5 Graduate Program in Epidemiology, Federal University of Rio Grande do Sul School of Medicine, Porto Alegre, RS, Brazil

Correspondence should be addressed to Eneida Rejane Rabelo-Silva; eneidarabelo@gmail.com

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Objective. To adapt and evaluate the psychometric properties of the Brazilian version of the SCHFI v 6.2. Methods. With the approval of the original author, we conducted a complete cross-cultural adaptation of the instrument (translation, synthesis, back translation, synthesis of back translation, expert committee review, and pretesting). The adapted version was named Brazilian version of the self-care of heart failure index v 6.2. The psychometric properties assessed were face validity and content validity (by expert committee review), construct validity (convergent validity and confirmatory factor analysis), and reliability. Results. Face validity and content validity were indicative of semantic, idiomatic, experimental, and conceptual equivalence. Convergent validity was demonstrated by a significant though moderate correlation ($r = -0.51$) on comparison with equivalent questions scores of the previously validated Brazilian European heart failure self-care behavior scale. Confirmatory factor analysis supported the original three-factor model as having the best fit, although similar results were obtained for inadequate fit indices. The reliability of the instrument, as expressed by Cronbach’s alpha, was 0.40, 0.82, and 0.93 for the self-care maintenance, self-care management, and self-care confidence scales, respectively. Conclusion. The SCHFI v 6.2 was successfully adapted for use in Brazil. Nevertheless, further studies should be carried out to improve its psychometric properties.

1. Introduction

Over the last few decades, treatment of heart failure (HF) has been optimized substantially through the advent of new therapies that have improved morbidity and mortality outcomes. These therapies, combined with nonpharmacological management strategies, have provided several benefits for patients, particularly in quality of life and rate of hospitalization due to decompensated HF [1, 2].

Within this context, nonpharmacological management, which encompasses a continuous process of patient education and development of self-care skills, has been widely studied and shown to be beneficial in the achievement and maintenance of clinical stability [2]. Among available self-care strategies, the multidisciplinary approach appears to be associated with the greatest benefit over time, improving quality of life, reducing readmission rates, and cutting health care costs [3, 4].

Self-care in HF is defined as a naturalistic decision-making process used to maintain physiologic stability (self-care maintenance) and respond to symptoms when they occur (self-care management) [3]. During this process of systematic patient education, skills such as interpreting sodium levels in nutrition facts labels, monitoring symptoms of HF
deterioration, and developing a setting-specific exercise plan (tactical skills), as well as adhering to dietary restrictions and taking medications in unexpected situations (situational skills), which are required for implementation of self-care by patients or their caregivers, come to the fore [5, 6].

Instruments and scales for assessment of self-care were developed in response to the need to evaluate the effectiveness of self-care guidance provided to patients and to measure the impact of self-care on clinical endpoints [7, 8]. However, the extent and maintenance of treatment adherence in chronic disease involves highly demanding self-care behaviors. Recent studies have demonstrated some limitations in the development and validation of self-care instruments for patients living with chronic illness [9]. One such limitation is the need for these instruments to be employed in clinical studies, so as to establish their actual applicability and effectiveness in the clinical setting of patient followup [10].

Few investigators have proposed validated, user-friendly instruments designed specifically for patients with HF [11]. Within this perspective, a team of US nurses developed the self-care of heart failure index (SCHFI), currently in version 6.2, which covers all essential aspects (early recognition of signs and symptoms of decompensation, evaluation of the relevance of these signs and symptoms, decision to take action in response to signs and symptoms, implementation of a treatment strategy, and evaluation of the effectiveness of the implemented strategy) involved in self-care of HF. The SCHFI scale can be used to assess self-care behaviors in three domains: maintenance, management, and confidence. This scale allows assessment of patients’ ability to recognize the signs and symptoms of HF decompensation, of the decision making process, and of the confidence in performing self-care actions [12].

The relevance of this study to clinical practice lies in its objective, which is to validate an instrument that assesses self-care in its different dimensions and, especially, identifies which dimension of self-care is impaired. This identification of barriers and challenges faced by patients allows planning and implementation of customized strategies. These strategies may improve patient adherence, knowledge, and self-care skills and, consequently, help patients achieve clinical stability. Within this context, the aim of this study was to adapt and evaluate the psychometric properties of the Brazilian version of the SCHFI v 6.2.

2. Methods

2.1. Study Design and Participants. This methodological study was conducted at a large teaching hospital in Southern Brazil. All adult patients with a diagnosis of HF (systolic or diastolic) who had received periodic followup at the HF clinic for at least 6 months and had attended at least one appointment with the heart failure nursing team during the year preceding the study were eligible for participation. We excluded patients with cognitive deficits that might hinder understanding of instrument items, based on a recorded history of dementia or other neurological conditions as well as on the investigator’s assessment of participant orientation to time and place before completion of the instrument.

Also, participants were considered to have some degree of cognitive decline if they had difficulty in answering any survey instrument items or required additional explanation after answering the questions. Patients with chronic obstructive pulmonary disease were also excluded (due to the difficulty of distinguishing COPD-related dyspnea from HF-related dyspnea), as were those with motor impairments or locomotor disturbances which would hinder assessment and grading of some items of the scale (e.g., items 4 and 7, which concern physical activity and exercise). The self-care management subscale was only administered to patients who had experienced signs or symptoms of decompensation in the one month preceding the study.

2.2. Self-Care of Heart Failure Index Version 6.2 (SCHFI v 6.2). The SCHFI v 6.2 scale, developed in the United States, comprises 22 items divided across three scales: self-care maintenance (10 items), self-care management (6 items), and self-care confidence (6 items). Answers for each item range from “never or rarely” to “always or daily” in the self-care maintenance scale, “not likely” to “very likely” in the Self-Care Management scale, and “not confident” to “extremely confident” in the Self-Care Confidence scale. Total scores for each scale are standardized to range from 0 to 100; higher scores reflect greater self-care ability, and self-care is considered adequate when all scales have scores of 70 or higher. The authors recommend that each scale should be administered separately and that the Self-Care Management scale should be administered only to patients who have experienced dyspnea and lower extremity edema within the last one month [12].

The reliability of the original scale was assessed by means of internal consistency, with Cronbach’s alpha coefficients of 0.55, 0.59, and 0.82 for the maintenance, management, and confidence scales, respectively. Confirmatory factor analysis yielded factor loadings with absolute values ranging from 0.09 to 0.60 (Maintenance), from 0.29 to 0.62 (Management), and from 0.49 to 0.79 (Confidence) [12].

2.3. Cross-Cultural Adaptation of the Instrument. Before the start of the cross-cultural adaptation process, we contacted the original author via email, seeking her consent for validation and use of the instrument in Brazil, which she promptly granted.

The cross-cultural adaptation process consisted of the following steps, as recommended in the literature [13]: translation, synthesis, back translation, synthesis of back translation, expert committee review of the translated version, and pretesting.

During the cross-cultural adaptation process, some changes were made to the wording of certain items, and some examples of daily routines were included in the interest of patient comprehension. In item 5, for instance, the wording “keep appointments” was replaced with the term “assiduously”; in item 8, the wording “Not take (one of your medicines)” was used instead of “Forget to take,” as patients in our setting often skip medication due to socioeconomic conditions and difficulty obtaining access to the health services rather than forgetfulness.
After convening the expert committee and seeking clarification of certain issues with the author of the original instrument, we had the Preliminary Adapted Version of the SCHFI v 6.2 available for pretesting.

2.4. Pretesting. Thirty patients were selected only for this stage. The mean time to completion of the three subscales was 8 minutes. No modifications were required after pretesting; therefore, the preliminary adapted version was kept unchanged as the final Portuguese version, which was named Brazilian Version of the Self-care of Heart Failure Index version 6.2, or SCHFI v 6.2 (Brazilian).

2.5. Assessment of Psychometric Properties. Psychometric testing of the scale was carried out as recommended elsewhere in the literature [14], in a process consisting of the following stages: face validity and content validity (by expert committee review), construct validity (convergent construct validity and confirmatory factor analysis), and reliability (by analysis of Cronbach’s alpha).

Assessment of face validity measured understanding and acceptance of the items of the scale, as expressed by a consensus among the members of the expert committee (two nurses with clinical expertise in the care of HF patients, a nurse with experience in the care of patients with heart disease who was also a teacher of Portuguese, a registered dietitian of the hospital outpatient HF clinic, a nurse with experience in the study methodology, the first author, and her academic advisor) and the study respondents (pretesting stage), with the chief purpose of assessing whether the instrument measured what it set out to measure [14]. Content validity was determined by a consensus of the expert committee as to the relevance of each instrument item for measurement of the parameters of interest.

In this study, convergent validity was assessed using the previously validated Brazilian Version of the European Heart Failure Self-care Behavior Scale, or EHFScBS (Brazilian) [11], as a gold standard. The validated EHFScBS (Brazilian) scale consists of 12 questions within a single domain related to self-care behavior. The responses for each item range from 1, “I completely agree,” to 5, “I do not agree at all,” on a five-point Likert-type scale. The total score is obtained by adding all of the answers and can range from 12 to 60. Lower values are indicative of better self-care. The items concern various self-care behaviors of patients with heart failure, such as daily weighing, rest, contacting a health care provider, fluid restriction, diet, medication adherence, annual flu vaccinations, and exercise. Cronbach’s alpha for the EHFScBS (Brazilian) was 0.70 [11].

Confirmatory factor analysis was performed to confirm the factor structure of the original instrument.

The reliability of the Brazilian Version of the Self-care of Heart Failure Index version 6.2 was verified by assessment of internal consistency (measured by Cronbach’s alpha).

The scale was administered to all participants by means of an interview, in a private room. On average, respondents took 8.2 ± 3 minutes to complete the scale.

2.6. Data Analysis. Continuous variables were expressed as means ± standard deviations. P values < 0.05 were considered statistically significant. Statistical analyses were conducted in the statistical package for the social sciences (SPSS) 18.0 software environment. Confirmatory factor analysis was performed with the aid of AMOS 18.0 software [15]. In addition to the overall chi-squared statistic, several overall goodness-of-fit indices were employed to examine the fit of the factor model with the following “rule-of-thumb” cutoff criteria for well-fitting models: comparative fit index (CFI) > 0.95, root mean square error of approximation (RMSEA) < 0.05, and normed fit index (NFI) > 0.95 [15]. Cronbach’s alpha coefficient was used to assess the internal consistency of the validated scale.

3. Results

3.1. Sociodemographic and Clinical Characteristics of the Sample. The study sample comprised 128 patients, the majority of whom were males (78.9%). Mean age was 61.4 ± 12.8 years, and most patients were retired (76.4%). The most common etiologies of HF were ischemic heart disease (41.4%) and hypertension (25%). The sample profile is described in greater detail in Table 1.

<table>
<thead>
<tr>
<th>Variables</th>
<th>n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, years*</td>
<td>61.4 ± 12.8</td>
</tr>
<tr>
<td>Sex, male</td>
<td></td>
</tr>
<tr>
<td>Employment status, inactive</td>
<td>101 (78.9)</td>
</tr>
<tr>
<td>Educational attainment, years†</td>
<td>85 (76.4)</td>
</tr>
<tr>
<td>Etiology of heart failure</td>
<td></td>
</tr>
<tr>
<td>Ischemic heart disease</td>
<td>53 (41.4)</td>
</tr>
<tr>
<td>Idiopathic</td>
<td>32 (25.0)</td>
</tr>
<tr>
<td>New York Heart Association (NYHA) Functional Class</td>
<td></td>
</tr>
<tr>
<td>I</td>
<td>37 (29.0)</td>
</tr>
<tr>
<td>II</td>
<td>65 (50.7)</td>
</tr>
<tr>
<td>III</td>
<td>26 (20.3)</td>
</tr>
<tr>
<td>Left ventricular ejection fraction (%)*</td>
<td>31.2 ± 12.7</td>
</tr>
<tr>
<td>Duration of heart failure, months‡</td>
<td>36 (17–58)</td>
</tr>
</tbody>
</table>

* Mean ± standard deviation; † median (interquartile range).
Validity Testing

3.2. Convergent Validity. A significant \( P = 0.017 \), though weak, inverse correlation \( r = -0.30 \) was found between overall scores for the Brazilian Version of the Self-care of Heart Failure Index v 6.2 and the Brazilian Version of the European Heart Failure Self-care Behavior Scale. On analysis of convergence between the five equivalent questions of the two scales, a significant \( P < 0.001 \), moderate, and inverse correlation \( r = -0.51 \) was found. An inverse correlation was expected as lower scores indicate higher self-care on the European heart failure self-care behavior scale.

3.3. Confirmatory Factor Analysis. We used confirmatory factor analysis to test a three-component model in which the items of each component were those of the original instrument. In the original model, correlation between self-care maintenance and self-care management was not considered. Goodness-of-fit indicators for the tested model, including the three SCHFI v 6.2 scales, were as follows (Figure 1).

Most items had factor loadings with greater absolute values than those of the original model. These values ranged from 0.11 to 0.95 (Figure 1).

3.4. Internal Consistency. Internal consistency was assessed by means of Cronbach’s alpha. The calculated coefficients were 0.40 for the self-care maintenance scale, 0.82 for the self-care management scale, and 0.93 for the self-care confidence scale.

3.5. Comparison between Mean Scores of the Brazilian Version of the Self-Care of Heart Failure Index v 6.2 and of the Original SCHFI v 6.2. The mean scores obtained with the Brazilian Version of the Self-care of Heart Failure Index v 6.2 were 57 ± 14.3 in the Maintenance scale, 47 ± 28.3 in the Management scale, and 58 ± 25.5 in the Confidence scale. All scores were lower than those obtained in the original study with a U.S. sample (Table 2).

4. Discussion

This was the first Latin American study to conduct cross-cultural adaptation and psychometric testing of a scale for assessment of self-care by HF patients, namely, the SCHFI v 6.2. This scale assesses self-care abilities at each stage of the self-care process (maintenance, management, and confidence) in patients with heart failure.

During the cross-cultural adaptation process, some terms and expressions were modified so as to facilitate understanding of scale items by patients and professionals who may wish to administer it, as well as to ensure cultural equivalence. Our communications with the author of the original scale allowed us to make minor modifications and add some real-world examples without affecting the substance of the scale. Testing of the Brazilian version of the European heart failure self-care behavior scale confirmed its convergent validity, both due to the statistical significance and to the strength of the inverse correlations. These results suggest that the component items of the two scales measure similar constructs [11].
Table 2: Scores obtained with the Brazilian version of the self-care of heart failure index v 6.2 and with the original self-care of heart failure index version 6.2.

<table>
<thead>
<tr>
<th>SCHFI v 6.2 Brazilian version scores (n = 128)</th>
<th>SCHFI v 6.2 scores in USA (n = 130)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Self-care maintenance</td>
<td>57 ± 14.3</td>
</tr>
<tr>
<td>Self-care management</td>
<td>47 ± 28.3</td>
</tr>
<tr>
<td>Self-care confidence</td>
<td>58 ± 25.5</td>
</tr>
</tbody>
</table>

All scores are expressed as mean ± standard deviation.

In confirmatory factor analysis, we tested a three-component model in which the items of each component were those of the original instrument. Analysis confirmed this model had the best fit.

As in the original instrument, the self-care management and self-care confidence scales had higher factor loadings than the maintenance scale [12]. The low factor loadings found for the self-care maintenance scale may mean that the defined questions do not reflect this construct accurately. For instance, item 5 (“How routinely do you... keep doctor or nurse appointments”) had a factor loading of 0.11, which means that only 1.2% of variation in this item is explained by self-care maintenance. This may be explained by the fact that study patients were treated under the auspices of the publicly funded unified health system, and may thus avoid missing appointments out of fear of losing access to care. Furthermore, the average number of visits per year is four at most, which further reinforces the importance of keeping all appointments, particularly as patients must refill their prescriptions. It bears stressing that adherence is self-reported, which may lead to some overestimation of assiduous medication use [16]. Furthermore, one may infer that adherence to medication use and attendance of appointments are behaviors that do not require major lifestyle changes and, therefore, are more easily achieved. Conversely, physical exercise, adherence to a proper diet, smoking cessation, and weight management are all directly related to lifestyle modifications that are difficult for patients to make, despite knowledge of the benefits of these practices [17].

Factor loadings for the self-care confidence subscale were exceedingly high (up to 0.95), which may suggest that these items are already explained by others. Items 19 and 20, which had the highest factor loadings (0.94 and 0.95 resp.), assess the importance of symptoms and the recognition of changes in one’s health. These behaviors are quite similar and interconnected, as management of chronic illness does not depend solely on the knowledge acquired over time through patient education programs. Self-care management also depends on personal resources, such as self-confidence, self-care skills, and the ability to recognize and manage changes in one’s health.

In the present study, reliability was assessed by means of internal consistency, as measured by Cronbach’s alpha. Coefficients for the self-care management and self-care confidence scales were adequate and similar to those found in the original study [12]. This suggests that the component items of the scale measure the same self-care attributes and are related to the overall scale as well as to self-care management and self-care confidence. In a validation study carried out in China, Cronbach’s alpha values were only provided for the scale as a whole (22 items), which is no longer advocated [18].

Cronbach’s alpha coefficients for the Self-Care Maintenance subscale were lower than those obtained for the two other subscales and lower than those obtained in the original study [12]. These values suggest that the component items of this subscale warrant special attention and should be tested in different patient populations to ascertain equivalence. We believe that some items of this subscale (such as “do some physical activity” and “use a system... to help you remember your medicines”) do not actually reflect superior self-care skills. Some patients, particularly those with NYHA class II or III HF, refrained from physical activity due to exercise intolerance and development of symptoms on exertion. Furthermore, the use of a system to remember to take one’s medications does not necessarily entail superior self-care. Due to the chronic nature of HF, many patients incorporate taking their medicines into their daily routines and do not need any system to help them remember.

Scores obtained for the self-care maintenance, self-care management, and self-care confidence scales of the Brazilian version of SCHFI v 6.2 were all below the defined cutoff for adequate self-care and were lower than those obtained in the original study and in later studies of adaptation and validation of the instrument for other cultures [12, 18, 19]. These findings are consistent with the existing literature, which suggests that approximately 50% of patients fail to comply with nonpharmacological measures (the behaviors assessed by the study instrument) [6]. The “Take an extra water pill” item of the Management subscale may also have contributed to lower scores, as the patient population from which our sample was drawn is not usually instructed in this practice. Another relevant factor concerned the item “Call your doctor or nurse for guidance” (“Contatar seu médico ou enfermeiro para orientação”). It bears stressing that the study was conducted at a public hospital, which has no 24-hour hotline to answer patient questions.

Self-care in HF still poses a challenge to providers, patients, and caregivers alike, but is an essential aspect of disease management. Hence, there is a pressing need for development of effective self-care strategies and, consequently, for assessment and measurement of changes in self-care behavior and of the self-care skills developed by patients.

5. Conclusion

The cross-cultural adaptation of a Brazilian Portuguese version of the SCHFI v 6.2 instrument followed the established
process recommended in the scientific literature, which yielded a scale successfully adapted to the Brazilian reality.

Convergent validity showed moderate correlation on comparison with equivalent question scores of the previously validated Brazilian European heart failure self-care behavior scale. Confirmatory factor analysis showed weak indices of CFA, and internal consistency testing demonstrated inadequate indicators for the maintenance scale alone. These findings suggest that further studies should be carried out to improve the psychometric properties of the SCHFI v.6.2.

The relevance of this study and future investigations to clinical practice lies in the fact that validated scales can help nursing teams implement individualized patient management strategies, enabling constant evaluation of patients’ self-care abilities, particularly with regard to the recognition of signs and symptoms of decompensation, symptom management, and confidence.

5.1. Limitations. Some items of the self-care maintenance scale, such as “keep appointments”, “call your doctor or nurse,” and “use a system to help you remember your medicines” were not applicable to the reality of the study sample. Therefore, the presence of these items may have had an adverse impact on the internal consistency of the scale.

Conflict of Interests

The authors declare that they have no conflict of interests.

Acknowledgments

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References


Research Article
Cancer, Health Literacy, and Happiness: Perspectives from Patients under Chemotherapy

Sara Maria Oliveira Pinto,¹ Silvia Maria Alves Caldeira Berenguer,² and José Carlos Amado Martins³,⁴

¹ Abel Salazar Biomedical Sciences Institute, University of Porto, Rua de Jorge Viterbo Ferreira No. 228, 4050-313 Oporto, Portugal
² Catholic University, Palma de Cima, 1649-023 Lisbon, Portugal
³ Medical-Surgical Unit, Nursing School of Coimbra, Avenida Bissaya Barreto-Apartado 7001, 3046-851 Coimbra, Portugal
⁴ Department of Human Sciences and Health, Medicine Faculty, University of Oporto, Al. Hernâni Monteiro, 4200-319 Porto, Oporto, Portugal

Correspondence should be addressed to Sara Maria Oliveira Pinto; sara.o.pinto@gmail.com

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Cancer is a dreaded disease that affects all dimensions of human life. In this context, issues related to the quality of life—as happiness, perception about health status, or health literacy—are important. This study aims to analyze the following topics the perception: patients' perceptions about their health status while undergoing chemotherapy, the satisfaction with the information relating to their health, their level of happiness, and their vision of the future. An observational, cross-sectional, and descriptive study was developed. Data were collected between May and July 2012 in the day hospital of a central hospital in northern Portugal. The sample was composed of 92 cancer patients who were asked to answer a questionnaire during chemotherapy. The results indicate that, despite this life-threatening disease, patients consider themselves fairly happy and have an optimistic view of the future. Information about their health condition and religious beliefs was important coping mechanisms to help deal with the suffering caused by the disease. The study highlights the importance of providing care in a holistic way. Nurses must be alert and available to listen, answer questions, provide supporting structures, or refer to other professionals when needed.

1. Introduction

The scientific-technological development that has occurred in the last half of the twentieth century determined important changes in the course of the disease, being the pathologies of chronic character the leading cause of death in modern societies. However, this increase in longevity brought another kind of concerns related to comorbidities and limitations that arise as a result of living with a chronic illness. In general, we live longer but this increase in life expectancy does not always correspond to better quality of life [1].

In this context, issues related to quality of life have been gaining special importance and are widely studied in various contexts, particularly in oncology. Cancer—which is one of the leading causes of death worldwide—is one of the most dreaded diseases in the present [2, 3]. The strong physical, psychological, social, emotional, and spiritual impact reminds the person of one’s vulnerability and leads one to wonder about the meaning of life, and that may cause suffering [4].

Recent studies have shown that the concept of quality of life is closely associated with self-perception about wellbeing, with the satisfaction with life and happiness [5]. In this context, health professionals, particularly in the context of palliative care—whose mission is to promote the best possible quality of life for the patient and family [6]—have been encouraged to investigate and find strategies that allow the person to find moments of happiness and wellbeing, even in difficult circumstances, as is the experience of a cancer or terminal disease [7].

Happiness is an essential component of quality of life, to the point that the World Health Organization recognized it
as part of the concept of health [8]. However, as documented by other authors [7], little is known about its significance for people living with advanced cancer. After a comprehensive review, we found some studies where the concept was explored in patients with cancer [7, 9], Parkinson’s disease [10], and Alzheimer’s disease [11]. Yet none of these was held in Portugal or in the context of palliative care, where the theme is especially important. These studies are recent and emerged in the last 10 years which suggests a growing interest in the topic in the context of health.

Previous research suggests that happiness is a complex multidimensional concept, influenced by individual and cultural factors, with strong repercussions in all dimensions of human life [7]. In a recent study, the authors concluded that happiness is perceived by patients with advanced cancer as a fundamental precursor to quality of life, helping them to live the remaining time in the best possible way [7].

Another concept that has been widely studied has been the concept of health literacy. The health literacy is defined as a person’s ability to obtain, process, and understand information on health and how this process can help one in decision-making [12, 13]. The research has suggested that health literacy helps people to make informed and aware decisions, which are extremely important factors in an increasingly complex health care system [9]. In addition to these considerations, efforts have been alerting health professionals to the fact of low literacy, particularly in cancer patients, being associated with lower levels of welfare, higher levels of anxiety and depression, erroneous conceptions about the disease, and, consequently, lower adherence to the therapeutic regimen and less satisfaction with the care provided [12, 14–16].

The information given to the patient as well as the decisions to be taken, particularly in contexts of severe disease, is difficult and with repercussions, not only for professionals but also for the patient and family. In this context, nurses assume a privileged position, because the proximity to the patient allows them to be more attentive to their needs and problems [17].

Assuming that happiness and health literacy are important to patients with advanced cancer, we conducted the present study, which aims at analyzing (a) the perception Portuguese cancer patients undergoing chemotherapy have about their health status, (b) the satisfaction they have with the information relating to their health status, (c) their level of happiness, and (d) how these patients perceive their own future.

2. Methods

2.1. Research Design, Sample, and Setting. An observational, cross-sectional, exploratory, and descriptive study was developed, aiming at understanding how information about the health status and their belief systems influence the vision of the future and happiness of people undergoing chemotherapy.

Portuguese cancer patients undergoing chemotherapy were the chosen population for this study. Due to the impossibility of accessing all these patients, it was decided to restrict the study to patients who undergone chemotherapy in the day hospital (ambulatory care) of a central hospital in northern Portugal. The reason of this choice is due to the fact that this is a large department, with patients from different age groups and also with different malignancies, facts that we considered important in order to obtain a representative sample.

The following inclusion criteria were defined: (a) 18-year olds, (b) Portuguese nationality, (c) malignant disease diagnosed, and (d) undergoing chemotherapy. For ethical and legal reasons, all patients under 18 and with cognitive limitations, as well as those undergoing chemotherapy for the first time were excluded from the study.

Data were collected between May 16, 2012, and July 16, 2012, according to instructions and availability of the service where the study was conducted. In order to assure the respect for ethical principles, particularly the nonmaleficence, and so as not to interfere with the care and service dynamics, data were collected during the treatments, which generally lasted several hours. In this period all patients undergoing chemotherapy were approached (regardless of the purpose of this be curative or palliative), up to the limit of the sample under study, and according to the inclusion and exclusion criteria defined. Only 10 out of the 102 patients approached refused to participate in the study. The sample was nonprobabilistic, consecutive, and consisted of 92 cancer patients.

2.2. Instruments. The data collection instrument was built by a self-completion questionnaire, consisting of two distinct parts.

In the first part, information to sociodemographic, clinical, and faith was requested. From the data collected here, we analyzed the following variables: gender, age, marital status, education, household composition, diagnosis, time on chemotherapy, purpose of chemotherapy, religion, religious practice (practicing or not practicing), and opinion about God.

In the second part of the instrument, which resulted from an adaptation of the Permanent Survey on Social Attitudes of the Portuguese [15], five closed-answer questions (Likert scale) related to the perception of health status, satisfaction with the information provided on the state of health, vision of the future, fear of the future, and the level of happiness (dependent and ordinal variables) were placed. The final instrument was reviewed by an expert panel constituted by the authors and three nurses (an expert in the validation of scales, a spirituality researcher and a palliative care expert). Subsequently, we performed a pre-test with 10 cancer patients receiving chemotherapy. This pre-test concluded that the instrument was simple, clear and objective, which is why it was not necessary to make changes to it.

2.3. Ethical Issues and Data Collection. The research project was previously approved by the ethics committee and the administration council of that institution. All participants gave their freely informed and written participation in the study. The data were analyzed jointly, ensuring anonymity and confidentiality of responses.
The information was analyzed using the Statistical Package for the Social Sciences program, version 18 for Windows, and descriptive statistics were used.

3. Findings

3.1. Sociodemographic, Clinical, and Religious Characteristics. The participants in the study (n = 92) were approximately 54 years old (mean = 54.17 years). The youngest patient was 18 and the oldest 79 years. In the total of respondents, 51.10% were male and 48.90% female. Most of them lived only with spouse (46.70%) and 38.00% with the spouse and children. Despite being with a malignant disease in an advanced stage, 2 patients (2.20%) reported living alone.

Regarding the qualifications, we found that the majority of subjects had only 4 years of education (47.90%), which corresponds to the elementary education in Portugal.

From a clinical standpoint, it was found that most respondents had bowel cancer (25.29%) and breast cancer (20.70%). The average time in chemotherapy was 11.80 months. Of the total respondents, 54.30% were in chemotherapy with curative intent and 45.70% in chemotherapy with palliative goals. The majority of individuals in palliative chemotherapy were males (29.30%) and had bowel cancer (10.90%). Patients in curative chemotherapy were essentially females (32.60%) and had breast cancer (17.40%).

In the item about religious beliefs, patients were questioned about their religion, religious practice, and beliefs about God. Six patients did not respond to the questions about “religion” and “religious practice.” The majority of claims to be Catholic (93.00%) and it was found that there is no great disparity between those who admit having a regular religious practice (51.10%) compared to those who do not have it (48.80%). All respondents answered the question about God’s existence. The vast majority has no doubts about God’s existence (60.90%). However, those who have a regular religious practice are those with more certainty (40.50%). Only one patient reported not believing in God.

3.2. Patient Perspectives on Perception about the State of Health, Information, Future Vision, and Happiness. When asked how they regarded their health status at that time, most patients (51.10%) rated it as “neither good nor bad.” Despite this neutral position, 30.40% considered that their health was “good,” being relatively low the percentage of patients who consider their health as “bad” or “very bad” (13.30%) (Table 1).

With regard to how they saw their future, few have considered it “very good” (7.60%), slightly higher than that found for the group of patients who considered their health status as “very good” (4.30%).

In general, despite the difficulties imposed by the disease, the vision of the future is always more optimistic than the perception of the current state of health: 35.90% perceives the future as “good” and although 3.30% consider their health very bad, only 2.20% believe that the future will be—itselvery bad. However, the great majority is afraid of the future (63.00%) and 18.50% reported being very frightened.

With regard to the degree of satisfaction with information on the health status—and despite not having analyzed the information they had—it was found that the great majority of the patients felt very satisfied (44.60%) or satisfied (29.30%) with the information about their health status.

In the last issue, participants were encouraged to think about all aspects of their life and assess their current state of happiness. In spite of the majority considering to be “fairly happy” (57.60%), it is important to note that

(i) there is a significant group of patients who considered themselves to be “very happy” (23.90%);
(ii) very few considered themselves unhappy (2.20%);
(iii) among those “fairly happy” considered, 64.30% were in palliative chemotherapy;
(iv) 16.70% of the patients in palliative chemotherapy considered themselves as very happy people.

Analyzing these items, the variables were crossed (Table 2).

It was found that there is a large percentage who considers their health as “good” or “very good” (35.20%), which is quite interesting considering they are individuals with a very serious disease. However, it is important to note that those who perceive their health status as “bad” or “very bad” are mostly in palliative chemotherapy (14.60%).

With regard to the vision of the future and happiness, it was found that satisfaction with information about the health status exerts an important influence.

In general, patients who considered themselves well-informed about their health status reported having no fear of the future (24.20%), and, despite living with a serious life-threatening cancer disease, they saw it as “good” (22.00%). On the other hand, when we perform the summation of the responses of those who consider themselves less informed about their health status, we found that 17.60% are afraid of the future.

Still regarding the variable “information,” it was found that those who consider themselves more informed about their health status, are also considered happier. In fact, 46.70% feel satisfied or very satisfied with the information relating to their health, considering themselves fairly happy or very happy. Those more informed about their health status, are also those who fear the future less (24.20%).

Finally, when the variables of the future vision and beliefs about God were crossed (Table 3), it was found that those who believe in God and have no doubts about His existence see the future as “neither good nor bad” (25.30%) or “good” (25.30%). Similarly, these are also the individuals who mostly refer not being afraid of the future (23.10%) or only slightly (19.80%).

4. Discussion

The results show us the perspective of a group of patients with advanced cancer in chemotherapy.

Previous studies have shown that cancer is one of the most feared diseases by modern societies, with strong impact on the quality of life of the human person, particularly during chemotherapy treatment [18].
Table 1: Perception of health status, vision and fear of the future, information, and happiness (n = 91 *).

<table>
<thead>
<tr>
<th>Perceived health status</th>
<th>Vision of the future</th>
<th>Fear of the future</th>
<th>Information about the state of health</th>
<th>Happiness</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>How do you consider your state of health at the moment?</td>
<td>How do you see your future?</td>
<td>I am afraid of the future.</td>
<td>I feel I am well informed on about my health.</td>
</tr>
<tr>
<td></td>
<td>n</td>
<td>%</td>
<td>n</td>
<td>%</td>
</tr>
<tr>
<td>Very bad</td>
<td>3</td>
<td>3.30</td>
<td>2</td>
<td>2.20</td>
</tr>
<tr>
<td>Bad</td>
<td>9</td>
<td>22.80</td>
<td>15</td>
<td>16.30</td>
</tr>
<tr>
<td>Neither good nor bad</td>
<td>47</td>
<td>29.30</td>
<td>34</td>
<td>37.00</td>
</tr>
<tr>
<td>Good</td>
<td>28</td>
<td>44.60</td>
<td>33</td>
<td>35.90</td>
</tr>
<tr>
<td>Very good</td>
<td>4</td>
<td>4.30</td>
<td>7</td>
<td>7.60</td>
</tr>
</tbody>
</table>

*1 missing.
**Table 2: State of health perceptions and purpose of chemotherapy, fear of the future, happiness, and information about the health status.**

(a) Purpose of chemotherapy

<table>
<thead>
<tr>
<th>State of health perceptions</th>
<th>Count</th>
<th>% of total</th>
<th>Count</th>
<th>% of total</th>
<th>Count</th>
<th>% of total</th>
</tr>
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<tbody>
<tr>
<td><strong>Very bad</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Count</td>
<td>2</td>
<td>4.00</td>
<td>1</td>
<td>2.40</td>
<td>3</td>
<td>3.30</td>
</tr>
<tr>
<td><strong>Bad</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Count</td>
<td>4</td>
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<td>5</td>
<td>12.20</td>
<td>9</td>
<td>9.90</td>
</tr>
<tr>
<td><strong>Neither good nor bad</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Count</td>
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(b) Information about the state of health

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(c) Information about the state of health

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<th>I quite agree</th>
<th>I totally agree</th>
<th>Total Count</th>
</tr>
</thead>
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*1 missing.

**Happiness**

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<th>I totally agree</th>
<th>Total Count</th>
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</tr>
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<td>4</td>
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<td>15</td>
</tr>
<tr>
<td>% of total</td>
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<td>7.70</td>
<td>4.40</td>
<td>3.30</td>
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<tr>
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<tr>
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<tr>
<td>% of total</td>
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<td>2.20</td>
<td>16.30</td>
<td>23.90</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>3</td>
<td>21</td>
<td>27</td>
<td>41</td>
<td>92</td>
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</tbody>
</table>
Other studies have documented that quality of life is closely linked to the perception that the person has in relation to one's wellbeing, life satisfaction, and happiness [7].

The study confirms this vision but it also adds new data, suggesting that religious beliefs and health literacy may have an important contribution in promoting wellbeing and patient’s quality of life.

Although all participants have had an advanced cancer, some of them in palliative chemotherapy, the vast majority has an optimistic view of the future and considers themselves as happy persons. The majority reported being afraid of the future but, despite this, their vision of the future has always been more positive than their perception about health status.

This optimistic vision is associated with hope, a concept closely associated with wellbeing and happiness and essential in the care of people with cancer. Previous studies have shown that the need to maintain a positive thinking is crucial because it helps the person to deal with the suffering caused by the disease, to restore the meaning of life and find purpose to continue [19–21].

It was also found that religious beliefs can have a significant impact on how a person views the future. Although the majority of respondents are Catholic, as fits the profile of Portuguese citizens, beliefs about God have varied. The study revealed that those who believed in a higher entity and not had any doubts about his existence had less fear of the future. These data confirm those obtained by other authors and show that religious and spiritual beliefs are closely associated with the concept of quality of life, helping the person to maintain hope, and dealing with the uncertainty of the future in a more effective way [20–22].

In addition to this positive view tendency, most respondents considered themselves happy or very happy, noting that the information that the patient has about their health—includes not only the information given, as well as how the person understood and perceived this information—is associated with poorer health outcomes, including lower adherence to the therapeutic regimen, misconceptions about the disease, and higher levels of depression and anxiety [12, 14–16].

The study shows, however, some limitations. The sample type (not randomized) does not allow the inference of the results for the population. Moreover, the nationality of the participants in the study may have influenced the results. Generally, the Portuguese are seen as optimistic people, who tend to face the future with hope, as suggested in previous

---

### Table 3: Vision of the future and opinion about God.

<table>
<thead>
<tr>
<th>Vision of the future</th>
<th>Opinion about God**</th>
<th>I</th>
<th>II</th>
<th>III</th>
<th>IV</th>
<th>V</th>
<th>VI</th>
<th>Total</th>
</tr>
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</tr>
<tr>
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<tr>
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<tr>
<td>Good</td>
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<td>2</td>
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<tr>
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<tr>
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<td>11.00</td>
<td>61.50</td>
<td>100.00</td>
<td></td>
</tr>
</tbody>
</table>

**(I) I do not believe in God. (II) I do not know if God exists or believe there is a way to know this. (III) I do not believe in a personal God, but I believe in the existence of a supreme force whatsoever. (IV) There are times when I believe in God and times when I do not. (V) In spite of my doubts, I feel that I believe in God. (VI) I know that God exists and I have no doubt about that.
studies [20, 21, 25]. For practical reasons, the study was limited to patients who carry out chemotherapy in day hospital. Within this group, patients undergoing chemotherapy for the first time were excluded. Although ethical motivations should prevail, it is important to note that these criteria limit the results. Thus, the data refer to the sample under study and future generalizations should be made with caution.

Despite these limitations, the present work encourages health care professionals to find ways of helping cancer patients live the period of the disease in the best possible way. The information transmitted and how the patient processes this information, along with the religious beliefs, can act as important coping mechanisms, helping the person to deal with suffering, to look to the future with hope and be happier.

5. Conclusions

Although all participants in the study had severe malignant disease, some of which in palliative care, it was found that—in general—they are happy people with an optimistic view of the future.

Information on health status, commonly referred to as health literacy, plays an important role in these results, showing that patients who feel well informed, fear less the future, perceive it as better and consider themselves happier.

Despite the study’s limitations, particularly with regard to the type of sampling (which is not random prevented us infer the results to the population), we believe that the results are important.

The study supports scientific evidence, particularly the idea that health literacy and promotion of happiness can have a strong impact on people’s quality of life with advanced chronic disease, helping them to live the moments of crisis in the best possible way.

The study has thus important implications for future research and for clinical practice, showing the importance of providing care in a holistic manner, directed to the ill person and not just to fight the disease. We live in a time characterized by technology and that mechanized vision should never be extended to the nursing care which is holistic and human in its nature. However, this study demonstrates the importance of humanizing care. Nurses must therefore be alert and seek to collect a range of information that may be important coping mechanisms such as religious beliefs, family support, and information about the health status. Another important aspect passes through the demystification of some wrong information people have about the disease and about cancer treatments, and which may affect how a person lives in the present and sees the future. Results show that information about the state of health is not only a fundamental human right, but also an important promoter of happiness, wellbeing, and therefore quality of life.

Cancer is the most feared disease in today’s society. Thus, it is absolutely essential that nurses help fight the fear associated with the disease and treatments, trying to be available to listen, answer questions, provide supporting structures, or refer to other professionals when needed. However, simple gestures such as praying with the ill person, the therapeutic touch, listening, or teaching the family can also be extremely important in helping to reduce the patient’s suffering and promoting their happiness and wellbeing.

Happiness, in turn, is determined by a set of circumstances where the health literacy and religious beliefs can play a key role.

Both concepts—health literacy and happiness—are closely associated with hope. However, more studies are needed to relate the association between these concepts and analyze the indexes of happiness based on the type of information given.

References


Clinical Study

Predictors of Better Self-Care in Patients with Heart Failure after Six Months of Follow-Up Home Visits

Melina Maria Trojahn, Karen Brasil Ruschel, Emiliane Nogueira de Souza, Cláudia Motta Mussi, Vânia Naomi Hirakata, Alexandra Nogueira Mello Lopes, and Eneida Rejane Rabelo-Silva

1 Cardiology Division, Heart Failure Clinic, Hospital de Clínicas de Porto Alegre, Porto Alegre, RS, Brazil
2 Cardiology Institute of Rio Grande Sul, Cardiology Fundation, Porto Alegre, RS, Brazil
3 Graduate Program of Cardiovascular Science, Federal University of Rio Grande do Sul, Porto Alegre, RS, Brazil
4 Federal University of Health Science of Porto Alegre, Porto Alegre, RS, Brazil
5 Statistics Division, Hospital de Clínicas de Porto Alegre, Porto Alegre, RS, Brazil
6 Graduate Program, School of Nursing, Federal University of Rio Grande do Sul, Rua São Manoel 963, Bairro Rio Branco, 90620-110 Porto Alegre, RS, Brazil

Correspondence should be addressed to Eneida Rejane Rabelo-Silva; eneidarabelo@gmail.com

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This study aimed to examine the predictors of better self-care behavior in patients with heart failure (HF) in a home visiting program. This is a longitudinal study nested in a randomized controlled trial (ISRCTN01213862) in which the home-based educational intervention consisted of a six-month followup that included four home visits by a nurse, interspersed with four telephone calls. The self-care score was measured at baseline and at six months using the Brazilian version of the European Heart Failure Self-Care Behaviour Scale. The associations included eight variables: age, sex, schooling, having received the intervention, social support, income, comorbidities, and symptom severity. A simple linear regression model was developed using significant variables ($P \leq 0.20$), followed by a multivariate model to determine the predictors of better self-care. One hundred eighty-eight patients completed the study. A better self-care behavior was associated with patients who received intervention ($P < 0.001$), had more years of schooling ($P = 0.016$), and had more comorbidities ($P = 0.008$). Having received the intervention ($P < 0.001$) and having a greater number of comorbidities ($P = 0.038$) were predictors of better self-care. In the multivariate regression model, being in the intervention group and having more comorbidities were a predictor of better self-care.

1. Introduction

Self-care in heart failure (HF) is defined as positive behaviors leading to decisions and actions that an individual can take to help maintain clinical stability and cope with the disease [1]. Studies indicate that the inability of patients to recognize signs and symptoms of congestive episodes and the lack of knowledge and poor adherence to treatment, components that are considered self-care measures, are precipitating factors leading to decompensation of HF [2–5]. Within this context, all self-care behaviors appear to be directly related to motivation, habits, and sociodemographic and clinical characteristics, factors that may affect the way individuals live their lives [1, 6–8].

In this sense, the home environment has gained attention as a potential setting for the development of education strategies and followup of patients with HF, as well as for the investigation of the benefits of such strategies and their effect on self-care behaviors [9–11]. Jaarsma et al. [9], in one of the first published studies on the topic, tested in a randomized controlled trial (RCT) the effect of an education strategy on self-care initiated during hospitalization, followed by a telephone call and a home visit within 10 days after hospital discharge. In the intervention group, the results demonstrated
a significant improvement in self-care behavior and adherence to treatment and fewer hospital readmissions within three months of discharge [9]. Recently, two RCTs developed in Latin America have also reported improvement in self-care skills and behavior of patients receiving home visits, telephone calls, and additional written instructions [10, 11].

Although recent studies have shown favorable results in patients receiving home visits for self-care education, in Latin America the predictors of a better self-care behavior in patients with HF are yet to be explored in this setting. This study aimed to examine the predictors of better self-care behavior in patients with HF in a home visiting program.

2. Patients and Methods

2.1. Study Design. This is a longitudinal study nested in an RCT called HELEN-I (ISRCTN01213862), whose primary aim was to verify the effect of a nursing educational intervention consisting of home visits and phone calls on patients' knowledge of the disease, self-care, and adherence to treatment. The results showed that alternating home visits with telephone calls during a six-month follow-up period for patients hospitalized for decompensated HF improved patients' knowledge of the disease, self-care skills, and adherence to treatment [11].

2.2. Participants. The sample included 188 adult patients diagnosed with HF and systolic dysfunction, hospitalized for decompensated HF. Patients with communication barriers, with a diagnosis of acute HF secondary to sepsis, myocarditis, or acute myocardial infarction, who lived more than 20 km from the institutions, or who could not be contacted by telephone were excluded from the study. Hospitalized patients were recruited from inpatient medical units and emergency departments by active search during daily visits by the study team to these units. The study was conducted at two referral centers for the treatment of patients with HF in the metropolitan area of Porto Alegre, city capital of Rio Grande do Sul, the southernmost state of Brazil, and approved by the Research Ethics Committees of both institutions (protocol numbers 09-III and 4339-09).

2.3. Data Collection and Study Intervention. Data on sociodemographic and clinical characteristics of patients were collected at baseline (upon inclusion in the study) and six months after hospital discharge. Eight sociodemographic and clinical variables were chosen to be tested for association with the outcome (better self-care): age, sex, years of schooling, having received the home-based educational intervention, social support, family income, comorbidities, and symptom severity.

The intervention group received four home visits by a nurse, interspersed with four telephone calls, in a six-month follow-up period for education on the disease, adherence to treatment, and self-care practices. The control group received all standard care in their institutions of origin, with no home visits or telephone contact. Both groups were assessed after six months of followup in the referral hospitals [11].

Self-care was assessed using the Brazilian version of the European Heart Failure Self-Care Behaviour Scale (EHF-ScBS) [12]. It consists of 12 questions that cover items concerning daily self-care activities: daily weighing (item 1), symptom recognition and seeking assistance (items 2–5), fluid restriction (item 6), daily rest (item 7), recognition of symptom worsening and seeking assistance (item 8), sodium restriction (item 9), correct use of medications (item 10), annual influenza vaccination (item 11), and exercising regularly (item 12). Scores are divided according to the patient's response on self-care practices. Each item is rated on a five-point scale between 1 (I completely agree) and 5 (I completely disagree), and lower scores indicate a better self-care behavior. Individual item scores are summed up to give a total score, ranging from 12 to 60.

2.4. Statistical Analysis. Data were analyzed using the Statistical Package for the Social Sciences (SPSS) version 18.0. Continuous variables were expressed as mean and standard deviation if normally distributed, and as median and interquartile range (25th–75th percentiles) if not normally distributed. Categorical variables were expressed as count and percentage. Relationships between sociodemographic and clinical variables and the self-care score were examined using a simple linear regression model. Variables that reached $P \leq 0.20$ in the univariate analysis were subsequently included in the multivariate analysis (multiple regression) in order to determine the predictors of better self-care. Comparisons between groups were performed using Student's $t$ test for continuous variables and the self-care score. Values were considered to be statistically significant if $P$ value was $<0.05$.

3. Results

3.1. Sociodemographic and Clinical Characteristics. A total of 188 patients were included in the study, 91 in the intervention group and 97 in the control group. The sociodemographic and clinical characteristics of patients are described in Table 1. Ischemic heart disease was the most common etiology of HF, and most patients were in New York Heart Association (NYHA) functional class III. The variables were not significantly different between groups.

3.2. Association between Sociodemographic and Clinical Characteristics and Self-Care Score at the End of Six Months. Eight sociodemographic and clinical variables (age, sex, years of schooling, having received the intervention, social support, family income, comorbidities, and symptom severity) were tested for association with a better self-care behavior at the end of six months of followup. Better self-care was associated with patients who received the educational intervention ($P < 0.001$), had more years of schooling ($P = 0.016$), and had more comorbidities ($P = 0.008$) (Table 2).

3.3. Predictors of Self-Care at the End of Six Months. In the model that included six variables with $P \leq 0.20$ (sex, years of schooling, having received the intervention, social support, family income, and comorbidities), having received
Table 1: Sociodemographic and clinical characteristics (n = 188).

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Intervention group n (%)</th>
<th>Control group n (%)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients</td>
<td>91 (48.4)</td>
<td>97 (51.5)</td>
<td></td>
</tr>
<tr>
<td>Age, years*</td>
<td>62.9 ± 13.5</td>
<td>62.9 ± 13</td>
<td>0.964</td>
</tr>
<tr>
<td>Caucasian</td>
<td>62 (68.1)</td>
<td>64 (66.0)</td>
<td>0.922</td>
</tr>
<tr>
<td>Sex, male</td>
<td>54 (59.3)</td>
<td>61 (62.9)</td>
<td>0.618</td>
</tr>
<tr>
<td>Marital status, married</td>
<td>58 (63.7)</td>
<td>60 (61.9)</td>
<td>0.530</td>
</tr>
<tr>
<td>Social support, family</td>
<td>82 (90.1)</td>
<td>82 (85.4)</td>
<td>0.330</td>
</tr>
<tr>
<td>Schooling, years*</td>
<td>6.81 ± 4.33</td>
<td>6.16 ± 4.28</td>
<td>0.317</td>
</tr>
<tr>
<td>Income, total value in US dollars†</td>
<td>600 (450–900)</td>
<td>650 (387–900)</td>
<td>0.698</td>
</tr>
<tr>
<td>Duration of disease, years‡</td>
<td>5 (1.75–12.7)</td>
<td>6 (3.5–11.5)</td>
<td>0.216</td>
</tr>
<tr>
<td>Etiology, ischemic</td>
<td>25 (35.4)</td>
<td>27 (32.9)</td>
<td>0.166</td>
</tr>
<tr>
<td>NYHA functional class‡</td>
<td></td>
<td></td>
<td>0.932</td>
</tr>
<tr>
<td>I</td>
<td>6 (6.9)</td>
<td>9 (9.4)</td>
<td></td>
</tr>
<tr>
<td>II</td>
<td>35 (40.2)</td>
<td>36 (37.5)</td>
<td></td>
</tr>
<tr>
<td>III</td>
<td>40 (46)</td>
<td>44 (45.8)</td>
<td></td>
</tr>
<tr>
<td>IV</td>
<td>6 (6.9)</td>
<td>7 (7.3)</td>
<td></td>
</tr>
<tr>
<td>Ejection fraction*</td>
<td>29.9 ± 10.8</td>
<td>31.4 ± 13.9</td>
<td>0.421</td>
</tr>
<tr>
<td>Comorbidities</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Systemic hypertension</td>
<td>56 (61.5)</td>
<td>70 (72.2)</td>
<td>0.121</td>
</tr>
<tr>
<td>Diabetes mellitus</td>
<td>35 (38.5)</td>
<td>34 (35.1)</td>
<td>0.628</td>
</tr>
<tr>
<td>Acute coronary syndrome</td>
<td>25 (27.5)</td>
<td>35 (36.1)</td>
<td>0.206</td>
</tr>
</tbody>
</table>

Categorical variables are expressed as n (%), and continuous variables are expressed as * mean ± standard deviation or † median and 25th–75th percentiles; ‡ New York Heart Association functional class; information was missing for 4 cases in the intervention group and 1 case in the control group.

Table 2: Association between sociodemographic and clinical characteristics and the self-care score at the end of six months.

<table>
<thead>
<tr>
<th>Variables</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>0.400</td>
</tr>
<tr>
<td>Sex</td>
<td>0.101</td>
</tr>
<tr>
<td>Years of schooling</td>
<td>0.016</td>
</tr>
<tr>
<td>Having received the intervention</td>
<td>0.001</td>
</tr>
<tr>
<td>Social support</td>
<td>0.197</td>
</tr>
<tr>
<td>Comorbidities</td>
<td>0.008</td>
</tr>
<tr>
<td>Symptom severity</td>
<td>0.110</td>
</tr>
<tr>
<td>Income</td>
<td>0.073</td>
</tr>
</tbody>
</table>

Previous studies have reported that patients with more than six years of schooling have a better self-care behavior due to better understanding of and consequent improved adherence to treatment [6, 8]. In a study involving 209 patients admitted to six hospitals in California, United States, schooling was identified as a predictor of better treatment adherence and better self-care (P = 0.009). Those authors demonstrated that formal education is generally associated with higher income levels, thus facilitating self-care [8]—although income was not a significant predictor in the present study. Studies suggest that formal education is associated with better understanding of and consequent greater adherence to recommendations and treatment, aspects that help patients remain clinically stable [8,13].

In the present study, having a greater number of comorbidities was a predictor of self-care, which is not consistent with the findings from a study involving inpatients from two hospitals in the United States [2]. However, other authors have shown that people with multiple chronic diseases are more likely to monitor their health in order to avoid clinical instability and subsequent hospitalization [14]. More recent studies contradict this hypothesis, suggesting that patients with multiple comorbidities find it more difficult to recognize the symptoms of each disease, which hinders their ability to learn about self-care and to recognize specific signs and symptoms [2,15]. Likewise, poor adherence to drug therapy, especially because of the large number of drugs taken, may be a potential barrier to the successful self-management of HF [16].

4. Discussion

This study is the first in Latin America to examine the association between sociodemographic and clinical variables and predictors of self-care in patients with HF. Patients who received home-based educational intervention, who had more years of schooling and who had a greater number of comorbidities showed a strong association with a better self-care behavior. Regarding the predictors, having received the educational intervention and having more comorbidities were identified as predictors of better self-care (Table 3).
Studies conducted to evaluate self-care behaviors among patients with HF suggest that having more years of schooling, more symptoms, fewer comorbidities, and being male are the most common predictors of self-care [2, 8]. In this study, having received the educational intervention and having more comorbidities were the only variables identified as predictors of self-care. These results suggest that educational approaches to improve patients’ knowledge of the disease and treatment should be implemented in different settings and that sociodemographic and clinical characteristics should be considered by the health care team in order to point out those variables predicting a better or worse self-care behavior.

Patient compliance with treatment regimens, aiming to achieve clinical stability in the followup of patients with HF, is a major challenge for health care professionals, and in this context self-care is a key element. For patients with HF, positive practices, such as weight control, fluid and sodium restriction, physical activity, annual vaccination, regular use of medication, and especially the development of skills for early recognition of signs and symptoms of decompensated HF and decision making when symptoms occur, are beneficial behaviors to achieve and maintain clinical stability over the long term.

5. Conclusions

Based on the present results, we can conclude that there was an association between a better self-care behavior and being allocated to the intervention group (who received education on the disease, self-care practices, and treatment), having more years of schooling and more comorbidities. In addition, being in the home visiting program and having a greater number of comorbidities were a predictor of better self-care. This study becomes relevant once sociodemographic and clinical predictors have been identified that lead to a better self-care behavior in patients with HF.

These results also highlight the importance of examining aspects associated with better self-care practices, as well as behaviors and education strategies to guide the patient toward better self-care skills. The recognition of these variables by the multidisciplinary health care team may help guide decisions about the best approach for patient followup.

Funding

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Conflict of Interests

The authors declare that they have no conflict of interests.

References


\[ R^2 = 0.336 \] —Coefficient of determination (general model).


Research Article

Health Literacy Influences Heart Failure Knowledge Attainment but Not Self-Efficacy for Self-Care or Adherence to Self-Care over Time


1 Assistant Professor of Pharmacy Practice, School of Pharmacy, Cedarville University, 251 N. Main Street, Cedarville, OH 45314, USA
2 School of Nursing, Purdue University, 502 N. University Street, JNSN 238, West Lafayette, IN 47907, USA
3 Center on Aging and the Life Course, Purdue University, West Lafayette, IN 47907, USA
4 Regenstrief Center for Healthcare Engineering, Purdue University, West Lafayette, IN 47907, USA
5 Office of Research & Innovation, Nursing Institute and CNS, Kaufman Center for Heart Failure, Heart and Vascular Institute, Cleveland Clinic, 9500 Euclid Avenue, J3-4, Cleveland, OH 44195, USA
6 Distinguished Professor of Sociology, Purdue University, Bill and Sally Hanley Hall, 1202 W. State Street, West Lafayette, IN 47907, USA
7 Pharmacy Administration, College of Pharmacy, Purdue University, Heine Pharmacy Building, 575 Stadium Mall Drive, West Lafayette, IN 47907, USA
8 Pharmacy Practice, College of Pharmacy, Purdue University, Heine Pharmacy Building, 575 Stadium Mall Drive, West Lafayette, IN 47907, USA

Correspondence should be addressed to Aleda M. H. Chen; amchen@cedarville.edu

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Background. Inadequate health literacy may be a barrier to gaining knowledge about heart failure (HF) self-care expectations, strengthening self-efficacy for self-care behaviors, and adhering to self-care behaviors over time. Objective. To examine if health literacy is associated with HF knowledge, self-efficacy, and self-care adherence longitudinally. Methods. Prior to education, newly referred patients at three HF clinics (N = 51, age: 64.7 ± 13.0 years) completed assessments of health literacy, HF knowledge, self-efficacy, and adherence to self-care at baseline, 2, and 4 months. Repeated measures analysis of variance with Bonferroni-adjusted alpha levels was used to test longitudinal outcomes. Results. Health literacy was associated with HF knowledge longitudinally (P < 0.001) but was not associated with self-efficacy self-care adherence. In posthoc analyses, participants with inadequate health literacy had less HF knowledge than participants with adequate (P < 0.001) but not marginal (P = 0.073) health literacy. Conclusions. Adequate health literacy was associated with greater HF knowledge but not self-efficacy or adherence to self-care expectations over time. If nurses understand patients' health literacy level, they may educate patients using methods that promote understanding of concepts. Since interventions that promote self-efficacy and adherence to self-care were not associated with health literacy level, new approaches must be examined.

1. Introduction

Heart failure is identified as a leading cause of hospitalizations [1], morbidity, mortality, and rising healthcare costs for nearly six million Americans [2, 3]. After a diagnosis of heart failure, patients must perform self-care behaviors to reduce negative clinical outcomes [4, 5]. Self-care is a decision-making process, where patients perform activities to prevent symptoms (maintenance) and respond to symptoms as they occur (management) [4]. Self-care maintenance activities for heart failure patients include exercising daily, eating a low sodium diet, monitoring fluid intake, and monitoring weight. Patients may respond to symptoms by engaging
in the following self-care management activities: consulting their healthcare provider, reducing fluid and sodium intake, and increasing the dose of a diuretic. However, patients’ adherence to recommended self-care behaviors varies greatly and is generally poor [5–7].

Multiple factors may affect patients’ adherence to heart failure self-care including heart failure knowledge. Patients may not have received recommended heart failure education [8, 9] if the heart failure diagnosis was secondary to another health problem, such as myocardial infarction, resulting in inadequate knowledge about heart failure [10]. Initial education about heart failure often occurs during hospitalization when the patient may be too ill or overwhelmed with acute care events, potentially reducing retention of information presented unless family members are available to be counseled [10]. Additional education occurs in the outpatient setting, but content variability can affect overall heart failure knowledge. Further, chronic heart failure is a complex condition to self-management. Patients must monitor their sodium intake, manage medications, manage fluids, perform physical activity, assess signs and symptoms of worsening condition, and follow up with healthcare providers [5, 8, 9]. Adherence to heart failure self-care regimens requires that patients apply heart failure knowledge and education principles when making decisions and managing situations [9]. Even when patients receive additional heart failure and self-care education in an outpatient setting based on clinical practice guidelines [8, 10], inadequate health literacy is a potential barrier that prevents knowledge and skills acquisition [5, 11–13].

Health literacy, defined as obtaining, understanding, and using health information, may impact knowledge gained during heart failure education and patient adherence to self-care in heart failure [13]. Prevalence of inadequate health literacy in patients with heart failure ranges from 17.5 to 41% [11, 14–16]. There is no consensus regarding the impact of health literacy on heart failure outcomes [13]. Patients with inadequate health literacy had less heart failure knowledge [17–19] and less adherence to heart failure related self-care regimen expectations [20, 21]; however, in a similarly designed, cross-sectional study, other researchers found no relationship between health literacy and self-care adherence [18].

Self-efficacy also may be influenced by health literacy. Self-efficacy, derived from Bandura’s social cognitive theory, is defined as an individual’s confidence in his or her ability to perform health behaviors [22, 23]. The level of self-efficacy an individual possesses influences adherence to goals and responses to challenges [22, 23]. Lack of disease-specific knowledge due to inadequate health literacy also may affect patients’ self-efficacy regarding their ability to adhere to complex self-care regimens. If individuals lacked self-efficacy (i.e., confidence) regarding their decisions, they did not carry out appropriate self-care [18, 19]; however, in an other research, a lack of patient self-efficacy did not alter adherence to self-care regimens [20].

Educational interventions designed for patients with inadequate health literacy are thought to improve disease knowledge and self-care adherence. Although educational interventions for patients with heart failure and inadequate health literacy improved knowledge, self-efficacy, daily weight measurements [11], and medication adherence [15, 21], one group of researchers found that the effects of education did not last past the intervention [15]. Previously, much of the research on health literacy in heart failure was focused on the impact of inadequate health literacy. For different health literacy levels, little is known about their association with changes in heart failure knowledge, self-efficacy for self-care, and adherence to self-care over time.

2. Objectives

The objectives of this study were to examine associations between health literacy level (inadequate, marginal, and adequate) and heart failure knowledge, self-efficacy for self-care, and self-care adherence longitudinally over a four-month period in community-dwelling adults.

3. Methods

This multicenter study used a correlational, longitudinal design with three data collection periods: baseline, two, and four months. Institutional Review Board (IRB) approval was obtained from each clinical data collection site and Purdue University.

3.1. Participants and Procedures. Participants were recruited from 2009 to 2011 at three heart failure clinics: Cleveland Clinic in the Heart and Vascular Institute (Cleveland, OH, USA), Indiana University Health-Bloomington Hospital, and Hospita Cardiopulmonary Rehab and Congestive Heart Failure Center (Bloomington, IN, USA), and Community Health Network Indiana Heart Hospital Healthy Hearts Center (Indianapolis, IN, USA). At each site, heart failure patient education was provided as part of standard care procedures and typically completed in the first two months of care. Education in these clinics is provided primarily by advanced practice nurses (APNs) or registered nurses with consults from registered dieticians or other healthcare providers as applicable. Content is based on heart failure guidelines and includes heart failure diagnosis, self-care, medications, diet, and exercise. The settings differed in that the environments of care were urban, rural, and community based, respectively.

Nursing staff identified new clinic referrals who would meet study inclusion criteria, a new clinic referral, at least 18 years of age, able to read and speak English, and no cognitive impairment based on clinical judgment. Patients were excluded if they resided in a skilled nursing facility or received home healthcare services. Eligible adult patients with heart failure were invited to participate at the initial clinic appointment by researchers who were not involved in direct patient care.

Questionnaires were administered by trained researchers or research assistants; direct patient care providers were not involved in recruitment or data collection. At baseline, questionnaires were administered in private areas of each outpatient heart failure clinic before patients received education. At two, and four months, questionnaires were mailed to
participants from the Bloomington Clinic and Community Health Network and were completed via telephone or by mail (at participant’s request) at the Cleveland Clinic. The two-months data collection point was chosen as patients completed education by two months. This allowed for a two months period without scheduled education before the four-month assessment.

3.2. Measures. Health literacy was measured using the Short-Form Test of Functional Health Literacy (S-TOFHLA) [24]. The S-TOFHLA consists of 36 reading comprehension items, which contain examples of commonly used healthcare materials, and is required to be completed within a 7-minute time frame. Scores were categorized as recommended: inadequate (0–16 points), marginal (17–22 points), and adequate (23–36 points). The S-TOFHLA is a reliable and valid measure of health literacy, with Cronbach’s alpha of 0.98 and established criterion validity [24].

Knowledge of heart failure was measured using the Heart Failure Knowledge Questionnaire (HFKQ). The HFKQ contains 14 close-ended items and one open-ended, item, and content includes heart failure pathology, symptoms, medications, and self-management. Scores range from 0 (lack of knowledge) to 15 (knowledgeable) and the previously reported Cronbach’s alpha of 0.62 [6]. In this study, Cronbach’s alpha at baseline assessment (n = 81) was similar at 0.66.

Self-efficacy for heart failure self-care and adherence to heart failure self-care behaviors were measured using the Self-Care Heart Failure Index v.6 (SCHFI) that assesses adherence to both self-care maintenance and management behaviors [4, 25]. Of 22 items, 6 items measure self-efficacy, 10 items measure self-care maintenance, and 6 items measure self-care management. Items were rated on a four-point response scale from 1 = never or rarely to 4 = always or daily for the maintenance subscale, from 1 = not confident to 4 = extremely confident for the confidence subscale, and 1 = not quickly, not likely, or not sure to 1 = very quickly, very likely, very sure for the management subscale; then each subscale score was standardized to 100 points [25]. In order to score subscale B (self-care management), patients must have experienced an exacerbation of heart failure within the past two months. A score of ≥70 was used as the cut-point to reflect self-care adequacy in each subscale. Psychometric performance of SCHFI was assessed previously and found to be valid and reliable (maintenance: alpha = 0.553, management: alpha = 0.597, confidence/self-efficacy: alpha = 0.827, and combined maintenance/management: alpha = 0.798) [4, 25, 26].

Patient characteristics were obtained at baseline and included gender, age, marital status, ethnicity/race, education, income, body mass index (BMI), and number of prescription medications.

3.3. Data Analysis. Descriptive statistics were calculated for patient characteristics and included frequencies and percentages for categorical variables and means and standard deviations for continuous variables. Associations between patient characteristics (age, education, BMI, and prescription medications) and study outcomes (heart failure knowledge, self-efficacy for self-care, and self-care adherence) were examined using Pearson correlations. Difference in baseline patient characteristics and characteristics of patients who completed all follow-up evaluations were assessed using t-tests, Mann-Whitney tests, or One-Way Analysis of Variance (ANOVA) with Bonferroni corrections for multiple comparisons, as appropriate. Differences in characteristics of patients who completed all follow-up evaluations by health literacy level were assessed using t-, Chi-squared, or Kruskal-Wallis tests, as appropriate. Differences in characteristics of patients who completed all follow-up evaluations by study outcome (heart failure knowledge, self-efficacy for self-care, self-care maintenance, and self-care management) were assessed using Pearson correlations or One-Way Analysis of Variance (ANOVA) with Bonferroni corrections for multiple comparisons, as appropriate.

Means and standard deviations were calculated for health literacy at baseline and for knowledge, self-efficacy, and self-care at each assessment period. A power analysis was performed to with a power of 0.8, an alpha of 0.05, and a medium effect size. From that power analysis, a sample size of at least 36 participants was needed to perform the repeated measures ANOVA. Repeated measures ANOVA were performed to determine if differences existed over time, and when significant differences were found, Bonferroni corrections were used to perform multiple comparisons. Profile plots also were generated. An a priori level of 0.05 was used for statistical significance. All analyses were performed using IBM SPSS v. 19.0 for Windows (Armonk, NY, USA).

4. Results

4.1. Participant Characteristics. Eighty one participants completed baseline questionnaires; however, analyses were based on participants (n = 51) who completed two-month and/or four-month assessments. Participants were generally young compared to registry data on heart failure, white, graduated from high school, and took nearly 9 prescription medications on a regular basis. Compared to the 81 patients who enrolled in the study, those completing follow-up data collections (n = 51) were not significantly different (P > 0.05, data not shown). All results hereafter will include only patients who completed all follow-up data collections (N = 51). There were significant differences by age, BMI, recruitment site, and marital status by health literacy level (Table 1). Participants with inadequate health literacy were significantly older and were more likely to be recruited from the Bloomington Hospital site. Participants with marginal health literacy had significantly higher BMI than those with adequate health literacy.

Of participant characteristics, there were differences in heart failure knowledge by age, years of education, recruitment site, and marital status (Table 2). In Bonferroni-adjusted posthoc tests for recruitment site and marital status, participants at Cleveland Clinic had significantly more knowledge at baseline than Bloomington Hospital (P = 0.015) and CHN (P = 0.029). Participants who were married had significantly more knowledge than those who were widowed at baseline (P = 0.001), two (P = 0.002), and four months (P = 0.004).
Table 1: Demographic information.

<table>
<thead>
<tr>
<th>Demographic characteristic</th>
<th>All participants</th>
<th>Inadequate health literacy N = 10</th>
<th>Marginal health literacy N = 5</th>
<th>Adequate health literacy N = 36</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, mean (SD), y</td>
<td>64.68 (13.04)</td>
<td>77.00 (11.79)*</td>
<td>69.20 (10.76)</td>
<td>60.97 (11.71)*</td>
<td>0.002</td>
</tr>
<tr>
<td>Years of education, mean (SD), y</td>
<td>13.72 (2.77)</td>
<td>11.89 (2.67)</td>
<td>13.2 (1.79)</td>
<td>14.27 (2.75)</td>
<td>0.061</td>
</tr>
<tr>
<td>BMI, mean (SD), kg/m²</td>
<td>29.84 (8.14)</td>
<td>28.37 (5.59)</td>
<td>38.42 (13.74)*</td>
<td>29.06 (7.31)*</td>
<td>0.042</td>
</tr>
<tr>
<td>Prescription medications, mean (SD)</td>
<td>8.78 (4.28)</td>
<td>9.30 (3.53)</td>
<td>10.80 (1.79)</td>
<td>8.36 (4.66)</td>
<td>0.456</td>
</tr>
<tr>
<td>Recruitment site, N (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>0.018</td>
</tr>
<tr>
<td>Bloomington hospital</td>
<td>19 (37.3)</td>
<td>7 (13.7)</td>
<td>3 (5.9)</td>
<td>9 (17.6)</td>
<td></td>
</tr>
<tr>
<td>Community health network</td>
<td>4 (7.8)</td>
<td>1 (2.0)</td>
<td>0 (0.0)</td>
<td>3 (5.9)</td>
<td></td>
</tr>
<tr>
<td>Cleveland clinic</td>
<td>28 (54.9)</td>
<td>2 (3.9)</td>
<td>2 (3.9)</td>
<td>24 (41.1)</td>
<td></td>
</tr>
<tr>
<td>Male, N (%)</td>
<td>29 (56.9)</td>
<td>5 (9.8)</td>
<td>3 (5.9)</td>
<td>21 (41.2)</td>
<td></td>
</tr>
<tr>
<td>Marital status, N (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>0.025</td>
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<tr>
<td>Unmarried</td>
<td>5 (9.8)</td>
<td>1 (2.0)</td>
<td>1 (2.0)</td>
<td>3 (5.9)</td>
<td></td>
</tr>
<tr>
<td>Married</td>
<td>34 (66.7)</td>
<td>3 (5.9)</td>
<td>2 (3.9)</td>
<td>29 (56.9)</td>
<td></td>
</tr>
<tr>
<td>Divorced/separated</td>
<td>3 (5.9)</td>
<td>0 (0.0)</td>
<td>1 (2.0)</td>
<td>2 (3.9)</td>
<td></td>
</tr>
<tr>
<td>Widowed</td>
<td>9 (17.6)</td>
<td>6 (11.8)</td>
<td>1 (2.0)</td>
<td>2 (3.9)</td>
<td></td>
</tr>
<tr>
<td>Ethnicity, N (%)</td>
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<td></td>
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<tr>
<td>Black/African American</td>
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<td>1 (2.0)</td>
<td>1 (2.0)</td>
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</tr>
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<td>White/Caucasian</td>
<td>45 (88.2)</td>
<td>9 (17.6)</td>
<td>4 (7.8)</td>
<td>32 (62.7)</td>
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</tr>
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<td>Hispanic/Latino</td>
<td>3 (5.9)</td>
<td>1 (2.0)</td>
<td>0 (0.0)</td>
<td>1 (2.0)</td>
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</tr>
<tr>
<td>Financial status, N (%)</td>
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<td></td>
<td></td>
<td>0.379</td>
</tr>
<tr>
<td>More than enough to make ends meet</td>
<td>22 (43.1)</td>
<td>4 (7.8)</td>
<td>1 (2.0)</td>
<td>17 (33.3)</td>
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<tr>
<td>Enough to make ends meet</td>
<td>20 (39.2)</td>
<td>5 (9.8)</td>
<td>2 (3.9)</td>
<td>13 (25.5)</td>
<td></td>
</tr>
<tr>
<td>Not enough to make ends meet</td>
<td>9 (17.6)</td>
<td>1 (2.0)</td>
<td>2 (3.9)</td>
<td>6 (11.8)</td>
<td></td>
</tr>
</tbody>
</table>

*Significant difference between groups in posthoc tests, P < 0.05.

All % calculated with a denominator of N = 51.

Table 2: Participant characteristics and their significant associations or differences in study outcomes.

<table>
<thead>
<tr>
<th></th>
<th>Baseline</th>
<th>Knowledge 2 months</th>
<th>Knowledge 4 months</th>
<th>Self-efficacy Baseline</th>
<th>Self-efficacy 2 months</th>
<th>Self-Care maintenance 4 months</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>r</td>
<td>−0.342</td>
<td>−0.482</td>
<td>−0.339</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>P</td>
<td>0.015</td>
<td>&lt;0.001</td>
<td>&lt;0.001</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Years of education</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>r</td>
<td>0.364</td>
<td>0.299</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>P</td>
<td>0.010</td>
<td>0.037</td>
<td></td>
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</tr>
<tr>
<td>BMI</td>
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<td></td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>r</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>−0.339</td>
<td>−0.322</td>
<td></td>
</tr>
<tr>
<td>P</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>0.017</td>
<td>0.028</td>
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</tr>
<tr>
<td>Recruitment site</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>F</td>
<td>6.535</td>
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<td></td>
<td>4.425</td>
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<td>3.824</td>
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<tr>
<td>P</td>
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<td>0.017</td>
<td></td>
<td>0.029</td>
</tr>
<tr>
<td>Marital status</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>F</td>
<td>5.779</td>
<td>5.169</td>
<td>4.789</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>P</td>
<td>0.002</td>
<td>0.004</td>
<td>0.005</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* Assessed using Pearson correlations.

** Assessed using One-Way Analysis of Variance.
Adequacy, according to the SCHFI, is on a scale of 0–100.

Possiblerange0–100.

Recruitment site and BMI. In Bonferroni-adjusted posthoc tests, participants at Bloomington Hospital had significantly higher self-care maintenance adherence than participants at the CHN site (P = 0.032) at baseline. BMI was negatively associated with self-efficacy for self-care at baseline and two months.

There were differences in self-care maintenance by recruitment site. In Bonferroni-adjusted posthoc tests, participants at Cleveland Clinic had significantly higher self-care maintenance adherence than participants at the CHN site (P = 0.026) at 4 months. There were no other significant differences in or associations with outcomes based on participant characteristics.

### Table 3: Health literacy, knowledge, self-efficacy, and self-care scores at baseline and followup overall and by health literacy level.

<table>
<thead>
<tr>
<th>Group</th>
<th>Assessment</th>
<th>Heart failure knowledge</th>
<th>Self-efficacy</th>
<th>Self-care maintenance</th>
<th>Self-care management</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Assessment</td>
<td>Mean ± SD</td>
<td>Meaning</td>
<td>Mean ± SD</td>
<td>Meaning</td>
</tr>
<tr>
<td>Overall</td>
<td>Baseline</td>
<td>8.2 ± 2.7</td>
<td>54.7% correct</td>
<td>69.6 ± 19.4</td>
<td>Not adequate</td>
</tr>
<tr>
<td></td>
<td>2 months</td>
<td>9.3 ± 3.3</td>
<td>62.0% correct</td>
<td>72.2 ± 15.5</td>
<td>Adequate</td>
</tr>
<tr>
<td></td>
<td>4 months</td>
<td>9.6 ± 2.4</td>
<td>64.0% correct</td>
<td>75.0 ± 16.0</td>
<td>Adequate</td>
</tr>
<tr>
<td>Inadequate health literacy</td>
<td>Baseline</td>
<td>5.3 ± 2.4</td>
<td>35.3% correct</td>
<td>64.2 ± 21.9</td>
<td>Not adequate</td>
</tr>
<tr>
<td></td>
<td>2 months</td>
<td>5.9 ± 2.5</td>
<td>39.3% correct</td>
<td>72.3 ± 16.0</td>
<td>Adequate</td>
</tr>
<tr>
<td></td>
<td>4 months</td>
<td>7.8 ± 1.7</td>
<td>52.0% correct</td>
<td>82.8 ± 19.4</td>
<td>Adequate</td>
</tr>
<tr>
<td>Marginal health literacy</td>
<td>Baseline</td>
<td>9.0 ± 1.6</td>
<td>60.0% correct</td>
<td>54.5 ± 10.0</td>
<td>Not adequate</td>
</tr>
<tr>
<td></td>
<td>2 months</td>
<td>9.0 ± 2.9</td>
<td>60.0% correct</td>
<td>67.8 ± 10.7</td>
<td>Not adequate</td>
</tr>
<tr>
<td></td>
<td>4 months</td>
<td>8.8 ± 3.8</td>
<td>58.7% correct</td>
<td>66.8 ± 6.7</td>
<td>Not adequate</td>
</tr>
<tr>
<td>Adequate health literacy</td>
<td>Baseline</td>
<td>8.8 ± 2.3</td>
<td>58.7% correct</td>
<td>73.0 ± 18.8</td>
<td>Adequate</td>
</tr>
<tr>
<td></td>
<td>2 months</td>
<td>10.2 ± 3.0</td>
<td>68.0% correct</td>
<td>76.3 ± 16.2</td>
<td>Adequate</td>
</tr>
<tr>
<td></td>
<td>4 months</td>
<td>10.3 ± 2.1</td>
<td>68.7% correct</td>
<td>74.3 ± 15.8</td>
<td>Adequate</td>
</tr>
</tbody>
</table>

*aPossible range 0–15.

*bPossible range 0–100.

*cAdequacy, according to the SCHFI, is at scores ≥70.

### Table 4: Longitudinal effects of health literacy on outcomes using repeated measures analysis of variance.

<table>
<thead>
<tr>
<th>Effect</th>
<th>Knowledge</th>
<th>Self-efficacy</th>
<th>Self-care maintenance</th>
<th>Self-care management</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Assessment</td>
<td>F</td>
<td>P</td>
<td>Assessment</td>
</tr>
<tr>
<td>Time</td>
<td>&lt;0.001</td>
<td>3.519</td>
<td>0.034</td>
<td>1.954</td>
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<tr>
<td>Health literacy</td>
<td>&lt;0.001</td>
<td>11.096</td>
<td>0.131</td>
<td>1.037</td>
</tr>
<tr>
<td>Time*health literacy</td>
<td>&lt;0.001</td>
<td>1.189</td>
<td>0.254</td>
<td>3.620</td>
</tr>
</tbody>
</table>

There were differences in self-efficacy for self-care by recruitment site and BMI. In Bonferroni-adjusted posthoc tests, participants at Bloomington Hospital had significantly lower self-efficacy for self-care than participants at the CHN site (P = 0.032) at baseline. BMI was negatively associated with self-efficacy for self-care at baseline two months.

There were differences in self-care maintenance by recruitment site. In Bonferroni-adjusted posthoc tests, participants at Cleveland Clinic had significantly higher self-care maintenance adherence than participants at the CHN site (P = 0.026) at 4 months. There were no other significant differences in or associations with outcomes based on participant characteristics.

4.2. Adequacy of Health Literacy and Outcomes. At baseline, mean health literacy was adequate, but heart failure knowledge was low (failing mean score by testing standards), and self-efficacy for self-care and adherence to self-care maintenance and management behaviors were below cut off scores, reflecting inadequacy (Table 3). Of participants, 41.2% had adequate self-efficacy for performing self-care at baseline.

By the four-month followup, knowledge level remained low but increased to 64% (equaling a “D grade” by testing standards), and self-efficacy for self-care behaviors and adherence to self-care increased to adequate levels. Patient knowledge and self-care maintenance significantly improved over time (P = 0.012 and P = 0.002, resp.), but patient self-care management and self-efficacy did not significantly improve over time (P = 0.754 and P = 0.148, resp.).

4.3. Assessment of the Impact of Baseline Health Literacy over Time. Health literacy categories at baseline were used to assess outcomes over time (Table 4). There were significant effects of health literacy on heart failure knowledge over time, but no effects of health literacy on other outcomes (self-efficacy and self-care). There was a significant effect of time on heart failure knowledge. There was no time-health literacy interaction, as evidenced by a nonsignificant P value and the profile plot (Figure 1), which indicated significant effects of both time and health literacy.

To further examine the differences in knowledge by health literacy level, Bonferroni-adjusted posthoc tests were performed, and patients with inadequate health literacy had significantly less knowledge than those with adequate (P < 0.001) but not marginal (P = 0.073) health literacy, as seen in Figure 1. Although patients with inadequate health literacy had a larger rise in heart failure knowledge score at 4 months compared to those with marginal and adequate health literacy at baseline, heart failure knowledge levels remained below that of patients with adequate health literacy (Figure 1).

5. Discussion

In this study, the importance of health literacy on heart failure knowledge score, self-efficacy for heart failure self-care, and
adherence to heart failure self-care was examined over a four-month period. There were positive, longitudinal associations between health literacy and knowledge (higher health literacy with greater knowledge) but not between health literacy and self-efficacy for self-care or self-care adherence. Traditional clinic-based education improved knowledge overall, but the knowledge level of individuals with inadequate health literacy never improved to the level of those with adequate health literacy. Therefore, traditional clinic-based education may not be the best method to improve heart failure knowledge gaps over time for patients with inadequate health literacy. Moreover, since adherence to heart failure self-care behaviors improves clinical outcomes in heart failure [5, 11, 27], determining reasons for nonadherence, beyond health literacy, may be a key element in promoting heart failure self-care maintenance and management.

Disease-specific education has been found to improve knowledge in heart failure [11, 28, 29]. In this study, patients with inadequate and adequate health literacy experienced gains in knowledge during traditional clinic-based education. DeWalt and colleagues found education for patients with inadequate health literacy improved heart failure knowledge [11]. Similarly, we found that patients with inadequate health literacy demonstrated improved heart failure knowledge over the course of traditional clinic-based education. Over time, patients with inadequate health literacy continued to experience knowledge gains but had less heart failure knowledge than patients with adequate health literacy across both assessments. Since the distribution of inadequate literacy patients in this study mirrors other research and the health literacy levels are representative of the general heart failure population [11, 14, 15], the results of this study indicate that traditional education efforts may not reduce the knowledge disparity between patients with inadequate and adequate health literacy. Furthermore, researchers found in a diabetes educational intervention that although all patients gained considerable knowledge, patients with low health literacy did not gain as much as higher health-literate patients [30].

In three other studies, researchers consistently found that health literacy and patient heart failure knowledge are related [17–19]. Similar to our study, these studies used the TOFHLA [19] or the S-TOFHLA [17, 18] to measure health literacy, but each study utilized different measures of heart failure knowledge. Despite differences in measuring heart failure knowledge, other studies confirmed our findings that patients with inadequate health literacy had less heart failure knowledge. Furthermore, posthoc power analyses revealed that there was sufficient power to examine the difference (using repeated measures ANOVA) between health literacy categories with regard to knowledge (partial $\eta^2 = 0.316$, power = 0.988). Clinic-based education improves heart failure knowledge for patients with inadequate health literacy. However, further educational efforts for patients with inadequate health literacy are needed to reduce the disparity in knowledge between patients with inadequate and adequate health literacy.

Interestingly, patients with marginal health literacy did not improve over time. The relationship between marginal health literacy and heart failure knowledge is not a common focus of most research. Researchers in one study found no association between marginal health literacy and heart failure knowledge [17], although researchers in another study found that patients with marginal health literacy had significantly less knowledge than those with adequate health literacy [18]. Other researchers have taken the approach of collapsing the categories of inadequate and marginal health into one category of low health literacy. Further longitudinal research is needed to support our findings regarding marginal health literacy and heart failure knowledge.

We were surprised that over time, health literacy category was not associated with self-efficacy for heart failure self-care and self-care adherence in newly referred patients to a heart failure clinic. However, this could be due to a lack of power to detect differences. Posthoc power analyses revealed a lack of power in assessing self-efficacy (partial $\eta^2 = 0.062$, power = 0.277), self-care maintenance (partial $\eta^2 = 0.065$, power = 0.337), or self-care management (partial $\eta^2 = 0.045$, power = 0.089). Since the self-care management scale could only be scored if participants had symptoms in the prior two months, only 13 patients had scorable self-care management responses at all three assessments (participants with symptoms at baseline $N = 39$, two months $N = 23$, and four months $N = 26$) and were eligible for repeated measures ANOVA.

In prior literature, relationships between health literacy and heart failure self-efficacy for self-care and self-care adherence were measured at only one point in time, and results were inconsistent. In a small, cross-sectional pilot
study, researchers found no relationship between health literacy and self-efficacy [20], similar to our results. In larger studies, relationships between health literacy and self-efficacy differed from ours. When 95 patients with chronic heart failure were assessed during hospital admission, a significant relationship between health literacy and self-efficacy was found on univariate analysis, but the sample was too small to complete multivariate analysis [18]. It is unknown if whether self-efficacy or patient characteristics (age, gender, etc.) would be mediators for the relationship between health literacy and self-care had further analyses been performed. In a large sample (N = 605), self-efficacy was a mediator between health literacy and self-care in a structural equation model [19]. To our knowledge, our research provides the first examination of health literacy and self-efficacy longitudinally. Further research with larger sample sizes and adequately powered to detect differences is needed to examine these relationships over time. With larger samples, significant baseline factors can be controlled for to learn the importance of health literacy on outcomes.

5.1. Limitations. Findings may be limited due to the majority of study participants having adequate health literacy scores. A new referral to a heart failure clinic may not necessarily mean a recent heart failure diagnosis. Patients may have had heart failure for some time and could have been treated elsewhere before referral. Previous heart failure education materials could have been developed based on low health literacy or reading levels, minimizing health literacy as an important factor in self-efficacy for self-care and self-care adherence. Prior education delivery and experiences in self-assessment and management of heart failure symptoms and outcomes of self-care behaviors could also have affected study findings, although heart failure knowledge, self-efficacy, and self-care adherence scores were below desired levels at baseline.

Participant recruitment and retention may impact study findings and contributed to a lack of statistical power to assess self-efficacy and self-care. A total of 80 participants were initially enrolled, but 51 completed the study. An attempt was made to minimize attrition by making multiple attempts for followup at each assessment, and there were no significant differences in demographic characteristics between those at baseline and those who completed the study. We found significant associations between several demographic characteristics and study outcomes. In particular, younger participant age and more years of formal education were associated with higher heart failure knowledge. However, due to attrition, multivariate regression between participant characteristics and outcomes (heart failure knowledge, self-efficacy for self-care, and self-care adherence) or between recruitment site (taking into account educational or patient differences) and outcomes was unable to be performed. Future work should include these characteristics and should be adequately powered to better assess self-efficacy, self-care maintenance, and self-care management.

Other limitations in this study include length of longitudinal assessment, potential of participants with mild cognitive dysfunction to be included, and the use of self-report measures that were valid and short but limited in scope. The four-month assessment (two months after education were completed) may not have been long enough to see the effects of health literacy on patient outcomes over time. However, Murray and colleagues [15] found that the effects of an educational intervention declined once the intervention ended, therefore, it is probable that the longitudinal effects could be seen at the four-month assessment. Future work should include a longer followup, such as six months or one year. While clinical judgment was utilized to exclude patients with cognitive impairment, some participants included in this study may have had undiagnosed mild cognitive impairment. Mild cognitive impairment has been found to lead to lower health literacy and poorer self-care and may have impacted results in this study.

6. Conclusions
Although health literacy was associated with patients’ gain in heart failure knowledge over time, particularly in patients with low health literacy, health literacy was not associated with heart failure self-efficacy in performing self-care or self-care adherence. Examining the influence of health literacy on heart failure knowledge, self-efficacy for self-care, and self-care adherence over four months clarified some of the cross-sectional findings related to knowledge, self-efficacy, and self-care; however, these relationships are complex and merit further study. Investigators should examine approaches and work collaboratively with healthcare professionals to improve knowledge gains among inadequate health literacy patients during clinic-based education.

Acknowledgments
This work was supported by a seed grant from the Purdue University Regenstrief Center for Healthcare Engineering, the Clifford Kinley Trust (Purdue University), the American Association of Heart Failure Nurses Bernard Saperstein Grant, and the Delta Omicron Chapter of Sigma Theta Tau International. Support for Aleda Chen while a graduate student was provided by the National Institute on Aging (T32AG025671), the Purdue University Center on Aging and the Life Course, and from the American Foundation for Pharmaceutical Excellence. The authors would like to thank Susie Carter, RN, BC, FAACVPR, and AACC, Manager of Cardiopulmonary Rehab at the Advanced Heart Care Center, Indiana University Health Bloomington Hospital, Jennifer Forney, BSN, RN, Ellen Slifcak, BA, RN, and Susan Krajewski BSN, RN, and MPA, Cleveland Clinic for their assistance and support of this project. Thanks are due to Mary Kiersma, Pharm.D., Ph.D., Director of Assessment at Manchester College, for her review of this paper.

References


Research Article

Type 2 Diabetes Risk among Asian Indians in the US: A Pilot Study

Annie Thomas and Alyce Ashcraft

1 Marcella Niehoff School of Nursing, Loyola University Chicago, 1032 W. Sheridan Road, Chicago, IL 60626, USA
2 School of Nursing, Texas Tech University Health Sciences Center, 3601 4th Street, Lubbock, TX 79430, USA

Correspondence should be addressed to Annie Thomas; atomas4@luc.edu

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The purpose of this pilot study was to investigate type 2 diabetes risk among Asian Indians of Kerala ethnicity living in a West Texas County of the USA. The study used a descriptive correlational design with thirty-seven adult nondiabetic Asian Indian subjects between 20 and 70 years of age. The measurement included nonbiochemical indices of obesity, family history of type 2 diabetes, length of immigration in the US, history of hypertension, physical activity pattern, and fruit and vegetable intake. The majority of the subjects showed an increased nonbiochemical indices corresponding with overweight and obesity, placing them at risk for type 2 diabetes and associated cardiovascular complications. The physical activity pattern indicated a sedentary lifestyle. The decreased physical activity was associated with a higher Body Mass Index (BMI) and body fat percentage; length of residence in the US greater than 10 years was associated with increased body fat percentage and BMI; family history of type 2 diabetes was associated with an increase in body fat percentage. Fruit and vegetable intake pattern was not associated with a risk for type 2 diabetes. Further studies are recommended for risk surveillance among Asian Indian population living in the US.

1. Introduction

The prevalence of type 2 diabetes is on the rise globally and has reached epidemic proportions in many countries. The number of adults affected by the disease in 2011 was 366 million, which is projected to increase to 552 million by 2030 [1]. An estimated 25.6 million Americans (11.3% of the population) have type 2 diabetes, and 1.9 million more adults are diagnosed with the disorder each year [2]. Type 2 diabetes is the fifth leading cause of death in the Asian American population. Among Asian Americans, Asian Indians have the highest prevalence of type 2 diabetes compared to other Asian subgroups. Based on the American Community Survey, between 2000 and 2010, the Asian Indian population in the USA grew by 67.60% (3.2 million) and represented the third largest Asian subgroup in the US [3]. Asian Indians who immigrated to Western countries are found to be at risk for the development of type 2 diabetes due to the metabolic impact of a westernized diet or reasons based on tissue resistance to insulin [4, 5]. Asian Indians living in India also face a similar threat related to type 2 diabetes. It is estimated that in another 20 years, nearly one fifth of world’s diabetic population will be in India. Asian Indians are more insulin resistant and hyperinsulinemic than whites which puts them at increased risk for diabetes and heart disease despite the absence of traditional risk factors and decreased body weight [6–8].

Epidemiological studies have shown that type 2 diabetes has a global distribution, and its prevalence varies from country to country, in different ethnic groups in the same country, and between the same ethnic groups undergoing internal or external migration. Populations with acculturation from traditional to modern lifestyle have a higher prevalence of type 2 diabetes, with the prevalence of type 2 diabetes in Asian Indians greater than 20 years old being higher than all other racial groups in the US [9–11]. A recent research study focusing on Asian Indians from the state of Michigan found a high prevalence of self-reported type 2 diabetes (20.1%) and elevated/abnormal A1C levels (A1C ≥ 6.5%: 22.6%). It exceeded the percentages of other ethnic
groups reported in the 2006–2008 Michigan Behavioral Risk Factor Survey (MBRFS) (8% for non-Hispanic whites, 13% for non-Hispanic blacks, 8.9% for Hispanic Latinos, and 15.6% for Native American/Alaskan natives) [12].

1.1. Background. Type 2 diabetes has been associated with reduced physical activity and seems to affect the risk of type 2 diabetes independent of diet. The level of physical activity is higher in ethnic groups living in their countries of origin as compared to the same ethnic groups living in the US [13–15]. Goel et al. [16] conducted a study to estimate the prevalence of obesity among US immigrant subgroups. The study found that the obesity pattern increased by the duration of stay in the US as evidenced by higher Body Mass Index (BMI) rate beginning after 10 years. The prevalence of obesity among immigrants living in the USA for 15 years approached that of US-born individuals. The study recommended early intervention with diet and physical activity which may represent an opportunity to prevent weight gain, obesity, and obesity-related chronic illnesses.

The National Health Interview Survey conducted during 1997–2008 on trends in the prevalence of type 2 diabetes reported two important determinants of obesity and type 2 diabetes in Asian immigrants: age at arrival and period of stay in the US. Findings indicated that the rise in obesity was higher during the first five years of stay in the US from the time of immigration. The prevalence of obesity and type 2 diabetes was greater for those who arrived at a relatively young age. Asian Indians had the highest prevalence of type 2 diabetes, followed by Filipinos, other Asians, and Chinese [4].

Family history has been shown to be a risk factor of number of diseases including type 2 diabetes. Family history, by itself, is most useful in predicting disease when multiple family members are affected. Family history of any specific disease reflects the consequences of genetic susceptibility, shared environment, and common behaviors [17]. In a study investigating the family history of type 2 diabetes and the prevalence of metabolic syndrome in adult Asian Indians, the family history of type 2 diabetes had significant effect on individuals compared to individuals having no history of type 2 diabetes. The study recommended using family history of type 2 diabetes as a predictive tool for early diagnosis and prevention of metabolic syndrome in Asian Indian population [18].

Recent studies have shown that type 2 diabetes can be prevented in high-risk subjects with impaired glucose tolerance by lifestyle intervention. Consumption of fruits, berries, and vegetables, the quantity and quality of dietary fat intake, fiber intake, and physical activity at work and/or on leisure time have been demonstrated to modify the risk of type 2 diabetes [16, 19].

Type 2 diabetes and high blood pressure are strongly linked with each other. High blood pressure can increase the progression of prediabetes into type 2 diabetes and cardiovascular complications [20]. A study conducted by Francis et al. examined risk factors affecting the progression to type 2 diabetes [21]. Individuals with hypertension were more likely to progress from prediabetes to type 2 diabetes. Individuals with type 2 diabetes have increased cardiovascular disease risk compared with those without type 2 diabetes [22]. It has an insidious onset with a long, latent, asymptomatic phase. The prediabetic stages also carry high risk for cardiovascular diseases (CVDs) and clustering of the cardiovascular risk factors [23]. Macrovascular complications are the most important causes of morbidity, mortality, and disability in people with type 2 diabetes. Asian Indians exhibit the highest ethnic-specific prevalence of CVD, with two to three times higher instances than among Caucasians. Asian Indians are at greater risk of developing coronary heart disease compared to other Asian subgroups [24].

Asian Americans are sometimes stereotyped as the “healthy minority.” Grouping Asian Americans into a single category hides the health risks of specific subgroups in the US [8]. They face some of the same limitations to good health as other minority groups. Language barriers interfere with receiving quality health care. Many Asian Americans do not know about the risk factors for disease or the role of preventive health care [25]. The cultural beliefs about health and illness often conflict with Western medicine, which keep some Asian Americans from seeking help for symptoms. Screening for type 2 diabetes risk and preventative measures has the potential to improve the health status of this minority population in the US [26].

Asian Indians living in the US are diverse. Cultural beliefs and practices vary from state to state in India and include dialect and religion as well as dietary habits (strict vegetarian versus nonvegetarian) [12]. The present study focused on Asian Indians from the Kerala state of India and living in the US. Kerala Indians represent a broader Asian Indian population in the US. Data are unavailable to indicate the percentages of Kerala Asian Indians living in the US. Given that limited studies have investigated the risk for type 2 diabetes among Asian Indians, it is necessary to describe the risk factors among Asian Indians and their subgroups living in the US. Such data would then be useful in planning a primary prevention program.

1.2. Study Aims. The aims of this pilot study were to (a) describe type 2 diabetes risk among Asian Indian adults of Kerala ethnicity living in the US and (b) to determine the relationship/association between physical activity, length of immigration, family history of type 2 diabetes, and fruit and vegetable intake with the anthropometric measures and body fat percentage.

2. Conceptual Framework

The Social Learning Theory and Health Belief Model [27] provided a conceptual framework to guide the study. The theory accounts for individual beliefs about contracting a disease and its potential effects on quality of life. The health belief model theorizes that people are not likely to take action for their health action unless (a) they are susceptible to the disease in question; (b) they believe that the disease would have serious effects on their lives, if they should contract
The university’s institutional review board approved the research procedures for the recruitment and data collection. All participants enrolled in the study spoke and read English. The purpose of the research was described in detail prior to obtaining written informed consent from all participants.

3.2. Ethical Considerations. The university’s institutional review board approved the research procedures for the recruitment and data collection. All participants enrolled in the study spoke and read English. The purpose of the research was described in detail prior to obtaining written informed consent from all participants.

3.3. Data Collection. Data were collected from all the participants during a twelve-week time period. It took approximately one hour to explain the consent details and to record the measurements from each subject. Participants returned the completed questionnaires the following week of the measurement procedures. The following measures were used to collect the data.

3.3.1. Demographic Data. Demographic data included age, gender, religious preference, food preference, length of residence in the US, family history of diabetes, and history of hypertension. The reference values for high blood pressure were systolic blood pressure greater than or equal to 140 mmHg or diastolic BP greater than or equal to 90 mmHg (adapted from the Centers for Disease Control (CDC)) [20]. The data on high blood pressure were obtained using an investigator developed self-report questionnaire.

3.3.2. Anthropometric Measures and Body Fat Percentage. Anthropometric measures included the following: height (measured by a Stadiometer using a centimeter scale), weight (measured by a Tanita scale), waist circumference (WC) (measured by a nonstretchable tape midway between the costal margins and the iliac crests with participants standing erect, at the end of normal expiration), hip circumference (measured around the widest part at the level of greater trochanters), and sagittal abdominal diameter (SAD) (measured by using Holtain Khan’s sliding abdominal caliper with parallel blades with the subjects in supine position, hips flexed with the maximum diameter of the abdomen in sagittal plane).

The body fat percentage was measured through bioelectrical impedance analysis using a Tanita scale (Tanita’s Patented BIA method). After entering the age, gender, and height, the subject was instructed to step on to the platform of the Tanita scale. Electrodes in the foot sensor pads send a low, safe signal through the body. Weight was calculated automatically along with body fat content in less than minute. The body fat percentage and anthropometric measures were obtained by experienced research personnel to ensure consistency with the data collection.

The reference values for the BMI were between 23–25 kg/m² and >25 kg/m² to delineate between overweight versus obesity. These values are recommended by the World Health Organization Western Pacific Region and International Obesity and International Association for the Study of Obesity for Asian populations [28].

The reference values for the SAD, WC, waist-hip ratio (WHR), and body fat percentage for the present study are selected based on the recommendations from the Chennai Urban Rural Epidemiology (CURE) Study [29], Indian Urban Based Study [30], and World Health Organization [28] recommendations. The reference values for WC were 87 cm and 82 cm for men and women, respectively. The reference value for the WHR was 0.88 and 0.81, and the SAD was ≥21.5 cm. The reference value for the body fat percentage was ≥25%. A gender specific reference value was not available for SAD and body fat percentage measures.

3.3.3. Global Physical Activity Questionnaire. The Global Physical Activity Questionnaire (GPAQ) is a standardized 16-item questionnaire developed by the World Health Organization [31]. GPAQ is a previously validated and accepted measure of physical activity. A nine country reliability and validity study of the GPAQ revealed that the reliability coefficients were of moderate to substantial strength (Kappa = 0.67–0.73, Spearman rho = 0.67–0.87). The criterion validity and content validity correlations of the GPAQ were 0.35 and 0.65 [32], respectively. The physical activity questionnaire includes the following physical activity patterns: activity at work, travel to and from places, recreational activities, and sedentary behavior. Levels of total physical activity were measured as metabolic equivalent tasks per week (METs/week). The amount of energy expended for different activities varies with
Table 1: Demographic variables.

<table>
<thead>
<tr>
<th>Variables</th>
<th>N</th>
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<td>Age (years)</td>
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<td></td>
<td>38.24 ± 16.24</td>
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<tr>
<td>20–29</td>
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<td>≥50</td>
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<td>Christian</td>
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<td>100</td>
<td></td>
</tr>
<tr>
<td>Others</td>
<td>—</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Food preferences</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nonvegetarian</td>
<td>33</td>
<td>89.18</td>
<td></td>
</tr>
<tr>
<td>Vegetarian</td>
<td>2</td>
<td>5.40</td>
<td></td>
</tr>
<tr>
<td>Others</td>
<td>2</td>
<td>5.40</td>
<td></td>
</tr>
<tr>
<td>Immigration time (in years)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1–5</td>
<td>17</td>
<td>45.94</td>
<td></td>
</tr>
<tr>
<td>5–10</td>
<td>5</td>
<td>13.54</td>
<td></td>
</tr>
<tr>
<td>15</td>
<td>15</td>
<td>40.52</td>
<td></td>
</tr>
<tr>
<td>Family history of type 2 diabetes</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>16</td>
<td>43.26</td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>21</td>
<td>56.82</td>
<td></td>
</tr>
<tr>
<td>History of hypertension (mm of Hg)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Normal: &lt;120/80–90</td>
<td>28</td>
<td>75.75</td>
<td></td>
</tr>
<tr>
<td>Prehypertension and hypertension: ≥120–140/90</td>
<td>9</td>
<td>24.32</td>
<td></td>
</tr>
<tr>
<td>Physical activity (MET/week)</td>
<td></td>
<td></td>
<td>2338.38 ± 1505.53</td>
</tr>
<tr>
<td>Normal: &gt;3000</td>
<td>12</td>
<td>32.42</td>
<td></td>
</tr>
<tr>
<td>Sedentary: &lt;3000</td>
<td>25</td>
<td>67.62</td>
<td></td>
</tr>
<tr>
<td>Fruit and vegetable consumption</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Normal: &gt;3-4 times/week</td>
<td>24</td>
<td>64.92</td>
<td></td>
</tr>
<tr>
<td>Type 2 diabetes risk: &lt;3-4 times/week</td>
<td>13</td>
<td>35.14</td>
<td></td>
</tr>
</tbody>
</table>

3.3.4. Food Frequency Questionnaire. The Food Frequency Questionnaire (FFQ) is a standardized 35-item questionnaire adapted from John Hopkins Weight Management Center. This questionnaire is used to assess overall dietary intake including fruits and vegetables. The reliability and validity of the FFQ has not been reported in the literature. This was one of the limitations of this pilot study. Two previous studies linked the consumption of fruits and vegetables less than 3-4 times/week with type 2 diabetes risk [9, 19]. Therefore, the present study measures only the fruits and vegetable consumption from the food frequency questionnaire.

3.4. Data Analysis. Descriptive statistics were used to analyze the demographic variables (age, gender, immigration period, family history of type 2 diabetes, and history of hypertension) and other type 2 diabetes risk variables (anthropometric measures, body fat percentage, physical inactivity, and fruits and vegetable intake). A Pearson’s correlation analysis (r) was used to examine the relationship of physical activity patterns with anthropometric measures of obesity and body fat percentage. $\chi^2$ test and Cramer’s $V$ ($V$) were used to examine the degree of association of categorical variables (family history of type 2 diabetes, immigration time in the US, and fruit and vegetable intake) with the anthropometric measures and body fat percentage. The correlations/associations are determined statistically significant at $P$ value less than or equal to 0.05 ($P \leq 0.05$). Data analysis was performed using SPSS software (version 14.0) (Cary, NC, USA).

4. Results

4.1. Description of Demographic/Type 2 Diabetes Risk Variables

4.1.1. Demographics. Demographic data is presented in Table 1. The sample consisted of 21 (56.76%) males and 16
(43.24%) females. The mean age was 38.24 (SD = 16.24) with majority in the age group of 20–29 (13, 35.12%) and 30–39 (13, 35.12%). The religious preference for all subjects in the study was Christian. The food preference was nonvegetarian for the majority of subjects (33, 89.18%). The length of immigration time in the US was between 1–5 years for 17 (45.94%) subjects, 5–10 years for 5 (13.54%), and >10 years for the other 15 (40.52%) subjects. Twenty-one subjects (56.82%) reported a family history of type 2 diabetes. Only 9 subjects reported hypertension, and most (n = 28, 75.75%) had a blood pressure value of <120/82 mmHg taken during the past one month before the study.

4.1.2. Anthropometric Measures and Body Fat Percentage. Anthropometric measures and body fat percentage data are presented in Table 2. The majority of subjects (n = 32, 86.48%) had a BMI ≥ 23 kg/m², of which 14 (37.83%) subjects had a BMI between 23 and 25 kg/m², and 18 (48.64%) subjects had a BMI > 25 kg/m². The mean BMI was 26.19 kg/m² (SD = 3.64). The mean BMI for the males was 27.84 kg/m² and 24.42 kg/m² for females. Consistent with this BMI, the body fat percentage for males was 29.46% and 26.82%, respectively. Waist circumference was ≥87 cm in 18 out of 21 males (48.65%) and ≥82 cm in 14 females (37.84%) out of the 16 screened. A waist circumference of >87 cm in males and >82 cm in females is suggestive of risk for type 2 diabetes.

The sagittal abdominal diameter was ≥21.5 cm in 21 subjects (56.72%) with a mean value of 22.2 cm (SD = 3.14). The SAD was found to be ≥21.5 cm in 14 males (66.66%) and in 7 females (43.75%). The SAD ≥ 21.5 cm indicates the risk for type 2 diabetes. The WHR was ≥0.89 in 15 males (40.54%) and ≥0.81 in 9 females (24.32%) with a mean value of 0.92 (SD = 0.07), suggesting a type 2 diabetes risk in majority of the subjects screened (see Table 2).

4.1.3. Physical Activity and Fruits/Vegetable Intake. The physical activity pattern of 25 subjects (67.62%) showed an activity level of <3000 MET/week, indicating sedentary behavior. Most of the subjects (n = 24, 64.92%) reported consuming fruits and vegetables more than 3-4 times/week (see Table 2).

4.2. Relationship/Association among Measures. The relationship between physical activity and body fat percentage were analyzed. The analysis showed a relationship with physical activity of <3000 MET/week and (a) BMI ≥ 23 kg/m² (r = 0.926, P = 0.032), (b) WC of ≥82 cm in females (r = 0.533, P = 0.066) and WC of >87 cm in males (r = 0.512, P = 0.062), (c) WHR of ≥0.81 in females (r = 0.467, P = 0.714) and WHR of ≥0.85 in males (r = 0.539, P = 0.082), (d) SAD of ≥21.5 cm (r = 0.32, P = 0.071), and (e) body fat percentage of ≥25% (r = 0.631, P = 0.041). The correlations were statistically significant for physical activity with BMI and body fat percentage.

Immigration time greater than 10 years in the US was associated with increased body fat percentage compared to other categories of immigration time in the US (χ² (4, N = 15) = 9.52, P = 0.041; Cramer’s V = 0.34). It was further associated with BMI ≥ 25 kg/m² (χ² (4, N = 3) = 10.24, P = 0.041; Cramer’s V = 0.38). The analysis revealed that the degree of association was statistically significant for the immigration time greater than 10 years with body fat percentage and BMI ≥ 25 kg/m². The immigration time over 10 years and other categories of immigration time in the US were not statistically significant with other anthropometric measures. Family history of type 2 diabetes was associated with increased body fat percentage, (χ² (2, N = 21) = 6.23, P = 0.041; Cramer’s V = 0.34) and was statistically significant. Those who were reporting an increased consumption of fruits and vegetables consumption did not show a statistical significant association with the anthropometric measures and body fat percentage.

Table 2: Type 2 diabetes risk categories for anthropometric measures and body fat percentage.

<table>
<thead>
<tr>
<th>Variables</th>
<th>N</th>
<th>%</th>
<th>Mean and SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>BMI (kg/m²)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Normal: &lt;23</td>
<td>5</td>
<td>13.52</td>
<td>26.19 ± 3.64</td>
</tr>
<tr>
<td>Overweight: 23–25</td>
<td>14</td>
<td>37.83</td>
<td></td>
</tr>
<tr>
<td>Obese: &gt;25</td>
<td>18</td>
<td>48.64</td>
<td></td>
</tr>
<tr>
<td>Body fat percentage</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Normal: &lt;25</td>
<td>15</td>
<td>40.56</td>
<td>28.63 ± 7.01</td>
</tr>
<tr>
<td>Type 2 diabetes risk: ≥25</td>
<td>22</td>
<td>59.54</td>
<td></td>
</tr>
<tr>
<td>Male (≥25)</td>
<td>21</td>
<td>56.76</td>
<td>29.46 ± 2.36</td>
</tr>
<tr>
<td>Female (≥25)</td>
<td>16</td>
<td>43.24</td>
<td>26.82 ± 4.12</td>
</tr>
<tr>
<td>Waist circumference (cm)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Normal: &lt;87</td>
<td>3</td>
<td>8.10</td>
<td>92.05 ± 9.94</td>
</tr>
<tr>
<td>Type 2 diabetes risk: ≥87</td>
<td>18</td>
<td>48.65</td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Normal: &lt;82</td>
<td>2</td>
<td>5.41</td>
<td>84.25 ± 7.18</td>
</tr>
<tr>
<td>Type 2 diabetes risk: ≥82</td>
<td>14</td>
<td>37.83</td>
<td></td>
</tr>
<tr>
<td>Sagittal abdominal diameter (cm)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Normal: &lt;21.5</td>
<td>16</td>
<td>43.24</td>
<td>22.22 ± 3.14</td>
</tr>
<tr>
<td>Type 2 diabetes risk: ≥21.5</td>
<td>21</td>
<td>56.72</td>
<td></td>
</tr>
<tr>
<td>Male (≥21.5)</td>
<td>14</td>
<td>66.66</td>
<td>22.61 ± 3.22</td>
</tr>
<tr>
<td>Female (≥21.5)</td>
<td>7</td>
<td>43.75</td>
<td>21.84 ± 3.34</td>
</tr>
<tr>
<td>Waist-hip ratio</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Normal: &lt;0.89</td>
<td>6</td>
<td>16.22</td>
<td>0.92 ± 0.07</td>
</tr>
<tr>
<td>Type 2 diabetes risk: ≥0.89</td>
<td>15</td>
<td>40.54</td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Normal: &lt;0.81</td>
<td>7</td>
<td>18.92</td>
<td>0.86 ± 0.17</td>
</tr>
<tr>
<td>Type 2 diabetes risk: ≥0.81</td>
<td>9</td>
<td>24.32</td>
<td></td>
</tr>
</tbody>
</table>
5. Discussion

The overall aim of this pilot study was to describe type 2 diabetes risk among Asian Indian adults of Kerala ethnicity living in the US. The analysis of BMI revealed that most of the women in this study were overweight and the men were obese. Asian Indians generally exhibit lower Body Mass Index and waist circumference and tend to accumulate intra-abdominal visceral fat when compared to Caucasians [12]. Studies report that BMI and waist circumference serve as parameters to estimate general or abdominal fat masses, respectively. The strength of association between waist circumference and type 2 diabetes risk depends on body mass index. Individuals of low or normal weight with a large waist circumference have the same risk of developing type 2 diabetes as preobese individuals with small waist circumference [29, 33]. The BMI and waist circumference were higher in most of the males and females screened in this study.

The sagittal abdominal diameter is a strong anthropometric marker of insulin resistance and hyperinsulinemia in obese men than the commonly used waist-to-hip ratio and other anthropometric measures. Sagittal abdominal diameter is a more independent measure compared with waist circumference to predict arterial stiffness in subjects with type 2 diabetes [34, 35]. Several common anthropometric measures correlate with body fat and abdominal fat. Obese individuals with excess visceral fat have an increased risk for the development of type 2 diabetes [8, 15]. The anthropometric measures and body fat percentage were higher in most of the subjects screened in this study, suggesting type 2 diabetes and cardiovascular disease risk in the Asian American Indians.

In a study that included Asian Indian immigrants living in the US, respondents had high physical inactivity but poor knowledge of cardiovascular disease risk factors [16]. The physical activity pattern of the majority of the subjects in our study showed an activity level of <3000 MET/week, indicating behaviors consistent with sedentary behavior. This study revealed that decreased physical activity was associated with higher BMI and body fat percentage in Asian Indians. This study finding was consistent with other studies focusing on physical activity patterns among Asian Indians living in the US [14, 15].

Studies have shown that adopting US norms and culture may lead to obesity and type 2 diabetes among immigrants as well as poor control of type 2 diabetes [36, 37]. The association between length of residence and the higher risk for obesity may be in part due to the adoption of poor dietary patterns and a sedentary lifestyle that is more typical of the host country [7, 8]. This study found that a length of residence in the US over 10 years was associated with an increase in the BMI and body fat percentage.

Family history has been shown to be a risk factor for the majority of chronic diseases such as type 2 diabetes and cardiovascular disease. Family history of diabetes is not only a risk factor, but it is also positively associated with risk awareness and risk-reducing behaviors [17, 18]. This pilot study revealed that a family history of type 2 diabetes was associated with higher body fat percentage.

The Diabetes Risk Score developed by Lindström and Tuomilehto [19] reported that consumption of fruits and vegetables less than 3-4 times/week predicts diabetes risk. The fruit and vegetable intake was more than 3-4 times/week for most of the subjects in the present study, indicating no predictable type 2 diabetes risk related to dietary pattern.

6. Limitations

This pilot study had the following limitations. It was conducted with a small sample of 37 Asian Indians of Kerala ethnicity living in a West Texas County. This county did not have many Asian Indian subgroups who met the inclusion criteria. A standardized type 2 diabetes risk assessment screening tool specific to Asian Indians living in USA has not been developed. Therefore, the reference values for the anthropometric measurements and body fat percentage are selected based on the recommendations from CURE Study [29], Indian Urban Based Study [30], and World Health Organization [28] criteria on obesity measures.

The 35-item Food Frequency Questionnaire (FFQ) developed by John Hopkins Weight Management Center measures various categories of individual dietary pattern. The reliability and validity of the FFQ has not been reported in the literature. Studies report that dietary recommendations for type 2 diabetes are focused mainly on relative dietary fat and carbohydrate content. Consumption of energy from protein at the expense of energy from either carbohydrate or fat contributes to disturbance of glucose metabolism and increased type 2 diabetes risks [9, 38]. The present study focused only on the consumption of fruits and vegetables intake per week to estimate type 2 diabetes risk [18].

The findings reflect the people of Kerala ethnicity, belonging to only one Asian Indian subpopulation, living in Texas. These immigrants settling in Texas and the South-West in general may have adopted eating habits consistent with the region; for example, eating calorie dense, deep fried foods, and red meat because of local influence. The dietary patterns among South Asians of Indian origin are variable and are also influenced by cultural/religious orientations. It is acknowledged that the sample does not represent all of South Asians/Asian Indians.

7. Conclusion and Recommendations

This pilot study used nonbiochemical measures of obesity, questionnaires to measure physical activity and fruits and vegetable intake, and self-report data on family history of type 2 diabetes, immigration time, history of hypertension, and fruit and vegetable intake to identify adults at risk for type 2 diabetes in Asian Indians of Kerala ethnicity living in a Southwestern Texas County of USA. The majority of subjects had higher indices of anthropometric measures and body fat percentage, placing them at risk for type 2 diabetes. The physical activity pattern of the majority of subjects showed a sedentary behavior. The physical activity level of <3000 MET/week was related to higher BMI and body fat percentage. Length of residence in the US greater
than 10 years showed a significant association with body fat percentage and BMI. Family history of type 2 diabetes was associated with an increase in body fat percentage. The fruit and vegetable intake was adequate among the subjects and did not show an association with measures of type 2 diabetes risk.

Many associations between measures were not statistically significant. This could be due to the small sample size used in this pilot study failing to show true statistical significance or true statistical insignificance for those measures that did not show significance. However, the screening for type 2 diabetes risk and the emergence of the risk variables might have alerted subjects to their susceptibility for developing type 2 diabetes [27].

A number of recommendations result from this study. First, Asian Americans are an incredibly diverse population. Their family roots trace to the Far East, Southeast Asia, or the Indian subcontinent. A future study should include a larger sample representing Asian Indian subgroups from different regions of the US. Another need is the development of a population-specific diabetes risk score or validation of an existing tool for screening among a larger Asian Indian population living in US. For example, the Finnish Diabetes Risk Score (FINDRISC) is a feasible, noninvasive tool for identifying subjects at risk for undetected diabetes and prediabetes among Finnish population [39]. A tool such as this might be adapted for an Asian Indian population.

Third, national surveys report that Asian American/Pacific Islanders (AAPIs) are one of the fastest growing immigrant populations in the US in recent years. Prevalence of metabolic syndrome and associated risk factors are also reported to be high in Asian Indians living in the USA [8, 22, 24, 31]. Therefore, the present study recommends that more aggressive efforts should be directed toward screening Asian Indian subgroups for type 2 diabetes risks and implementing primary prevention approaches.

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References


Review Article

Measuring Comorbidity in Cardiovascular Research: A Systematic Review

Harleah G. Buck, Jabar A. Akbar, Sarah Jingying Zhang, and Janet A. Prvu Bettger

1 School of Nursing, The Pennsylvania State University, 201 Health and Human Development East, University Park, PA 16802, USA
2 School of Nursing, Duke University, Duke University Medical Center 3322, 307 Trent Drive, Durham, NC 27710, USA

Correspondence should be addressed to Harleah G. Buck; hgb2@psu.edu

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Background. Everything known about the roles, relationships, and repercussions of comorbidity in cardiovascular disease is shaped by how comorbidity is currently measured. Objectives. To critically examine how comorbidity is measured in randomized controlled trials or clinical trials and prospective observational studies in acute myocardial infarction (AMI), heart failure (HF), or stroke. Design. Systematic review of studies of hospitalized adults from MEDLINE CINAHL, PsychINFO, and ISI Web of Science Social Science databases. At least two reviewers screened and extracted all data. Results. From 1432 reviewed abstracts, 26 studies were included (AMI $n=8$, HF $n=11$, stroke $n=7$). Five studies used an instrument to measure comorbidity while the remaining used the presence or absence of an unsubstantiated list of individual diseases. Comorbidity data were obtained from 1–4 different sources with 35% of studies not reporting the source. A year-by-year analysis showed no changes in measurement. Conclusions. The measurement of comorbidity remains limited to a list of conditions without stated rationale or standards increasing the likelihood that the true impact is underestimated.

1. Introduction

Heart disease and stroke, common cardiovascular diseases, are the third and fourth leading causes of disease burden and the primary causes of death worldwide [1, 2]. Cardiovascular disease (CVD), a systemic disease, rarely occurs alone so it is common to find multiple comorbid conditions in the setting of CVD, particularly in the older adult population who bear a disproportionate share of the comorbidity burden [3]. Comorbidity, at this time, is generally understood to be the presence of other disease entities in the setting of an index disease or condition [4]. However, everything known about the roles, relationships, and repercussions of comorbidity in CVD is shaped by how comorbidity is currently measured. The actual burden of comorbid conditions and the impact on outcomes in CVD may not be fully realized as a result of methodologic limitations (Table 1). During the 1970s Kaplan and Feinstein [5] investigated taxonomic problems with classifying comorbidity which they defined as "any distinct additional clinical entity that has existed or that may occur during the clinical course of a patient who has the index disease under study" [6, page 456-7]. According to their conceptualization, comorbidity played one of three roles in relation to the index disease-diagnostic, prognostic, or pathogenic [6]. From this definition and conceptualization they then developed criteria for classifying individuals which could be used by other researchers [5]. Following this early work, Charlson and colleagues [7] in the 1980s developed an instrument, the Charlson Comorbidity Index (CCI), rather than a list of criteria to measure comorbidity. The stated goal of the instrument was to control for sicker individuals in longitudinal clinical trials. The CCI had an advantage of simplicity and ease of use over previous methods, such as Kaplan and Feinstein’s [7]. In the 1990s Deyo et al. [8] and D’Hoore et al. [9] each adapted the CCI for use with administrative datasets. During this same timeframe Elixhauser et al. [10]
developed a novel measure which defined comorbidity as a "clinical condition that exists before a patient's admission to the hospital, is not related to the principal reason for the hospitalization, and is likely to be a significant factor influencing mortality and resource use in the hospital" (page 10). With this definition Elixhauser clearly delineated that it was the context, hospitalization, not the existence of an index disease, which determined the definition of comorbidity. In all three measures (Deyo, D’Hoore, and Elixhauser) comorbidity was still viewed primarily as a burdensome clinical phenomenon.

The challenge of managing and measuring comorbidity is gaining increased attention with the worldwide aging of the population [11–14]. In a previous paper published by our group of scientists [15] a systematic review and evolutionary analysis of the use of comorbidity in the empiric literature for adults undergoing care transitions was conducted. The aim of that study was to answer the question as to what was known about the definition, use, and measurement of comorbidity in this at-risk population. However, the lack of robust measurement in almost two thirds of the studies limited what could be stated with any confidence about comorbidity. Attention was drawn to the need for clarity, transparency, and standardization in the measurement of comorbidity in that review. Subsequently, a subgroup was formed to target the measurement of comorbidity in our particular area of expertise—CVD. Specifically, we returned to the original large, comprehensive dataset of studies ($n = 5,917$) and selected out those studies that identified acute myocardial infarction (AMI), heart failure (HF), or stroke as the index disease of the study ($n = 1432$). We then carefully analyzed the measurement of comorbidity in those studies. Our findings are presented in this paper.

Despite more than 30 years of comorbidity measurement, a rigorous systematic review of the measurement of comorbid conditions in CVD outcomes research, particularly in the AMI, HF, or stroke population, has not been conducted and disseminated. Both clinicians and policymakers need to know precisely what is meant by the term comorbidity and how the comorbidity data is measured for two critical reasons—(1) the importance of comorbidity as a descriptor of patient populations; (2) the importance of comorbidity as a potential predictor or modifier of the effect of clinical interventions on outcomes. Imprecise measurement of comorbidities may be creating an incomplete picture of the problem and a misestimation of individual and health system outcomes resulting from unmeasured or mismeasured comorbid conditions in CVD. In addition, variation of comorbidity measurement across studies limits the ability

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### Table 1: Historical overview of the measurement of comorbidity.

<table>
<thead>
<tr>
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<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Time frame</strong></td>
<td>1970s</td>
<td>1980s</td>
<td>1990s</td>
<td>1990s</td>
<td>1990s</td>
</tr>
<tr>
<td><strong>Purpose</strong></td>
<td>Classify patients for therapeutic and statistical reasons</td>
<td>Prospectively identify persons at greater risk of death from comorbid diseases</td>
<td>Adapted the CCI for use with administrative datasets</td>
<td>Adapted the CCI for use with administrative datasets</td>
<td>Predict resource use or clinical outcomes</td>
</tr>
<tr>
<td><strong>Original population</strong></td>
<td>Diabetics</td>
<td>Medical patients</td>
<td>Medicare lumbar spinal surgery patients</td>
<td>Hospitalized patients in Quebec, CAN</td>
<td>Acute care patients in CA</td>
</tr>
<tr>
<td><strong>Measurement method</strong></td>
<td>Clinician derived from symptom patterns, disease duration, physical exam, and lab tests</td>
<td>Clinician scored from list of weighted diseases Validated against Kaplan and Feinstein [5]</td>
<td>Used ICD-9-CM codes equivalent to diseases in the CCI</td>
<td>Implemented an algorithm to map the ICD-9 codes to CCI components</td>
<td>Developed a set of 30 comorbidities with their ICD-9-CM codes</td>
</tr>
<tr>
<td><strong>Predictors of comorbidity</strong></td>
<td>Clinical (e.g., vascular or nonvascular diseases) variables</td>
<td>Sociodemographic and clinical variables</td>
<td>Sociodemographic variables and clinical variables</td>
<td>Sociodemographic and clinical variables</td>
<td>Sociodemographic and clinical variables</td>
</tr>
<tr>
<td><strong>Outcomes assessed</strong></td>
<td>Mortality or vascular complications for those patients who survived</td>
<td>Mortality</td>
<td>Mortality, hospital complications and treatments, discharge destinations</td>
<td>Inpatient mortality</td>
<td>Mortality and fiscal</td>
</tr>
<tr>
<td><strong>Surrogate terms for comorbidity</strong></td>
<td>Episodic events, disease, ailment, and chronic condition</td>
<td>Common conditions</td>
<td>Chronic conditions</td>
<td>Complications (if iatrogenic)</td>
<td>Clinical condition, preexisting condition</td>
</tr>
</tbody>
</table>

CCI: Charlson Comorbidity Index, ICD: International Statistical Classification of Diseases.
of investigators to aggregate data and conduct meta-analyses necessary for the development of comparative effectiveness research and evidence-based practice protocols.

Thus, the purpose of this systematic review was to examine the state of the measurement of comorbidity in randomized controlled trials (RCTs) or clinical trials and prospective observational studies of adults hospitalized for an AMI, HF, or stroke. Specifically, we sought to answer four key questions related to the measurement of comorbidity in outcomes research for these three populations: (1) how is comorbidity defined, identified, and measured in studies of acute MI, HF, and stroke? (2) What are the psychometric properties of the measures and indices used? (3) How were the measures used and for what outcomes? (4) Do the definitions, measures, or uses vary by year of publication?

2. Methods

2.1. Eligibility Criteria. Comorbidity was defined inclusively as any other chronic condition in the presence of AMI, HF, or stroke. To determine the earliest year of publication for inclusion, formal measures of comorbidity were reviewed to identify the year in which commonly used instruments were published (earliest dated to 1969); consequently, articles published in English between 1965 and July 31, 2009, in peer-reviewed journals affiliated with the electronic databases listed below were considered eligible for this systematic review. The search was restricted to randomized controlled trials (RCTs) or clinical trials and prospective observational studies. The rationale for restricting to these types of trials was to exclude studies in which the investigators did not have control over study design related to the measurement of comorbidity as would take place, for example, in retrospective analyses or registry data where existing data is used. If the investigator had control over the measurement of comorbidity (even if the data was obtained from medical records), the study was considered eligible.

2.2. Information Sources. A comprehensive search of the literature was devised and conducted using MEDLINE accessed via PubMed, Cumulative Index of Nursing and Allied Health Literature (CINAHL), PsychINFO, and ISI Web of Science Social Science databases for the original dataset from our previous study [15]. Diverse databases were used to obtain perspectives from multiple disciplines and include both physical and mental health comorbidities.

2.3. Search. Search terms for the original dataset [4, 13, 16] were identified from national reports on comorbidity and concept analyses. Search terms and strategies were developed in consultation with a medical librarian. Although our search strategies were specific to each database due to the options available to customize, our basic search strategy used the National Library of Medicine’s Medical Subject Headings (MeSH) key word nomenclature developed for MEDLINE. The exact search strings used in our strategy are given in Appendix/Supplement A (See Supplementary Material available online at http://dx.doi.org/10.1155/2013/563246). The literature search syntax used keywords with the most inclusive suffix. All related terms and combinations of these terms related to the concept of comorbidity (i.e., multimorbidity, co-occurring, coexisting, risk factors, complications, etc.) were used. The literature search for this current analysis was further refined to identify studies including the diagnoses of interest AMI, HF, and stroke as index conditions.

2.4. Study Selection

2.4.1. By Diagnosis. Selected studies were limited to those with adult populations (age ≥ 19 years) hospitalized for an AMI, HF, or stroke. AMI was defined as either ST elevation or non-ST elevation acute MI. Heart failure was defined as an individual having the stated diagnosis on hospital admission (either preserved or reduced systolic function). Stroke was defined as a focal neurologic deficit lasting >24 hours attributed to a cerebral vascular cause of either ischemic stroke or intracerebral hemorrhage or, of shorter duration, a transient ischemic attack. To provide a more homogeneous population for analysis, patients with subarachnoid hemorrhage (often developed secondarily to injury), unstable angina, or symptoms consistent with an acute coronary syndrome (often a preliminary diagnosis) without documented evidence of myocardial ischemia or injury were excluded. Studies reporting populations with mixed CVD diagnoses at enrollment were also excluded.

2.4.2. By Design. We included randomized controlled trials (RCTs) or clinical trials and prospective observational studies. To be included studies had to report original data with the baseline assessment occurring during the hospitalization and at least one clinical site of multisite studies was to be in the United States. This criterion, once again, provided a more homogeneous sample which would facilitate translation of the findings into specific, contextually appropriate recommendations. Retrospective studies designed to use administrative, registry, or public or private claims data were excluded for the reason stated earlier. Secondary analysis, in which the research aim was developed after the dataset existed, was also excluded for the same reason. Meta-analyses, systematic reviews, case reports, editorials, letters to the editor, and pilot studies were also excluded.

2.4.3. Selection Process. Using prespecified criteria (Appendix/Supplement B), each title and abstract were examined independently by two reviewers for potential relevance. Articles included by any reviewer underwent full-text screening where two independent reviewers read each article to determine if it met eligibility criteria. When the paired reviewers arrived at different decisions about whether to include or exclude an article, they reconciled the difference together with a third-party arbitrator. Articles meeting eligibility criteria advanced to data abstraction.

We hypothesized that RCTs, in particular, might be less likely to use terms related to comorbidity in the primary outcomes paper (and thus, not be identified by our search). To account for the known prevalence of secondary analysis in CVD trials and to improve the external validity of this systematic review, in a second step we examined the full
text article of each RCT identified by an excluded secondary analysis \( (n = 18) \) from our original search which otherwise met our inclusion criteria. The primary outcomes article and, when published separately, the baseline characteristics or study design articles were identified. These articles advanced to data abstraction as a subanalysis.

2.5. Data Collection Process. The data extraction form was piloted by three investigators with eight studies. Included studies were then abstracted onto the data form by one reviewer and the data confirmed by a second team member. We employed internal quality-monitoring checks through every phase of the project to reduce bias, enhance consistency, and verify accuracy. Examples of internal monitoring procedures were confirmation of study eligibility at each phase (abstract screening, full-text screening, and data abstraction), involvement of two individuals for each level of screening and for data abstraction of each article, and agreement of at least two investigators on all included studies and the data extracted.

2.6. Data Items. Abstracted data elements included first and last author discipline, geographic study location, study design, setting, sample size, patient characteristics (index condition and age), definition of comorbidity, the data source for the comorbidity data, comorbidity measure used, whether the measure was modified from its original use and if so how, stated validity and reliability of the measure, how the comorbidity data or measure was employed in the study, main study outcomes, stated or reviewer-observed limitations of the study related to measurement of comorbidities, and an overview of the study (purpose or question, analytic approach, and main study findings). Conflicting data were resolved by a third reviewer.

2.7. Synthesis of Results. Data were summarized across studies to answer key questions 1–3, and then between study variations by index condition, study design and year published were analyzed to answer key question 4. The subanalysis of RCTs identified by excluded secondary analyses focused on key questions 1 and 2 to determine how comorbidities were defined, identified, and measured in this body of literature and the psychometric properties of any indices.

3. Results

3.1. Study Selection and Characteristics. Of the 1432 CVD publications reviewed, 26 studies (AMI \( n = 8 \), HF \( n = 11 \), stroke \( n = 7 \)) and 5 RCTs (identified by excluded secondary analyses from our original search) met the inclusion criteria (Figure 1) and were analyzed (Table 2). The 26 studies were primarily published in cardiology journals (\( n = 11 \)), by physicians (\( n = 24 \)), and conducted in the USA (\( n = 25 \)).

3.2. Synthesis of Results

3.2.1. Key Question 1: How Is Comorbidity Defined, Identified, and Measured in Studies of Acute MI, HF, and Stroke? The following terms were used synonymously to define comorbid conditions: comorbid, concomitant, or underlying diseases or conditions (\( n = 8 \)), risk factors (\( n = 5 \)), relevant clinical variables or data (\( n = 5 \)), patient or clinical characteristics (\( n = 4 \)), past medical history (\( n = 2 \)), or chronic medical conditions or diseases (\( n = 2 \)) in the reviewed studies. The comorbidity data were identified and obtained from 1–4 different sources for a single study including medical records (\( n = 13 \)), clinician judgment (\( n = 8 \)), self/proxy report (\( n = 7 \)), or DSM-III criteria (\( n = 3 \)). In 35% of the studies (\( n = 9 \)) the data source for comorbidities was not reported (Table 3).

Comorbidities were most commonly recorded, measured, and then analyzed as the presence of individual diseases, conditions, or risk factors (\( n = 21 \)) or laboratory values indicating disease (i.e., lipid levels) without prespecified criteria given for what was or was not counted as comorbidity. The list of individual diseases was unique to each of the 26 studies reviewed. Diabetes was the most frequently measured comorbidity (\( n = 21 \)), followed by hypertension (\( n = 19 \)), dyslipidemia (\( n = 9 \)), and COPD (\( n = 6 \)). Studies generally controlled for cardiovascular diseases other than the index condition. For example, if AMI was the index condition, HF and stroke would be considered comorbidity and controlled for in the analyses. The literature supporting the selection of the conditions and diseases was not cited, and individual conditions defined by some studies as “past medical history” were referred to as “baseline demographics” or “characteristics” in other studies. Definitions of comorbidity or any of the surrogate terms were not provided in any of the reviewed studies.

The subanalysis of the RCTs identified by excluded secondary analyses (\( n = 18 \)) from our original search revealed that three of these studies used data from primary studies already reviewed in this paper. The 15 remaining secondary analysis papers used data from five clinical trials. Each of these clinical trials used a list of conditions. All five trials (CADILLAC [43], ENRICHD [44], ExTRACT-TIMI 25 [45], GUSTO [46], and VALIANT [47]) identified and analyzed comorbidity as the presence or absence of reported conditions which were identified by laboratory values or preadmission pharmacological therapy. When compared by index diagnosis (e.g., AMI, HF, stroke), the measurement of comorbidities reported in each trial revealed the use of a list of conditions unique to each trial.

3.2.2. Key Question 2: What Are the Psychometric Properties of the Measures and Indices Used? Only five of the 26 studies and one trial in our subanalysis sample reported the use of an established instrument to measure comorbidities [17, 18, 25, 26, 36, 44]. In these five studies and one trial, no evidence was included for the construct validity or reliability (via coefficient alpha) of the instrument for use with the specific study population. All but one study [17] in the overall review (\( n = 25 \)) had sufficient sample size to provide for the assessment of these statistics to allow for greater confidence in the interpretation of the results from the instruments.

3.2.3. Key Question 3: How Were the Measures Used and for What Outcomes? Three studies examined only medical
comorbidities using the CCI. Chin and Goldman [25] used the CCI as a summary measure of coexisting diseases to identify predictors of readmission or death for patients admitted to the hospital with shortness of breath, fatigue, or HF. Rocha and colleagues [17], with Charlson as a coauthor, used the CCI to assess medical comorbidity in a study that evaluated potential predictors of posttraumatic stress disorder in AMI. The ENRICHD trial [44] tested an intervention for treating depression and low perceived social support after AMI. The mean CCI score was reported as a medical characteristic in the primary outcomes paper of the ENRICHD trial but not the baseline characteristics paper or secondary analysis that was identified in our search. The primary outcomes paper explained the CCI’s use only as a footnote in the demographics table.

Two studies examined comorbid depression using different instruments, while a third study examined depression plus other medical conditions. Kishi and colleagues [36] assessed comorbid depression in stroke patients using the Hamilton Depression Rating Scale. Romanelli et al. [18] measured comorbid depression in older adults with AMI using the Beck Depression Inventory. Fulop et al. [26] examined both comorbid depression and medical conditions separately using the Duke Severity of Illness Checklist to derive both an overall disease severity score and then an individual comorbidity score to control the effects of severity of illness on medical resource use in older adults with HF while also examining comorbid depression as measured by the Geriatric Depression Scale.

Comorbidity was used in multiple ways in the analyses of the reviewed studies (Table 3). The majority of the studies (n = 20) used comorbidity as a covariate. However, comorbidity was also used as a predictor (n = 7), outcome (n = 3), and descriptor (n = 2). Reported outcomes of comorbidity were increased morbidity (n = 12), health service utilization (n = 7), mortality (n = 7), and quality of life (n = 3).

3.2.4. Key Question 4: Do the Definitions, Measures, or Uses Vary by Year of Publication? A year-by-year analysis of the studies showed no changes in definitions or measurement over the 14 years of publication. No pattern of improving definition and operationalization of the variable, such as standardization or a theoretically derived definition, or greater use of validated instruments was found when the studies were analyzed by year or decade or when they were examined by study design.
Table 2: Demographics of the studies by diagnosis.

<table>
<thead>
<tr>
<th></th>
<th>AMI</th>
<th>HF</th>
<th>Stroke</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Journal type</th>
<th>Cardiac [20, 22, 24], nephrology [19], general medicine [21], nursing [23], psychology [17], and geriatric [18]</th>
<th>Cardiac [25, 29–32, 34, 35], psychology [26, 33], general medicine [27], and geriatric [28].</th>
<th>Neurology/stroke [36, 39–42], cardiology [37], and psychology [38]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Author discipline</td>
<td>Medicine [18, 19, 21, 24], medicine plus another discipline [17, 20, 22], or nursing [23]</td>
<td>Medicine [25–27, 29–32, 34, 35], medicine plus another discipline [33], or nursing [28]</td>
<td>Medicine [36–42]</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Country of study</th>
<th>USA except one [22]</th>
<th>USA</th>
<th>USA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Study question related to comorbidity</td>
<td>3 [17, 19, 21]</td>
<td>4 [25, 26, 31, 33]</td>
<td>3 [36, 38, 40]</td>
</tr>
<tr>
<td>Used a comorbidity instrument</td>
<td>CCI [17]</td>
<td>CCI [25], Duke Severity of Illness Checklist [26], Geriatric Depression Scale [26], and Beck Depression Inventory [31, 33]</td>
<td>Hamilton Depression Rating Scale [36]</td>
</tr>
<tr>
<td>Main outcomes</td>
<td>Mortality [18, 19, 21, 22], morbidity [20, 21, 23, 24], and disability [17]</td>
<td>Mortality [25, 27, 31], disability [26, 28, 33], QoL [28], and health service utilization [25, 28–30, 32, 34]</td>
<td>Morbidity [38–40, 42], QoL [37, 38], and health service utilization [41]</td>
</tr>
</tbody>
</table>

CCI: Charlson Comorbidity Index, QoL: quality of life.

4. Discussion

4.1. Summary of Evidence. The purpose of this systematic review was to examine the measurement of comorbidity in CVD clinical trials. We identified that 21 out of 26 studies measured comorbidities with a list of unsubstantiated diseases without defining comorbidity while using multiple data sources or leaving the data source unknown. This is particularly troubling given the multiple valid and reliable measures available to researchers [11, 48]. In the small number of studies utilizing an instrument, the CCI was the most frequently used. Equally troubling was the finding that measurement did not change or advance during a time period when the methodology of CVD trials was improving overall [49]. In the following section, we will discuss the two challenges experienced in conducting this systematic review followed by the three potential threats to the validity of comorbidity measurement that we identified.

4.2. Two Challenges in Conducting a Review of Comorbidity Measurement in CVD Trials. A major challenge in conducting this review arose from the a priori decision to use only prospectively collected data. While this decision was made to capture studies where the investigators designed the study and therefore determined how comorbidity was measured, this resulted in a surprisingly low number of studies. Thus, while we started with a relatively robust pool (n = 1432), resulting in 151 studies for full screening, when all mixed cohort populations, registry studies, and secondary analysis or retrospective studies were excluded the final set of studies was a relatively small sample of 26. We addressed this challenge by then adding a subanalysis of the methods papers of the RCTs identified (but excluded) as secondary analyses. This particular challenge highlights that many published CVD papers are derived from previously collected data for which the measurement of comorbidity was never the main outcome of interest. If the validity of the comorbidity data in the parent trial suffers from internal threats, these threats carry over into all subsequent secondary analyses and what is known or knowable about comorbidity suffers. This systematic review draws attention to the critical need to strengthen the measurement of comorbidity in future multinational CVD clinical trials so that the relationships between comorbidity and outcomes can be trusted. The trustworthiness of these relationships becomes especially important when translating intervention studies into clinical practice for more heterogeneous populations.

A second challenge was the lack of a single, logically coherent, definition of comorbidity in CVD research. Despite constructing an electronic literature search using related terms (n = 27) identified from national reports and concept analyses on the topic of comorbidities [15], it is likely that studies of adults hospitalized for AMI, stroke, or HF were not identified. In addition, focusing on clinical trials, with their known exclusion of the complex chronically ill, may have introduced bias in the findings. The exclusion
<table>
<thead>
<tr>
<th>Investigators</th>
<th>Index condition</th>
<th>Sample</th>
<th>Definition of comorbidity</th>
<th>Diseases listed (instrument)</th>
<th>Data source</th>
<th>Comorbidity used as</th>
</tr>
</thead>
<tbody>
<tr>
<td>Afshinnia et al. [19]</td>
<td>AMI</td>
<td>n = 220</td>
<td>No definition comorbid diseases, conditions, underlying diseases</td>
<td>HTN, DM, HF, sepsis, anemia, cardiorespiratory arrest</td>
<td>Patient, family Clinician judgment Medical records</td>
<td>Covariate</td>
</tr>
<tr>
<td>Afzal et al. [34]</td>
<td>HF</td>
<td>n = 163</td>
<td>No definition comorbid conditions, risk factors</td>
<td>HTN, DM, Hx of MI/stroke</td>
<td>Clinician judgment Medical records</td>
<td>Covariate</td>
</tr>
<tr>
<td>Ariyarajah et al. [37]</td>
<td>Stroke</td>
<td>n = 66</td>
<td>No definition common medical comorbidities risk factors</td>
<td>Hx of stroke, Afib CAD, MS, MR, dilated, restrictive, and hypertrophic cardiomyopathy, hyperlipidemia, DM, hyper/hypothyroid, COPD, HF, MI</td>
<td>Medical records</td>
<td>Covariate</td>
</tr>
<tr>
<td>Castillo et al. [38]</td>
<td>Stroke</td>
<td>n = 142</td>
<td>No definition comorbid depression</td>
<td>Depression</td>
<td>Clinical judgment using DSM-III criteria</td>
<td>Predictor interaction term</td>
</tr>
<tr>
<td>Chin and Goldman [25]</td>
<td>HF</td>
<td>n = 257</td>
<td>No definition</td>
<td>Hx of HF, MI, HTN, DM (Charlson Comorbidity Index)</td>
<td>Medical records</td>
<td>Predictor and covariate</td>
</tr>
<tr>
<td>Freedland et al. [33]</td>
<td>HF</td>
<td>n = 613</td>
<td>No definition comorbid medical condition</td>
<td>Hx of HF, MI, anemia, arthritis, CAD, CVA, DM, GI disorder, HTN, COPD, sleep apnea, renal disease Hx of 1 or more comorbid medical conditions (Beck Depression Inventory)</td>
<td>Clinical judgment using the diagnostic interview schedule medical records</td>
<td>Predictor, covariate, outcome</td>
</tr>
<tr>
<td>Fulop et al. [26]</td>
<td>HF</td>
<td>n = 203</td>
<td>No definition</td>
<td>(Geriatric Depression Scale; Duke University severity of illness checklist)</td>
<td>Patient Clinician judgment Medical records</td>
<td>Covariate</td>
</tr>
<tr>
<td>Goonewardena et al. [32]</td>
<td>HF</td>
<td>n = 75</td>
<td>No definition</td>
<td>HTN, DM, COPD, CKD, Afib, depression</td>
<td>Unclear</td>
<td>Covariate</td>
</tr>
<tr>
<td>Jiang et al. [31]</td>
<td>HF</td>
<td>n = 1,006</td>
<td>No definition concomitant illnesses, clinical characteristics</td>
<td>Hx MI, DM</td>
<td>Medical records</td>
<td>Covariate</td>
</tr>
<tr>
<td>Kimmelstiel et al. [30]</td>
<td>HF</td>
<td>n = 200</td>
<td>No definition</td>
<td>HTN, DM</td>
<td>Patient Medical records</td>
<td>Covariate</td>
</tr>
<tr>
<td>Kishi et al. [36]</td>
<td>Stroke</td>
<td>n = 301</td>
<td>No definition</td>
<td>(Hamilton Depression Rating Scale)</td>
<td>Patient Clinician judgment using the DSM-III criteria</td>
<td>Predictor</td>
</tr>
<tr>
<td>Sert Kuniyoshi et al. [20]</td>
<td>AMI</td>
<td>n = 92</td>
<td>No definition characteristics</td>
<td>HTN, DM, HF hypercholesterolemia</td>
<td>Unclear</td>
<td>Covariate</td>
</tr>
<tr>
<td>Lakiredddy et al. [21]</td>
<td>AMI</td>
<td>n = 376</td>
<td>No definition characteristics</td>
<td>HTN, Hx MI, DM hypercholesterolemia</td>
<td>Unclear</td>
<td>Predictor covariate</td>
</tr>
<tr>
<td>Malki et al. [29]</td>
<td>HF</td>
<td>n = 187</td>
<td>No definition</td>
<td>HTN, DM, Hx MI, stroke</td>
<td>Clinician judgment</td>
<td>Covariate</td>
</tr>
</tbody>
</table>
Table 3: Continued.

<table>
<thead>
<tr>
<th>Investigators</th>
<th>Index condition</th>
<th>Sample</th>
<th>Definition of comorbidity terms</th>
<th>Diseases listed (instrument)</th>
<th>Data source</th>
<th>Comorbidity used as</th>
</tr>
</thead>
<tbody>
<tr>
<td>Marrugat et al. [22]</td>
<td>AMI</td>
<td>$n = 1460$</td>
<td>No definition clinical variables</td>
<td>CKD, COPD, DM, HTN, PVD</td>
<td>Unclear</td>
<td>Covariate</td>
</tr>
<tr>
<td>Mehta et al. [39]</td>
<td>Stroke</td>
<td>$n = 80$</td>
<td>No definition clinical data, other diseases, risk factors</td>
<td>HTN, DM, CHD, dyslipidemia</td>
<td>Unclear</td>
<td>Covariate</td>
</tr>
<tr>
<td>Moroney et al. [40]</td>
<td>Stroke</td>
<td>$n = 185$</td>
<td>No definition risk factor</td>
<td>Angina, MI, HF, and valvular heart disease</td>
<td>Patient, Family, Key informants</td>
<td>Medical record</td>
</tr>
<tr>
<td>Naylor et al. [28]</td>
<td>HF</td>
<td>$n = 239$</td>
<td>No definition medical conditions, health conditions</td>
<td>CAD, HTN, Afib, DM, pulmonary disease</td>
<td>Medical record</td>
<td>Covariate</td>
</tr>
<tr>
<td>Quinn [23]</td>
<td>AMI</td>
<td>$n = 100$</td>
<td>No definition disease history clinical variables past medical history</td>
<td>Hx of Angina, CAD, HTN, DM, hyperlipidemia, smoking (past/current), previous MI</td>
<td>Medical record</td>
<td>Covariate</td>
</tr>
<tr>
<td>Rehan et al. [24]</td>
<td>AMI</td>
<td>$n = 92$</td>
<td>No definition baseline demographics</td>
<td>Hx of CAD, HTN, HF, DM</td>
<td>Unclear</td>
<td>Descriptor</td>
</tr>
<tr>
<td>Rocha et al. [17]</td>
<td>AMI</td>
<td>$n = 25$</td>
<td>No definition</td>
<td>(Charlson Comorbidity Index for medical comorbidities; SCID and IES-R for PTSD)</td>
<td>Patient, Medical record</td>
<td>Predictor, outcome</td>
</tr>
<tr>
<td>Romanelli et al. [18]</td>
<td>AMI</td>
<td>$n = 153$</td>
<td>No definition</td>
<td>Depression DM, COPD, HTN, hyperlipidemia, CKD, (Beck Depression Index)</td>
<td>Patient, Clinician judgment using the DSM-III Medical record</td>
<td>Predictor, outcome</td>
</tr>
<tr>
<td>Sakr et al. [27]</td>
<td>HF</td>
<td>$n = 34$</td>
<td>No definition risk factor</td>
<td>CAD, CKD, pneumonia, DM, HTN, HF</td>
<td>Unclear</td>
<td>Covariate</td>
</tr>
<tr>
<td>Shah et al. [41]</td>
<td>Stroke</td>
<td>$n = 81$</td>
<td>No definition clinical data</td>
<td>DM, HTN, hypercholesterolemia, CAD, Afib, Hx of stroke</td>
<td>Unclear</td>
<td>Covariate</td>
</tr>
<tr>
<td>Soman et al. [35]</td>
<td>HF</td>
<td>$n = 201$</td>
<td>No definition relevant clinical variables</td>
<td>CAD, Hx of MI DM, HTN, lipid abnormalities</td>
<td>Clinician judgment</td>
<td>Covariate</td>
</tr>
<tr>
<td>Stead et al. [42]</td>
<td>Stroke</td>
<td>$n = 418$</td>
<td>No definition</td>
<td>HTN, DM, Afib, Hx of TIA, and stroke</td>
<td>Unclear</td>
<td>Descriptor</td>
</tr>
</tbody>
</table>


Diseases listed are in regular font. Instruments used in the study are in bold.

of meta-analyses, because of their potential for including studies already captured in the systematic search, may have excluded equally valid, but unincluded, studies. Adding to this challenge there was a lack of salient information about comorbidity and its measurement in the studies that we did identify and review. We hypothesize that manuscript length restrictions in the particular studies that we reviewed could have constrained the capacity of authors to fully describe each variable and source of information. Our review of the methodology papers from the subanalysis of the larger clinical trials supported this, when little to no information was found regarding rationales for particular conditions measured or the data source on the conditions. Or it is possible that among clinicians the definitions of risk factor or clinical characteristics may be assumed common knowledge needing no further explanation. However, this review showed that despite the paucity of information on the measurement of comorbidity, what could be determined was that each study
uniquely operationalized the term comorbidity and how it was employed statistically.

4.3. Three Potential Threats to the Validity of Comorbidity Measurement

4.3.1. Heterogeneity in Data Sources. Heterogeneity in the comorbidity data or what is measured was noted in a recent systematic review of multimorbidity instruments which found that 59% of the studies analyzed used a list of diseases without any indication of the rationale behind the selection of the specific conditions [11]. Our analysis of CVD studies supports this finding but highlights an additional potential threat in what is measured—the lack of definitions for what is considered comorbidity. The selection of conditions without a stated rationale, as we found, presents an internal threat to the validity of the study by potentially introducing investigator bias. For example, important confounding conditions could be excluded because investigators have not traditionally measured them. The threat is increased when data for these comorbidity lists come from multiple sources such as patient or proxy self-report, clinician assessment, and medical records as was also found in this review. Concordance between different data sources in comorbidity is known to be problematic [50]; however, the use of a validated index does not assure freedom from internal threats to validity. The two studies in our review that used the CCI appear to have accrued the information from chart review [25] or clinician administered interview [17]—two very different data sources making comparisons of their findings problematic. Further heterogeneity in the data arises from the use of administrative datasets as noted earlier [51]. The Elixhauser measure and Deyo and D’Hoore’s adaptation of the CCI all depend on International Statistical Classification of Diseases (ICD) codes. Use of ICD codes has such problems as the known underreporting of comorbidities [9], difficulties in distinguishing comorbidities from complications of treatment or severity indicators for the index disease [10], code selection associated with better payment [8], and database-specific limitations (e.g., number of comorbidities allowed by the database) [9]. But despite these limitations, each comorbidity measure has been shown to strongly predict complications, functional decline, and death in hospitalized adults [7–10].

In recognizing these limitations, investigators leading prospective studies have the opportunity to design the measurement of comorbidities to reduce the likelihood of heterogeneity with its missingsness and inaccuracies. Recognizing that 50% of the studies in this review relied on medical records as a data source for comorbidity, it might be informative to review and synthesize how comorbidity is measured among studies relying on medical record data accrued for clinical practice rather than research. Whether the use of clinical data versus research data results in differences in prediction of patient outcomes is an interesting and needed line of inquiry.

4.3.2. Variability in Measurement. Variability in measurement practices or how comorbidity is measured presents the second potential threat to the validity of comorbidity measurement in CVD trials. A national report on comorbidities highlighted that the definition and measurement of comorbidity in clinical trials is known to vary based on the aims and outcomes of the studies [4]. Comorbidity is gaining increasing attention while its measurement, as documented in this review, apparently remains static over time and without standards for parameters. Past and current trends in measurement may reflect mentoring networks and research training rather than best practice (e.g., measurement is guided by who is part of the research team and how they were trained). This variability presents several threats. For example, in one HF study reviewed [25] the investigators used the CCI to measure comorbidity while also controlling for HTN, creatinine, and DM (all measured in the CCI) individually in some of their analyses. This leads to potentially weighting or confounding in the analysis and makes assessing the outcomes problematic. In observational studies, the prevalence of particular comorbid conditions may be under (or over) estimated or under (or over) reported, and their influence on outcomes unknown if this is a routine practice. When comparing clinical trials with similar aims and outcomes, an accurate estimate of the effect size may be difficult to assess if comorbidities were measured differently in different intervention studies. Meta-analyses may be unknowingly amalgamating vastly different populations because of variability in the measurement. This paper confirms this documented variability in measurement.

4.3.3. Meaningfulness of the Findings. The third potential threat to the validity of comorbidity has direct patient care implications. Even if the measurement of comorbidity was to improve significantly, the impact of this to the individual patient is unclear. While we may be able to report the amount of variance that a particular disease accounts for in a particular outcome, as to whether that is meaningful to the individual patient is unknown and perhaps currently unknowable. Furthermore, there may be unknown, unmeasured confounders that would come to light when patients’ chronic illness experiences are carefully explored. For example, by exploring the patient experience of comorbidity we might discover why patient nonadherence to treatment rates in chronic illness (comorbidity) has stayed fairly stable over several decades at approximately 50% [52]. This lack of empiric studies into the patient comorbidity experience was noted by our group in an earlier conceptual study [15]. By continuing to measure comorbidity as we always have we derive no new knowledge that might lead to improvements in patient care.

5. Conclusion

This systematic review suggested that the burden of comorbidity for individuals with CVD may not be fully realized as a result of methodologic limitations in the prospective studies we reviewed. CVD outcomes research would benefit from the development of a standard definition and standard measures that all studies could use. Furthermore, research is needed into how to best capture and measure patient-reported...
experiences with comorbid conditions. We recommend that future studies be designed using valid and reliable indices or appropriate or theoretically chosen comorbidities when indices are not appropriate and transparency in all studies by providing the rationale and limitations for one approach to measuring comorbidities over another.

Conflict of Interests

The authors have no conflict of interests to report.

References


[29] Q. Malik, N. D. Sharma, A. Afzal et al., “Clinical presentation, hospital length of stay, and readmission rate in patients with
heart failure with preserved and decreased left ventricular systolic function,” Clinical Cardiology, vol. 25, no. 4, pp. 149–152, 2002.


