A Canadian, multicentre, randomized clinical trial of home-based pulmonary rehabilitation in chronic obstructive pulmonary disease: Rationale and methods

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BACKGROUND: Pulmonary rehabilitation remains largely underused. Self-monitored, home-based rehabilitation is a promising approach to improving the availability of pulmonary rehabilitation.
OBJECTIVE: To report the rationale and methods of a trial comparing the effectiveness of self-monitored, home-based rehabilitation with hospital-based, outpatient rehabilitation in patients with chronic obstructive pulmonary disease (COPD).
STUDY DESIGN: A parallel-group, randomized, noninferiority, multicentre trial will be performed with 240 patients with moderate to severe COPD.
INTERVENTION: Patients will be randomly assigned to conventional, supervised, hospital-based outpatient rehabilitation or self-monitored, home-based rehabilitation. Both interventions will include a standardized, comprehensive self-management program, in addition to the hospital-based outpatient or home-based exercise program. After the three-month intervention, patients in both groups will be encouraged to continue exercising at home. Patients will be assessed monthy with telephone interviews and in person at enrollment, three months and 12 months.
OUTCOMES: The dyspnea domain of the Chronic Respiratory Questionnaire (CRQ) at 12 months is the primary outcome variable. Secondary outcome variables include total and domain-specific CRQ scores; exercise tolerance and activity of daily living; health service use over the one-year study period; and direct and indirect costs of COPD treatment.
ANALYSIS: An intent-to-treat approach will be used as the primary analysis. The primary analysis will focus on the change in the CRQ dyspnea score using a two-sided *t* distribution based on 95% CIs. The same approach will be used for secondary continuous outcome variables.
CONCLUSION: The present trial will address two unresolved issues in pulmonary rehabilitation for patients with COPD: the short-term and long-term effectiveness of home-based pulmonary rehabilitation strategies. The authors will also determine if home-based pulmonary rehabilitation can reduce health service use (eg, hospitalizations and emergency visits) and if it can be done at a lower cost than the traditional hospital-based outpatient pulmonary rehabilitation.

Key Words: *COPD; Exercise; Rehabilitation*

Essai clinique randomisé multicentrique canadien sur la réadaptation pulmonaire à domicile dans la maladie pulmonaire obstructive chronique : Raison d'être et méthodes

HISTORIQUE : La réadaptation pulmonaire reste pour une bonne part sous-utilisée. Une réadaptation autosurveillée à domicile constitue une approche prometteuse pour assurer l'accès à la réadaptation pulmonaire.
OBJECTIF : Expliquer la raison d'être et les méthodes utilisées lors d'un essai comparant l'efficacité d'une réadaptation à domicile autosurveillée et d'une réadaptation en clinique externe à l'hôpital chez des patients atteints de maladie pulmonaire obstructive chronique (MPOC).
MODÈLE DE L'ÉTUDE : Essai multicentrique randomisé, avec groupe parallèle, selon une hypothèse de non-infériorité, qui regroupera 240 patients atteints de MPOC de modérée à sévère.
INTERVENTION : Les patients seront assignés aléatoirement à une réadaptation classique supervisée en clinique externe à l'hôpital ou à une réadaptation à domicile autosurveillée. Les deux interventions incluront un programme standardisé et complet d'autotraitement en plus du programme d'exercice en clinique externe à l'hôpital ou à domicile. Après trois mois d'intervention, les patients des deux groupes seront encouragés à poursuivre leurs exercices à domicile. Les patients seront évalués tous les

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mois au moyen d'entrevues téléphoniques et en personne au moment de l'inscription, après trois et douze mois.

PARAMÈTRES : La principale variable paramétrique sera l'évaluation de la dyspnée au moyen du questionnaire CRQ (pour *Chronic Respiratory Questionnaire*) à douze mois. Les variables paramétriques secondaires sont les indices du CRQ spécifiques au domaine et totaux, la tolérance à l'effort, les activités de la vie courante, le recours aux services de santé pendant l'année que durera l'étude et les coûts directs et indirects du traitement de la MPOC.

ANALYSE : Une approche en intention de traiter sera utilisée comme analyse principale. Cette analyse principale s'attardera au changement du score d'évaluation de la dyspnée au CRQ à l'aide d'un test bilatéral, sur la base d'un IC de 95 %. La même approche servira pour la mesure des variables paramétriques secondaires continues.

CONCLUSION : Le présent essai tentera de clarifier deux enjeux non résolus en matière de réadaptation pulmonaire chez les patients atteints de MPOC : l'efficacité à court et à long terme de stratégies de réadaptation pulmonaire à domicile. Les auteurs détermineront en outre si la réadaptation pulmonaire à domicile peut réduire le recours aux services de santé (p. ex., hospitalisation et consultation aux urgences) et s'il est possible d'y recourir à moindre coût que dans les cas de réadaptation pulmonaire classique en clinique externe dans les hôpitaux.

Pulmonary rehabilitation focuses on the multiple needs of patients with chronic obstructive pulmonary disease (COPD) and offers the best chance to address the disabling features of this chronic and progressive disease. Despite well documented efficacy (1), pulmonary rehabilitation remains largely underused (2). Several factors may explain this apparent contrast between the efficacy of rehabilitation and the small number of patients undertaking this effective therapeutic modality. The low availability of pulmonary rehabilitation programs is one factor. Pulmonary rehabilitation in an outpatient, hospital-based setting requires qualified health care professionals, equipment and facilities that entail significant upfront costs. In addition, our experience indicates that up to 50% of the patients to whom pulmonary rehabilitation is offered cannot participate because of transportation difficulties (unpublished data).

In Canada, pulmonary rehabilitation is generally accomplished in an outpatient, hospital-based setting, particularly now that inpatient care is more difficult to justify when the patient is not acutely ill (2). In 1999, there were only 44 pulmonary rehabilitation programs across the country, which had the capacity to enroll only 4000 to 5000 patients with COPD per year (2). Therefore, this intervention is available to less than 1% of all patients with COPD in Canada (2) and pulmonary rehabilitation in a hospital-based setting is not accessible to the majority of patients with COPD. Strategies should be developed to improve the availability of pulmonary rehabilitation at a lower cost. In this regard, self-monitored, home-based rehabilitation is a promising approach.

The present clinical trial is designed to compare the effectiveness of self-monitored, home-based rehabilitation with hospital-based outpatient rehabilitation in improving the quality of life in patients with COPD. Our primary hypothesis is that self-monitored, home-based rehabilitation is as effective as hospital-based outpatient rehabilitation for improving dyspnea at one year. We also hypothesize that self-monitored, home-based rehabilitation has a lower cost and is as effective as hospital-based outpatient rehabilitation with respect to improving health-related quality of life, exercise tolerance and activities of daily living.

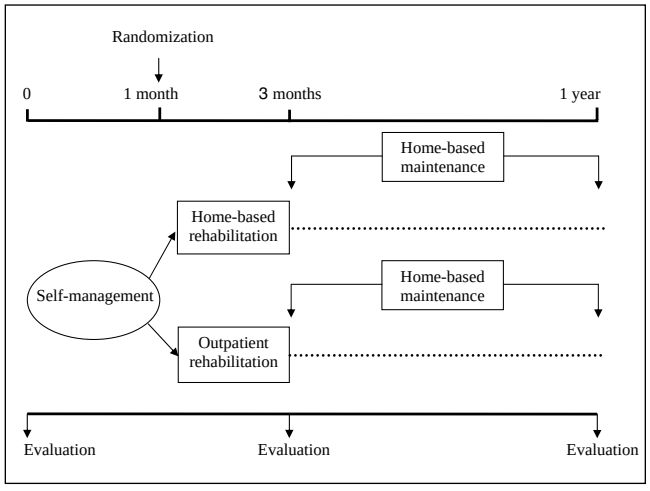

Figure 1) *Study protocol*

METHODS

Study design

The present study is a parallel-group, randomized, multicentre noninferiority trial involving 10 participating rehabilitation centres across Canada (Figure 1). Two-hundred forty patients with COPD will be randomly assigned to either self-monitored, home-based rehabilitation or supervised, hospital-based outpatient rehabilitation. After taking part in a four-week long group program teaching self-management called *Living Well with COPD*, patients are randomly allocated to home- versus hospital-based outpatient rehabilitation (eight weeks) and subsequently followed for 40 weeks after completion of the rehabilitation program. For each patient, the total study duration from baseline to final evaluation will be 12 months. Patients are contacted monthly via telephone interviews and are assessed in person at the time of enrolment, three months (after completion of the rehabilitation program) and 12 months (long term). An independent, blinded research assistant is responsible for the evaluations and phone interviews in each centre. Written informed consent to participate in the study will be obtained from all patients.

Patient selection

Patients with moderate to severe COPD and with moderate disability (6 min walking distance of greater than 110 m) will be included in the present study. These criteria will exclude patients with minimal potential for improvement and a high likelihood of withdrawal. Patients will be 40 years of age and older and be former or current smokers with stable COPD (no clinical evidence of an acute exacerbation in the past four weeks, ie, no change in dyspnea, or volume or colour of sputum). Each patient will have a postbronchodilator forced expiratory volume in 1 s (FEV_1) of less than 70% of the predicted value and an FEV_1 to forced vital capacity ratio of less than 0.70. Patients with asthma as a primary diagnosis and those with comorbidities, such as left congestive heart failure, terminal disease, dementia or uncontrolled psychiatric illness, will be excluded. Patients who have previously taken part in a respiratory rehabilitation program and those in a long-term care facility will also be excluded. The need for supplemental O_2 at rest or during exercise is not a contraindication for participation in the present study.

Trial interventions

The trial interventions include a comprehensive self-management education program (*Living Well with COPD*) for all patients, in addition to the home-based or hospital-based exercise program. Two sessions (1 h each) will be taught by a trained health professional in group sessions (eight to 10 patients per group) for four weeks. The self-management program consists of an educational flipchart and seven skill-oriented, self-help, patient workbook modules. This program has previously been implemented and evaluated quantitatively (3,4) and qualitatively (5). A detailed description of this program has been published elsewhere (3).

After the four-week self-management program, patients will be randomly allocated to either the home-based or hospital-based outpatient exercise program. The hospital-based outpatient exercise program is based on the authors' previous experience (6) and recommendations (7), and will combine aerobic and strength exercises. The aerobic training will consist of exercise on a cycle ergometer for 30 min at an intensity up to 80% of the maximal work rate, performed three times per week for eight weeks under the supervision of a physiotherapist or an exercise specialist. Heart rate will be monitored and recorded at 15 s intervals during the training sessions using a heart rate monitor (Polar S610, Polar Electro Inc, USA). At the end of the training program, the stored data will be downloaded to a computer and analyzed using the monitor's companion software (Polar Electro Inc, USA). Arm and leg muscle strengthening exercises will be performed using elastic bands, free weights and sand bags. The home-based exercise program is a self-monitored and minimally supervised program. The aerobic training will consist of exercise on a cycle ergometer for 40 min at an intensity up to 60% of the maximal work rate, performed three times per week for eight weeks. Individual teaching with practice and feedback will be performed by a physiotherapist or an exercise specialist to initiate the program and to ensure complete understanding from the participants. Thereafter, the supervision will be done using weekly telephone calls to reinforce the importance of the exercises and detect problems related to home exercise training. Aerobic training will be done on a portable cycle ergometer on which the resistance can be manually adjusted. To ensure the safety of the participants, a lower intensity of training was chosen for the home-based program compared with that of the directly supervised program. Both programs will require equivalent relative energy demands because the home-based program will be performed for a longer duration. The training intensity will be monitored and recorded using a digital heart rate monitoring device (Polar S610). Arm and leg muscle exercises will be performed in a similar fashion to the hospital-based, outpatient exercise program. Patients involved in the home-based program will be provided with the necessary equipment (cycle ergometer, elastic bands, free weights and sand bags) for the duration of the training program.

The maintenance exercise program is identical for both programs. Although the home-training equipment will be recovered at the end of the eight-week exercise program, patients from both groups will be encouraged to buy their own equipment and to continue exercising at home at least three times per week for 30 min to 45 min per session. Patients in both groups will be contacted every two months by a case manager to reinforce the importance of exercise and other components of the education program. The case manager is also available by telephone for advice and treatment supervision. Any questions or problems related to the maintenance exercise program at home are referred to the physiotherapist or exercise specialist.

Cointerventions

Concomitant treatments will be documented over the one-year study. Smoking cessation is encouraged and patients are offered support. Pharmacological treatments, home O_2 or additional care and health services remain the decision of the treating physician. The patient is asked to communicate any changes made to their treatment regimen to the research team. Acute exacerbations of the disease are to be treated with short courses of antibiotics and/or systemic corticosteroids as part of a customized action plan.

Method and concealment of randomization

Patients are randomized during the fourth week after taking part in the group teaching program. The randomization procedures have been developed and implemented by Gestion Recherche Clinique Qualité (GEREQ) electronic data management (Canada), an independent central unit that has been contracted by the investigators. The randomization is done through a secured Web site by a person uninvolved in the study procedures. Randomization is stratified per centre and sex using blocks of two patients. A blind code is generated for each patient. The results are kept secret from the evaluator by all means possible.

Outcome measures

The primary outcome measure is dyspnea at 12 months as assessed by the dyspnea domain of the Chronic Respiratory Questionnaire (CRQ). Secondary outcome variables are the total CRQ score and subscores for the fatigue, emotion and mastery domains at three and 12 months; exercise tolerance (6 min walking distance and submaximal cycle exercise test) and activity of daily living (assessed using the London Chest Activity Daily Living scale [8]) at three and 12 months; dyspnea domain at three months; and health service use (physician and emergency department visits, and hospitalizations) over the one-year study period. Every report of respiratory symptom changes (dyspnea, increase sputum or change in sputum colour) of at least 24 h duration, related unscheduled physician visit(s), and emergency department and hospital admission(s) are recorded using the standardized monthly telephone interview. Finally, the costs of COPD treatment for the two intervention groups, based on the use of the intervention resources and other management of COPD over the one-year study period, will be measured.

Sample size and power calculation

The primary objective of the present trial is to assess whether home-based rehabilitation is as effective as hospital-based outpatient rehabilitation. The primary outcome is the 12-month change in the dyspnea domain of the CRQ. Previous work by the authors (9) showed that the SD of the change in dyspnea scores in patients similar to those who will be enrolled in the present study was 1.0. To protect against potential underestimation of the sample size, an SD that is somewhat larger (ie, 1.10) is assumed. A difference of 0.5 is recognized as the minimal clinically relevant difference to distinguish treatments on the dyspnea subscale of the CRQ (10). Using 0.5 as the allowable margin of difference in the sample size determination for a noninferiority study with an alpha of 0.025 and $1-\beta$ of 0.90, the required sample size would be approximately 204 total patients, with 102 in each group. Although the authors will attempt to minimize the number of dropouts and will actively seek to obtain follow-up data from those patients who cease rehabilitation, the authors feel it is prudent to allow for attrition. Based on a previous study in a similar patient population (3), an attrition

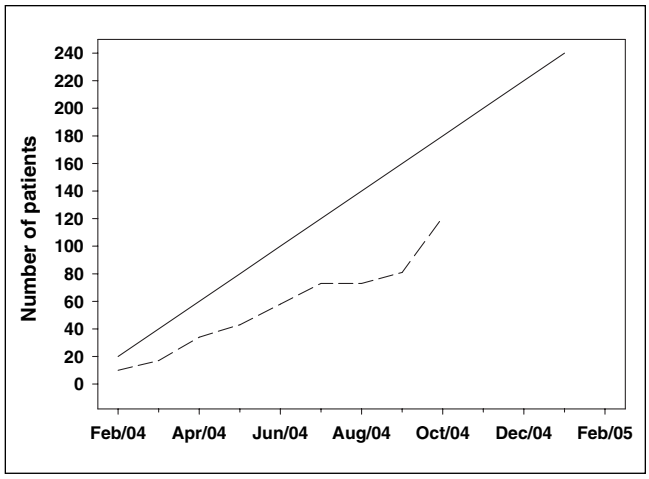

Figure 2) *Recruitment rate. The continuous line indicates predicted recruitment, while the dashed line represents the cumulative recruitment. Apr April; Aug August; Dec December; Feb February; Jun June; Oct October*

rate of 15% is anticipated. Accordingly, a total of 240 patients, 120 per group, will be randomized.

Data analysis

The primary objective is to assess whether patients with COPD undergoing home-based rehabilitation would be disadvantaged relative to a group of similar patients undergoing hospital-based outpatient rehabilitation. In noninferiority and equivalence studies of drugs, the role of intent-to-treat and per protocol analysis often becomes reversed, with intent-to-treat analysis being criticized as potentially anticonservative. However, in the context of rehabilitation, it is felt that using a per protocol analysis, ie, restricting the primary analysis to patients judged compliant, would be perceived as biasing the results in favour of home rehabilitation. Accordingly, the authors plan to use an intent-to-treat approach as the primary analysis. In keeping with the nature of the study, the primary analysis will focus on the change in dyspnea score using two-sided *t* distribution-based 95% CIs (corresponding to one-sided 97.5% CIs). The same approach will be used for secondary continuous outcomes, such as exercise performance. CIs for differences in the rates of exacerbations and hospitalizations during the one-year follow-up period will be calculated. Similar calculations will be done for secondary dichotomous outcomes. Additional secondary analysis to examine the robustness of the findings will involve model-based adjustments incorporating disease severity (FEV_1 and home O_2), comorbidity, sex, age, education and smoking status, using either multiple linear or logistic analyses, or when time-to-event occurrence is of interest, Cox regressions. The effect of different approaches for dealing with missing data, including multiple imputation methods, will be explored. When a per protocol approach is used, any changes to the findings will be examined.

Economic analysis

The estimates of the costs of COPD treatment for the two intervention groups will be based on the use of the intervention resources and other management of COPD during the study period. To the extent that is practical, the social perspective for these analyses will be adopted, and patients' time and travel costs associated with seeking medical care will be estimated. The first analysis will be a cost identification study – a description of the costs of the two treatment arms during the study. If the study demonstrates that the treatment arms are clinically equivalent, then the cost identification data can be used (in situations in which both treatment types are feasible) to determine which treatment arm minimizes costs. If one of the treatment arms is clinically superior and less costly, then this strategy is clearly dominant. However, in the case where one strategy is both more costly and more effective, a cost-effectiveness ratio will be estimated using the CRQ, which has been used as a clinical measure of effectiveness in previous studies for the cost-effectiveness of COPD interventions. CIs for the cost-effectiveness ratio will be based on bootstrap methods.

Trial management

Trial coordination is done through the Centre de Recherche de l'Hôpital Laval in Quebec, Quebec, and the Clinical Research Unit of the Montreal Chest Institute of the Royal Victoria Hospital in Montreal, Quebec. The Trial Steering Committee consists of two co-principal investigators (both of whom are respirologists) two other respirologists, one exercise physiologist, one biostatistician and one health economist. The Steering Committee has been responsible for developing the study protocol and modifying all policies regarding the trial, and will supervise the data analysis and write all publications. Database management is done using the GEREQ electronic data management, with a Web-based data entry system for management and quality control.

Recruitment to date

The first patient was recruited to the trial and randomized in February 2004, and it is expected that randomization will take place over a one-year period. As of November 2004, 121 patients had been recruited and randomized in the trial. The recruitment rate is somewhat slower than expected (Figure 2). Due to the complexity of the study intervention, the authors have elected to initiate the study one centre at a time. This allows for close monitoring during the initial phase of the study and will optimize the quality of the data.

DISCUSSION

In Canada, pulmonary rehabilitation is most commonly delivered in a hospital-based outpatient setting (2). It has proven to be effective (11) and offers close supervision by qualified staff. Interaction between participants may help to keep them motivated and increase compliance with the program. While the short-term efficacy of this rehabilitation strategy is clearly established, issues related to the limited availability and accessibility of these programs for the growing number of patients with COPD need to be addressed. Several strategies can be used to resolve this problem, including inpatient hospital-based programs (12), community-based programs (13) and home-based programs (14). We believe that home-based rehabilitation is the most promising and realistic approach to improving accessibility to pulmonary rehabilitation in the context of the Canadian health care system and its financial constraints. Although quite effective, inpatient, hospital-based rehabilitation is likely the most costly strategy (15), and it would be difficult to justify its widespread use as the first-line rehabilitation intervention. Rather, this approach would seem to be particularly tailored to the needs of the most disabled patients. Community-based rehabilitation is often confused

with home-based rehabilitation. A major difference is that community-based rehabilitation involves direct patient supervision and regular visits with health care professionals (13,16). In fact, it replicates the professional, technical and financial requirements of hospital-based outpatient rehabilitation programs at the community level. Home-based rehabilitation, as implemented in the present study, implies minimum attended supervision – the training program will be largely self-monitored.

The present clinical trial is based on two pivotal studies previously conducted by our group (3,14). We addressed the safety and efficacy of home exercise training in 19 patients with severe emphysema in preparation for lung volume reduction surgery (14). We found that home exercise training was effective in improving exercise tolerance and quality of life. Although this study demonstrated the feasibility and safety of a self-monitored, home-based rehabilitation program for patients with severe COPD, the results should be interpreted with caution because of the absence of a control group and the highly selected patient population. We also conducted a parallel-group, randomized, multicentre trial comparing the efficacy of a disease-specific, self-management program with usual care in patients with COPD (3). The program was provided entirely at home by a trained health professional. The main outcome measures were quality of life and health care use at one year. Patients included in that study were, on average, 70 years of age and had an FEV_1 of 1.00 L. The main findings were a marked reduction in the use of health care services (3) and cost-saving (4) in the intervention group. Hospital admissions were reduced by 40% in the intervention group compared with the usual care group, and admissions for other health problems were reduced by 57% (3). Emergency department visits were reduced by 41%. However, the changes in quality of life were modest and there was no improvement in functional status in the intervention group (3). These findings were not unexpected because education alone has not been shown to improve exercise tolerance and dyspnea (17). Our interpretation of these results is that the exercise component of the program did not receive enough emphasis in the self-management program. We also learned that it is crucial to involve a health care professional with experience in exercise training for patients with COPD to ensure the effectiveness of this component of rehabilitation.

Our experience, as well as that of others, suggest that home-based rehabilitation can be safely implemented in patients with COPD and that it is an effective alternative to outpatient and directly supervised exercise training (18). However, published studies on home rehabilitation (14,18-22) have been either uncontrolled or have had a small number of patients. Thus, the medical community is not ready to recommend widespread use of home-based rehabilitation because its efficacy has not been adequately compared with that of hospital-based outpatient rehabilitation.

Assessing compliance with exercise in any unsupervised setting is a challenge. In the present study, compliance with the exercise program will be evaluated objectively in both groups using a computerized heart rate monitor, allowing us to indirectly record the training intensities for all training sessions. This will provide data about the feasibility of home exercise training as performed in the present trial and will also help establish whether the improvement in quality of life is related to training intensity.

The safety of exercise training for patients with COPD in general, and home-based rehabilitation specifically, is an important concern. In patients with COPD, cardiovascular comorbidities, such as hypertension and coronary artery disease, are not uncommon. There are no large studies on home-based rehabilitation in COPD that address the issue of safety. The experience with home-based rehabilitation (14,18,20-22) indicates that it can be used safely as long as there is adequate medical and exercise evaluation at the beginning of the program (14). It is also known that the general risk of cardiovascular events after exercise is very low in a population older than 50 years of age, although data specifically obtained from patients with COPD do not exist. We believe that our trial will provide valuable information about the safety of home rehabilitation in COPD.

The present clinical trial was made possible through the commitment of different medical and research organizations throughout the country, including the Respiratory Research Network of the Fonds de la Recherché en Santé du Québec, the Canadian Institutes of Health Research and GEREQ. The present study was deemed feasible because a strong Canadian group of investigators in the field of COPD was interested in participating. Despite the worldwide efforts toward smoking cessation and the fact that COPD is the subject of intense research, this medical problem is expected to grow markedly in the coming 20 years. A strong partnership between Canadian research organizations and COPD investigators is essential to ensure the ability of Canadians to maintain and further develop their role as international leaders in the rapidly expanding field of COPD research.

The present trial will combine self-management education and exercise training. The study will address the long- and short-term effectiveness of home-based pulmonary rehabilitation. As well, it will assess if the described home-based modality can reduce health service use, such as hospitalizations and emergency visits, and if it can be done at a lower cost than traditional hospital-based, outpatient pulmonary rehabilitation. Practical and valuable information derived from the present trial could have a major impact on the practice of pulmonary rehabilitation. The high level of evidence, based on important outcomes, should be sufficiently strong to influence the decisions of third party payers of rehabilitation to expand the availability of pulmonary rehabilitation.

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