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Research Article

Near-Infrared Spectroscopic Screening for Bladder Disease in Africa: Training Rural Clinic Staff to Collect Data of Diagnostic Quality

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Background. While near-infrared spectroscopy (NIRS) has recognized relevance for developing countries, biomedical applications are rare. This reflects the cost and complexity of NIRS and the convention of comprehensive training for accurate data collection. In an international initiative using transcutaneous NIRS to screen for bladder disease in Africa, we evaluated if interactive training enabled clinic staff to collect data accurately. *Methods*. Workshop training in a Ugandan medical clinic on NIRS monitoring theory; bladder physiology and chromophore changes occurring with disease; device orientation; device positioning over the bladder, monitoring subjects during voiding; and saving/uploading data. Participation in patient screening followed with observation, assistance, and then data collection. Evaluation comprised conduct of serial independent screenings with analysis if saved files were of diagnostic quality. *Results*. 10 individuals attended 1-hour workshops and then 0.5–3.0 hours of screening. Five then felt able to conduct screening independently and all collected data were of diagnostic quality (>5 consecutive patients); all had participated in screening for >1.5 hours (6+ subjects); less participation allowed competent assistance but not consistent adherence to the monitoring protocol. *Conclusion*. A simplified NIRS system, small-group theory/orientation workshops, and >1.5 hours of 1 : 1 training during screening enabled clinic staff in Africa to collect accurate NIRS data.

1. Introduction

In recent years near-infrared spectroscopy (NIRS) has benefited the developing world through a broad range of applications. The techniques and technical specifications of the instruments employed are many and varied, as the index of articles in this journal regularly confirms. This diversity and capacity for accurate, reliable, rapid, and nondestructive analysis enables NIRS to be used in multiple contexts that range from compositional, functional, and sensory analysis of seeds, grains, plants, and many fruit and vegetable crops, through the study of soils and chemical compounds, improvement of food production, and animal husbandry, to the structure and purity of pharmaceutical products and multiple industrial applications [1–14]. In contrast, clinical biomedical applications are rare; even in the developed world, effective human use of NIRS is not widespread and in resource-poor environments was unknown until recently [15–19].

In 2011 the cerebral effects of falciparum malaria in India were investigated using NIRS [16]. A portable, low cost, and easy-to-use NIRS system had to be developed to do this, but what was observed demonstrated that biomedical applications of NIRS have clear relevance in the context of improving global health. In cerebral malaria, NIRS-derived oscillations in cerebral oxygenation correlated with the severity of the disease. Subsequently functional NIRS (fNIRS) has been applied to the challenge of malnutrition; ongoing research on cognitive memory of infants in rural Gambia aims to develop a viable technology for use in resource-poor settings that can assess brain development and provide parameters both to drive and to evaluate effective interventions for malnutrition [17]. For example, it is proposed that evaluating brain function in early life will allow the timing, nature, and impact of pre- and postnatal nutritional insults to be assessed.

Currently, assessment methodologies in developing countries that provide quantifiable data are mostly limited to documenting established pathology rather than evolving disease, and assessments predominantly only provide estimates of the burden of disease [20]. This is true for many conditions, including bladder disease in adults, the condition of interest in our application of NIRS to improve global health. So often, NIRS has only been spoken of as having "potential" for clinical biomedical applications, but now even for low resource settings technology as complex as fNIRS has been modified, transported to rural areas, and used successfully to collect important data in African infants [17].

Contemporaneously, our project has developed a compact, self-contained version of our NIRS-based bladder monitoring technology to address a global health issue of importance in rural Uganda. This in an initiative funded by Grand Challenges Canada to establish how a continuous wave (CW), spatially resolved (SR) spectroscopy system can be used by local health care providers in rural clinics to identify early signs of bladder outlet obstruction. The relevance of such assessment is that this form of bladder disease is common in the developing world, NIRS can identify physiologic parameters in the bladder that allow early diagnosis, and inexpensive medications are then available that can alleviate a patient's symptoms and slow further evolution of their pathology [18, 21].

Currently, however, the norm is late diagnosis which causes great hardship, in large part because, in low resource settings, the specialists and testing methods relied on for diagnosis in industrialized countries are a great rarity. Hence, patients commonly only seek care when their urine flow is almost completely obstructed, and then suprapubic catheter insertion to drain retained urine is often required, in many cases permanently. The negative impact on quality of life of having bladder disease is considerable, significant morbidity is common, serious complications include urinary tract infection, septicemia (bacteria in the blood stream), and irreversible renal damage often causing premature death [22].

In addition to viable NIRS systems for low resource settings needing to be inexpensive, self-contained, and "user friendly" and have validated measurement parameters, for widespread application to occur, cultural acceptability of the protocol for assessment and the ability to train local staff to operate the NIRS system independently from expert researchers are required. This paper reports a pilot field trial that evaluated these elements of translation from "bench" to rural African "bedside."

2. Materials and Methods

2.1. Hypotheses. We hypothesize (1) that an inexpensive, self-contained, "user friendly" optical device using near-infrared spectroscopy (NIRS) can be used independently by lay staff in rural clinics to screen for early signs of obstructive bladder disease in men in Uganda following completion of a theoretical and practical training program, (2) that patients will find the screening method culturally acceptable and they and their health care providers will regard the new knowledge and treatment options that result beneficial, and (3) that a field trial involving Ugandan clinic staff will provide feedback able to make the device more applicable for use in a low resource environment and aid independent use by local operators.

2.2. The NIRS Device. The device used in this project evolved through a series of prototypes and custom software upgrades. Design criteria to suit it for use in rural Africa included a "user friendly" interface and operating software intended to make it intuitively operable by anyone familiar with use of technology at the level of an Android cell phone, with core features based on our validated optical method for noninvasive transcutaneous diagnosis of bladder outlet obstruction [23]. The result was a custom-made miniature, self-contained unit with wireless capacity. The NIR light source comes from 3 paired light emitting diodes (LEDs) with wavelengths of 760 and 850 nm; these are configured for spatially resolved measurement of oxygen saturation in addition to monitoring changes in oxygenated (O_2Hb) and deoxygenated hemoglobin (HHb) from baseline. Power comes from a rechargeable lithium ion polymer battery with a 6-hour monitoring capacity or from AC power via a mini-USB cable connected to a laptop computer. Data are collected at 36 Hz; an 8 MB memory can be used for internal storage, or raw optical data are transferred via Bluetooth® to a remote computer that controls the device and analyses, displays, and stores data. Analysis is made from two source-detector distances and graphic display of chromophore changes and an absolute measure of oxygen saturation are managed by custom software. The device is encased in a plastic housing, weighs 58 gm, and has a sufficiently small form factor to not be a burden for the wearer. The full specifications and field trials to optimize photon penetration and confirm diagnostic accuracy have been described previously [18, 19, 24]; elements of the system are illustrated in Figure 1.

2.3. Measurement Parameters. Changes in chromophore concentration (O_2Hb, HHb) and total hemoglobin (O_2Hb + HHb = tHb) are monitored from baseline and an absolute measure of tissue oxygenation (TOI%) quantified in real

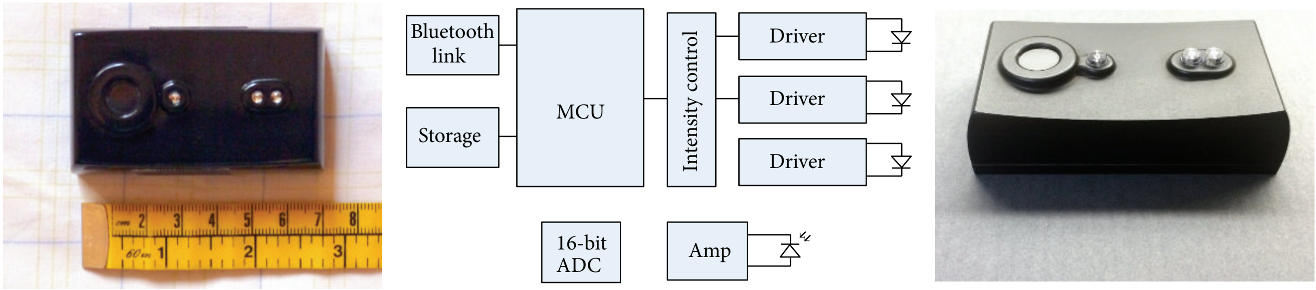

Figure 1: CW SR NIRS device. First prototype; block diagram and device as field tested.

(a) (b)

Figure 2: Positioning the device over the bladder using the bony landmark of the symphysis pubis (a); the device taped in place and steadied against the skin by the subject prior to spontaneous voiding (b).

time. Raw optical data are converted to a graphic display. As validated in other biomedical applications using CW NIRS, such chromophore data allow changes in tissue hemodynamics and oxygenation to be inferred [25]; in bladder NIRS, such changes occur as the detrusor muscle contracts during spontaneous voiding [23, 26]. The physiologic changes in the microcirculation of the detrusor differ in health and disease and characteristic patterns of change have been described which can contribute to diagnosis [23]. In this project, the presence of bladder outlet obstruction (BOO) results in a negative trend in O_2Hb/tHb. We have previously reported on the comparable diagnostic accuracy of NIRS to invasive pressure flow studies for bladder outlet obstruction (88% specificity, 84% precision), also that real time diagnosis is possible through analysis of the NIRS-derived trends of chromophore change using a validated algorithm [23, 27, 28], and that these concepts remain valid when monitoring the bladder through pigmented skin [18, 19].

2.4. The Screening Protocol. All participants signed informed consent translated into their local dialect.

The NIRS device is first correctly positioned on the patient over a full bladder. The best way to do this in rural clinics was developed by our Ugandan colleagues [19]. It is easiest to identify the bony landmark of the symphysis pubis with the patient lying supine and using the index finger to identify the prominence of the pubic bone by palpation. The center of the device's lower edge is then placed against the finger palpating the symphysis pubis (Figure 2). This sequence locates the NIRS emitter/detector on the skin of the abdomen 2 cm above the symphysis in the midline and over the bladder, and the device is taped in place. The patient then stands and ensures continued apposition of the emitter detector array against the skin with their own fingers (Figure 2) and, when instructed to do so, passes urine spontaneously into a graduated container; this allows simultaneous NIRS screening of bladder emptying with recording of the volume of urine passed. The data collection sequence for the operator is shown in Table 1.

2.5. The Training Program. Training Ugandan medical clinic staff to use the device involved two elements; small group interactive workshops lasting about 1 hour and participation as an assistant in patient screening sessions for between 0.5 and 3.0 hours; the actual duration depended on clinical duties necessitated by operating in a busy medical clinic. Workshops provided (a) theory on NIRS physics, methods and limitations of measurement, bladder physiology, and changes in chromophore concentration occurring with disease; (b) orientation to the NIRS system (device and computer); (c) the screening protocol, correct positioning of the device over the bladder, and the logistics of monitoring subjects during voiding; and (d) the way to control the device and save data with the controlling computer (Figure 3). Participation in patient screening involved observation first, followed by assistance with screening and then data collection under supervision.

2.6. Evaluation. Following training, staff were given the opportunity to decide if they felt able to conduct screening independently. The data sets collected by those who chose to perform screening were saved by the operator; graphs were

Table 1: NIRS bladder screening protocol. The sequence of actions, commands, and computer entries required from the operator for collection of each data set once the device is applied to the skin over the bladder and the patient is standing ready to void.

Step	Action
1	*Activate* the link between the device and the controlling computer
2	Press the "*Start*" control on the computer to begin data collection
3	*Collect baseline* data for 15 seconds
4	Give the patient the instruction "*Permission to void*"
5	Press **"***Mark***"** control on the computer when **"***Permission to void*" is given
6	Press "*Mark***"** *when urine flow starts*
7	Press "*Mark***"** *when urine flow ends*
8	Collect data for a further 15 seconds
9	Press "*Stop*" control to stop data collection
10	Press "*Save*" to store the *data file*
11	*Enter patient information* (including age, body mass index, symptom score, and voided volume) and notes on any issues are the logistics of screening
12	*Save* data as a *patient file*
13	*Upload* anonymous data file via the Internet

Figure 3: Small group training workshop in a rural clinic. "Hands-on" training with tablet computer interface. The tablet is connected to NIRS device via a USB charging/data transfer cable.

later generated from each data set which were evaluated as to whether or not they contained data of diagnostic quality. This was determined by whether or not trend data relied on by the diagnostic algorithm used to identify the presence or absence of bladder disease were evident in the oxygenated, deoxygenated, and total hemoglobin concentration changes from baseline.

Patients and staff were asked for feedback about the device, screening protocol, and conduct of the field trial. Answers were content-coded and ranked for frequency. Clinic staff involved in assisting or conducting independent screening were asked to indicate what modifications to the device and operating software they thought could make it easier for them to screen patients independently in the future.

3. Results

3.1. Training. Ten staff members from a Ugandan medical clinic were oriented to the device in 3 training workshops so the groups were small and the interactive format allowed dialogue to ensure comprehension of concepts and confirm orientation to, and competence with, the components and practical operation of the system. The sessions were conducted in English and this is the language for the software programs and control commands on the computer. However, also having the ability to add clarification in the local dialect facilitated comprehension. The contribution of a young Ugandan was integral to effective training for the computer-driven elements of screening. The duration of these workshops was in the order of 1 hour but varied somewhat, being driven by the rate of knowledge and skill acquisition of the participants. The educational level of the staff trained ranged from 4 years of high school education to graduate studies in nursing or as a laboratory technician.

It became apparent that the duration of participation in screening was the principal factor that determined whether or not individuals were able to achieve independent screening. After about 1 hour, sufficient familiarity was apparent for staff to orient patients to the screening process and contribute confidently to one or more elements of data collection. The 5 members of staff who were involved in screening for >1.5 hours and/or assisted with successful data collection obtained in 6 or more patients proved to be able to conduct screening and fully competent when doing so independently. This group included one lay assistant in addition to two nurses, one lab technician, and one physician; all collected 5 or more data sets of diagnostic quality. The limiting factor with less exposure was not related to comprehension of theoretical concepts or lack of understanding of individual components of the screening protocol, but rather an inability to complete the data collection sequence without "stumbling" at some point, compromising the integrity of the screening protocol. Clearly there is a "learning curve" with application of NIRS technology, but in our trainees it was repetition of the data collection protocol that proved to be central to the ability to ultimately perform independently. As a group, the Ugandan staff appeared to be predominantly haptic learners (those who learn by "doing"), which emphasized the importance of ensuring that the participatory phase provided during any training program is of adequate length.

Most of the staff had written down the key points and sequence to be followed during screening and were good at prompting each other when working collaboratively, but the short time line for completing all the steps and actions required between the patient's being readied to void and completion of the screening protocol means that the command and action sequence must be committed to memory as there is no time for reference back to a written check list over the short time frame it takes most subjects to empty their bladder. There may however be merit in having a knowledgeable assistant present to compliment the skills of a fully trained operator when local staff began screening independently.

3.2. Cultural Acceptability. Clinic staff were all enthusiastic and motivated both to learn how to screen and to have new knowledge and options to promote early diagnosis of bladder disease and offer proactive treatment. Ugandan men in the target age group (40–50 years) proved to be wholly willing to be screened after hearing an explanation of what was involved. None had any problem with the application of the device to the suprapubic skin over their bladder nor the protocol to screen them in the local clinic as they emptied their bladder. Many expressed satisfaction or surprise at the end of screening that it was a painless assessment that only required them to pass their urine. Questions asked predominantly related to when NIRS screening could be made available for others and how much the test would cost when introduced. Frequent comments were made that the conduct of the field trial of the device and/or staff training had raised awareness in the community as a whole of the possibility for and associated benefits of early diagnosis of bladder disease and particularly added new knowledge that medical treatment was available.

3.3. Device Modification. The size and form factor of the device prototypes were acceptable to clinic staff. They readily understood the basic principles underlying NIRS monitoring and found the controlling software program no more complex to operate than that in mobile devices with which they were already familiar. There was a preference for a laptop computer rather than a tablet to operate the device, enter demographic data, and save and upload data files and also for Bluetooth capacity rather than USB cable connection between the device and the computer/tablet. The small touch points on a tablet screen and lack of illuminated "back button" did not lend themselves to ease of use. Improvements suggested to facilitate operation in the rural clinic environment included the following: having an app to link the device to the computer contained in an Android phone platform, larger touch pad sensors and/or illuminated control buttons, and a simplified display that prioritizes actions by providing logical actions in sequence rather than multiple options continuously on screen.

4. Discussion

This study established that staff in a rural Ugandan medical clinic can collect NIRS screening data of diagnostic quality independently after a combination of workshop orientation and participation in the screening of patients with experienced investigators. The CW NIRS system was specifically designed for use in Africa and intended for operation entirely by local staff. Conduct of the workshops with very small groups using an interactive format and emphasizing "hands on" operation of the system appeared beneficial. Learning to correctly position the device over the bladder was the key procedural skill to learn. The ability to screen independently and obtain data of diagnostic quality was a factor of the duration of the practical experience gained working collaboratively in patient screening with an experienced NIRS operator. This experience appeared to provide "haptic" learning where "doing" each of the steps involved in the protocol sequentially and often, generated the familiarity necessary for each of the steps and actions required in the screening protocol to be followed without delay or interruption.

The relative simplicity of the NIRS device was also a key factor aiding successful use by Ugandan staff. The screening system obviously incorporates the core elements that made our original bladder monitoring concept possible, but was designed from the outset to be "user friendly" and run on software simple enough to make it intuitively operable by anyone familiar with Android cell phone technology. This is also a basic CW NIRS device in contrast to the fNIRS system that introduced NIRS technology to Africa. Consequently our device is inexpensive, is already simple enough to be made widely available, and significantly has now also been used in a wholly rural clinic setting with successful screening done entirely by trained local staff.

Importantly, the training provided to local staff conducting NIRS bladder screening did not seek to give them diagnostic skills. While an experienced researcher can readily identify if the hemodynamic changes and oxygen consumption in the bladder wall are normal or abnormal from the graphs of chromophore change generated, where bladder screening is done by staff in local clinics, this is not an objective. The intention is that the data obtained either undergo automated diagnosis using algorithm analysis that can be incorporated into the controlling computer or are sent securely via the Internet for expert review. In this way, the conduct of the screening test can be done remotely in any clinics wherever performing the NIRS screen is within the capacity of health care personnel, but the diagnosis is provided for the patient using validated diagnostic algorithm methodology or where necessary by expert review.

We recognize that there are limitations in our report including testing of the device in only one region, as education and cultural differences will exist between countries. We also recognize that the sample size is small but it was as large as our funding allowed. A larger prospective study is planned to validate the findings from this pilot study.

There are obvious challenges associated with introducing biomedical applications of NIRS into low resource settings, but some of the day-to-day realities impacting the potential for success may be overlooked. We often had to accommodate small room size, which made teaching sessions for staff and data collection with patients a challenge, especially where we had additional observers/collaborators present. It also emphasized the logistic benefits of having a compact system in a confined space and justified the small extra cost of including wireless capacity to link the device worn by the patient to the controlling computer (Bluetooth connectivity is much more practical than having the restraint of USB cable linkage). Loss of power (electricity supply outages) impacted data collection where daylight was limited (e.g., note taking and connecting equipment become difficult) and emphasized the importance of choosing operating features on the computer or tablet interface carefully (e.g., having adequately sized and illuminated touch controls pads or keys on the interface). Keeping all components adequately charged also required planning and discipline. Weather obviously impacts travel, but the noise of tropical rain on a metal roof can compromise the ability to hear, teach, or instruct patients.

With the fNIRS system used in The Gambia, portability was achieved, but being a complex system transport "using a 4×4 vehicle" was involved. It was also reported to be suitable for use in settings "not dedicated for cognitive assessment measures" but "not yet in wholly rural settings." Ease of use was demonstrated by about 20 minutes being required to study each infant, with approximately 40 studies conducted over 8 days [17]. In comparison, the CW SR NIRS bladder screening system can be transported as easily as a laptop computer and the field trial took place in a wholly rural community. Data collection took a comparable amount of time, around 20 minutes to study each patient; this included obtaining informed consent, completion of a verbal and visual symptom score, and conduct of transcutaneous monitoring during spontaneous bladder emptying. The fNIRS system may be used in future in a rural setting rather than at one central location; a field-based battery power system is envisaged for this. However, power outages of the scale we encountered may impact this ability. Importantly in both the CW NIRS and fNIRS study populations the technology was well received by patients, community members, and field workers. Field workers helped to run the fNIRS studies and are viewed as potentially able to run the technology alone with further training—what that training would involve is not described [17].

In the developing world, there are probably many global health issues where using biomedical applications of NIRS clinically will offer potential benefit. Bladder disease may not seem to be among the first priorities. But, by 2018, an estimated 2.3 billion individuals worldwide will be affected by bladder disease, with 1.1 billion having bladder outlet obstruction. The burden of bladder disease is also estimated to be greatest in the developing world with numbers of affected individuals expected to increase from 2008 numbers by the greatest amount in Africa (rising by 30%) [20]. It has been established that obstructive bladder disease in rural Africa causes a considerable health burden [22, 29]. Now NIRS screening for early signs of bladder disease is a simple, culturally acceptable, painless, and complication-free way to positively impact this common health problem that can be offered by appropriately trained local staff.

Conflict of Interests

The authors declare that there is no conflict of interests regarding the publication of this paper.

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