Validation of electronic urinary incontinence questionnaires

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Objective: *To investigate whether there is any significant difference between the electronic and the paper-based version of Urogenital Distress Inventory-6 questionnaire (UDI-6) and the Incontinence Impact Questionnaire-7 questionnaire (IIQ-7).*

Materials and methods: *An electronic questionnaire and clinical tool was developed using a combination of open source questionnaire software and custom programming that closely replicated the paper version of the UDI-6 and IIQ-7 questionnaires.*

Ethics were reviewed and approved by the University Health Network of Toronto. The study randomized participants from the Urinary Incontinence Clinic to either complete the paper-and-pen version of the questionnaires or the electronic version at the beginning of their clinic visit. Sample size was determined to be 50 to sufficiently power the study but due to early closing of the clinic only 26 participants could be enrolled in the study.

Results and conclusion: *The study found that there was no significant difference ($p < .05$) between the standardized pen-and-paper and electronic versions of the UDI-6 and IIQ-7. The electronic version can be used in place of the paper version facilitating physicians understanding and monitoring of the impact of incontinence on patients in order to formulate an appropriate treatment plan.*

Key Words: electronic, incontinence, questionnaire

Background

Urinary incontinence affects 3% to 55% of the population, depending on the definition of incontinence used and the age of the population studied.[1] The segment of the population most affected is older women (17%-55%).[1] Urinary incontinence is associated with poor quality of life,[2] poor self-rated health,[3] social isolation,[4] depressive symptoms[5] and decline in instrumental activities of daily living.[6]

Physicians need to understand and monitor the impact incontinence is having on their older female patients if they hope to be able to effectively help manage this condition. One way to do this is to monitor patient responses to the Urogenital Distress Inventory-6 (UDI-6),[7] which is a questionnaire designed to evaluate symptom distress in incontinent women, and the Incontinence Impact Questionnaire-7 (IIQ-7),[7] which is a questionnaire designed to evaluate life impact of incontinence on women. These are validated, pen-and-paper questionnaires able to detect clinical improvement, having both been found to correlate 0.43 and 0.46 respectively with change (pre-treatment– post-treatment) in number of incontinent episodes reported.[7] We developed an electronic version of these questionnaires in an effort to assist physicians in the management and monitoring of female patients with urinary incontinence.

Questionnaires are commonly used in the clinical setting to help efficiently gather medical information. There is evidence that, compared to paper forms, electronic forms of questionnaires may minimize missing or problematic responses and are preferred by patients.[8] Computer-based quality of life questionnaires may actually improve the physician-patient interaction regarding these issues.[9] The aim of this study was to validate the developed electronic version of the UDI-6 and IIQ-7 questionnaires with the standardized pen-and-version.

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Methods

Development of electronic questionnaires

When developing the electronic version of the UDI-6 and the IIQ-7, the standardized paper-and-pen

questionnaires were closely replicated. We also took into account that women with urinary incontinence are often older. Some of these older women may be less familiar with computer technology and may have sensory and functional limitations.

Development of the electronic version of the questionnaires involved development of a web-based questionnaire system. The web-based questionnaire system has three components: administrative, patient, and provider. The administrative component provides a means of managing users. There are three types of users, an administrative user who can manage all other users, a patient/participant user who is assigned questionnaires for completion, and a provider user who can review the questionnaire results and scores.

The administrative, patient/participant, and provider components were developed by reviewing the required functionality with the health care providers. The administrative, patient/participant, and provider components were developed using PHP and MySQL web technologies. The patient/participant component provides functions for the patient user to answer the questionnaires. The presentation, development, and administration of the questionnaires used PHPSurveyor (http://phpsurveyor.sourceforge.net/ version 0.99dev01), an open-source questionnaire system written in PHP and MySQL database technologies.

We conducted two rounds of heuristic evaluation and two user reviews in order to test the usability of the system. Figure 1 is an example of the electronic version of UDI-6 presented to the patient/participant. Figure 2 is an example of the electronic version of IIQ-7 presented to the patient/participant.

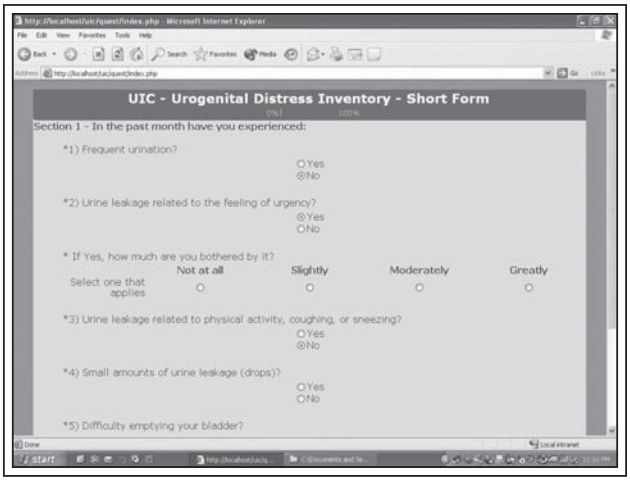

Figure 1. Electronic version of Urogenital Distress Inventory-6.

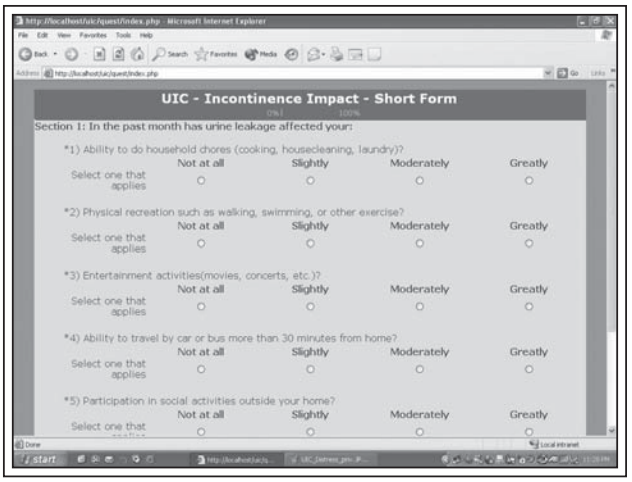

Figure 2. Electronic version of Incontinence Impact Questionnaire-7.

Study design

This was a prospective study comparing the paper-and-pen version to the electronic version of the UDI-6 and IIQ-7 questionnaires. Participants were randomized to either complete the paper-and-pen version of the questionnaires or the electronic version at the beginning of their clinic visit. The participants completed the alternate version at the end of the clinic visit. Before completing the electronic version on a Sony VAIO laptop computer, participants were provided with some minimal instruction on the use of the mouse, keyboard, and questionnaire navigation.

The two versions were tested at the same clinic visit due to the fact that scores change with change in clinical status. The interval between testing was a minimum of 20-30 minutes, during which time the participants completed their usual clinic visit. This short retest period ensured no clinical change occurred between administrations. During retesting the participants did not have access to their initial responses in an effort to minimize recall bias. Randomization was done using a random digits table and sealed opaque envelopes opened in sequential order. The primary outcome was differences in paired questionnaire scores, as well as the correlation between questionnaire scores. The Research Ethics Board at the University Health Network, Toronto approved this study.

Participants

Twenty-six women, attending an incontinence clinic for women 50 years of age or older at a university-affiliated hospital in Toronto, Canada were enrolled between March 2006 and July 2006. All those enrolled were capable of consenting to participate, could read and speak English,

TABLE 1. **Comparison of scores for the UDI-6 and IIQ-7**

	Observations	Mean score (95% CI)	p-value
UDI-6			
Electronic version	22	41.2 (33.3-49.0)	
Pen-and-paper version	22	47.2 (37.4-57.1)	0.09
IIQ-7			
Electronic version	21	50.1 (37.1-63.1)	
Pen-and-paper version	21	46.3 (27.9-58.9)	0.37

and were able to fill out the questionnaires independently or with some assistance. Informed written consent was obtained before patients were enrolled. Patients were only eligible to be enrolled once.

Analysis

To determine if the delivery methods were equivalent, a paired Student t-test and Pearson's correlation were performed on the scores for each of the questionnaires. Statistical analysis was done using STATA Version 8.0.

The initial sample size targeted was 50, however, as the result of staffing issues the incontinence clinic was closed in July 2006. Twenty-six patients were enrolled prior to the clinic's closure.

Results

Complete data was available for over 80% of participants. Twenty-two participants completed all the questions in both versions of the UDI-6 and twenty-one completed both versions of the IIQ-7. For the UDI-6, electronic data was missing from three participants and paper data was missing from a fourth. Data was missing for the electronic version of the IIQ-7 from five participants, while there was no data missing from the paper version. There was no significant difference between the pen-and-paper and electronic versions of the UDI-6 ($p = 0.09$) or the IIQ-7 ($p = 0.4$), Table 1. There was good correlation between the pen-and-paper version and the electronic version of the UDI-6 ($r = 0.7$). The two versions of the IIQ-7 were also well correlated ($r = 0.8$).

Discussion

The electronic version of the UDI-6 and IIQ-7 was found to be statistically comparable to the standardized pen-and-paper version. This electronic version may make it easier and more usable for clinicians to monitor the impact urinary incontinence and its treatments are having on older female patients, as the questionnaires scores can be easily tracked and graphically displayed over time.

Presentation and usability are important factors to consider when developing electronic health questionnaires. The electronic questionnaire system can present questions in a number of varied ways. By employing a heuristic review by usability experts, we considered the impact of color, format, and font size on the older user when developing this electronic version of the questionnaires. This electronic version attempted to present questions in a manner that closely mimicked that of the pen-and-paper version, which was to present all related questions on one page. Electronic questionnaires can present questions one per electronic-page however participants can lose context.[12] By presenting questions one at a time participants' concentration is continuously interrupted and impedes the flow of the questionnaire.[13] The heuristic review also indicated that the electronic version of the questionnaire should also present all questions on one page and also minimizing horizontal scroll.

The UDI-6 uses a question skip pattern, which presents all questions at once on the paper version. On the electronic version, the skip pattern only shows when the user selects the trigger decision (in this case answering "yes" to part one of a question). This difference in the operating of the electronic question, where additional choices are only shown once the trigger decision is selected, may affect what the users choose.[12] In the paper version the user can view the skip question, which may affect the users' response to the question. The electronic version skip question is only revealed if the skip question choice is selected. The results of this study however did not specifically examine using skip patterns in paper versus electronic format.

The IIQ-7 requires two sections on paper that equates to having two sections for the electronic format. Arranging questions into various sections or groupings changes the participant's cognitive context and increases the correlation between related questions.[14,15] This can ultimately change the way the participants answers the questions.[15] The key point is that grouping related questions on the same page ensures that participants can maintain a situated context and ensures that distraction from changing

pages is minimized. The electronic version breaks the two sections of the IIQ-7 into two distinct pages, while in the pen-and-paper version the sections are on the same page. However, both versions ultimately had the same groupings of questions.

Our finding that the electronic version of the UDI-6 and IIQ-7 questionnaires appears to be valid is strengthened by the high correlation found with the pen-and-paper version for both of the questionnaires. Nonetheless, the findings should be interpreted in light of the fact the study included a relatively small sample size. Others have also found that there is no difference between electronic questionnaires compared to the paper version of the questionnaire. Studies of the electronic versus paper presentation of short form 36 (SF-36) General Health Questionnaire found that there was no difference.[16,17] Similar results comparing electronic to paper presentation of Quality of Life (QOL) also discovered no difference.[18-24] A number of papers found that using the electronic questionnaires were preferred over paper. In Ryan et al study[16] of the comparison of electronic version of the short form SF-36 to paper found 71% preferred the electronic version. In another study of electronic versus paper determined 51% preferred electronic, 31% had no preference, and 21% preferred the paper version.[19] While this study did not examine participant preference as part of this study but the expectation is that similar results would have been obtained if participants' preference had been determined.

There were three (14%) participants' data missing from the electronic version and one (4.5%) from the paper version of UDI-6 questionnaire. In the case of IIQ-7 5 participants' data was missing from the electronic version of the questionnaire as compared to none on the paper version. While there was no formal analysis of why there was more data missing in the electronic version of the questionnaire compared to the paper participants. The reason maybe that the clinic population consisted mainly women 50 years or older who maybe are still more comfortable with paper questionnaires as demonstrated by the higher completion rates on UDI-6 and UII-7 paper questionnaire. A study conducted in 2002 among a random sample of 501 adults, of whom 251 were women over the age 55, found that 36% of women used a computer and that 80% used a computer more than twice a week.[10] Older people are quickly becoming more Internet and computer savvy therefore over time will become more adapt at entering information into a computer and missing data maybe reduced.[11] Additionally, this study did not implement some of electronic design features, which help to reduce missing data.

In Ryan, Corry, Attewell, and Smithson comparison of presenting SF36 as either in electronic or paper format found no missing data when the questionnaire is presented electronically versus 44% of the paper questionnaire had one or more missing data or response problems.[16] In a study of 557 patients in two different out-patient clinics measuring patient perception of quality of care (QPP) electronic questionnaire presented using a touch screen found no missing data with presenting the questions one screen at a time.[18] The computer used for this study was a small format Sony VAIO laptop, which may have also been a factor as compared to other questionnaire presented on larger touch screens.[18,22,25]

Patients presented with the paper questionnaire, 14% were missing one or more data points.[18] In another study of 149 cancer patients who were administered a quality of life questionnaire reported that there was no missing data from the electronic version of questionnaire.[22] The paper questionnaire was delivered as a scanner readable form and only 12 out of 158 paper questionnaires could only be read successfully.[22] The ability to directly input answers into an electronic questionnaire can improve data-quality and reduced potential for missing data.[22] Additionally, the design of the electronic questionnaire for this study did not use mandatory entry fields. The lack of use of mandatory fields was to ensure the paper and electronic questionnaire were comparable since the paper questionnaire the user is not forced to provide an entry in order to proceed to the next question.

There are a number of limitations to this study. The calculated sample size of 50 was determined to ensure the study was sufficiently statistically powered however only 26 participants could be enrolled before the clinic closure. We determined there was no statistical difference between electronic and paper questionnaires for UDI-6 and IIQ-7 which is in agreement with other similar QOL and SF-36 studies comparing the difference between electronic to paper.[18-26] This study focused on determining if there was any difference between electronic and paper presentation of UDI-6 and IIQ-7 but did not examine participants' preference for the presentation of the questionnaire. The study did not explore the optimum method to present the electronic UDI-6 and IIQ- 7 questionnaires. The electronic presentation of the questionnaire had high occurrence of missing data, which may be tied to peoples' preference for or ability to use the electronic media. While there were a number of limitations we believe that the results provide an indication that UDI-6 and IIQ- 7 questionnaires can be presented electronically. The ability to present questionnaires electronically can allow for integration into electronic clinical systems that can add information to an electronic patient record or electronic medical record of the patient disease pathology and treatment courses.

Future work

With the closing of the Urinary Incontinence Clinic further work to incorporate electronic questionnaire will have to be adapted to other clinics that use similar questionnaires. The software was built in a modular fashion and the work to migrate to another clinical setting is minimal. Examples of other clinics that use similar questionnaires are rheumatology, which uses the Health Assessment Questionnaire (HAQ).[27] Further work should be undertaken to investigate the utility of providing electronic questionnaire results to physicians and the affect on the way of practice.

Conclusion

There was no significant difference in scores between the standardized pen-and-paper and newly developed electronic versions of the UDI-6 and the IIQ-7. This suggests that the electronic version of the UDI-6 and IIQ-7 questionnaires is also valid for use in the management of urinary incontinence among older female patients. □

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