

# The Incontinence Quality of Life Instrument in a survey of primary care patients

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- **OBJECTIVE:** To assess the performance of the Incontinence Quality of Life (I-QOL) Instrument in measuring the impact of urinary incontinence on the quality of life of family medicine patients.
- **STUDY DESIGN:** Postal survey. Multiple imputation of missing answers. Linear regression analysis of I-QOL predictors. Comparison by receiver operating characteristic of the I-QOL and the Short Form 12 (SF-12).
- **POPULATION:** Women 45 years or older attending either of 2 family medicine clinics. Response rate was 605 (61%) of 992.
- **OUTCOMES MEASURED:** Prevalence of stress, urge, and mixed incontinence. Scores on the I-QOL and SF-12 instruments.
- **RESULTS:** Of the 605 respondents, 310 (51%) reported urinary incontinence in the month before the survey. At least 1 item was missing on 19% of the I-QOL scales and scores were imputed. The relation between I-QOL and the number of leakage episodes was nonlinear. I-QOL scores decreased with the number of episodes, the amount of leakage, and poorer general health. There was no association between the I-QOL and age, education, or the type of incontinence. The I-QOL was more sensitive than the SF-12 to the statement that “urinary incontinence is a problem.”
- **CONCLUSIONS:** The I-QOL is a useful instrument for the investigation of incontinence related quality of life in the community setting.

**key words** Incontinence; quality of life; survey; women’s health. (J Fam Pract 2002; 51:00-00)

Urinary incontinence is a common problem among primary care patients.<sup>1</sup> In recent years, patient perceptions of quality of life have become increasingly important in the evaluation of health conditions and their treatment.<sup>2</sup> Specific instruments have been developed for the evaluation of the health-related quality of life of women reporting urinary incontinence.<sup>3,4</sup> Wagner and colleagues developed a self-report quality of life measure specific to urinary incontinence (the Incontinence Quality of Life Instrument; I-QOL) that could be used as an outcome measure in clinical trials and patient care centers.<sup>5</sup> The developers tested the instrument on a sample of 62 subjects and reported that the I-QOL was more sensitive than a generic instrument, such as the Short Form 36 (SF-36), in detecting differences between levels of

self-perceived incontinence severity. In a follow-up study,<sup>6</sup> incontinent women (141 with stress and 147 with mixed urinary incontinence) completed the I-QOL and comparative instruments at screening, pretreatment, and 4 follow-up visits during participation in a randomized trial assessing the efficacy of a medication for incontinence. Those investigators reported that, in the clinical trial, the I-QOL proved to be valid, reproducible, and responsive to treatment for urinary incontinence in women.

The aim of our study was to measure the prevalence of urinary incontinence and its impact on quality of life, in a population of community dwelling women. We selected the I-QOL and the Short Form 12 (SF-12)<sup>7</sup> as specific and generic instruments, respectively, for the measurement of quality of life among incontinent women. In this report we describe the performance of the I-QOL in the community setting.

## ■ METHODS

### Subjects

The subjects were women 45 years or older who attended either of 2 participating family medicine clinics in the city of Hamilton, Ontario. This was a postal survey using a modified Dillman method.<sup>8</sup> The Dillman method calls for 3 mailings and a reminder postcard. Because of budgetary constraints we planned an initial mailing, followed by a reminder postcard and a second mailing to nonrespondents. Our budget permitted a sample size of about 1000, so that questionnaires were sent to all eligible patients attending the smaller clinic and to a random sample drawn from the roster of the larger clinic.

The initial mailing was sent to 1082 women. Ninety envelopes were returned undeliverable; in addition, 115 women returned the survey but selected the option of nonparticipation. The final response rate was 605 (61%) of 992.

### Survey questions

Two questions inquired about the presence of incontinence: (1) "During the past month have you ever experienced urine loss (wet yourself) when coughing, laughing, or doing some other activity?" (2) "During the past month have you ever had to pee and then wet yourself before getting to the toilet?" We classified incontinence as "stress incontinence" if respondents replied "yes" to question 1; as "urge incontinence" if they replied "yes" to question 2; and as "mixed incontinence" if they responded "yes" to both. In addition, we asked, "Is wetting yourself a problem that interferes with your day-to-day activities or bothers you in other ways?" We also inquired about the number of daytime and nighttime leaking episodes in an average week and the amount of wetness (underwear or pad only, outer clothing, urine runs down legs, or pools on floor). The survey included 2 health-related quality of life instruments, the I-QOL and the SF-12,<sup>7</sup> a generic instrument.

### Statistical analysis

Handling missing responses. Missing data is a common problem in survey research. Until recently, the only methods widely available for analyzing incomplete data focused on "removing" the missing values by ignoring subjects with incomplete information or by substituting plausible values (eg, means or regression predictions) for the missing items. These ad hoc methods, although simple to implement, have serious drawbacks,<sup>9</sup> including the potential introduction of bias. In the past 2 decades, substantial progress has been made in developing statistical procedures for missing data. In an incomplete data set, the observed values provide indirect evidence about the likely values of the unobserved data and one can use the available data to make estimates of the values of the missing data. Because any one estimate is uncertain, one may repeat the process a number of times and then average over these estimates for the missing values in the statistical analysis. Rubin developed the paradigm of multiple imputation, which carries out the averaging via simulation; each missing value is replaced by plausible values drawn from their predictive distribution.<sup>10</sup> The variation among the number of imputations reflects the uncertainty with which the missing values can be predicted from the observed ones. After performing identical analyses on each data set, the results are combined according to simple rules

to produce overall estimates and standard errors that reflect missing-data uncertainty. We used the publicly available software program, Amelia,<sup>11</sup> to generate 5 data sets containing imputed values for those subjects with missing values for I-QOL. Variables in the imputation model included age, education, type of incontinence, number of incontinent episodes, I-QOL, and scores on the physical and mental components of the SF-12.

Regression analysis. Logistic regression was used to investigate factors associated with incomplete responses to the I-QOL instrument. The relations between the I-QOL scores and predictor variables were modeled with multiple linear regression. Before the regression, we used generalized additive models,<sup>12</sup> a method that uses data smoothers to graphically display the pattern of relationships, to explore the shape of nonlinear relations, and suggest linearizing transformations. Model checking included an analysis of residuals.<sup>13</sup>

An important measure of the impact of incontinence is whether or not subjects consider their incontinence to be a “problem.” To compare the performance of the I-QOL and generic quality of life measures in discriminating between women who found and did not find their incontinence to be a problem, we computed the area under receiver operating characteristic curves.<sup>14</sup> Computations were done with the Stata statistical package.<sup>15</sup>

## ■ RESULTS

### Prevalence of incontinence

Of the 605 respondents, 310 (51%) reported urinary incontinence in the month before the survey. **Table 1** shows the distribution of the respondents by age and incontinence status. Among our respondents, the prevalence of incontinence decreased slightly with age, a trend of borderline statistical significance ( $P = .08$ ). Most surveys have reported that the prevalence of incontinence increases with age. We have no explanation for why this was not the case in our survey.

### Incomplete responses to the I-QOL

The I-QOL is a questionnaire instrument with 22 items and the score is computed from all items. In such a situation, missing responses might be an important problem, leading to the reduction of sample size and study power. In our survey, 11 subjects (3.5%) replied to none of the I-QOL items; however, at least 1 item was missing for 49 other subjects. Thirty subjects missed 1 item, 4 missed 2 items, 3 missed 3 items, and 12 each missed 4 to 20 items. The number of missing responses for the 22 questions ranged from 5% to 7%, with the exception of the statement, “I worry about having sex,” for which the missing rate was 13%. Even though the missing rate for individual items was no higher than 13%, only 250 (80.7%) of I-QOL scores were complete.

**Table 2** shows those variables significantly associated with incomplete response in a logistic regression model. Older women and women who had not graduated from high school were less likely to return a completed instrument, as were women who reported only urge incontinence. In addition, women who reported that incontinence was a problem were less likely to complete all the questions. These associations suggested that omitting women with incomplete responses from the analyses of I-QOL might introduce selection bias. We managed this problem by making use of the methods of multiple imputation.

### Associations of I-QOL with incontinence factors

The I-QOL is scored in the range of 0 to 100, with lower scores indicating lower quality of life. The mean value of I-QOL among respondents was 83 (range, 15-100). We anticipated that the I-QOL scores would vary systematically with incontinence-related factors and planned to investigate these relationships with a linear regression model. We suspected, however, that the relationships between I-QOL and the number of daytime and nighttime episodes of incontinence might be nonlinear. We thus explored these relations with nonparametric regression methods, and **Figure 1** shows the relations as estimated with a generalized additive model.<sup>12</sup> The method of generalized additive models is a computer-intensive one that makes no prior assumptions about the shape of the relations between the outcome and the

explanatory variables. It fits smooth, arbitrarily shaped functions to the data by a method that is a generalization of the “moving average.” **Figure 1** shows that the I-QOL decreased as the number of incontinence episodes increased, but then reached a plateau when the frequency of occurrence was about 1 episode per day. In other words, quality of life worsened as the number of incontinence episodes increased from less than once per week to once per day. However, once incontinence was occurring daily, there was no further decrease in the perceived quality of life as incontinence episodes became more frequent than once per day. We found that these plateau relations could be satisfactorily modeled with logarithmic transformations of the number of incontinence episodes; ie,  $\log(\text{number of incontinence episodes per week} + 1)$ , where the 1 has been added to avoid  $\log(0)$ , which is undefined mathematically.

The following candidate variables were chosen for inclusion in an initial regression model for the I-QOL scores: age, type of incontinence (stress, urge, mixed), incontinence is perceived as a “problem” (yes/no), log-transformed number of daytime and nighttime incontinence episodes, amount of wetting (wets outer clothing or runs down leg/wets pad or underpants only), self-reported health status (excellent to poor), and education. In this initial model, there was no significant association between I-QOL scores and age, type of incontinence, or education. These variables thus were not retained in the final model, which is shown in **Table 3**. The model provided a good fit to the data ( $F_{8,190} = 43.1$ ;  $P < .0001$ ;  $R^2 = .64$ ). In addition to presenting the results of the model that excluded subjects with incomplete I-QOL scores, **Table 3** shows the results of the model that included these subjects by using imputed values. There were only minor differences between the models. The I-QOL score decreased as the number of daytime and nighttime incontinence episodes increased and as the amount of urine loss increased. After controlling for other variables, the I-QOL averaged 12 points fewer among those women who considered their incontinence problematic. Further, there was a strong relation between the I-QOL and self-reported general health status.

## ■ DISCUSSION

Urinary incontinence is common among women in the community, but loss of bladder control is perceived quite differently by various respondents. In a survey of 36,000 Americans with incontinence, Jeter and Wagner reported that 17% described their incontinence as a major problem with important social implications,<sup>1</sup> but the rest described it as a relatively minor problem with limited impact on their respective lifestyles. Self-administered quality of life instruments are valuable in measuring the impact of incontinence on the lives of subjects, of identifying subjects among whom interventions might have a beneficial impact on quality of life, and in following the natural history of incontinence and its treatment.

One of these instruments, the I-QOL, has been used in the clinical trial setting. We were impressed with reports of its performance and selected it for use in a postal survey of community dwelling patients of 2 family medicine clinics. It was immediately apparent that the 22-item length of the instrument posed problems in a postal survey because, even though the missing rate for individual items was no higher than 13%, only 80.7% of I-QOL scores were complete. We found that older, less educated subjects were more likely to return incomplete questionnaires. We did not contact subjects to obtain responses to the omitted questions. Rather, we chose to make use of responses to other questions to impute the missing I-QOL scores. Although the differential response rates suggested the possibility of selection bias, there was in fact little difference in the coefficients of regression models when using complete versus complete plus imputed data.

As reported by Patrick and colleagues in the clinical trial context,<sup>6</sup> we found that the I-QOL score correlates strongly with physical measures of the extent of incontinence, including the number of incontinence episodes and the amount of wetting. Similar to those researchers, we found no relation between the I-QOL and age, education, or the type of incontinence. These are desirable properties for a condition-specific quality of life instrument; it is responsive to the impact of incontinence on the quality of life and not to “nuisance” variables. Another desirable characteristic was that the I-QOL correlates strongly with the statement, “wetting is a problem.” **Figure 2** shows the relations between the I-QOL score and the probability that a respondent would state that incontinence is a problem. To understand **Figure 2**, consider that each subject will agree or disagree with the statement, “wetting is a problem.” Each subject thus appears on the graph at a probability level of 0 or 1. Because there is considerable overlap of the data points on the display, the point for each subject has been “jittered,” ie, given a random amount of vertical displacement to better display the density of data points in relation to the I-QOL. The curve on the plot is the fit of a “loess” smoother to the data points.<sup>16</sup> This smoother

is, in essence, a running weighted average of the proportion of subjects who reported that wetting is a problem. When the I-QOL score was low, there was a high probability that incontinence would be seen as a problem. The I-QOL score at which 50% of women found incontinence to be a problem was about 77, and the probability declined rapidly after that.

There were significant correlations between the I-QOL score and the subscales of the SF-12 generic quality of life instrument ( $r = .49$  for the mental component of the SF-12 and  $r = .33$  for the physical component). We found, however, that the I-QOL was more sensitive than the generic instruments in identifying subjects who considered incontinence to be a problem. This is shown in the receiver operating characteristic curves displayed in **Figure 3**. The area under the I-QOL receiver operating characteristic curve was 0.84, compared with 0.63 for the medical component scale and 0.58 for the physical component scale of the SF-12. It is reassuring that a condition-specific instrument performs better than a generic one.

We note some limitations to this study. Estimates of prevalence in the published epidemiologic data on urinary incontinence often vary widely. These large variations are derived mainly from the wide range in definitions used, differences in survey setting, and methodology used. The overall prevalence rate of 51% reported in our survey is high. Further, the prevalence of incontinence among our respondents appeared to decrease slightly with age. One possible explanation and limitation of our study is that respondents self-selected to participate. The other limitation is that older, incontinent women likely were underrepresented in our sample due to institutionalization and survivor bias. The end result is that the prevalence of incontinence might have been overestimated for younger respondents (incontinent younger women more likely to respond) and underestimated for the older respondents (incontinent older women less likely to dwell in communities). The choice of our sampling frame and thus our ability to generalize the findings to other settings also might be viewed as problematic. This was not intended to be a community sample. We were interested in the impact of urinary incontinence on women attending family medicine clinics because these women are our patients and we have the opportunity to intervene to improve their quality of life.

Another limitation was that our questionnaire was available only in English. This might have affected our response rate and generalizability of these findings.

Despite these limitations, we believe the I-QOL is a useful instrument for the investigation of incontinence-related quality of life in the community and the clinical trial setting. We have begun to use the I-QOL among patients attending an incontinence clinic. We have found it to be well received and plan to report on its performance in this setting in the near future.

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