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The Development of the Revised Urinary Incontinence Scale (RUIS)

Abstract

This paper reports on innovative work aimed at adapting a urinary continence measure for Australian conditions. Following recommendations made by the Continence Outcomes Measurement Suite (COMS) Project (Thomas, et al. 2006), two brief urinary incontinence measures, the Incontinence Severity Index (ISI) and the Urogenital Distress Inventory (UDI-6) were included in a community population survey (N = 3015) to obtain current prevalence estimates for urinary incontinence in Australia.

This large dataset also allowed for the psychometric examination of these instruments and their item properties, e.g. examining item endorsement and discrimination, item-total correlations and Cronbach's Alpha, as well as the use of Exploratory Factor Analysis (EFA) and Item Response Theory (IRT) approaches. During the course of this analysis it became apparent that these two measures could be improved by combining their best items into a new scale, the Revised Urinary Incontinence Scale (RUIS).

This new instrument has good psychometric properties (including a Cronbach's Alpha of 0.91) and could be considered by clinicians, researchers and epidemiologists looking for a short, valid and reliable scale of urinary incontinence (as defined by leakage).

However, further research is currently being undertaken to examine their broader applicability in clinical settings (where there would also be a greater number of people with moderate to severe incontinence symptoms). Recent psychometric evidence using a then-test procedure suggests that this new instrument is sensitive to urinary incontinence treatment outcomes.

Introduction

A Continence Outcome Measurement Suite (COMS) Project was commissioned by the Australian Government Department of Health and Ageing, National Continence Management Strategy Research Program with the goal of recommending a suite of continence outcome measures to be used by clinicians and researchers in Australia.

This project was finalised in early 2006 (Thomas et al., 2006). Recommendations from this report led to a related project *Measuring Incontinence in Australia* (Hawthorne, 2006) which assessed a number of the recommended measures (the Urogenital Distress Inventory 6 [Uebersax et al., 1995], the Incontinence Severity Index [Sandvik et al., 1993], and the Wexner Faecal Continence Grading Scale [Jorge and Wexner, 1993]) by including them in the autumn 2004 South Australian Health Omnibus Survey (SAHOS) (Harrison Health Research, 2004).

This study provided Australian prevalence estimates for both faecal and urinary incontinence based on this community population survey.

For urinary incontinence, the results suggested that the preferred urinary incontinence measure was the Incontinence Severity Index (ISI). It was found to possess superior measurement properties in comparison with the Urogenital Distress Inventory (UDI-6).

Because the UDI-6 measures the impact of urinary incontinence on peoples' lives rather than incontinence per se, and may contain items that may be endorsed by those without urinary incontinence, the UDI-6 may overstate incontinence prevalence and the impact of this on peoples' lives (defined as their health status and their quality of life).

Given its poor performance, there was a case for major revision of the UDI-6. Although the ISI was the preferred measure, it violated the assumptions of classic psychometric theory relating to scale stability as it contains only two items, further research into its properties was also recommended.

The main purpose of the *Refining Continence Measurement Tools* project was to undertake further analysis of the SAHOS dataset to refine the incontinence measures to provide better instruments for the assessment of urinary and faecal incontinence in Australia. This paper reports on the development of the Revised Urinary Incontinence Scale.

Methods

This section includes information about the instruments, a brief description of the SAHOS survey, and an outline of the psychometric analyses.

Instruments

The UDI-6 and the ISI were included in the 2004 South Australian Health Omnibus Survey (Harrison Health Research, 2004) as they were commonly used urinary incontinence measures and were recommended by Thomas et al. (2006) in the COMS Project.

The Urogenital Distress Inventory (UDI) and the Incontinence Impact Questionnaire (IIQ) were developed by Shumaker, Wyman, Uebersax, McClish & Fantl (1994) to assess the impact of urinary incontinence symptoms upon quality of life for women.

The original forms of the IIQ and the UDI had 30 and 19 items respectively but work by Uebersax, Wyman, Shumaker, McClish and Fantl (1995) created a 7 item version of the IIQ and a 6 item version of the UDI. The UDI assesses symptoms of incontinence whereas the IIQ focuses on the impact of these symptoms on everyday life. For the latter reason the UDI-6 was included in the community population survey (see Figure 1 which describes the UDI-6).

Figure 1 – The UDI-6

The UDI-6 items ask the respondent “Do you experience and, if so, how much are you bothered by” the following list of symptoms:

- Frequent urination
- Urine leakage related to the feeling of urgency
- Urine leakage related to physical activity, coughing or sneezing
- Small amounts of urine leakage (drops)
- Difficulty emptying your bladder
- Pain or discomfort in the lower abdominal or genital area

The response scale is:

- Not at all (0)
- Slightly (1)
- Moderately (2)
- Greatly (3)

Score range = 0 – 18 points

The Incontinence Severity Index (ISI) was developed by Sandvik et al. (1993) and has been used in Norwegian epidemiological surveys of health problems (Sandvik et al., 1993; Hannestad et al., 2000). Although developed for epidemiological surveys slightly modified versions of ISI have been used in the evaluation of treatment programs in general practice (Seim et al., 1996; Holtedahl et al., 1998; Melville et al., 2003).

The Incontinence Severity Index (ISI) originally consisted of two items, one with 4 response levels and the other with two response levels (Sandvik et al., 1993). In 2000, the instrument developers altered the second item’s response scales from 2 to 3 levels, creating a four-level severity index (Sandvik et al., 2000). The four-level severity index is reported here whereas the earlier version of this instrument is reviewed by Thomas et al. (2006) in the COMS report. The following figure outlines the instrument’s structure:

Figure 2 – The ISI

<i>How often do you experience urine leakage?</i>	
Never	= 0
Less than once a month	= 1
A few times a month	= 2
A few times a week	= 3
Every day and/or night	= 4
 <i>How much urine do you lose each time?</i>	
None	= 0
Drops	= 1
Small splashes	= 2
More	= 3
 The Severity index = (points for frequency) x (points for amount)	
 Score range: 0 – 12 points (0 = no incontinence, 1 - 2 = slight incontinence, 3 - 6 = moderate incontinence, 8 - 9 = severe incontinence, 12 = very severe incontinence)	

In summary, the ISI asks two questions about urinary incontinence leakage (frequency * amount), while the UDI-6 is a short version of a larger symptom inventory and consists of 6 items asking about the experience and bothersomeness of urogenital symptoms associated with urinary incontinence.

A brief description of the SAHOS Survey

In the 2004 South Australian Health Omnibus Survey, all locations throughout South Australia with over 1,000 inhabitants were sampled. Sampling was from ABS 2001 Census collection districts, using a random starting point and attempting to survey every 4th dwelling. The response rate was 72%. 4,700 households were selected with 3015 interviews achieved. The sample comprised a total of 1202 males and 1713 females. It should be noted that incontinence prevalence in the 75+ age group is probably underestimated as this survey only includes those in community residences.

Psychometric Analysis

This standard psychometric analysis used standard Classical Test Theory (CTT) approaches to examine item properties. These included: examination of item descriptive statistics, item endorsement and discrimination, item-total correlations and internal consistency reliability, and Exploratory Factor Analysis (EFA). Item Response Theory (IRT) was also used to examine item properties.

For the psychometric analyses, unweighted data from the SAHOS study was used for all adults, over the age of 18 years; while for the prevalence estimates the data was weighted by probability of selection and ABS 2001 Census data to ensure representation. All the urinary items were pooled for analysis.

Results

The results of this psychometric analysis can be broken into three parts: Item endorsement and discrimination; Item-total correlations and internal consistency reliability; and Exploratory Factor

Analysis (EFA). Descriptive statistics will be presented at the end of this analysis allowing for comparison between the revised scale and the original instruments.

Item endorsement and discrimination

Detailed analysis of item endorsement and discrimination issues is provided in Sansoni et al. (2006) but for this work, a short and simple way to explore these issues is to examine prevalence rates. For example, the overall urinary incontinence prevalence estimates for the 2004 SAHOS sample for the ISI were 24% and 47% for the UDI-6 indicating a large discrepancy (Hawthorne, 2006). It appears that some items on UDI may be gaining endorsement from conditions other than urinary incontinence. If items on frequency of urination and abdominal pain are removed from the UDI-6, prevalence drops to 36% overall and there is greater case agreement (87%) with ISI. If ‘emptying bladder’ is removed prevalence = 32%.

Item-total correlations and internal consistency reliability

The internal consistency for the UDI-6 was 0.78 and for the ISI was 0.83 (Pearson’s correlation was used as there were only two items). Table 1 below shows that for the UDI-6 the corrected item - total correlations for items (emptying bladder) and (pain lower abdominal) are low, just above 0.20 which is at the lower end of the acceptable range (Streiner and Norman, 2003). The Cronbach’s alpha data shows that if either of these items were deleted it would not affect the overall internal consistency of the scale. If both these items were deleted it would slightly increase the internal consistency of the scale to 0.81.

Table 1 – Corrected Item - Total Correlations and Cronbach’s Alpha if the item was deleted for each item of the UDI-6

UDI- 6 Item	Corrected – Item Total Correlation	Cronbach’s Alpha if Item Deleted
Frequent urination	0.56	0.75
Urgency leakage	0.70	0.70
Stress leakage	0.57	0.73
Leak small amount	0.69	0.71
Emptying bladder	0.37	0.78
Pain lower abdominal	0.32	0.79

Exploratory Factor Analysis (EFA)

The method of exploratory factor analysis used was principal components analysis for extraction (eigenvalues > 1.00) with varimax rotation. This analysis produced a 2 factor structure explaining 67% of the variance (see Table 2). For the urinary incontinence items, Rotated Factor 1 accounted for a large proportion of the variance (53.43%), while Rotated Factor 2 accounted for only 13.58%. Rotated Factor 1 appears to represent the common factor of urinary leakage / incontinence, while Rotated Factor 2 seems to reflect other urological symptoms like lower abdominal pain and bladder emptying. The UDI-6 item on frequent urination loaded equally on both factors.

Table 2 – Rotated Factor Matrix for the items from the UDI-6 and ISI

Urinary Item	Factor 1	Factor 2
Frequent urination	0.48	0.49
Urgency leakage	0.74	0.33
Stress leakage	0.82	0.09
Leak small amount	0.85	0.22
Emptying bladder	0.14	0.76
Pain lower abdominal	0.09	0.75
Leakage frequency	0.89	0.16
Leakage amount	0.89	0.13

In summary, it was found that removal of the UDI-6 items on emptying bladder and pain lower abdominal improved item-total correlations and internal consistency reliability and produced prevalence rates closer to that of the ISI. Also it was found that one factor, urinary incontinence leakage) from a two factor solution, explained a large amount of variance in the sample (53%).

This data then lead to the development of the Revised Urinary Incontinence Scales (RUIS) which takes the five best items which loaded on the urinary leakage factor (Factor 1). The items comprising this revised scale include the three items from the UDI-6 (urine leakage related to the feeling of urgency, urine leakage related to physical activity, coughing or sneezing, small amounts of urine leakage [drops]) as well as the two items (frequency * amount) from the ISI.

The IRT analysis undertaken also confirmed the findings from the Exploratory Factor Analysis (EFA) – also identifying problems with the pain lower abdominal and emptying bladder items from the UDI-6. Further details of this analysis can be found in Sansoni et al., 2006.

Descriptive Statistics

The descriptive statistics for the ISI, UDI-6 and the RUIS for males and females from the 2004 SAHOS Community sample are depicted below in Tables 3 and 4.

Table 3 – Descriptive statistics for the ISI, UDI-6 and the RUIS for males from the 2004 SAHOS Community sample

	N	Mean	SD	Median	Range	
ISI	1204	0.24	0.93	0.00	0	12
UDI-6	1203	0.98	1.85	0.00	0	16
RUIS	1203	0.70	1.82	0.00	0	14

Table 4 – Descriptive statistics for the ISI, UDI-6 and the RUIS for females from the 2004 SAHOS Community sample

	N	Mean	SD	Median	Range	
ISI	1712	0.98	1.96	0	0	12
UDI-6	1714	2.13	2.72	1	0	18
RUIS	1712	2.47	3.31	1	0	16

In examining these statistics, one finds the endorsement rate of the urinary incontinence items is low for all instruments, which is what would be expected in a community population sample. The overall Cronbach’s Alpha for the RUIS was 0.91 from the SAHOS Community Sample indicating excellent internal consistency reliability and this is better than the other two instruments (ISI = 0.83, UDI-6 = 0.78).

RUIS: Patient Satisfaction Clinical Study

In order to obtain preliminary data in a clinical setting the RUIS was also included in a clinical study which examined patient satisfaction with treatment for urinary incontinence.

The study took place at specialist centres at St. George Hospital in Sydney and at the Royal Women’s Hospital in Melbourne. A final sample of women (N=178) who had treatment for urinary incontinence in the previous 12 months were asked to participate in a post survey by completing a questionnaire. Treatment for urinary incontinence included: surgery only, physiotherapy only or mixed approaches.

The postal questionnaire asked about type of incontinence, pre-treatment incontinence status, treatment, post-treatment incontinence status, expectations of treatment and included four standard patient satisfaction questionnaires.

Patients were asked to respond to the urinary incontinence measures, including the RUIS, retrospectively and concurrently using the then-test procedure.

Table 5 indicates the average score (retrospective) for patients seeking treatment for urinary incontinence in a clinical sample was 11.56 on the RUIS, as contrasted with 2.47 for the sample of females from the community survey. This suggests that the RUIS can describe more severe cases of incontinence.

Table 5 – Summary statistics from the Patient Satisfaction Clinical Study

	N	Mean	SD	Median	Range	
RUIS Pre (retrospective)	163	11.56	3.31	12	1	16
RUIS Post (current)	163	5.04	3.93	5	0	16
RUIS Then-test change score	163	6.50	4.67	7	- 5	16

Figures 3 and 4 provide histograms of the distributions on the RUIS pre treatment and post treatment, using the then-test procedure, comparing current (post treatment) with recalled or retrospective incontinence (pre treatment).

They show that for many of the female patients in this group that their scores moved from high to low. This is very encouraging in regard to the instrument's ability to assess sensitivity towards treatment change.

Figure 3 – RUIS Score Histogram Pre-Treatment

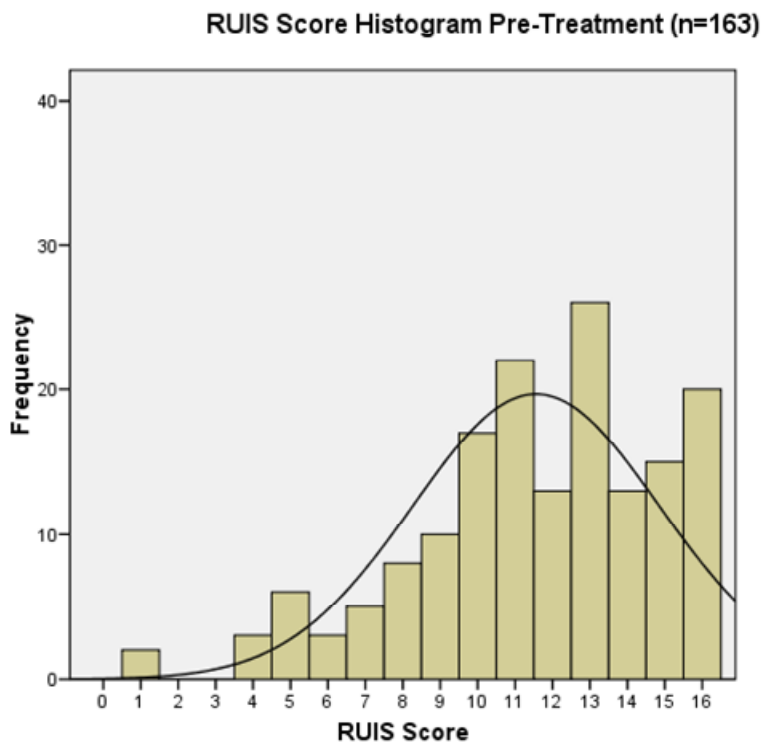


Figure 4 – RUIS Score Histogram Post-Treatment

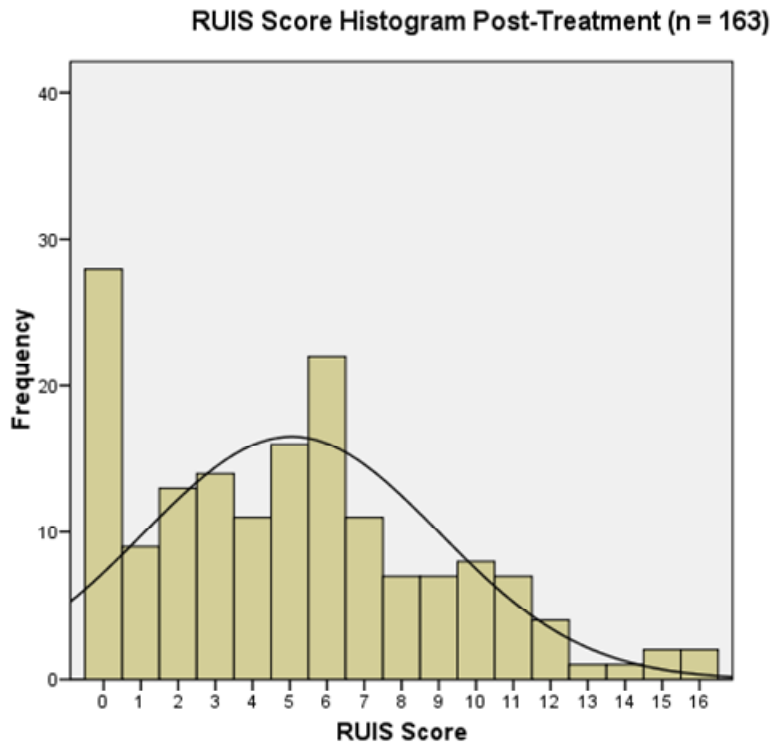


Table 6 examines the floor and ceiling effects on the RUIS for female patients in this clinical group. These percentage results are just within the acceptable limits of 15% at both extremities of the scale (Bot et al., 2004); with some minor refinement being required at the upper-end of the RUIS.

Table 6 – Floor and Ceiling Effects for the RUIS from the Patient Satisfaction Clinical Study

	%	Freq	N
RUIS Pre (retrospective)			
Percentage of clients at floor	0.0	0	163
Percentage of clients at ceiling	12.3	20	163
RUIS Post (current)			
Percentage of clients at floor	17.2	28	163
Percentage of clients at ceiling	1.2	2	163

Discussion

From this psychometric analysis, the Revised Urinary Incontinence Scales (RUIS) was developed and it appears to have better psychometric properties than the original measures. However, one of the limitations of this study is that it uses community survey data that is collected from face to face interviews. This data is at the level of subjective reports of incontinence symptoms rather than

confirmed diagnoses. This community survey approach will also exclude those currently placed in institutional settings (e.g. nursing homes).

These considerations mean that in a community survey there will be a limited range of responses to incontinence items particularly those pertaining to the more severe levels of symptoms. It will thus be necessary to trial the revised measure in a range of clinical settings in follow-up field trials - specialist continence clinics, general practice and community care settings, as well as residential care settings. (It is also noted that there is limited Australian prevalence data available for continence conditions for those in aged care residential.) In summary, further research is needed to examine the broader applicability of the RUIS and the other measures in clinical settings (where there would also be a greater number of people with moderate to severe incontinence symptoms). The Patient Satisfaction Clinical Study reported here presents some promising preliminary data with female patients in this regard.

Clinical field trials in different settings would enable the datasets to be merged and would permit a more comprehensive analysis, and by replication allow for a more definitive conclusion concerning the revised measure (i.e. confirming whether the RUIS has superior psychometric properties in clinical settings).

Recently developed questionnaires could also be included in the proposed clinical field trials. These include: the patient-rated global assessments of treatment benefit, satisfaction and the willingness to continue treatment (Pleil et al., 2005), and the Patient Global Impression of improvement and severity for incontinence (Yalcin and Bump, 2003).

Conclusions

From a psychometric examination of the properties of the ISI and the UDI-6, a new scale, the RUIS, was developed. The RUIS has good psychometric properties and could be considered by clinicians, researchers and epidemiologists looking for a short, valid and reliable scale of urinary incontinence (as defined by leakage). It is noted that this scale has been derived from statistical modelling and it is currently being further assessed in clinical settings. Some clinical data has been collected during a recent patient satisfaction study but further clinical data, particularly from males, needs to be collected.

Attachment A provides a copy of the instrument and its scoring instructions.

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ATTACHMENT A

Revised Urinary Incontinence Scale (RUIS)

Do you experience and if so how much are you bothered by:

1. **Urine leakage related to the feeling of urgency**
 - *Not at all (0)*
 - *Slightly (1)*
 - *Moderately (2)*
 - *Greatly (3)*

2. **Urine leakage related to physical activity, coughing or sneezing**
 - *Not at all (0)*
 - *Slightly (1)*
 - *Moderately (2)*
 - *Greatly (3)*

3. **Small amounts of urine leakage (drops)**
 - *Not at all (0)*
 - *Slightly (1)*
 - *Moderately (2)*
 - *Greatly (3)*

4. **How often do you experience urine leakage?**
 - *Never (0)*
 - *Less than once a month (1)*
 - *A few times a month (2)*
 - *A few times a week (3)*
 - *Every day and/or night (4)*

5. **How much urine do you lose each time?**
 - *None (0)*
 - *Drops (1)*
 - *Small splashes (2)*
 - *More (3)*

References:

Sandvik H, Seim A, Vanvik A and Hunskaar S (2000) *A severity index for epidemiological surveys of female urinary incontinence: Comparison with 48-hour Pad-Weighing Tests.* Neurourology and Urodynamics. Vol. 19, pp. 137-145.

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Revised Urinary Incontinence Scale Scoring Instructions

People respond to the Revised Urinary Incontinence Scale (RUIS) questions by selecting one particular response option from the set of standard response options for each question. These response options can then be scored by using the numbers presented in brackets to the right of each response option. The RUIS total score is then calculated by adding up a person's score for each question. Adding the score for each of the five questions results in a possible score range of 0 - 16. At this stage, there is no data about grouping people into valid clinical categories representing different severity levels of incontinence (e.g. mild, moderate, or severe); however, further clinical research is being undertaken to provide this information.

This scale includes both questions from the Incontinence Severity Index (ISI; Sandvik, Seim, Vanvik, and Hunskaar, 2000) and therefore an ISI score can also be calculated. This is done by multiplying the scores from questions 4 and 5, resulting in a score range from 0 to 12, where a 0 score represents no incontinence. Scores from 1 to 12 are grouped into the following four severity levels:

- 1 - 2 = slight
- 3 - 6 = moderate
- 8 - 9 = severe
- 12 = very severe

Finally, users should check that each question has a response option selected in order to avoid any missing data. This is because missing data can not be adjusted for in short scales like the RUIS.

Reference:

Sandvik H, Seim A, Vanvik A and Hunskaar S (2000) *A severity index for epidemiological surveys of female urinary incontinence: comparison with 48-hour pad-weighing tests.* Neurourology and Urodynamics. Vol. 19, pp. 137-145.