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Validity of the incontinence severity index: comparison with pad-weighing tests

Received: 5 January 2004 / Accepted: 23 November 2005 / Published online: 18 March 2006
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Abstract The incontinence severity index (ISI) consists of two questions, regarding frequency and amount of leakage. It categorizes urinary incontinence (UI) into slight, moderate, severe, and very severe. The purpose of this study was to test its validity. The index was compared with the results of pad-weighing tests performed by 200 incontinent women referred to a hospital clinic and 103 at a primary care incontinence clinic. Inconvenience was scored by a six-level Likert scale. Mean pad-weighing results (grams per 24 hours, 95% confidence intervals) were 7 (4–10) for slight, 39 (26–51) for moderate, 102 (75–128) for severe, and 200 (131–268) for very severe UI. Spearman's correlation coefficient for pad-weighing results and severity index was 0.58 ($p < 0.01$), and inconvenience increased significantly with increasing severity. The ISI demonstrated good criterion validity against 24-h pad tests. Good construct validity was indicated by a clear link between ISI and inconvenience.

Keywords Urinary incontinence · Severity of illness index · Pad-weighing tests · Comparative study

Introduction

Many authors have investigated the prevalence of female urinary incontinence (UI), often with widely differing

prevalence estimates, even when seemingly comparable settings and age groups have been studied [1]. Some studies have included large numbers of women with only slight leakage, who would probably object to being labeled incontinent. The 2nd International Consultation on Incontinence recommended development of standardized instruments for epidemiological research, including a screening question, frequency measure, quantity of urine loss, duration, type, and severity [1].

The incontinence severity index (ISI) was developed for use in epidemiological surveys to identify women with different severity of urinary leakage. It consists of two questions, regarding frequency (four levels) and amount (three levels) of leakage (Table 1). The ISI has been validated against pad tests in several studies [2–4]. Due to limited power, the first study was only able to validate a simplified three-level version of the ISI [2]. In a second study, more women were included, and we were able to show that the full four-level index was just as valid [3]. We recommend using the four-level index since it also gives a more balanced distribution in clinical materials.

The ISI has also been validated by a Scottish group who demonstrated that its reliability and responsiveness were also good [4]. Over the years, the ISI has been used in many different studies of UI, both epidemiological [5–10] and clinical [11–16], and it has received the highest recommendation from the 2nd and 3rd International Consultation on Incontinence [17, 18].

Maximum utility of the ISI requires that it can demonstrate validity in different countries and different clinical settings (primary and secondary care). The purpose of this study was to test its validity in a Spanish sample.

Materials and methods

The ISI was translated from English to Spanish and from Norwegian to Spanish by two independent translators

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Table 1 Questions used to assess the degree of UI in women

English	Spanish
<i>How often do you experience urinary leakage?</i>	<i>¿Con que frecuencia se le escapa la orina?</i>
1. Less than once a month	1. Menos de una vez al mes
2. A few times a month	2. Algunas veces al mes
3. A few times a week	3. Algunas veces a la semana
4. Every day and/or night	4. Todos los días y/o noches
<i>How much urine do you lose each time?</i>	<i>¿Qué cantidad de orina se le escapa cada vez?</i>
1. Drops	1. Gotas (muy poca cantidad)
2. Small splashes	2. Chorro pequeño (una cantidad moderada)
3. More	3. Mucha cantidad

The severity index is created by multiplying the results of the two questions, and then categorizing it as follows: 1–2=slight, 3–6=moderate, 8–9=severe, 12=very severe
For statistical purposes in follow-up studies, we recommend adding the value 0 (zero) for those who become continent

who thereafter agreed upon the final version of the questionnaire.

The study was conducted in 2004 among 200 incontinent women referred to the urogynecology unit at the Hospital Clínic, University of Barcelona, and among 103 incontinent women referred to a primary care incontinence clinic. Patients with stage III and IV prolapse were excluded from the study.

All the women were asked to perform a pad test at home [19–21]. They were instructed to wear preweighed pads day and night during a 24-h period. Each pad was packed in a bag marked with the patient's details and the dry weight of the pad. The women changed pads when required, putting used pads back into their bags. The pads were returned to the clinic for reweighing, and the weight gain was noted.

Before performing the pad test, all the women were categorized via the ISI. They were asked how often they experienced urinary leakage and how much urine they

usually lost each time. Frequency (four levels) was multiplied by the amount of leakage (three levels). The resulting index values (1–12) were further categorized into slight, moderate, severe, and very severe (Table 1).

A patient was considered to have stress incontinence if she answered affirmatively to the question: "Do you have urine leakage when you cough, sneeze, make an effort or do physical exercise?" Likewise, she was considered to have urge incontinence if she answered affirmatively to the question: "Do you have urine leakage when you have a sudden feeling of wanting to pass water and you can't hang on long enough?" If she answered affirmatively to both questions, she was considered to have mixed incontinence.

Patients attending the hospital clinic were also subjected to urodynamic evaluation, and they were asked how much they were inconvenienced by their incontinence symptoms: "In the past month (30 days), when you have experienced UI symptoms, how much did they incon-

Table 2 Distribution of type and severity of UI among women recruited from hospital and primary care in Spain

	Spain			Norway
	Primary care (n=103)	Hospital (n=200)	All (n=303)	All (n=315)
Mean age (years)	59	58	58	54
Type of incontinence (%)				
Stress	55	53	54	54
Urge	19	18	19	8
Mixed	24	24	24	37
Other/none	1	6	4	1
Severity of incontinence (%)				
Slight	9	9	9	12
Moderate	53	34	41	50
Severe	28	41	37	28
Very severe	9	16	14	10

For comparison, results from a similar Norwegian study is included [3]

Inconvenience

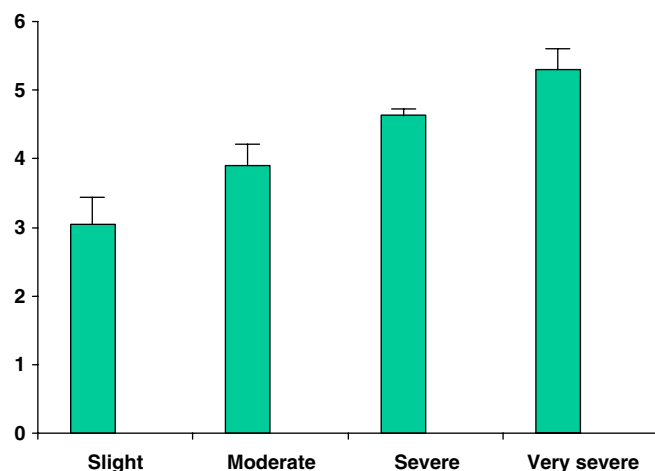


Fig. 1 Reported inconvenience (mean scores with 95% CIs) associated with increasing levels of the severity index

venience you?" They were made to choose among six answers, scored from 1 to 6 (not at all, slightly, somewhat, moderately, very much, and extremely).

Results of the pad tests (grams per 24 hours) are presented as means with 95% confidence interval (CI) and medians. *t* tests were used when comparing means, whereas chi-square tests were used when comparing proportions. Spearman's correlation coefficients (*R*) were calculated when comparing pad tests with inconvenience score and severity index. Statistical significance was accepted at the 5% level ($p < 0.05$).

Results

Mean age of the women was 58 years (median 58, range 27–85), with no difference between hospital and primary care. Also, the distribution of different types of incontinence did not differ between hospital and primary care, but severity was greater in hospital when measured by the severity index ($p < 0.05$; Table 2). When measured by pad tests, however, the difference between hospital and primary care was not significant. The mean result of the pad tests was 78 g/24 h (95% CI 63–92, median 22, range 0–987). Five (2%) of the pad tests showed no weight gain.

The older half of the women (59 years and above) leaked more than the younger ones (100 vs 52 g/24 h, $p < 0.001$). Nevertheless, older women were not more inconvenienced by their incontinence than the younger ones (inconvenience score 4.0 vs 4.4). Reported inconvenience increased significantly with increasing severity of leakage when measured by the severity index (Fig. 1). Inconvenience also correlated significantly with the pad tests ($R = 0.49$, $p < 0.01$).

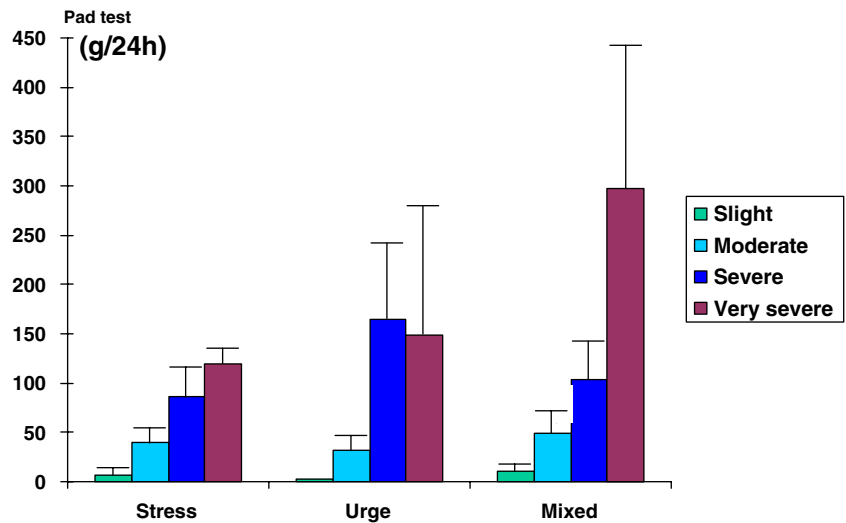
The severity index correlated significantly with the pad tests ($R = 0.58$, $p < 0.01$). Results of the pad tests according to reported amount and frequency of leakage as well as severity index are shown in Table 3. None of the differences between primary care and hospital was significant. Separate analyses of pad tests at different ISI levels were also carried out for stress, urge, and mixed incontinence (Fig. 2).

Table 3 Results of pad tests (grams per 24 hours) in hospital and primary care, according to reported amount and frequency of leakage as well as severity index

	Spain				Norway			
	Primary care (<i>n</i> =103)		Hospital (<i>n</i> =200)		All (<i>n</i> =303)		All (<i>n</i> =315)	
	Mean (95% CI)	Median	Mean (95% CI)	Median	Mean (95% CI)	Median	Mean (95% CI)	Median
Reported amount								
Drops	33 (17–48)	14	38 (17–59)	12	36 (23–49)	13	13 (9–17)	5
Small splashes	67 (30–103)	27	81 (57–105)	30	78 (58–98)	30	38 (29–47)	18
More	199 (39–359)	123	183 (117–249)	122	187 (126–249)	122	96 (65–128)	52
Reported frequency								
Less than once a month	7 (1–13)	8	9 (2–16)	7	8 (4–13)	7	6 (2–9)	4
A few times a month	23 (–10–56)	7	6 (2–9)	4	12 (1–24)	5	11 (7–16)	3
A few times a week	45 (12–78)	17	46 (13–79)	11	45 (22–69)	16	27 (15–39)	13
Every day and/or night	87 (47–126)	36	114 (88–139)	57	105 (84–126)	46	62 (49–75)	29
Severity index								
Slight	10 (2–17)	7	6 (3–9)	5	7 (4–10)	6	6 (2–9)	3
Moderate	32 (17–47)	14	44 (24–63)	17	39 (26–51)	14	23 (15–30)	10
Severe	100 (49–151)	37	102 (70–134)	42	102 (75–128)	38	52 (38–65)	25
Very severe	223 (–8–453)	123	193 (124–261)	126	200 (131–268)	123	122 (84–159)	87

For comparison, results from a similar Norwegian study is included [3]

Fig. 2 Results of pad tests (grams per 24 hours with 95% CIs) for different levels of severity and types of incontinence



Discussion

In this Spanish sample, the ISI clearly demonstrated good criterion validity against 24-h pad tests, like previously shown in Norway and Scotland [2–4]. Given the simplicity of the ISI, it would have been surprising if a Spanish version would behave differently. However, health measurement scales should always be tested for validity after having been translated into a new language. An additional strength of the present study is the fact that the validity was equally good in primary care and hospital. Although impaired by wide CIs, validity was also demonstrated for different types of incontinence. In addition, good construct validity was indicated by the clear link between ISI and inconvenience, also in line with previous studies [2].

Although the ISI demonstrated good validity in defining groups with different severity, there was considerable overlap in the range of pad test results between the four severity groups. This means that although the ISI is valid for clinical and epidemiological research, it should not be regarded as a substitute for pad-weighing tests in individual cases.

A pad test is not, however, a perfect “gold standard” for measuring UI severity, but a 24-h test correlates well with symptoms of incontinence and has good reproducibility [20]. However, Lose et al. [22] found the reproducibility of the 24-h test insufficiently satisfactory to recommend its use in comparative scientific studies. Increasing test duration to 48 or 72 h slightly increases reliability but decreases patient compliance [19, 21]. The 24-h pad test is considered to be positive if the pad weight gain is ≥ 4 g/24 h [20].

Recently, the 1-h pad-test definitions for mild, moderate, and severe incontinence were used to categorize the 24-h test values in a similar way. This revealed that moderate incontinence ranged from 21 to 74 g/24 h, with mild and severe incontinence below and above this range, respectively [23]. These results correspond well with our findings.

In the present study, the women defined as slightly incontinent had a mean pad weight gain of 7 g/24 h, compared with 6 g/24 h in a similar Norwegian study [3]. However, the mean pad weight gain in the total sample was 78 g/24 h, as opposed to only 39 g/24 h in the Norwegian study. This can at least partly be explained by the fact that there were more women with severe and very severe incontinence in the Spanish sample. The Spanish women were older than the Norwegians, and it is well known that the severity of incontinence increases with advancing age [1, 2, 5].

This tendency toward more severe incontinence may also explain why the mean pad weight gain is higher in the ISI category *very severe* in the Spanish sample. However, it cannot explain why the pad weight gain in Spain is also higher in the ISI categories *moderate* and *severe*. Since differences between mean test results in large groups cannot be explained by low reproducibility of the test, there may have been systematic differences in how the pad tests have been performed in Norway and Spain. In the Norwegian sample, 48-h tests were used (although results were given per 24 hours), and it is known that increasing the length of test periods may decrease patient compliance [21]. There were more completely negative tests in the Norwegian sample (8%), possibly an indication of lower compliance [3].

So far, only one study has looked into the reliability and responsiveness of the ISI. Hanley et al. [4] found that 88% of the incontinent women recorded the same (three-level) ISI category 3 days apart ($\kappa=0.78$). Furthermore, 60% moved to a lower ISI category after treatment. In the future, it is important to repeat these analyses in different settings, and it is our intention to do so in this Spanish sample.

Acknowledgement The study was supported by a research grant from Eli Lilly Spain to the Fundacion Clinic for Biomedical Research.

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