Concordance Between One-hour Pad Test and Subjective Assessment of Stress Incontinence


OBJECTIVES
To examine the concordance among the 1-hour pad test results, subjective questions regarding incontinence, and a quality-of-life questionnaire to assess the role of the pad test as a noninvasive measurement tool in clinical trials. The 1-hour nonstandard pad test is one of several quantitative tools used to measure urinary incontinence; however, its utility has been questioned.

METHODS
The study subjects were women participating in 2 clinical trials evaluating noninvasive interventions: circulatory muscle exercises versus pelvic floor muscle training for urinary incontinence. The quantity of urinary leakage according to the pad test and questions regarding subjective urinary leakage from the quality-of-life questionnaire were evaluated for all study subjects combined and in subgroups.

RESULTS
A total of 731 clinical pad tests were evaluated from the 2 trials. Significant associations were found between several questions regarding subjective leakage and the pad test results in the study subgroups. A significant correlation was seen between the pad test results and the quality-of-life questionnaire scores ($r = 0.14$ before intervention and $r = 0.42$ after intervention in the combined studies; $P < .05$).

CONCLUSIONS
The 1-hour pad test demonstrated concordance with subjective assessment tools for urinary incontinence and should be considered a part of the armamentarium for assessing the severity of this condition. UROLOGY xx: xxx, xxxx. © 2010 Elsevier Inc.

The 1-hour clinical pad test is 1 of several quantitative tools recommended by the International Continence Society for assessing the extent of urinary incontinence. The International Urogynecological Association has recently recommended the pad test for clinical studies to measure urinary leakage. The test is used as an objective assessment to distinguish between continence and incontinent patients and as an evaluation instrument before and after interventions. A 1-g gain in pad weight is considered a positive result (i.e., proof of incontinence). However, a wide variation has been seen in the 1-hour pad test results, although the reproducibility has been improved with standard bladder filling or ultrasound scanning.

Despite its disadvantages, for lack of a better clinical, noninvasive quantitative tool, we chose the 1-hour pad test (nonstandard, without catheterization) as the main assessment tool in 2 randomized clinical trials: a pilot trial and a community-based trial, testing the effectiveness of circulatory muscle exercises versus pelvic floor muscle training for stress urinary incontinence (SUI) in women. We assumed that women who chose to participate in a study of exercise treatment of SUI would not easily accept invasive testing. The 1-hour clinical pad test was followed by completion of a questionnaire that included items regarding subjective urinary symptoms and quality of life.

The present study's objective was to examine the association between the results of the 1-hour clinical pad test and the findings from subjective questions regarding urinary incontinence and a quality-of-life questionnaire to assess the role of the pad test as a valid quantitative tool for use in clinical trials. The construct validity of a tool is determined by consistent associations between the tool and other variables that reasonably link together. Because we did not use a reference standard objective measurement of urinary leakage, we inferred construct validity when the results of the pad test showed concordance with subjective measures of SUI.

MATERIAL AND METHODS
Women eligible to participate in both trials were aged 25-55 years, with a positive pad test result of at least 1 g of urinary leakage.

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leakage. Women with SUI complaints but without a demonstrated leakage of >=1 g on the pad test, those with genital prolapse of grade 3 or greater; pregnant or breastfeeding women; those within 12 weeks of delivery, 6 weeks of abortion, or 6 months of pelvic surgery, and those with any previous surgery for urinary incontinence, previous pelvic radiotherapy, or with a significant comorbidity that limited physical activity were excluded.8,9

All participants underwent quantitative and qualitative assessments of urinary leakage.

**Quantitative Assessment**

The 1-hour clinical pad test was performed in the pilot study according to the International Continence Society instructions, which include not voiding for 2 hours before the pad test and to wear a weighed pad.8,9 The participants were asked to sit and drink 500 mL of sodium-free water. Next, the women were instructed to walk for 30 minutes. The walk included going up and down 24 steps. On returning to the clinic, the participants were instructed to perform several activities, including standing and sitting 10 times, coughing vigorously 10 times, running in place for 1 minute, picking up an object from the floor 3 times, and putting their hands under water for 1 minute. After the activities were completed, the pad was weighed to measure the amount of urinary leakage.

From the results of the pilot study, the instructions were modified for the community-based trial. The participating women were instructed to avoid coffee/tea containing drinks for 2 hours before the test, to drink low-sodium (9 mg/L) water instead of sodium-free water, and to add 5 jumping jacks as a part of the physical activities. The 1-hour clinical pad test is intended to simulate the stimuli of everyday life. All nurses involved in performing the pad test had received previous training from the primary investigator. No urodynamic tests were performed.

**Qualitative Assessment**

The participants completed health and urinary leakage questionnaires. Questions regarding urinary leakage were determined from variables used in other validated questionnaires that had been partially modified to meet the needs of a Hebrew-speaking population8,9,10 and were pretested in the pilot study.9 Additionally, after Hebrew validation, we administered a quality-of-life questionnaire.11 The scoring was determined from 22 items, each measured on a 0-10 scale and subdivided into 3 subscores: (a) avoidance and limiting behavior score—8 items; (b) psychosocial impact score—9 items; and (c) social embarrassment score—5 items.12

**Ethical Issues**

The Hadassah-Hebrew University institutional review board (Helsinki Committee) approved both trials, and all women provided written informed consent after receiving an explanation of the study goals and procedures.

**Statistical Analysis**

The associations between the pad test results and subjective assessments of urinary leakage (amount, level of annoyance, and frequency of leakage in general and during the past week) were examined using linear models. The associations between the pad test results and quality-of-life scores were evaluated using Pearson’s correlation coefficient, and confidence intervals were calculated using Fisher’s Z-transformation. Separate analyses were conducted for each study (pilot study and community-based trial) and of measurements taken before and after the intervention (the latter by intervention group). Finally, the results for the 2 studies were combined to obtain overall measures of association. In the combined analysis, the linear models were adjusted for study type, and the correlation coefficients and confidence intervals were combined using inverse variance weights.

**RESULTS**

A total of 731 pad tests were performed on 496 women (100 women from 2001 to 2002 in the pilot study and 396 women from 2004 to 2006 in the community-based trial). Of these, 35 (pilot study) and 151 (community-based trial) women did not enter the intervention trials because they had not met the inclusion criteria of a pad test result of >=1 g or had prolapse >2 cm, or met other exclusion criteria. A total of 59 (pilot study) and 147 (community-based trial) women met the inclusion criteria and participated in the interventions. A total of 59 women from the pilot study and 176 from the community-based trial were retested after 12 weeks of intervention. The remainder did not return for the postintervention pad test and thus only provided 1 observation to the study (Fig. 1).

Of the participants, 28 (48.3%) in the pilot study and 147 (61.5%) in the community-based trial were aged...
Table 2. Associations between pad test and subjective questions regarding urinary incontinence before and after intervention

<table>
<thead>
<tr>
<th>Computed Studies Before Intervention</th>
<th></th>
<th>Community-Based Trial After Intervention</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Pad Test</strong></td>
<td><strong>Results</strong></td>
<td><strong>Paula</strong></td>
</tr>
<tr>
<td>Amount*</td>
<td>Patients (n)</td>
<td>Mean ± SD</td>
</tr>
<tr>
<td>Few drops/small amount</td>
<td>152 (50.8)</td>
<td>7.6 ± 9.1 †</td>
</tr>
<tr>
<td>Moderate amount</td>
<td>123 (41.1)</td>
<td>13.4 ± 14.2</td>
</tr>
<tr>
<td>Large amount</td>
<td>17 (5.7)</td>
<td>16.7 ± 14.5</td>
</tr>
<tr>
<td>Annoyance</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Not at all/seldom</td>
<td>16 (5.4)</td>
<td>7.0 ± 8.8</td>
</tr>
<tr>
<td>Sometimes</td>
<td>97 (32.7)</td>
<td>9.7 ± 11.7</td>
</tr>
<tr>
<td>Often/very often</td>
<td>187 (62.0)</td>
<td>11.3 ± 12.7</td>
</tr>
<tr>
<td>Frequency</td>
<td></td>
<td></td>
</tr>
<tr>
<td>≥1x/mo/once every 2 mo</td>
<td>20 (7.0)</td>
<td>6.5 ± 6.2 †</td>
</tr>
<tr>
<td>≥1x/wk</td>
<td>86 (30.0)</td>
<td>8.1 ± 10.5</td>
</tr>
<tr>
<td>Leakage during past week</td>
<td>121 (63.1)</td>
<td>12.3 ± 13.3</td>
</tr>
<tr>
<td>Never</td>
<td>25 (8.7)</td>
<td>5.2 ± 6.0 †</td>
</tr>
<tr>
<td>Once-twice</td>
<td>133 (46.3)</td>
<td>8.9 ± 10.6</td>
</tr>
<tr>
<td>Three times or more</td>
<td>129 (44.9)</td>
<td>13.1 ± 13.6</td>
</tr>
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Paula, circular muscle exercises; PFMT, pelvic floor muscle training.

Data in parentheses are percentages.

* Some categories were combined owing to distribution of participants' responses.
† P < .01.
‡ P < .05.

20-50 years and 30 (51.7%) and 92 (38.5%) were aged 51-65 years, respectively (Table 1). SUI was reported by 97% (pilot study) and 99% (community-based trial) of the participants, and 50% (pilot study) and 43% (community-based trial) of the participants reported mixed incontinence (ie, also had feelings of urgency). The mean pad test results were 10.4 ± 15.6 g in the pilot study and 11.5 ± 15.3 g in the community-based trial before the intervention. Two outliers with baseline results of 106.2 g from the pilot study and 138.5 g from the community-based trial were not included in the results (Table 1).

In the combined studies, significant associations were found between the pad test results and questions regarding the leakage amount and leakage frequency during the past week before the intervention. For example, of the women reporting leakage of "a few drops" or "a small amount," the mean pad test result was 7.6 ± 9.1 g compared with 16.7 ± 14.5 g among those reporting "a large amount" (P < .01; Table 2).

After the interventions, in the community-based trial, all subjective questions showed significant associations with the pad test results in both exercise groups, with the exception of the frequency question in the circular muscle exercises group (Table 2).

Before the intervention, the analysis on the results from both studies noted a statistically significant correlation of 0.14 between the pad test results and the quality-of-life total score (P < .05). Similar correlations were observed for the scores of avoidance and limiting behavior and for psychosocial impact. The combined analysis of measurements taken after the intervention showed substantial correlation coefficients between the pad test results and overall quality of life, with subscores of 0.77-0.42 (P < .05; Table 3).

**COMMENT**

To assess the role of the pad test as a valid tool in measuring female SUI we analyzed our pad test experience and assessed the concordance between the pad test results and subjective urinary question results and responses regarding female incontinence using a quality-of-life questionnaire. The pad test was performed on 56 women and served as both a useful diagnostic tool for confirming SUI and as a quantitative test to assess urinary leakage before and after an intervention. To the best of our knowledge, this is 1 of the largest reported databases using the 1-hour clinical pad test and evaluating its performance characteristics. The test was easy to perform and relatively inexpensive and was considered an acceptable tool by the women tested.

In addition to the advantages of this tool, it has some disadvantages. A total of 35 women (35%) were excluded from our pilot study and 147 (31.1%) excluded from the community-based trial. These women reported symptoms of urinary leakage and were interested in entering the studies but did not show urinary leakage with the 1-hour pad test using a threshold of 1 g. These findings were similar to those from other studies in which 30% of women reported that the pad test results, followed by ultrasonography, did not represent their normal leakage. A 1-g threshold excluded some incontinent women from the study, because they did not meet the inclusion criteria. An option exists of repeating the test, and we did so in some cases, but the problem remains if, with the
repeated test, the threshold has not been achieved. Ringhamer et al.\textsuperscript{16} suggested that in questionable cases, a urine tracing method be used to avoid the predetermined cutoff level, and Arvonen et al.\textsuperscript{17} recommended additional tests under specific conditions for those women who experienced urinary leakage that could not be demonstrated. To enhance our ability to study the incontinent women, we added an additional provocation in the community-based trial, namely 5 jumping jacks, to stimulate leakage.\textsuperscript{9} The ratio between the tested women and eligible women changed from 1:1.5 in the pilot study to 1:1.6 in community-based trial; thus, resulting in decreases in the length of the study’s measurement and its costs. This relation might have also resulted from a deviation from the International Continence Society recommendations used in the pilot study,\textsuperscript{1} by asking the participants to avoid caffeinated drinks 2 hours before the test in the community-based trial. In contrast, other trials required drinking avoidance for 24 hours before the test.\textsuperscript{15} Also, we changed the protocol in the community-based trial to include low-sodium water (9 mg/L) instead of sodium-free water,\textsuperscript{19} in addition to added jumping jacks, as reported in another trial.\textsuperscript{20} We found these modifications contributed to the standardization of the test and increased the number of potentially eligible women. Other researchers have modified the pad test by adding an ultrasound scan before conducting the pad test to measure the functional bladder capacity and showed good test-retest reliability.\textsuperscript{7} It is clear that standardization is lacking and acceptable guidelines are needed.\textsuperscript{5,21}

We found a significant association between the subjective questions regarding urinary leakage and the pad test results in both studies after the intervention, but it was not as strong as the correlation found between subjective reports of leakage frequency and volume and the pad test results that was reported by Jackson et al.\textsuperscript{12} (r ≥ 0.5). However, their population entered the study after urodynamic evaluation, which could have contributed to the stronger correlation.\textsuperscript{12} Abdel-fattah et al.\textsuperscript{11} showed a correlation of \( r = 0.48 \) between a leakage severity scale and the pad test results. The difference between the results might have resulted from their use of a general scale regarding urinary incontinence versus our specific questions regarding the amount, frequency, and so forth and their use of the standard pad test.

We found a significant, but modest, correlation between the pad test results and the scores of the quality-of-life questionnaire, a validated measure of the quality of life with incontinence,\textsuperscript{22,23} before the intervention (r = 0.143) and a substantially significant correlation after the intervention (r = 0.472). The smaller correlation coefficient observed before the intervention versus after stemmed from the truncated range that characterized the data before the intervention, because only women with pad test results of ≥1 g were recruited for the study.

It could be questioned whether the pad test is needed as a quantitative tool or whether questionnaires could

<table>
<thead>
<tr>
<th>Table 3. Estimated correlation coefficients and 95% confidence intervals for association between pad test and quality of life scores.</th>
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</thead>
<tbody>
<tr>
<td><strong>Quality of Life Scale Score</strong></td>
</tr>
<tr>
<td><strong>Total quality of life score</strong></td>
</tr>
<tr>
<td>Paula</td>
</tr>
<tr>
<td>PFMT</td>
</tr>
<tr>
<td><strong>Aviation and limiting behavior</strong></td>
</tr>
<tr>
<td>Paula</td>
</tr>
<tr>
<td>PFMT</td>
</tr>
<tr>
<td><strong>Psychosocial impact</strong></td>
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<tr>
<td>Paula</td>
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<tr>
<td>PFMT</td>
</tr>
<tr>
<td><strong>Social embarrassment score</strong></td>
</tr>
<tr>
<td>Paula</td>
</tr>
<tr>
<td>PFMT</td>
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</tbody>
</table>

**Abbreviations as in Table 2.**
used alone, such as was concluded by Abdel-fattah et al. 22 The pad test is 1 of few quantitative tools used for assessing urinary incontinence, and, despite its low reproducibility, no superior, noninvasive clinical tool is available. In women with SUI after urodynamic evaluation, Franco et al. 24 described low correlations between the pad test results and a variety of questionnaires, with the greatest correlation of 0.177 found between the pad test results and quality-of-life questionnaire results. In our studies, the population did not undergo urodynamic testing, which might have influenced the correlation results.

In contrast to the findings from Abdel-fattah et al., 22 we have demonstrated that the pad test is a useful tool, allowing quantitative comparisons before and after intervention. We believe it can serve as 1 element of the armamentarium that includes a detailed patient history and validated questionnaires that include questions of symptoms and quality-of-life measures. We agree with Nygaard 4 that physiologic and subjective outcomes should be measured in clinical trials because every tool can contribute to the clinical information. Listening to women's complaints and assessing their condition using a number of different tools could assist in tailoring suitable treatments to them.

CONCLUSIONS

The 1-hour pad test should be 1 of several assessment instruments used to measure female urinary leakage when used together with patient history and subjective questionnaires regarding urinary incontinence and quality of life.

References


