

## 8 HOURS HOME PAD TEST – A USEFUL INSTRUMENT FOR ASSESSMENT OF URINARY INCONTINENCE AND COMPARISON OF OUTCOMES

### Hypothesis / aims of study

To examine the 8 hours home pad weight gain (PWG) test as a valid medium-length assessment tool for urinary incontinence and as a comparison tool for success of treatments for stress urinary incontinence (SUI).

### Study design, materials and methods

A novel, disposable, flexible intra-vaginal device for the conservative treatment of SUI in women was tested for efficacy, safety and quality of life. Sixty women with severe SUI were recruited to wear pre-weighed pads during a 7-day control period followed by a 28-day device usage period along with the pre-weighed pad, for 8h daily, during the daytime. Women were instructed to carry on with their normal daytime activity during the whole length of the control and study periods, but also perform predefined physical activity at least once, before emptying their bladder. They were allowed to use as many pads as they needed. There were three reasons for using the pad test for 8 hours daily - the need to have a long enough daily investigation period, the wish to gain good participants' compliance, and the ability for daily monitoring of PWG, as research nurses arrived every night at participants' homes to collect and weigh the used pads.

Meta-analysis was performed on 23 articles from the literature, 10 dealing with 24 hours home pad tests (including 2230 subjects), 7 dealing with 48 hours home pad tests (including 798 subjects), and 7 articles dealing with a 1 hour office test (according to ICS guidelines, 1119 subjects). 1 article dealt with both 1 hour and 24 hours tests. Results were compared with those achieved during the 8 hours PWG test.

### Results

60 women were recruited, and 50 (83%) completed the study. Among the group of study completers PWG decreased by 86%, from an average of 16.85gr/8h to 1.96gr/8h. Over the entire 28-day device usage period, daily 8 hours PWG decreased steadily during the first 6 days of device usage and remained stable at approximately 2g/8h from day 7 through the end of the device usage period. 47 women (94%) achieved a  $\geq 70\%$  reduction in PWG ( $P < 0.001$ ). Mean total score for IIQ-7 decreased from 41.89 to 4.41 at pre and post-study visits, respectively ( $P < 0.001$ ), and mean score for UDI-6 decreased from 48.22 to 11.56 at pre and post-study visits, respectively ( $P < 0.001$ ). The percentage of patients reporting any incontinence episodes on any particular day decreased from 100% at baseline to 8% at the end of the study.

The 8 hours PWG test was found to be very easy to perform, participants' compliance was high, and there was still enough time for the daily collection of used pads.

Meta-analysis showed no statistical difference between 24 and 48 hours home tests, regarding the average PWG, being 1.81 g/h for 24h tests and 3.05 g/h for 48h tests ( $p=0.09$ ). The difference between the average 8 hours test PWG (2.05g/h) versus the 1 hour test PWG (28.66g/h) was statistically significant ( $p=0.009$ ) and so was the difference between the 24/48 hours tests versus the 1 hour test ( $p < 0.001$ ). However, there was no significant difference between average 8 hours test PWG (2.05g/h) and average 24/48 hours tests PWG (3.14g/h) ( $p=0.65$ ).

### Interpretation of results

Various pad tests are frequently used to determine the existence of urinary leakage, to compare severity of incontinence, and to define success of treatments. Short (office) tests are easy to perform, last ~60 minutes (range 20-120) and the average leakage (gr/1h) is usually high. These tests do not always reflect the true daily incontinence. Long (home) tests last 24/48 hours, better reflect the daily leakage, but compliance of patients may be low due to their length. There is a need for an intermediate length home test which will reflect severity of incontinence over a relatively long period of time, that will also enable researchers to repeat testing as needed, with good patients' compliance.

Average PWG/h during the home 8 hours PWG test was found to be close to the average PWG/h during the 24/48 hours tests. Correlation between the 8h test pad weight reduction to two other efficacy parameters (IIQ-7 and UDI-6 questionnaires) was positive and significant ( $p$ -values of 0.031 and 0.001, respectively). This indicates that the 8h test positively correlates to other efficacy measures.

### Concluding message

The intermediate length 8 hours home PWG test is a useful tool, comparable to the long 24/48 hours home PWG tests. Due to its several advantages for both patients and researchers, including low burden on daily life and high compliance, there is a higher ability to recruit participants and perform longer surveys. It may therefore be considered as a simple and reliable way for comparison of results before and after treatments.

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<b>Is this a clinical trial?</b>	Yes
<b>Is this study registered in a public clinical trials registry?</b>	No
<b>What were the subjects in the study?</b>	HUMAN
<b>Was this study approved by an ethics committee?</b>	Yes
<b>Specify Name of Ethics Committee</b>	Assuta Medical Centers, Tel-Aviv, Israel & Hasharon Medical Center, Petach Tikva, Israel
<b>Was the Declaration of Helsinki followed?</b>	Yes
<b>Was informed consent obtained from the patients?</b>	Yes