

## VALIDITY AND RELIABILITY OF A PAD TEST IN QUANTIFYING A SIMULATED URINE LEAK IN HEALTHY CONTINENT FEMALES

### Hypothesis / Aims of Study

The pad test is a common measure of assessing the degree of urinary incontinence. However, there are still unresolved issues regarding the test's validity and reliability, such as pad brand and the duration of the test [1,2]. The purpose of this study was to assess the validity and reliability of a super-absorbent urinary continence pad in quantifying urine leak. A simulated urine leak using 0.9% saline and two sequential 12 hr time blocks (AM and PM) were used as a model system. The primary hypothesis was that there would be no difference between pre and post  $12 \pm 2$  hr pad weights. The secondary hypothesis was that pre and post  $12 \pm 2$  hr pad weights would be equivalent for AM and PM time blocks.

### Study Design, Materials and Methods

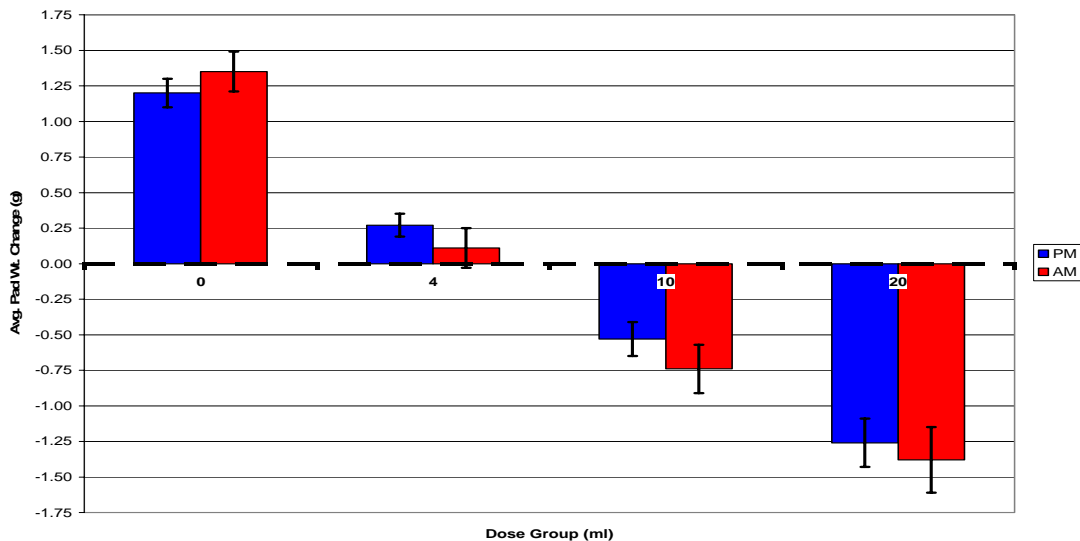
This study was an IRB-approved prospective study using healthy continent female volunteers consisting of medical school staff, faculty, students, and students' spouses. Commercially available super absorbent urinary incontinence pads (Extra Plus, Tena®, Eddystone, PA) were used in this study. Each pad was pre-dosed with 0.9% saline (0 ml, 4 ml, 10 ml or 20 ml) and presented in random order to simulate varying degrees of urine leak from and was worn according to manufacturer's direction for  $12 \pm 2$  hrs. Two twelve-hour time blocks (AM and PM) were used to approximate the 24 hour pad test. Each subject wore a total of 16 pads, consisting of two AM and two PM sessions for each pad dose over an eleven-day period. The key measurement was the change in pad weight over a  $12 \pm 2$  hr period

### Results

Twenty-five subjects completed the study. The primary null hypothesis (i.e.,  $Wt_{0hrs} = Wt_{12hrs}$ ) was rejected. The average change in pad weight for each dose of saline ( $\pm$  SEM) was as follows: 0 ml,  $1.27 \pm 0.09$  g; 4 ml,  $0.19 \pm 0.08$  g; 10 ml,  $-0.63 \pm 0.10$  g; 20 ml,  $-1.32 \pm 0.14$  g. These data are depicted in the figure below. There were no statistically significant differences between the AM and PM results at any pad dose. Thus, the secondary hypothesis (i.e.,  $Wtchange_{PM} = Wtchange_{AM}$ ) was not rejected.

Fig

1.



### Interpretation of Results

The same brand of extra-absorbent pads was used throughout the study to minimize the effects pad brand on the results. Pad weight in the 0 ml dose group showed a weight increase of  $1.27 \pm 0.09$  g, reflecting a net gain over the 12 hr period. These data indicate that pads worn by normal, healthy continent females show a small and consistent weight gain, which may be used as a baseline when determining whether or not a patient is continent. Bodily secretions and evaporative loss contribute to the uncertainty in the measurement, and should be taken into consideration when using this methodology to quantify urine leakage.

### Concluding Message

In this study normally continent females demonstrated a net gain in dry pad weight over a 12 hour period. This gain should be taken into consideration when using this methodology to quantify urine leakage. The results of this study indicate that the 2x12 hr pad test can be used as an effective and reliable measure of urine leak; being more practical and less invasive than short duration tests that require bladder loading (e.g., 1 hr rapid pad test). Methodological uncertainties need to be taken into consideration when applying these techniques.

1. 2<sup>nd</sup> *International Consultation on Incontinence*, 2<sup>nd</sup> Edition 2002. Committee 8C: 462-463.
2. The 24-Hour Pad Test: Pad Composition Affects Accuracy. International Continence Society, Annual Meeting, Paris, 2004, Abstract # 122.

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