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THE LEAK SCORE – A NOVEL INSTRUMENT TO ASSESS SUBJECTIVE SEVERITY OF FEMALE STRESS URINARY INCONTINENCE AND EFFICACY OF TREATMENT

Hypothesis / aims of study:
To assess validity and reliability of a novel scoring system designed to define perception of urinary leakage by women, during various daily physical activities. This scoring system serves as an instrument for defining subjective severity of stress urinary incontinence (SUI) and for comparing success of treatment.

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, initially during a 7-day control period, and then during a subsequent 28-day device usage period. Pads were worn for 8h daily, during the daytime.
The Leak Score, an author compiled scoring system, was used to measure the perception of leakage by assessing the influence of 8 different effort demanding activities - coughing, laughing, sneezing, walking, running, jumping, lifting and gymnastics - on urinary leakage. Possible responses were "not at all", "slightly", "moderate", "greatly", and "irrelevant", respectively scored as 0, 1, 2, 3, and NA. Additional study endpoints were the % reduction of PWG, the percentage of women who achieved ≥ 70% PWG reduction, and the percentage of patients reporting any incontinence episodes on any particular day. Quality of life was assessed by using IIQ-7 & UDI-6 questionnaires.

Results
50 women (83%) completed the study. 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 ≥ 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.

Interpretation of results
Clinicians evaluating patients after surgical or non-surgical procedures are mainly interested in a patient's subjective perception of being dry. Quality of life questionnaires are used primarily for research purposes and are not typically employed in day-to-day clinical practice. Subjective perception of improvement may be the most important measure of success for any treatment of SUI. Therefore, this newly developed questionnaire was designed to provide an efficient tool for assessment and comparisons.
The Leak Score questionnaire demonstrated statistically significant improvements in mean total and all subscale scores by the end of the study (all *P* values < 0.001). Mean total score for the Leak Score decreased from 89.4 to 22.3 at pre and post study visits. This scoring system has a good reliability, with Cronbach Alpha = 0.86. Changes in the Leak Score positively correlated to other subjective and objective measures (% reduction of PWG and total scores of IIQ-7 & UDI-6, correlation coefficients ranging from 0.48 to 0.70, all p<0.0001), demonstrating the questionnaire's concurrent validity. The relation between leak score results and the presence of rectocele proved to be insignificant (p=0.301) demonstrating the questionnaire's divergent validity

Concluding message
The Leak Score questionnaire is a reliable and valid instrument to assess the degree of perception of urinary leakage while performing various effort demanding activities, and as a subjective measure of treatment success.

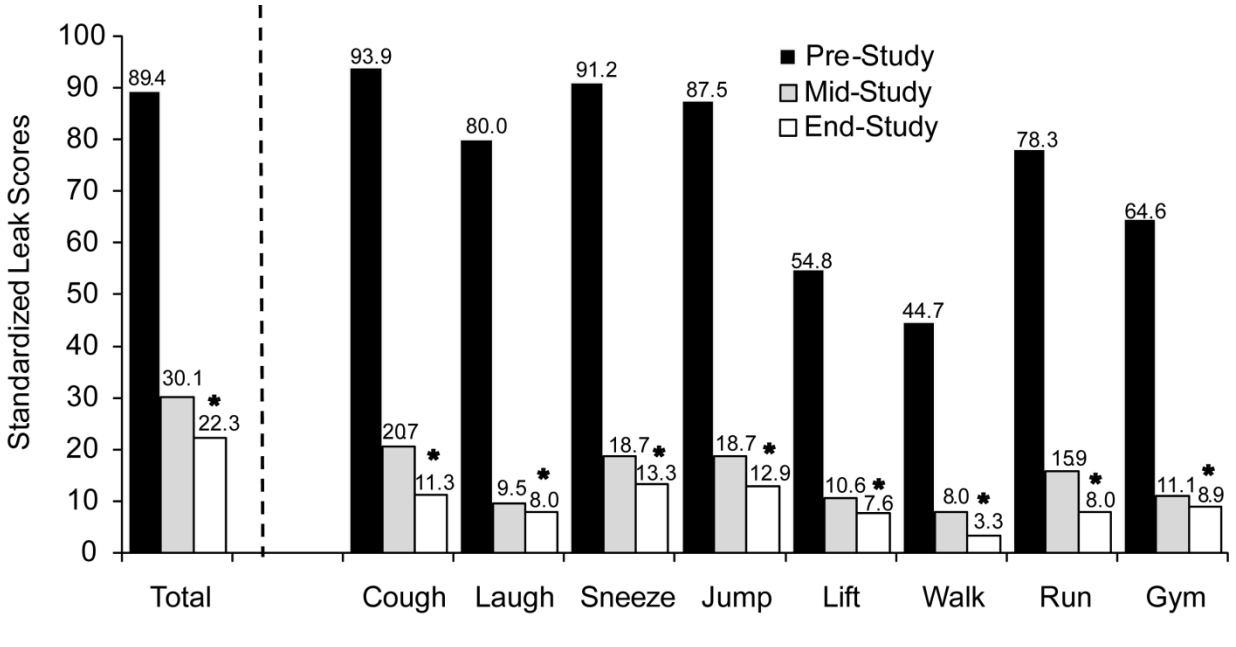

Figure:
Results of the Leak Score. Perception of leakage during the 8 different activities (before the study, during, and by the end) is demonstrated for comparison (All P-values < 0.001).

Specify source of funding or grant	**ConTIPI Ltd, Medical Devices, sponsored the study as part of its research & development of medical devices**
Is this a clinical trial?	**Yes**
Is this study registered in a public clinical trials registry?	**No**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**Yes**
Specify Name of Ethics Committee	**Assuta Medical Centers, Tel Aviv, Israel & Hasharon Medical Centers, Petach Tikva, Israel**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**