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A NOVEL SELF INSERTED INTRA-VAGINAL DEVICE IS SIGNIFICANTLY IMPROVING QUALITY OF LIFE OF WOMEN WITH URINARY STRESS INCONTINENCE

Aims of study
Stress urinary incontinence (SUI) is a common condition that significantly impairs quality of life and distresses many women. Conservative treatments are few and have lower success rates than surgery. We have developed a novel, disposable, intra-vaginal device for treatment of SUI in women. Aim of the study was to assess improvement in quality of life (QoL) in women before and during treatment with the device.

Study design, materials and methods
This non absorbable tampon-like device is inserted vaginally by the woman using an applicator. After insertion, the device opens to produce sub-urethral, tension-free support. By the end of use, the device is removed by a pull of a string for disposal. This multi-centre open-label study enrolled women with severe SUI. Inclusion criteria included age 18-70 years, familiarity with the use of vaginal tampons, SUI as determined by urodynamic assessment, and normal voiding without abnormal residual urine. Each woman underwent 1 day of pre-treatment assessment, 7 days of a control period during which she wore a pre-weighed pad for 8 hours daily for measurement of Pad Weight Gain (PWG), 28 days of device usage with same pre-weighed pads, and 1 day of post-study assessment. Direct questioning regarding feeling of leakage and two validated questionnaires (IIQ-7 and UDI-6) were used to assess the effects of treatment on various domains of QoL. Quality of life questionnaires were used prior to the study, during a mid-study appointment, and at the post-study assessment. Direct questioning was done every night.

Results
60 women were enrolled, and 50 of them (83%) completed the study. The mean age was 50.6 years, with a range of 31 to 70. During the control period, PWG ranged between 5.29g/8h to 40.55g/8h, with an average of 16.85g/8h. PWG decreased steadily during the first 6 days of device usage and was stable from day 7 through the end of the study period at an average of 2.23g/8h (range 0.29-4.79g/8h), a mean reduction of 86±9% ($p<0.0001$). 40 of 50 patients (80%) experienced >80% reduction in PWG with use. During the last 3 weeks of use, women reported feeling dry on 92% of days.
Results of the IIQ-7 questionnaire showed a decrease from 8.72 points to 1.44 and 0.92 before, during, and after the study, respectively. The UDI-6 scores showed the same tendency, with a reduction from 8.68 points to 2.94 and 2.08, before, during, and after the study, respectively (Figure 1). For each questionnaire, the total score was statistically significantly lower during and after treatment compared with the pre-trial period (Duncan multiple comparison test for all pair wise comparisons), demonstrating an overall statistically significant improvement in the QoL (Table 1).

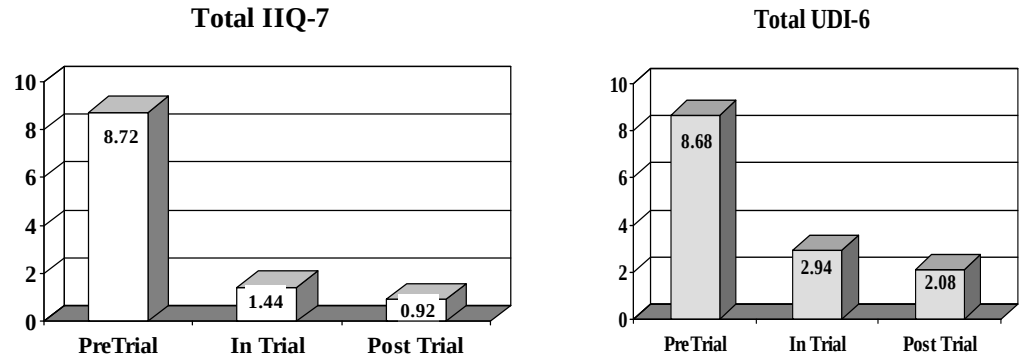

Figure 1: Total IIQ-7 & UDI-6 scores, before, during and after the study

		Pre study	Mid	Post study
Questionnaire	Time			
IIQ-7	Pre study		Significant	Significant
	Mid	Significant		
	Post study	Significant		
UDI-6	Pre study		Significant	Significant
	Mid	Significant		
	Post study	Significant		

Table 1: Duncan multiple comparison test for all pair wise comparisons, for IIQ-7 & UDI-6 before, during, and after the study

In all four domains of IIQ-7 (physical, travel, social & emotional), marked differences between pre-study and in-study scores were noted. In the UDI-6, such marked differences were noted for stress and irritative domains, but not for the obstructive one.

Interpretation of results

The new intra-vaginal device has shown itself to be highly effective in reducing urinary incontinence in women. Besides the beneficial objective effects, quality of life increased significantly. This QoL effect is achieved mainly due to the fact that participants have become continent again, but it is also possible that specific factors inherent within the device, such as being a conservative method of treatment, and the ease & comfort of use, have also contributed greatly.

Concluding message

Treatment of women suffering from SUI with the newly developed intra-vaginal device significantly improves QoL as assessed by 2 validated instruments.

FUNDING: ConTIPI Ltd, Medical Devices, funded the study as a regulatory trial during its development of incontinence aids

CLINICAL TRIAL REGISTRATION: This clinical trial has not yet been registered in a public clinical trials registry.

HUMAN SUBJECTS: This study was approved by the Assuta Medical Centers, Tel Aviv, Israel, Rabin Medical Center, Petah Tikva, Israel and followed the Declaration of Helsinki Informed consent was obtained from the patients.