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EFFICACY AND SAFETY OF A NOVEL INTRA-VAGINAL DEVICE FOR THE TREATMENT OF STRESS URINARY INCONTINENCE

Hypothesis / aims of study
Stress urinary incontinence (SUI) is a common condition that distresses many women. Conservative treatments are few and have lower success rates than surgery. We have evaluated the efficacy and safety of a novel disposable intra-vaginal device for treatment of SUI. The primary hypothesis was that device use will reduce urinary incontinence by 70%, demonstrated by reduction of Pad Weight Gain (PWG).
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 PWG, 28 days of device usage with same pre-weighed pads, and 1 day of post-study assessment. Peak Flow Rate (Qmax) and Post Void Residual urine (PVR) were compared with and without the device. Adverse Event (AE) reports were collected daily during the study
Results
60 patients were enrolled and 50 (83%) (Mean age 50.6 years, range 31-70) completed the study. 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) (Figure 1), 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.

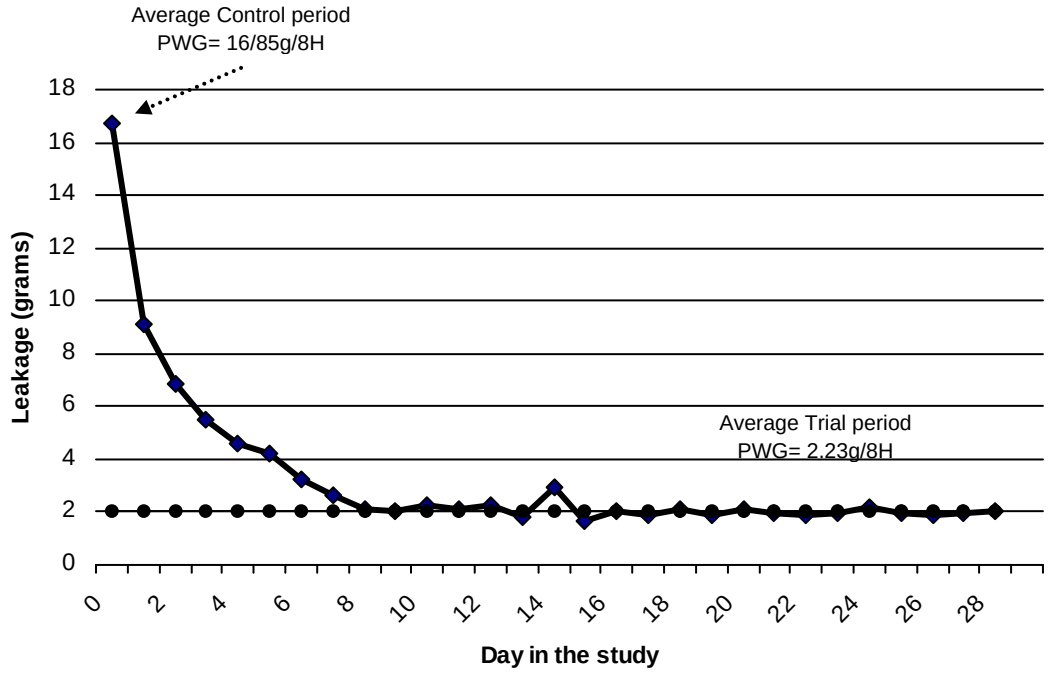

Figure 1: By the 7th day of device use, PWG decreased from an average of 16.85 g/8h during the control period to a stable average of 2.23 g/8h.

Participants were encouraged to report any unusual event. 41 participants (68%) reported some adverse events, all of them were mild. The most common AEs were discomfort, pain, and spotting, all from the genital tract. Overall there were 97 events over the 28 planned days of the study. Altogether there were 1475 days of trial; hence AE's occurred in 6.6% of the days. 78% of these events occurred during the first 2 weeks, while women were becoming accustomed to the device. No increase in infections (vaginal & urinary) or erosions of the vaginal mucosa were observed. There were no differences in Qmax and PVR before and during the study
Interpretation of results
Surgical procedures for treating SUI are considered to be more successful than the currently known conservative treatments. This novel, easy to use intra-vaginal device proves that conservative means of treatment may also have high success rate, yet being suitable for more women, regardless of accompanying illnesses and even with severe forms of incontinence.

After a short learning period, all of the participants in the study experienced a dramatic reduction of urinary leakage, and average PWG went down to low levels which may be seen in continent women. This effect is sustained during the whole length of use. Besides the drop in actual amount of leaked urine, frequency of incontinence dropped substantially to 8% only, after the first two weeks of device use.

Concluding message

This novel intra-vaginal device was highly effective in reducing SUI and was well tolerated.

FUNDING: ConTIPI Ltd, Medical Devices, funded the study as a regulatory trial during the 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.