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EFFECTIVENESS AND SAFETY OF A NEW DISPOSABLE VAGINAL DEVICE FOR THE NON-SURGICAL MANAGEMENT OF PELVIC ORGAN PROLAPSE (POP) IN WOMEN

Hypothesis / aims of study:

Most women, who suffer from POP, and desire treatment, can be successfully managed with non-invasive management. Currently, this involves using vaginal pessaries, mainly ring-shaped. Existing pessaries are reusable only devices which require medical assistance for insertion and removal, are used for long periods and are associated with discomfort, pain, bleeding, vaginal wall pressure trauma, discharge and smell.

A new disposable vaginal device for the management of POP was developed. The device is inserted vaginally in very small dimensions within an applicator, by the user herself, at her home environment. Within the vagina the device opens to become a ring of up to 91 mm (various sizes). Following insertion, the applicator is removed and discarded and the device may remain within the vagina for up to seven days, when the user pulls a string and the device collapses and is comfortably removed from the vagina in small dimensions, for disposal. The user may insert the next device immediately or later, at her will.

The aim of the study was to evaluate effectiveness (objective & subjective) and safety of the new disposable vaginal device, when used as intended by the user herself at her home environment.

Study design, materials and methods

The study was prospective, multi clinic, single arm, open label, hypothesis driven and statistically powered, home use performance study. Screening was conducted during visits 1&2. Following size fitting in visit 2, subjects were sent home with the device in situ for 40-80 hours to ascertain proper fit, and seen again during visit 3. Device usage period started following visit 3 and lasted 45 days, through visit 5. During that time subjects were allowed to use as many devices as they wished, for a period of 1-7 days each, to suit their needs and life style. Subjects were also examined during mid-study visit (4), about 2 weeks following visit 3. They were examined vaginally within each of the visits, with the device in situ (visits 2-5), to assess prolapse reduction & integrity of vaginal walls. During the device usage period, subjects had to fill out a diary, denoting each device's usage length, functionality and adverse events. Findings and results from visits 1 and 5 were compared, including POP symptom scores & QoL questionnaires.

Four almost identical device models were tested sequentially along 3 identical parts of the study (parts A, B, C), where part C was the pivotal study, using the final finished version of the device. Statistical analysis was done on results from both the pivotal study (part C only) and all parts (pooled analysis, parts A, B & C). The 1st performance endpoint was the percentage of subjects with an improvement from baseline of at least 1 POP-Q stage.

Results

52 subjects completed the study in 3 clinics. 24 completed one part of the study, 14 completed 2 parts, and 14 used the device during 3 parts, altogether 94 usage cycles in which 1556 devices were used over 3530 usage days, an average of 36.1±5.70 days per subject (pooled analysis, parts A, B & C, 94 usage cycles). 41/52 subjects took part in the pivotal study (part C only, 41 usage cycles) where they used 591 devices over 1556 usage days, an average of 37±5.3 usage days per subject.

Mean age was 60.4 , mean BMI was 25.8, and 81.1% of the subjects were postmenopausal.

In the pooled analysis population, 66 subjects (70.2%) had POP-Q stage 3 prolapse, while 28 (29.8%) had POP-Q stage 2 prolapse, at study start. At visit 5, 90 subjects (97.8%) had complete reduction of the prolapse (stage 0), while 2 subjects (2.2%) had POP-Q stage 1 prolapse. Objective assessment showed that 100% of subjects had 2 POP-Q stages reduction while using the device and 97% of subjects with stage 3 prolapse (64/66) had 3 stages reduction ($p<0.0001$). Subjective assessment of POP related symptoms (Figure 1) was carried out using an author compiled symptom scoring system which showed mean improvement from 29 (V1) to 2.7 (V5) ($P<0.0001$). Modified PFIQ-20 QoL questionnaire showed significant improvement in QoL, from score of 33.6 to 5.1 ($p<0.0001$), and modified PFIQ-7 showed improvement from 24.9 to 0.7 ($p<0.0001$).

Overall, within the pooled analysis group, there were 91 device related adverse events (AE's) which were recorded daily in a diary, and all recovered. There were no serious AE's, most AE's were mild (98.9%), of short duration and anticipated (87.9%), and included mainly spotting, discomfort and some pain. 62 AE's occurred during part A, 8 during part B and 21 during part C. Most adverse events occurred within 7 days from study start, and before using the first 5 devices (learning curve). There were no cases of vaginal infections, and there was only one case of urinary infection.

Satisfaction rate by users was high and most users considered the device as easy to use.

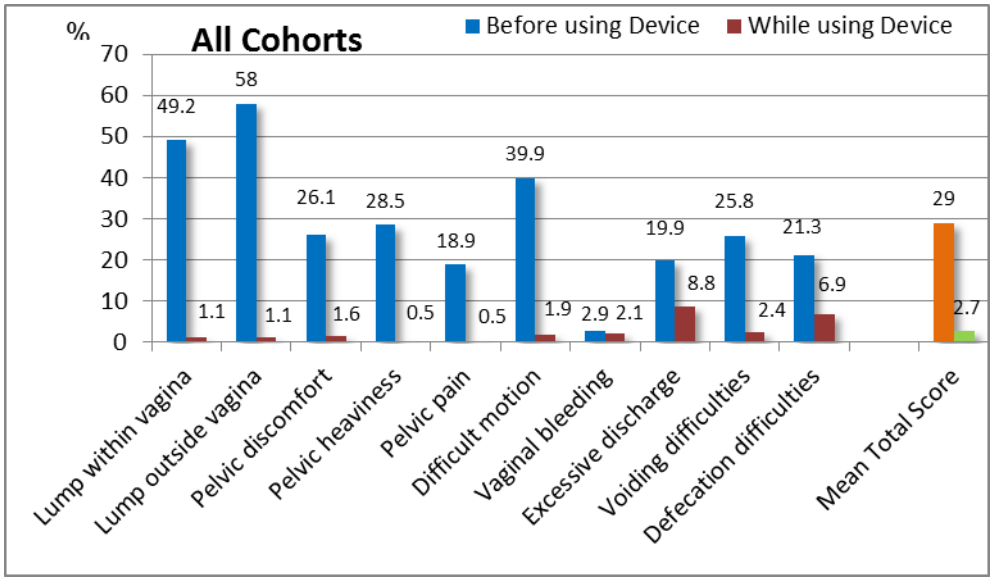

Figure 1- Subjective assessment of POP related symptoms, before and while using the device (author compiled symptom scoring system, 3530 usage days, 1556 devices (P<0.0001)).

Interpretation of results

All study endpoints were met successfully. Reduction of at least 2 POP-Q stages was demonstrated in all 100% of subjects, but more importantly – alleviation of POP symptoms was significant (Fig 1), with significant improve in QoL.

Any vaginal device is expected to cause some discomfort, spotting or pain, during initial usage, mainly in postmenopausal women. Therefore, these AE's, specifically when daily recorded (as compared to questioning only at study-end) exhibit very low level of mild complaints.

Concluding message

This new disposable vaginal device for the management of POP was found to be efficacious (with significant objective prolapse reduction and subjective relief of POP symptoms) and safe for use, with minimal mild and anticipated AE's.

Disclosures

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