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CLINICAL CHARACTERISTICS ASSOCIATED WITH SUCCESSFUL USE OF A NOVEL VAGINAL BOWEL CONTROL (VBC) SYSTEM FOR THE TREATMENT OF FECAL INCONTINENCE

Hypothesis / aims of study

Current treatment options for fecal incontinence (FI) have limitations in efficacy, morbidity, and cost. The vaginal bowel control (VBC) system is a novel, non-surgical treatment option that consists of a pressure-regulated pump and an insert with a silicone base and posteriorly-directed balloon, designed to reversibly deflect the rectovaginal septum and interrupt the passage of stool. The primary study outcome, reported separately, demonstrated 79% (48/61) of intent-to-treat subjects and 86%, or 48/56, of per protocol subjects achieved treatment success, defined as ≥50% reduction in fecal incontinent episodes (IEs)/week.[1] There were no serious device-related adverse events experienced by any patients involved in any portion of the study.
Because many FI treatments are only effective for a limited patient population or only offer limited impact on FI symptoms, in this study we sought to understand the clinical characteristics associated with overall insert fitting success, including ability to fit the insert and the insert's influence on the range of bowel symptomology. The objectives of this secondary analysis were to evaluate factors that predict successful insert fitting and to assess the interaction between baseline FI episode characteristics and treatment efficacy.

Study design, materials and methods

This was an IRB-approved, multi-center, prospective, open-label clinical study in women with FI. Inclusion criteria were: age 19-75, history of FI ≥6 months, ≥4 fecal IEs during 2-week bowel diary, and successful fitting. Subjects were seen for a baseline study visit, consisting of a comprehensive history and baseline pelvic examination. Subjects then completed a 2-week baseline diary, including entries for: continent bowel movements, staining, minor FI episodes, and major FI episodes. For each event, stool consistency as determined by Bristol Stool Score and presence of fecal urgency were recorded. If the subject recorded ≥4 episodes of minor or major soiling, she proceeded to a trial insert fitting. If an insert size was found that was stable and comfortable, the subject was sent home to wear it for approximately one week. If a successful fit was achieved, the subject was sent out for a 1-month treatment period, in which she would record the last 2 weeks in a treatment diary, capturing the same metrics as the baseline diary. Data from the subject's demographic and clinical baseline intake were compared across successful and unsuccessful fitting groups. Multivariate, logistic regression analysis was performed. Paired T-tests were used to characterize the difference in FI episode types from baseline to the 1 month outcome time-point.

Results

Six clinical sites in the U.S. recruited women from August 2012 through October 2013. Overall, insert fitting was attempted in 112 and 61/112 (55%) were successfully fit and entered the treatment portion of the study. A summary of characteristics associated with successful versus failed fittings is noted in Table 1. Multivariate logistic regression analysis revealed that only previous prolapse surgery (p=.0008), shorter vaginal length (p=.042), and vaginal atrophy (p=.012) were associated with unsuccessful insert fitting. Table 2 shows the interaction between baseline FI episode characteristics and treatment effect (% reduction in # FI episodes). A significant reduction in IEs was seen in both solid and liquid FI episodes, major and minor FI episodes, and episodes with and without a sense of fecal urgency.

Table 1. Fitting Predictors

	Unsuccessfully Fit	Successfully Fit	p-value* (univariate)	p-value* (multivariate)
Age, years; mean (SD)	63.3 (8.7)	60.9 (9.4)	0.16	0.134
Ethnic origin	-	-	0.082	-
Body-mass index; mean (SD)	27.3 (5.3)	28.1 (6.6)	0.48	-
# of Vaginal Births – mean (SD)	2.0 (1.1)	2.1 (1.0)	0.50	-
Menopause Status; pre & peri / post	4%/96%	15%/85%	0.012	0.262
Sexual Activity; Y/N	37%	44%	0.19	-
Prior Hysterectomy; Y/N	69%	48%	0.029	0.506
Prior Prolapse Surgery[1]; Y/N	33%	8%	0.0006	0.0008
Vaginal Length, cm; mean (SD)	8.0 (1.1)	8.7 (1.3)	0.0011	0.042
Degree of Vaginal Atrophy[2]	-	-	0.014	0.012
Tissue Compliance	-	-	0.075	0.590

*Logistic regression. [1]Includes any vaginal prolapse surgery, excluding hysterectomy. [2]Characterized as: none, mild, moderate, severe.

Table 2: Baseline FI Characteristics and treatment success

	Baseline*	1-mo*	% Change in # of FI episodes	p-value†
Major FI soiling episodes	3.2 (±4.1)	0.6 (±1.2)	-81%	<0.0001
Minor FI soiling episodes	8.4 (±7.5)	1.5 (±2.3)	-82%	<0.0001
FI episodes associated with urgency	6.6 (±6.8)	1.1 (±2.1)	-83%	<0.0001
FI episodes not associated with urgency	4.8 (±6.5)	0.9 (±1.8)	-81%	<0.0001
FI episodes with loose stool (Bristol Score 6-7)	5.1 (±5.8)	1.2 (±2.4)	-76%	<0.0001
FI episodes with normal stool (Bristol Score 1-5)	6.1 (±7.4)	0.9 (±1.6)	-86%	<0.0001

*2-week diary. †Paired T test

Interpretation of results

Shorter vaginal length, vaginal atrophy and previous prolapse surgery were associated with increased risk of insert fitting failure. Previous prolapse surgery may cause changes to the shape or quality of the vaginal walls, possibly making it harder to accommodate the insert. A shorter vagina may provide less proximal space for the insert to dwell, causing it to slip downwards and create discomfort.

This information can be used to counsel patient expectations regarding the VBC insert fitting experience. Since not all women with these criteria failed VBC fitting, however, an attempt should be made given the low-risk nature of the therapy. This fitting information is also valuable in directing the development of a wider range of size offerings to fit a higher percentage of patients in the future.

Once successfully fit, the insert reduced IEs regardless of baseline FI episode characteristics, including size, urgency, and consistency. Of particular note is the improvement in episodes with loose stool, as the insert mechanism (temporary occlusion of the rectum) may not have been expected to reduce liquid stool events.

The ability of the insert to address the range of FI symptomology is a significant advantage considering the heterogenous presentation of FI. This may be due to the insert's dynamic mechanism, which allows for greater rectal occlusion than other types of implants with a single state (e.g. slings, bulking agents). The concept of a dynamic vaginal balloon that reversibly deflects the rectovaginal septum above the sphincter complex and interrupts the passage of stool represents a paradigm shift in fecal incontinence management.

Concluding message

Shorter vaginal length, vaginal atrophy, and previous prolapse surgery were associated with increased risk of unsuccessful fitting. This information can be used to counsel patient expectations regarding the VBC fitting experience. Successfully fit inserts reduced fecal IEs regardless of baseline FI episode characteristics.

References

1. Richter HE, Matthews CA, Varma MG, Takase-Sanchez M, Hale D, VanDrie D, Muir T. Clinical Efficacy and Safety Evaluation of a Vaginal Bowel Control (VBC) Device for the Treatment of Fecal Incontinence. Accepted for presentation at AUGS-IUGA 2014.

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