Urogynecology Digest

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Is a vaginal bowel control system effective for the treatment of fecal incontinence?

A vaginal bowel-control system for the treatment of fecal incontinence. Richter HE, Matthews CA, Muir T, Takase-Sanchez MM, Hale D, Van Drie D, Varma MG. *Obstet Gynecol* 2015; 125: 540–547

This prospective study evaluated the effectiveness and safety of a vaginal bowel control device (Eclipse system) for the treatment of fecal incontinence. The device is described in the FDA news release¹ as follows: “The Eclipse System is intended to treat FI in women 18 to 75 years old who have had four or more FI episodes in a two-week period. The device includes an inflatable balloon, which is placed in the vagina. Upon inflation, the balloon exerts pressure through the vaginal wall onto the rectal area, thereby reducing the number of FI episodes. The device is initially fitted and inflated by a clinician (with the use of a pump) and after proper fitting, the patient can inflate and deflate the device at home as needed. The device should be removed periodically for cleaning”.

Two hundred patients consented to enrolment in the study but the majority were excluded because of insufficient incontinence episodes. Out of the 110 patients who were eligible and underwent the fitting assessment, 61 achieved a successful fit.

Patients were analysed at the end of 1 month and were invited to participate in an optional extended-wear period of another 2 months. The primary outcome of treatment success was defined as a 50 % or greater reduction of incontinence episodes at 1 month and the secondary outcomes measured symptom improvement based on the Fecal Incontinence Quality of Life scale, the Modified Manchester Health Questionnaire and the Patient Global Impression of Improvement. Success was high at the end of 1 month, with the intention to treat success 78.7 % and per-protocol success 85.7 %, and this was maintained at 3 months (86.5 %). 41.1 % achieved complete

continence at 1 month. There was a significant improvement in the Fecal Incontinence Quality of Life and Modified Manchester scores, which were statistically significant. Most adverse events were mild (pelvic cramping or discomfort) and the majority occurred during the fitting period.

Fecal incontinence is an embarrassing issue that is seldom addressed. Causes are multifactorial and numerous treatments, including medical therapy, biofeedback, injectable anal bulking agents, anal plugs, anal sphincteroplasty, artificial anal sphincter and sacral nerve modulation, are available. However, some of the treatments are invasive and have high complication rates. The use of a vaginal bowel control device that appears to be low-risk and easily reversible would be ideal if it had a high success rate. This study showed that the use of the Eclipse system was successful in the short term, with a high satisfaction rate. However, 45 % of women eligible for the study could not be successfully fitted with the device. The authors note that this is a higher rate compared with pessary fitting for prolapse. Given that this is a new device, with future training and introduction of different sizes, the fitting of the system should improve. It is reassuring to note that most adverse events were mild, but periodic monitoring of the vaginal epithelium is advisable. Long-term success and adverse events are important when introducing new devices and we await those results.

Are we adhering to reporting guidelines when publishing articles?

The explicit mentioning of reporting guidelines in urogynecology journals in 2013: a bibliometric study Koch M, Riss P, Umek W, Hanzal E. *Neurourol. Urodynam.* DOI: [10.1002/nau.22726](https://doi.org/10.1002/nau.22726)

This study was a search of all urogynaecology journals published between January and December 2013 in three major urogynaecology journals (*Neurourology and Urodynamics* [NAU], *International Urogynecology Journal* [IJU], *Female*

Pelvic Medicine and Reconstructive Surgery [FPMRS]) and three general gynaecology journals (*American Journal of Obstetrics and Gynecology [AJOG]*, *Obstetrics and Gynecology [Green]* and *BJOG: An International Journal of Obstetrics and Gynaecology [BJOG]*). The aim was to determine the extent to which relevant reporting guidelines (RGs) are explicitly mentioned in published articles and if the results conformed to journal requirements.

Two hundred and ninety-six studies were included after journals were assessed electronically and searched for systematic reviews, randomised controlled trials (RCTs), cohort studies, case-control studies and cross-sectional studies by two independent investigators and then assessed if they conformed to the PRISMA, CONSORT or STROBE criteria. All systematic reviews were published by *NAU* and the *IUJ*, which do not require a checklist for PRISMA. 54 % of systematic reviews adhered to the PRISMA checklist. Despite all journals apart from *FPMRS* requiring the use of CONSORT guidelines for RCTs, only 25 % (10 out of 40) adhered to the guidelines. The lowest adherence rate was 1.2 % for observational studies (STROBE), which was the most frequent study type ($n=243$). *Green*, *AJOG* and *BJOG* require the STROBE checklist to be completed for submission, yet only 2 out of 34 articles conformed.

Reporting guidelines are important in the course of writing up scientific work and can expose deficiencies in a trial design and prevent implementation of potentially biased research results. The authors limited their search to three specific urogynaecology journals and three general gynaecology and obstetrics journals as a representative comparison; hence, some urogynaecology articles could have been missed. However, because of the variable use of RGs in the different journals, even in those with a higher impact factor, they believe that these results would apply to other journals. With the CROWN (CoRe Outcomes in Women's Health) initiative encouraging researchers to use standardised outcome measures for all clinical trials and adhering to RGs, results can be streamlined. It also facilitates the comparability and reproducibility of studies. If we believe adherence to RGs is important in improving the quality of a study, should journals be rejecting articles that are not compliant? This may be difficult in the short term because of logistical issues, but it is something we should strive for.

How does an internet-based treatment program for stress urinary incontinence compare with a program sent by post?

Internet-based treatment of stress urinary incontinence: 1- and 2 years results of a randomised controlled trial with focus on pelvic floor muscle training. Sjoström M, Umeffjord G, Stenlund H, Carlbring P, Andersson G, Samuelsson E. doi: 10.1111/bju.13091

This RCT compared the long-term outcomes of two types of treatment programs for stress urinary incontinence (SUI) based on pelvic floor muscle therapy (PFMT). 250 community dwelling women were recruited if they had SUI ≥ 1 /week based on validated self-assessed questionnaires, a 2-day bladder diary and a telephone interview with a urotherapist. They were then randomised to 3 months of treatment with an internet-based treatment program ($n=124$) with continuous support from an urotherapist or to a program sent by post where they trained on their own ($n=126$). There was no face to face contact with participants at any time.

There was a highly significant ($p<0.001$) improvement in the primary outcomes of ICIQ-UI SF and ICIQ-LUTSqol after 1 and 2 years compared with baseline and there were no significant differences between the groups. These improvements occurred within the first 4 months and were sustained in the long term. Women in the internet group reported that they were much or very much improved at 2 years and there was statistically significant improvement in the health-specific QOL compared with participants in the postal group. There was no difference between the two groups who reported that they were performing PFMT (≥ 1 /week), but this was quite low at 32.4 % at 1 year and 34.9 % at 2 years. Satisfaction rate with treatment was similar in both groups (64.9 % internet vs 58.2 % postal). 12.3 % of women sought other SUI care after 2 years and the surgery rate was 5.2 % after 2 years. The rate of subjects lost to follow-up was high at 38 %.

This study showed that an internet-based program is as effective as a postal program in the long term. There was no face to face contact in either of the intervention arms. While the NICE guidelines and ICS recommend supervised PFMT, the authors noted a recent study that showed that 83.4 % of women could contract their pelvic floor muscles at the first attempt or could learn after a short verbal cue, which is reflected in the statistically significant improvement in the ICIQ-UI SF and ICIQ-LUTSqol. The internet-based program may become the program of choice as women may prefer it for issues they perceive as embarrassing and as health systems try to improve the cost effectiveness of delivering a program. The authors undertook a cost-effectiveness evaluation and found that the extra cost per quality-adjusted life year (QALY) gained through the use of the internet-based program compared with the postal program ranged from €200 to €7,253. It is also flexible and convenient. However, a large proportion of women in this study were highly educated and more likely to have access to the internet; hence, it cannot be applied to populations with a low socioeconomic background. There was also a high drop-out rate and while SUI is a dynamic condition that can improve, most of the patients who dropped out were young, had more severe leakage and may have opted for surgical management.