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A NEW INTRAVAGINAL DEVICE FOR STRESS INCONTINENCE IN WOMEN.

Aim

The study aimed to compare the ease of use, acceptability and efficacy of two intravaginal devices in urinary stress incontinence A currently marketed device Conveen Continence Guard CCG1 (Coloplast A/S, Copenhagen), was compared to a new version, the Contrelle Continence Tampon (CCG2) which was designed to be easier for women to use

Methods

The study was a multi-centre prospective, randomised crossover study carried out in centres in Denmark, Australia and the UK

Women with the prevailing symptom of stress incontinence were recruited Those with mainly irritative symptoms, significant urogenital prolapse, vaginitis or untreated urinary tract infection were excluded

Gynaecological examination, vaginal swabs and urine culture were performed at each visit. Free flow rate and measurement of post micturition residual were recorded Women also completed two 24hr pad weighing tests and a frequency volume chart

Each device was available in three sizes, women assessed which suited them best and were given a five week supply of this size Each devices was worn for up to 16 hours a day The devices were used daily and towards the end of the five week period the clinical assessment was repeated Women then crossed into the other arm of the study and repeated the process with the other device

Results.

A total of sixty one women were recruited into the study Thirty eight (62%)of these women successfully completed the study 23 (37%) withdrew before completion. The results from those women completing the study were analysed.

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At the time of recruitment 78% of women reported leakage of urine on a daily basis and 18.4% reported leakage several times a week The remaining woman reported leakage during exercise. Prior to using the devices 24hr pad tests showed a median loss of 70.5g a day (range from 18 to 208g). Pad weight tests when using the two devices are shown in the table

Pad test losses.

	Median Pad Weight (g)	**Significance (Wilcoxon)**
Without device	70.5	
With CCG 1	17.5	0 0001
With CCG2	9	0.0001
CCG1 compared toCCG2		0.025

The pad weighing tests indicate that both devices reduced urinary leakage, the CCG2 was, however, reduced median urine loss significantly more than the CCG1.

Frequency of micturition, flow rates and urinary residual volumes were not significantly affected nor was there any significant incidence of urine or vaginal infection with either device The incidence of vaginal irritation was extremely low. Women found both devices equally easy to preare and use although the CCG2 was easier to insert,(p=0 15 Wilcoxon paired test) Both devices were used by women for a median 12 5 hours a day and were equally stable during activity once in place

94% of the women in the study wished to continue to use one or other of the devices, 73% preferring the CCG2 over the CCG1

Conclusions

The relatively high drop-out rate in this study amongst women who found the devices uncomfortable or ineffective demonstrates that intravaginal devices will not be suitable for ***all*** women Nevertheless, of women who completing the study the high proportion who wished to continue to use the devices demonstrates that they are a valuable treatment option for stress incontinence for a significant number of women. They can enable women to resume normal activity and exercise and prevent or reduce the need for incontinence pads

Intravaginal devices such as these have been previously shown to be both safe and effective for long term use [1,2] In this study both devices were effective but the new version of the device appears to offer improved efficacy and greater ease of use and patient acceptability. This study is continuing in order to assess the acceptability and efficacy of these devices in larger numbers of women and over longer term use.

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1 Thyssen H Lose G Acta Obstet Gynecol Scand 1996; 75· 170-173.

2 Thyssen H Lose G Int urogynecol J 1997, 8: 130-133.