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THE 'CONTIFORM' INTRAVAGINAL DEVICE IN THE TREATMENT OF GENUINE STRESS INCONTINENCE (GSI)

Aims of Study

The surgical treatment of GSI has an 80 – 90% cure rate but can be complicated by denovo detrusor instability and voiding difficulty post operatively. Intravaginal devices may be difficult to fit but once in situ can have similar success rates with fewer complications. 'Contiform' is a new device that is shaped rather like a large tampon and is amenable to self insertion by the patient. It should therefore be easier to use and should not require close medical or nursing monitoring. We aimed to assess efficacy eg reduced urinary leakage and improvement in quality of life indices, record adverse events and identify those who can be readily fitted and respond best.

Methods

Local ethical committee approval was obtained and recruitment undertaken prospectively from a tertiary urogynaecology clinic. GSI was diagnosed by videourodynamics and patients with proven detrusor overactivity were excluded. Those with vaginal prolapse beyond the introitus were excluded as the device is not intended for use in such patients. Previous continence surgery was not an exclusion criterion. All post menopausal women used systemic hormone replacement therapy or vaginal oestrogen. Patients were asked to use the device for 3 to 4 weeks and to become comfortable with self insertion and removal. The primary outcome measure was the 24 hour pad test, mild / moderate / severe was defined as < 30, 31 –100, >100mls / 24 hours. Secondary outcomes were alterations in scores from the SF12, short versions of the Urinary Distress Inventory (UDI) & Incontinence Impact Questionnaire (IIQ) and a 20 point incontinence score. Based upon previous experience with other intravaginal devices our target sample size is 75 patients.

Results

Thus far, 41 women have been invited to participate. Of these patients 5 declined outright, 2 withdrew before fitting the device, 3 were unable to retain it, 5 could not fit it themselves (total not completing protocol = 15 / 41, 37%): 6 are still in progress.

To date, 20 women have used it for a median of 21 days and of this group the median age was 49 years (45-54.25), BMI was 26.2 (22.83-28), parity was 2.5 (2-3), all typical of our clinic. 11 (55%) were premenopausal, 8 (40%) had undergone hysterectomy and 3 (15%) a previous continence procedure.

Of the sample, 4 of 20 patients were dry (20%): 1 of 9 in the mild group vs 3 of 11 in the moderate / severe group (Fisher's Exact Test A=2.2, p=0.59)

Table 1. Urinary loss on 24 hour pad testing (g)

Group	Pre Treatment (g / 24 hours)	Wearing 'Contiform' (g / 24 hours)	Wilcoxon Signed Rank Test
Whole group (n=20)	22.3 (8.2 – 67.6)	8.2 (2.7 – 17.7)	P=0.006
Mild loss (n=9)	8.2 (5.6 – 10.4)	7.4 (3.8 – 13.3)	p=1
Moderate / severe loss (n=11)	65.2 (33.9 - 107)	13.7 (0 – 26.5)	P=0.002

Uroflowmetry with the device in-situ revealed no decrease in peak flow rate. The median baseline flow rate was 30.5mls/sec (13 - 37.7). With 'Contiform' fitted it was 27.9mls/sec (12.8 – 36.8), Mann Whitney–U, p=0.73.

Women to felt competent at insertion and removal of the device after a median of 2 days (1-5.25).

There were no significant changes in any quality of life test but a trend toward improvement was evident in all but the mental component of the SF12 (but numbers are still accruing).

Table 2. Changes in Quality of Life Scores

	Pre Treatment	Post Treatment	Wilcoxon Signed Rank Test
Physical Component score of SF-12	40.9 (29.1 – 53.1)	51.7 (35.4 – 55.9)	p=0.21
Mental Component Score of SF-12	54.1 (49 – 57.4)	55.9 (46.1 – 60.5)	p=1
Urogenital Distress Inventory	38.8 (33.3 – 55.5)	33.3 (17.8 – 55.4)	p=0.10
Incontinence Impact Questionnaire	33.3 (14.9 – 55.9)	30.9 (15.5 – 44.7)	p=0.38
20 point incontinence questionnaire	9.5 (6.5 – 12.7)	9 (4 – 10)	p=0.13

No serious adverse events were recorded. However, 4 women have since opted for surgery, 3 of 12 from the mod / severe group and 1/8 from the mild group (Fisher's exact test A=2.4, p=0.62) .

Conclusions

In this study population, 'Contiform' significantly reduces urinary leakage in women with GSI. Though only 20% were rendered completely dry many had major benefit. Insertion / removal technique is generally learnt quickly. The device appears to have place in treating GSI in women who do not want surgery. Recruitment is continuing.

References

1) 24 Hour Pad Test: Normal values in older continent women. Neurourol Urodyn 2001;20:569 – 570.