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Harvey M[1], Day A[1]
1. *Queen's University*

THE TREATMENT OF STRESS URINARY INCONTINENCE USING AN INCONTINENCE RING: A RANDOMIZED, CROSS-OVER TRIAL.

Hypothesis / aims of study

To determine the effect of the incontinence ring (IR) on continence, quality of life and urodynamic studies (UDS) in a group of women with stress urinary incontinence (SUI).

Study design, materials and methods

We performed a crossover, randomized, non-blinded controlled trial, set in a small size academic referral center. Women with predominantly SUI, confirmed urodynamic stress incontinence but no prolapse (defined as POPQ>2), detrusor overactivity on UDS, infection or pregnancy were recruited and randomized to a treatment sequence: control-IR (CR) or IR-control (RC). Randomization was achieved through a computerized system generating random numbers. Assignation of the treatment sequence was placed in order in an opaque sealed numbered envelop opened after randomization. Each treatment periods were 4 weeks long and separated by a 2 week washout period. During the control period, women received no intervention. The 2x2 cm knob is placed at the mid-urethra level, approximately 1.5 cm from the external urethral meatus, with the back of the IR to be positioned in the posterior fornix. One week after initial fitting, women were reassessed. IR size was adjusted according to comfort and continence level.

The primary outcome was the difference in the number of incontinent episodes per week (IEF/w) from a 7 day diary, obtained in the last week of each treatment period. Secondary outcomes included: UDI score, subjective cure rate (score = 0 on UDI6 SUI question), quality of life (IQOL, SF12), UDS cure rate, flow rate, postvoid residual and comfort (100 mm visual analogue scale VAS).

Outcomes were compared between the post IR and the post control assessments except for peak flow which was compared between the post IR and baseline assessments. The primary outcome and UDI 3 score were compared by the sign tests. All other outcomes were compared by the paired Ttest. The IEF/w were compared between groups at the end of the 1st treatment period to confirm the conclusions without relying on the no carryover assumption. All tests are 2-sided without adjustment of multiplicity for secondary outcomes.

Based on an alpha of 0.05, power of 80%, a minimally clinical difference in IEF/w of 9.5 (50% improvement, which is the minimum improvement shown to improve quality of life)[1] and a 2-period crossover study, the necessary number of subjects for each sequences was 16.

Results

Twenty-nine eligible patients were enrolled. Three patients withdrew prior to baseline assessment and are excluded from all analyses leaving 14 and 12 patients randomized to the CR and RC sequences respectively. Three patients could not be fitted and one missing the diary value at the end of the IR period are considered failures. The median number of fitting was 2. Mean (sd) age was 52 (11), mean BMI was 29 (7); 85% were parous and 30% postmenopausal. The median [Q1-Q3] number of IEF/w at baseline was 10 [5-28]. Four women has intrinsic sphincteric deficiency (vesical leak point pressure < 60cmH_2O at 300 cc).

Compared to the end of the control period, 19 women recorded an improvement at the end of the ring period, one remained the same and two reported a higher IEF/w after using the IR ($p<0.001$ for 2 versus 19 by sign test). An IEF/w decrease ≥ 50% was noted in 13 (50%) patients of whom 5 (19%) were continent with the IR. The reported median [Q1-Q3] of IEF/w after the IR and control period were 3 [1-8] and 8 [5-30] respectively. The median [Q1-Q3] absolute decrease in IEF/w from the control period was 5 [1-27] while the median percentage reduction [Q1-Q3] was 82% [33%-97%] (p <0.0001).

Secondary objectives are presented in the table. Seven women were subjectively cured on UDI, and 4 women on UDS. The VAS result for comfort was not significant.

Outcome difference, Ring-Control periods

	n	Mean	Standard Deviation	Median	Lower Quartile	Upper Quartile	*p*
UDI score (0-100)	22	-21.8	25.1	-16.7	-38.9	-5.6	< .001
UDI 3 response (0-3)	24	-1.2	1.3	-1.0	-2.0	0.0	< 0.02
I-QOL score (0-100)	24	13.7	18.6	12.3	0.9	26.4	< 0.02
Comfort (100 mm VAS)	24	-1.0	2.5	-0.1	-2.0	0	ns
SF-12 (PCS)	24	3.1	5.6				< 0.02
SF-12 (MCS)	24	-1.1	7.0				ns
Peak flow rate (ml/sec)	24	-0.5	14.6				ns
Post void residual (ml)	20	-36	69				< 0.05

After the IR period, 25 women stated they would continue to use the incontinence IR after the completion of the study and 6 would no longer want surgery to control their urinary incontinence.

Interpretation of results

An improvement ≥ 50% is considered the minimum level of improvement leading to an improved quality of life. This minimal level of response was achieved in half the women, with no impact on voiding or comfort. Immediate cure of their incontinence was seen in 20% of women. Corresponding improvement in incontinence specific and generic quality of life were noted.

Concluding message

This therapeutic approach, widely acceptable in this group of women, is effective at once in most women and should be part of first line therapy of SUI as it is cheap and safe.

References
1. Neurourol Urodyn 2005;24(5/6):463-4

Specify source of funding or grant	**PSI Foundation Inc.**
Is this a clinical trial?	**Yes**
Is this study registered in a public clinical trials registry?	**Yes**
Specify Name of Public Registry, Registration Number	**ClinicalTrials.gov Identifier NCT00427778**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**Yes**
Specify Name of Ethics Committee	**QUEEN'S UNIVERSITY AND AFFILIATED TEACHING HOSPITALS HEALTH SCIENCES HUMAN RESEARCH ETHICS BOARD**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**