

NATIONAL INSTITUTE FOR CLINICAL EXCELLENCE

INTERVENTIONAL PROCEDURES PROGRAMME

Interventional procedures overview of extraurethral (non-circumferential) retropubic adjustable compression devices for stress urinary incontinence

Introduction

This overview has been prepared to assist members of the Interventional Procedures Advisory Committee (IPAC) in making recommendations about the safety and efficacy of an interventional procedure. It is based on a rapid review of the medical literature and specialist opinion. It should not be regarded as a definitive assessment of the procedure.

Date prepared

This overview was prepared in December 2004.

Procedure name

- Extraurethral (non-circumferential) retropubic adjustable compression devices for stress urinary incontinence.

Specialty societies

- British Association of Urological Surgeons.
- Royal College of Obstetricians and Gynaecologists.

Description

Indications

Stress urinary incontinence.

Stress urinary incontinence is the involuntary leakage of urine during exercise or certain movements such as coughing, sneezing and laughing. It is usually due to weak or damaged muscles in the pelvic floor or sphincter. Estimates of the overall prevalence of any incontinence have varied between 10 and 52% of adult women.¹

Current treatment and alternatives

Conservative treatments include pelvic floor muscle training, electrical stimulation, and biofeedback. Surgery is usually used if conservative treatments fail. There are four main types of surgical intervention: colposuspension, insertion of a tension-free vaginal tape, traditional suburethral slings, and injectable agents. Of these four operation types, colposuspension and the insertion of a tension-free vaginal tape are currently the most common.

Colposuspension (open or laparoscopic) involves lifting the tissues near the bladder neck and proximal urethra, and suturing them in place. Insertion of a tension-free

vaginal tape is a minimal access procedure that involves passing a polypropylene tape beneath the urethra to restore it to its correct position.

What the procedure involves

Using either local or regional anaesthesia, specially designed introducers are used to insert two small silicone balloons via a percutaneous perineal approach. Under radiological guidance, one balloon is positioned on either side of the urethra, close to the bladder neck. The balloons are filled with a mixture of water and contrast to enable the positioning to be confirmed. Each balloon is then attached to a subcutaneous port sited in the major labia. These ports can be used to add or remove fluid to the balloon postoperatively, thereby achieving the best balance between controlled leakage and voiding.

Efficacy

A multicentre case-series study of 170 women reported that there was a statistically significant increase in the mean abdominal leak point pressure after the procedure (from 60.6 cm/H₂O to 86.2 cm/H₂O, $p = 0.003$). There was also a significant increase in the mean quality of life score, from 35 at baseline to 70 at 12 months ($p < 0.0001$). Of the 34% (58/170) of women followed up for 2 years, 83% (48/58) were either dry or significantly improved.

The Specialist Advisors stated that there is a lack of long term data.

Safety

The most common adverse event was urinary tract infection, which affected 15% (25/170) of women in one study. Other complications included balloon dislocation in 13% (22/170), port erosion in 10% (17/170), bladder perforation in 8% (14/170), sexual discomfort in 2% (3/170) and urgency in 1% (2/170) of women. A second study reported that 5% (2/37) of women experienced urethral pain after the procedure.

The Specialist Advisors stated that potential adverse events include infection, erosion of the device into the vagina or urethra, urinary retention, urethral injury, and urethral or vaginal pain.

Literature review

Rapid review of literature

The medical literature was searched to identify studies and reviews relevant to adjustable intramural urethral implants for stress urinary incontinence. Searches were conducted via the following databases, covering the period from their commencement to November 2004: MEDLINE, PREMEDLINE, EMBASE, Cochrane Library and Science Citation Index. Trial registries and the Internet were also searched. No language restriction was applied to the searches.

The following selection criteria were applied to the abstracts identified by the literature search. Where these criteria could not be determined from the abstracts the full paper was retrieved.

Inclusion criteria for identification of relevant studies

Characteristic	Criteria
Publication type	Clinical studies included. Emphasis was placed on identifying good quality studies. Abstracts were excluded where no clinical outcomes were reported, or where the paper was a review, editorial, laboratory or animal study.
Patient	Women with stress urinary incontinence.
Intervention/test	Insertion of extraurethral (non-circumferential) retropubic adjustable compression devices.
Outcome	Articles were retrieved if the abstract contained information relevant to the safety and/or efficacy.
Language	Non-English-language articles were excluded unless they were thought to add substantively to the English-language evidence base.

List of studies included in the overview

This overview is based on five conference abstracts reporting the results of case-series studies. It is likely that all the reports relate to the same multicentre study.

Table 1 Summary of key efficacy and safety findings on extraurethral (non-circumferential) retropubic adjustable compression devices for female stress urinary incontinence

Abbreviations used: SUI = stress urinary incontinence, I-QOL = Incontinence Quality of Life, UDI = Urogenital Distress Inventory			
Study Details	Key efficacy findings	Key safety findings	Comments
<p>Kocjancic E (2004)²</p> <p>Case series</p> <p>1999 onwards</p> <p>Multi-centre (Italy, France, Germany, Brazil, Austria)</p> <p>170 women</p> <p>Mean age: 61.4 years (range 22 to 94)</p> <p>44% (75/170) type II SUI 56% (95/170) type III SUI</p> <p>30% (60/170) of women had prior multiple surgeries, including colposuspension, slingplasty, bulking agents, or an artificial urinary sphincter.</p> <p>Inclusion criteria: type II or type III SUI</p> <p>Mean follow-up: 14 months (range 1 to 24)</p>	<p>Outcome measures: abdominal leak point pressure measurements and quality of life questionnaires (I-QOL).</p> <p>Mean abdominal leak point pressure before surgery = 60.6 cm/H₂O. Mean abdominal leak point pressure after surgery = 86.2 cm/H₂O (p = 0.0032)</p> <p>Mean I-QOL score at baseline = 35.2 Mean I-QOL score at 12 months = 69.9 (p < 0.0001)</p> <p>After 2 years follow-up, 83% (48/58) of women were either dry or significantly improved.</p>	<p>Complications</p> <ul style="list-style-type: none"> • Bladder perforation = 8% (14/170) • Pelvic pain = 4% (7/170) • Urgency = 1% (2/170) • Port erosion = 10% (17/170) • Balloon dislocation = 13% (22/170) • Urinary tract infection = 15% (25/170) • Sexual discomfort = 2% (3/170) 	<p>Conference abstract.</p> <p>66% (113/170) of patients reached 12 months of follow-up.</p> <p>34% (58/170) of patients reached 24 months of follow-up.</p>

Abbreviations used: SUI = stress urinary incontinence, I-QOL = Incontinence Quality of Life, UDI = Urogenital Distress Inventory			
Study Details	Key efficacy findings	Key safety findings	Comments
<p>Staeher MD (2004)³</p> <p>Case series</p> <p>Multicentre (Germany, Austria, Switzerland, Italy, France, Brazil, USA)</p> <p>49 women</p> <p>Mean age: 59.5 years</p> <p>Inclusion criteria: women with at least one prior surgical treatment for stress urinary incontinence.</p> <p>Follow-up: 6 to 24 months</p>	<p>Outcome measures: Direct visual stress test and standardised quality of life questionnaire for incontinence (I-QOL).</p> <p>I-QOL scores improved from 30 at baseline to 70 at 6 months ($p < 0.0001$), 72 at 12 months ($p < 0.0001$) and 79 at 24 months ($p < 0.003$).</p> <p>Dry or mild leakage (direct visual stress test):</p> <ul style="list-style-type: none"> • 6 months = 83% (20/24) • 12 months = 87% (14/16) • 24 months = 100% (5/5) 	<p>Complications</p> <ul style="list-style-type: none"> • Balloon failure • Bladder perforation • Balloon or port erosion • Vaginal perforation • Urethral perforation • Balloon migration • Urge incontinence <p>The numbers of patients affected were not stated.</p>	<p>Conference abstract.</p> <p>49% (24/49) of patients were assessed at 6 months.</p> <p>Only 10% (5/49) of patients were available for the 24 month follow-up assessment.</p>

Abbreviations used: SUI = stress urinary incontinence, I-QOL = Incontinence Quality of Life, UDI = Urogenital Distress Inventory			
Study Details	Key efficacy findings	Key safety findings	Comments
<p>Sauter T (2003)⁴</p> <p>Case series</p> <p>Multicentre (Brazil, Germany, Italy, France, Austria, USA)</p> <p>120 women</p> <p>Inclusion criteria: type II or type III SUI</p> <p>55% (66/120) of women had previously undergone at least one incontinence procedure, including bulking agents, slingplasty, colposuspension or hydraulic sphincter.</p> <p>Follow-up: 1 to 12 months</p>	<p>Outcome measure: urodynamic measurements and the Incontinence Quality of Life Questionnaire (I-QOL)</p> <p>Recurrent patients Mean I-QOL scores improved from 31 to 68 at 6 months ($p < 0.0001$).</p> <p>Leakage experienced on direct visual stress test at baseline was reduced from 93% (61/66) to 33% (11/33) at 6 months ($p < 0.002$).</p> <p>Patients with maximum urethral closure pressure < 30 cm/H₂O Mean I-QOL scores improved from 34 to 66 at 6 months ($n = 40$, $p < 0.0001$).</p> <p>Leakage experienced on direct visual stress test at baseline was reduced from 96% (44/46) to 40% (17/28) at 6 months ($n = 46$, $p < 0.0013$).</p> <p>Patients with abdominal leak point pressure < 60 cm/H₂O Mean I-QOL scores improved from 32 to 64 at 6 months ($n = 72$, $p < 0.0001$).</p> <p>Leakage experienced on direct visual stress test at baseline was reduced from 92% (74/80) to 36% (17/46) at 6 months ($n = 80$, $p < 0.002$).</p>	<p>Not reported.</p>	<p>Conference abstract.</p>

Abbreviations used: SUI = stress urinary incontinence, I-QOL = Incontinence Quality of Life, UDI = Urogenital Distress Inventory			
Study Details	Key efficacy findings	Key safety findings	Comments
<p>Kocjancic E (2003)⁵</p> <p>Case series</p> <p>1999 onwards</p> <p>Italy</p> <p>37 women</p> <p>Mean age: 58.5 years (range 22 to 84)</p> <p>59% (22/37) type II SUI 41% (15/37) type III SUI</p> <p>57% (21/37) of women had had prior urogenital surgery.</p> <p>Inclusion criteria: type II or type III SUI</p> <p>Follow-up: 1 to 24 months</p>	<p>Outcome measures: quality of life questionnaires (I-QOL and UDI).</p> <p>Dry at 24 months = 47% (7/15)</p> <p>Improved (1 pad daily but substantially satisfied with outcome) at 24 months = 27% (4/15)</p> <p>Number of adjustments required to achieve continence:</p> <ul style="list-style-type: none"> • None = 24% (9/37) • One = 56% (20/37) • Two = 10% (4/37) • Three = 10% (4/37) <p>Mean I-QOL score:</p> <ul style="list-style-type: none"> • Baseline (37 patients) = 32 • 1 month follow-up (31 patients) = 45, p = 0.0002 • 3 month follow-up (26 patients) = 64, p < 0.0001 • 6 month follow-up (23 patients) = 63, p < 0.0001 • 12 month follow-up (19 patients) = 62, p < 0.0004 • 24 month follow-up (11 patients) = 75, p = 0.0001 	<p>Complications</p> <ul style="list-style-type: none"> • Urethral pain = 5% (2/37) • Transient discomfort during sexual intercourse = 3% (1/37) <p>No cases of urinary retention were reported.</p>	<p>Conference abstract.</p> <p>40.5% (15/37) of patients reached 24 months of follow-up.</p>

Abbreviations used: SUI = stress urinary incontinence, I-QOL = Incontinence Quality of Life, UDI = Urogenital Distress Inventory			
Study Details	Key efficacy findings	Key safety findings	Comments
Pacetta AM (2001) ⁶ Case series Brazil 17 women Median age: 45 years (range 31 to 64) Inclusion criteria: type II or type III SUI 18% (3/17) of women had had previous surgery Follow-up: 1 to 18 months	Outcome measures: clinical evaluation, complete urodynamics and quality of life questionnaires (I-QOL, UDI and IIQ). Continent at 30 days after surgery: 65% (11/17) An additional 4 patients achieved continence after adjustment of the balloon volume. Mean abdominal leak point pressure before surgery = 73.5 cm/H ₂ O. Mean abdominal leak point pressure after surgery = 110.4 cm/H ₂ O. Maximum urethral closure pressure before surgery = 30.1 cm/H ₂ O. Maximum urethral closure pressure after surgery = 35.3 cm/H ₂ O (p < 0.05). There was significant improvement in the quality of life questionnaire data after the procedure. Balloon re-implanted or repositioned = 35% (6/17)	Complications <ul style="list-style-type: none"> Discomfort during sexual intercourse = 33% (3/9) Extrusion of balloon due to malpositioning or initial over filling = 18% (3/17) No urinary retention or urethral pain.	Conference abstract. 10 patients were followed up for more than 6 months; 6 patients were followed up between 12 and 18 months.

Validity and generalisability of the studies

Three of the five studies report results from a multicentre study and it is difficult to ascertain the total number of patients treated overall.^{2,3,4} The two remaining studies also appear to be from centres participating in this larger study.^{5,6} There is, therefore, likely to be considerable overlap between all of the studies presented in this overview.

All of the studies have been reported only as conference abstracts and the results presented may be less reliable than those published as full papers in peer-reviewed journals.

The studies all present preliminary data and there are a high proportion of patients that have not completed the full follow-up period.

Specialist Advisors' opinions

Specialist advice was sought from consultants who have been nominated or ratified by their Specialist Society or Royal College.

This is definitely a novel procedure with uncertain safety and efficacy.

The standard approaches to treating stress urinary incontinence include intramural injection of bulking agents, colposuspension, pubovaginal slings, and the use of artificial sphincters.

The key efficacy outcomes are subjective and objective improvement or cure of incontinence, and improvement in quality of life.

The procedure is likely to have a minor impact on the NHS, in terms of numbers of patients eligible for treatment and the use of resources.

The procedure may be useful for selected groups of patients, such as those in whom more conventional procedures have failed.

There are concerns about the long-term efficacy of the procedure and more research is needed.

Issues for consideration by IPAC

A NICE consultation scope for a guideline titled 'Urinary incontinence: the management of urinary incontinence in women', was issued at the end of August 2004. The development of the guideline recommendations will begin in October 2004. The expected date of issue of the guideline is October 2006.

The BAUS Section of Female and Reconstructive Urology established an incontinence surgery database in August 2004. The database will be accessible to all members of the BAUS Section of Female and Reconstructive Urology. Initially, it will not be collecting outcome data and only those people who wish to submit their data will do so. The British Society of Urogynaecology (BSUG) has also established an audit system for incontinence surgery and this will include outcome data. At present, the database may only be accessed by BSUG members via the Secretariat.

References

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2. Kocjancic E, Costa P, Sauter T, et al. European prospective multi-centre experience with adjustable continence therapy (ACT) periurethral prosthetic implantation results at 12 to 24 months. *International Continence Society and International Urogynaecological Association joint meeting 2004, Paris, France. Conference abstract No. 305.* August 2004.
3. Staehler M, Sauter T, Kocjancic E, et al. An international multicenter study of the treatment of female recurrent stress urinary incontinence using the minimally invasive adjustable continence therapy (ACT). *American Urological Association annual meeting 2004. Conference abstract.* May 2004.
4. Sauter T, Kocjancic E, Costa P, et al. Worldwide experience with ACT™ (Adjustable Continence Therapy) for female stress urinary incontinence: analysis of safety and efficacy. *European Urology Supplements 2* 2003; 1: 196.
5. Kocjancic E, Carone R, Crivellaro S, et al. The adjustable continence therapy in female stress urinary incontinence; the Italian experience. *International Continence Society annual meeting 2003, Florence. Conference abstract No. 401.* 2003.
6. Pacetta A, Sadi M, Almeida F, et al. Experience with the adjustable continence therapy (ACT) balloon for the treatment of women with stress urinary incontinence. *International Urogynecology Journal* 2001; 12: 137.

Appendix B: Literature search for extraurethral (non-circumferential) retropubic adjustable compression devices for stress urinary incontinence

The following search strategy was used to identify papers in Medline. A similar strategy was used to identify papers in EMBASE, Current Contents, PreMedline and all EMB databases.

For all other databases a simple search strategy using the key words in the title was employed.

1. Urinary Incontinence, Stress/
2. balloon.mp.
3. ACT.mp.
4. urethral.mp.
5. adjust\$.mp.
6. 2 or 3 or 5
7. 1 and 4 and 6