

NATIONAL INSTITUTE FOR CLINICAL EXCELLENCE

INTERVENTIONAL PROCEDURES PROGRAMME

Interventional procedure overview of cystourethropexy (Vesica[®])

Introduction

This overview has been prepared to assist members of IPAC advise on the safety and efficacy of an interventional procedure previously reviewed by SERNIP. It is based on a rapid survey of published literature, review of the procedure by one or more specialist advisor(s) and review of the content of the SERNIP file. It should not be regarded as a definitive assessment of the procedure.

Procedure name

Cystourethropexy (Vesica[®])

SERNIP procedure number

72

Specialty society

Royal College of Obstetricians and Gynaecologists
British Association of Urological Surgeons

Indication(s)

Stress incontinence refers to urine leakage that occurs when the pressure within the abdomen is raised, during, for example, lifting, coughing or laughing. It is often due to damage to the pelvic muscles during childbirth, which leads to the bladder 'dropping', so that the normal muscular mechanism of preventing flow of urine into the urethra is disturbed.

Stress incontinence should be distinguished from urge incontinence; the latter is commonly due to detrusor overactivity, in which the bladder contracts involuntarily

Stress urinary incontinence is a common problem. During 2000/2001, about 10,000 operations on the outlet of the female bladder were carried out in England (Source: Hospital Episode Statistics, ungrossed for missing data, Department of Health). About 4000 were open abdominal operations, and about 3000 were transvaginal.

Summary of procedure

Most women with stress incontinence are treated without surgery. Traditional surgical options in women with severe stress incontinence include hysterectomy, laparoscopic or open colposuspension and sling procedures. Minimally invasive procedures that can be carried out under local anaesthetic or sedation have been developed recently. These include needle suspension procedures, which may have a shorter recovery time and fewer complications than traditional surgical approaches.

Vesica cystourethropexy is a minimally invasive bladder neck needle suspension procedure, which involves making small incisions in the lower abdominal wall and screwing bone anchors into the pubic bone. Sutures are passed into the vagina on either side of the bladder neck. These sutures are then elevated and tied to the bone anchors to suspend the bladder neck. Vesica refers to the type of bone anchor.

An alternative to sutures is a pubovaginal sling passed around the vagina and anchored using Vesica bone anchors. One version of the Vesica sling kit was withdrawn in the USA in 1999 following reports of vaginal erosion, bleeding and wound dehiscence.

Literature review

Appraisal criteria

We included studies of cystourethropexy using the Vesica bone anchoring system.

List of studies found

We found one Cochrane systematic review on bladder neck needle suspension.¹ It concluded that bladder neck needle suspension surgery had higher morbidity and lower cure rate than open abdominal retropubic suspension. The evidence was limited by poor quality trials. None of the trials included in the review used the Vesica bone anchoring system.

We found no controlled studies.

We found eighteen reports of case series. The table describes the six largest of these.²⁻⁷ Smaller series are listed in the annex.

Summary of key efficacy and safety findings (1)

| Authors, location, date, patients | Key efficacy findings | Key safety findings | Key reliability and validity issues |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p>Benderev T²</p> <p>Case series California, USA Date not stated (published 1994) Suture colposuspension n=150 women with stress incontinence Type I to III</p> | <p>No efficacy findings reported</p> | <p>Complications:</p> <ul style="list-style-type: none"> • infection of suprapubic area: 'rare' • osteitis pubis: none • chronic urinary retention: none | <p>Uncontrolled case series</p> <p>No efficacy findings reported</p> <p>No longer term outcomes reported</p> |
| <p>Stram TR³</p> <p>Case series New York state, USA 1996 to 1999 Pubovaginal sling n=82 women with intrinsic urethral sphincter dysfunction (Type III), average age 67</p> <p>Coexisting detrusor instability: n=59</p> <p>Mean follow up: 14 months</p> | <p>Stress incontinence cured 'completely' or 'almost completely': 80%</p> | <p>Complications:</p> <ul style="list-style-type: none"> • osteomyelitis pubis: 3 women • self-catheterisation required >9 months: 2 women • postoperative incontinence: 21 women | <p>Uncontrolled case series</p> <p>Reported as conference abstract only</p> <p>Many included women had detrusor instability as well as stress incontinence</p> <p>Authors no longer use bone anchors as cure rates were not improved and caused additional morbidity</p> <p>Measurement methods for outcomes not reported</p> |
| <p>Appel RA⁴</p> <p>Case series Ohio, USA Date not stated (published 1996) Suture colposuspension n=71 women with Type I or II stress urinary incontinence</p> <p>Mean follow up: 12 months</p> | <p>'Cure' rate: 94%</p> <p>Patient acceptance: 'high'</p> | <p>Overall morbidity 'minimal'</p> <p>Complications:</p> <ul style="list-style-type: none"> • retropubic abscess: 1 woman • chronic wound infection: 1 woman • chronic urinary retention: none • osteitis pubis: none | <p>Uncontrolled case series</p> <p>Measurement methods for outcomes not reported</p> |

Summary of key efficacy and safety findings (2)

| Authors, location, date, patients | Key efficacy findings | Key safety findings | Key reliability and validity issues |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p>Appel RA⁵</p> <p>Case series Cleveland, Ohio USA Date not stated (published 1997)</p> <ul style="list-style-type: none"> Suture colposuspension; n=71; minimum follow up: 3 years Pubovaginal sling using endopelvic fascia; n=40; minimum follow up: 2 years Synthetic pubovaginal sling; n=78; minimum follow up: 2 years | <p>Suture colposuspension:</p> <ul style="list-style-type: none"> stress incontinence 'cured': 82% <p>Pubovaginal sling using endopelvic fascia:</p> <ul style="list-style-type: none"> stress incontinence 'cured': 98% <p>Synthetic pubovaginal sling:</p> <ul style="list-style-type: none"> stress incontinence 'cured': 94% | <p>Suture colposuspension:</p> <ul style="list-style-type: none"> osteomyelitis: 2 women <p>Pubovaginal sling using endopelvic fascia:</p> <ul style="list-style-type: none"> recurrence of stress incontinence: 1 woman urinary retention resolving in < 3 weeks: 4 women new detrusor instability for <2 months: 3 women <p>Synthetic pubovaginal sling:</p> <ul style="list-style-type: none"> urinary retention requiring surgery: 3 women | <p>Uncontrolled case series</p> <p>The women having suture colposuspension may be the same series in reference 4</p> <p>Measurement methods for outcomes not reported</p> <p>Severity of incontinence in included women not described</p> |
| <p>Haab RA⁶</p> <p>Case series</p> <p>Paris, France Series initiated 1994 Suture colposuspension n=40 women with Type I or II stress incontinence, mean age 60 years</p> <p>Follow up: 1-2 years</p> <p>Exclusion criteria: detrusor instability; sphincter deficiency; grade 2 or 3 cystocele; previous incontinence procedures</p> | <p>Incontinence 'resolved': 92%</p> <p>Mean time to return to normal activities: 2 weeks</p> | <p>Complications:</p> <ul style="list-style-type: none"> urinary retention resolving in <3 weeks: 8 women urinary tract infection: 3 women conversion to general anaesthetic: 1 woman bone infection: none <p>'No major complications' occurred</p> | <p>Uncontrolled case series</p> <p>Measurement methods for outcomes not reported</p> |

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|------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------|
| <p>Ried SV and Parys BT (2003)⁷</p> <p>Case series UK 1994 – 1997 n=41 percutaneous bladder neck suspension</p> <p>Follow-up: 5 years</p> | <p>95% of women reported complete dryness at 6 months</p> <p>'only half' the women remained dry at 12 months</p> <p>at 5 years 85% had recurrence of stress incontinence</p> | <p>Complications:</p> <ul style="list-style-type: none"> • 20% of patients developed wound infections secondary to haematomas in the suprapubic incisions and • 10% required a period of intermittent self-catheterization • suture entered the bladder 4 patients | <p>Uncontrolled case series Abstract</p> <p>Patients assessed 6, 12 months and 5 years.</p> |
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Validity and generalisability of the studies

The studies were carried out in settings applicable to the UK.

We found case series only. These provide limited evidence on the efficacy of the Vesica cystourethropexy bone anchoring system.

Studies examined both pubovaginal sling for suspension of the bladder neck and examined suture suspension.

Some studies included women with all types of stress incontinence, only women with Type I and Type II stress incontinence, and in one study only women with Type III stress incontinence.³

All the case series were relatively large, so do provide some information on safety of the procedure. However, only four of the studies followed up women for at least one year, and only one for five years.⁷ Limited information is therefore available on long term outcomes.

Criteria for selecting women for needle suspension surgery rather than other procedures were not described.

Bazian comments

Benefits and harms may be dependent on whether sling or suture technique is used and the severity of stress incontinence.

Specialist advisor's opinion / advisors' opinions

Specialist advice was sought from the Royal College of Obstetricians and Gynaecologists and the British Association of Urological Surgeons.

The procedure is virtually obsolete due to complications and poor long-term efficacy.

Issues for consideration by IPAC

None other than those discussed above.

References

1. Glazener CM, Cooper K. Bladder neck needle suspension for urinary incontinence in women (Cochrane Review). In: The Cochrane Library, Issue 3 2002. Oxford: Update Software
2. Benderev TV. A modified percutaneous outpatient bladder neck suspension system. J Urol 1994; 152: 2316-2320
3. Stram TR, Ablove RH, Lobel RW. Infectious complications of vaginal wall suburethral slings with suprapubic bone anchors. Int Urogynecol J 2000; supplement 1: abstract 015
4. Appell RA, Rackley RR, Dmochowski RR. Vesica percutaneous bladder neck stabilization. J Endourol 1996; 10: 221-225.
5. Appell RA. The use of bone anchoring in the surgical management of female stress urinary incontinence. World J Urol 1997; 15: 300-305.
6. Haab F, Leach GE. Feasibility of outpatient percutaneous bladder neck suspension under local anesthesia. Urology 1997; 50: 585-587
7. Parys, BT, and Reid, SV The rise and demise of the Vesica procedure: lessons to be learned about bladder neck suspension. Abstract presented at the Annual Meeting of the British Association of Urological Surgeons 2003; Abstract no 125

Annex: References to smaller studies

| Reference | Number of study participants |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------|
| Use of a bone anchoring needle suspension for genuine stress urinary incontinence. Proc Am Urol Assoc 1995; 153 (suppl): 432A-abstract 814 | 40 suture |
| Leach GE. Local anesthesia for urologic procedures. Urology 1996; 48: 284-8 | 40 suture |
| Schultheiss D, Hofner K, Oelke M, Grunewald V, Jonas U. Does bone anchor fixation improve the outcome of percutaneous bladder neck suspension in female stress urinary incontinence? Brit J Urol 1998; 82:192-5 | 37 suture |
| Hom D, Desautel MG, Lumerman JH. Et al. Pubovaginal sling using polypropylene mesh and Vesica bone anchors. Urology 1998; 51: 708-713 | 35 sling |
| Haab F, Cortesse A, Rode P et al. Treatment of stress urinary incontinence with percutaneous colposuspension: unsatisfactory technique. Progres en Urologie 2001; 11: 336-339 | 34 suture |
| Simonazzi M, Larosa M, Sebastio N, Ferretti S, Salsi P, Cortellini P. The mini-invasive surgery of stress urinary incontinence (SUI): the use of the Vesica kit. Acta Biomedica de l'Ateneo Parmense 1997; 68:59-65 | 13 suture 7 sling |
| Batista Miranda JE, Arano Bertran P, Errando Smet C. Percutaneous urethral suspension with bone anchorage (Vesica) in the treatment of stress urinary incontinence. Results after a year of follow up. Actas Urologicas Espanolas 1998; 22: 671-676 | 14 unknown if sling or suture |
| Komatsu F, Inoue Y, Yoshimichi J et al. Surgical results using vesica bone anchoring system in the treatment of female urinary stress incontinence. Nishinohon J Urol 2000; 62: 125-128 | 10 suture 1 sling |
| Yokoyama T, Ozawa H, Hashimoto H et al. Experience of Vesica™ percutaneous bladder neck stabilization for female urinary stress incontinence. Nishinohon Journal of Urology 1999; 61: 554-557 | 9 unknown if sling or suture |
| Sato H, Shiroma K, Miyazawa K et al. Treatment of stress incontinence percutaneous bladder neck stabilisation. Hinyokoka Kiyp – Acta Urologica Japonica 1999; 45: 817-819 | 9 unknown if sling or suture |
| Yoshimura Y, Hashimoto T, Honda K et al. The voiding after the suburethral sling operation, obstructive or non-obstructive? Hinyokoka Kiyp – Acta Urologica Japonica 2001; 47: 83-88 | 7 sling |
| Shetty SD, Kirkemo AK. Bilateral bone anchor vaginal vault suspension: an initial report of a new technique. Tech Urol 1997; 3: 1-5 | 6 suture |

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