

## NATIONAL INSTITUTE FOR CLINICAL EXCELLENCE

### INTERVENTIONAL PROCEDURES ADVISORY COMMITTEE

#### Interventional procedure overview of cystourethropexy (In-tac®)

##### **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 specialist advisors and review of the content of the SERNIP file. It should not be regarded as a definitive assessment of the procedure.

##### **Procedure name**

Cystourethropexy (In-tac®)

##### **Specialty society**

Royal College of Obstetricians and Gynaecologists  
British Association of Urological Surgeons

##### **Indication(s)**

Stress urinary incontinence in women.

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 surgery to lift the uterus (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.

In-Tac cystourethropexy is a minimally invasive bladder neck needle suspension procedure. The anterior vaginal wall is pushed forwards so that the surgeon can feel the pubic bone, so that the bone anchors can be screwed into the bone through the vaginal wall. Then sutures are passed into the vaginal wall on either side of the bladder neck, pulled upwards to elevate the vaginal wall and the bladder neck with it. These sutures are then tied to the bone anchors.

In-tac refers to the type of bone anchor. The anchors are manufactured by Influence Medical Technologies, based in Lancashire, UK.

## **Literature review**

### **Appraisal criteria**

We included studies of cystourethropexy using the In-tac bone anchoring system.

### **List of studies found**

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

We found no controlled studies.

We found seven case series. The table describes the four largest of these.<sup>1-5</sup> 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>Tsivian, A et al (2003)<sup>2</sup></p> <p>Case series<br/>Israel<br/>1995 -1997</p> <p>n=31 women with type I or type II stress incontinence, mean age 58, range 36 to 81 years</p> <p>Mean follow up 67.7 months, range 60 to 76 months</p>  | <p>At follow-up at least 60 months (n=28)</p> <ul style="list-style-type: none"> <li>• completely continent 6 women</li> <li>• underwent another procedures 6 women</li> </ul>   | <p>Complications</p> <ul style="list-style-type: none"> <li>• post operative urinary infection 1 patient</li> <li>• sutures entered the bladder 5 patients</li> <li>• sutures through vaginal tissue 1 patient</li> <li>• vesicovaginal fistula developed 1 patient</li> <li>• anhors became detached 8 patients</li> <li>• pubic osteomyelitis 1 patient</li> <li>• vaginal granuloma 2 patients</li> <li>• dyspareunia 3 patients</li> </ul>  | <p>Result was classified as a success if the patient was completely continent and did not require any pad protection.</p> <p>Limited information</p> <p>Unclear when complications occurred.</p> <p>3 patients were lost to follow-up</p> |
| <p>Levin S<sup>3</sup></p> <p>Case series<br/>Haifa and Holon, Israel<br/>1995 to 1996</p> <p>n=61 women with type I or type II stress incontinence, mean age 52, range 38 to 81 years</p> <p>Mean follow up 12 months, range 3 to 30 months</p> <p>Exclusion criteria: neurogenic bladder; history of recurrent urinary tract infection; intrinsic sphincteric deficiency (Type III); bladder tumour</p> | <p>At 12 months:</p> <ul style="list-style-type: none"> <li>• completely continent (&lt;2g urine in pad test): 50 women</li> </ul> <p>Cure rate decreased from 90% at 3 months to 82% at 11 months</p> <p>Requirement for pain medication: 'minimal'</p> | <p>Complications:</p> <ul style="list-style-type: none"> <li>• transient dyspareunia: 3 women</li> <li>• urinary tract infection: 1 woman</li> <li>• sutures entered bladder: 2 women</li> <li>• urethral injuries: none</li> <li>• haemorrhage: none</li> </ul> <p>Delayed complications:</p> <ul style="list-style-type: none"> <li>• at 3 months, vaginal wall prolapse: 1 woman</li> <li>• at 6 months, vesicovaginal fistula and total incontinence: 1 woman</li> <li>• at 12 months, anchors detached: 1 woman</li> </ul> | <p>Uncontrolled case series</p> <p>Short follow up</p> <p>Women with severe stress incontinence excluded</p>  |

|  |  |  |   |
|--|--|--|---|
| <p>Nativ O<sup>4</sup></p> <p>Case series<br/>Haifa and Holon, Israel<br/>1995 to 1996</p> <p>n=50 women with type I or type II stress incontinence, mean age 51, range 38 to 81</p> <p>Mean follow up: 12 months, range 3 to 21 months</p> <p>Exclusion criteria: neurogenic bladder; history of recurrent urinary tract infection; intrinsic sphincteric deficiency (Type III); bladder tumour</p> | <p>At 12 months:</p> <ul style="list-style-type: none"> <li>completely continent (&lt;2g urine in pad test): 41 women</li> </ul> | <p>Complications:</p> <ul style="list-style-type: none"> <li>transient dyspareunia: 3 women</li> <li>urinary tract infection: 1 woman</li> <li>sutures entered bladder: 2 women</li> <li>urethral injuries: none</li> <li>haemorrhage: none</li> </ul> <p>Delayed complications:</p> <p>At 6 months</p> <ul style="list-style-type: none"> <li>incontinence from undetected suture through bladder: 1 woman</li> </ul> | <p>Uncontrolled case series</p> <p>Women may also be included in Levin<sup>2</sup></p> <p>Short follow up</p> <p>Women with severe stress incontinence excluded</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>El-Toukhy TAA<sup>b</sup></p> <p>Case series<br/>Kent, UK<br/>1997 to 1998</p> <p>n=30 women with stress incontinence,<br/>mean age 54, range 36 to 74</p> <p>Mean follow up: 12 months, range 3-21<br/>months</p> <p>Exclusion criteria: detrusor instability;<br/>neurogenic bladder; urinary tract infection</p> | <p>Reported no urinary leak 6 weeks: 27/30</p> <p>Reported no urinary leak 12 months:<br/>24/30</p> <p>Satisfied with operation 12 months: 25/30</p> <p>All women walking within 24 hours of<br/>surgery</p> | <p>'No intra-operative complications'</p> <p>Complications:</p> <ul style="list-style-type: none"> <li>• pyrexia: 1 woman</li> <li>• urinary tract infection: 3 women</li> <li>• dyspareunia: 7 women</li> <li>• detached bone anchors: 2 women</li> </ul> | <p>Uncontrolled case series</p> <p>Short follow up</p> <p>Severity of incontinence in excluded<br/>women not described</p> |

### **Validity and generalisability of the studies**

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

We found small case series only. These provide limited evidence on the efficacy and safety of the In-Tac cystourethropexy bone anchoring system compared with other minimally invasive techniques or traditional surgical approaches.

Only one case series study had follow-up longer than one year.

Criteria for selecting women for needle suspension surgery rather than other procedures were not described. In one of the studies,<sup>2</sup> the severity criteria for inclusion were not described; the other two<sup>3,4</sup> excluded women with severe 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.*

- 'In-Tac<sup>®</sup> cystourethropexy is almost unused as it confers no benefit over other procedures'
- there is a risk of osteitis pubis
- '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. Tsvian, A, Shtricker, A, Levin S, Sidi A. Bone Anchor 4-corner cystourethropexy: long-term results. The Journal of Urology 2003; 169: 2244-2245
3. Levin S, Bennet AE, Levin D, Danielli L, Levin R, Sidi A. Minimally invasive surgical treatment of female stress urinary incontinence. Int Urogynecol J 1998; 9: 405-408
4. Nativ O, Levine S, Madjar S, Issaq E, Moskovitz B, Beyari M. Incisionless per vaginal bone anchor cystourethropexy for the treatment of female stress incontinence: Experience with the first 50 patients. J Urol 1997; 158: 1742-1744
5. El Toukhy TA, Tolba MA, Davies AE. Assessment of a new bone anchor system for the treatment of female genuine stress incontinence. BJU International 1999; 84: 780-784

## Annex: References to smaller studies

| Reference   | Number of study participants |
|---|------------------------------|
| MacGibbon A, Brieger G, Korda A. Incisionless cystourethropexy -the In-tac device - an initial experience. Austral NZ J Obstet Gynaecol 2000; 40: 59-61       | 15                           |
| Nativ O, Moskovitz B, Issaq E et al. Bladder neck suspension using bone anchors for the treatment of female stress incontinence. ASAIO Journal 1997; 43:204-8 | 15                           |
| Levin S, Bennet AE. Transvaginal four-corner cystourethropexy using bone anchors. J Pelvic Surg 1999; 5: 216-220  | 11                           |

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