NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

INTERVENTIONAL PROCEDURES PROGRAMME

Interventional procedure overview of Retrograde urethral sphincterometry

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 April 2005.

Procedure name

Urethral retro-resistance pressure (URP) measurement.

Specialty societies

- Royal College of Obstetricians and Gynaecologists
- British Association for Urological Surgeons
- British Society of Urogynaecologists

Description

Indications

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 and connective tissues in the pelvic floor and urethral sphincter.

Urethral retro-resistance pressure (URP) is the fluid pressure needed to open, and just keep open, a closed urethra by the retrograde infusion of fluid. This

has been proposed as an assessment of urethral function in women with symptoms of stress urinary incontinence.

Current treatment and alternatives

Diagnosis of stress urinary incontinence is usually based on symptoms, examination and exclusion of underlying causes or comorbidity.

Urodynamic measurements including assessment of urethral function may also be undertaken; however, none of these tests have the capacity to diagnose urinary stress incontinence. Tests of urethral function include urethral pressure profilometry (UPP) and Valsalva leak point pressure. Videocystourethrography may also be used for indirect assessment of urethral function with simultaneous radiological evaluation.

URP has been proposed as a new test of urethral function. This procedure eliminates the need for a urethral catheter and may have a role in the diagnosis of stress urinary incontinence.

What the procedure involves

The procedure involves placing a cone-shaped meatus device a few millimetres (around 5 mm) into the external urethral meatus. The device then infuses fluid at a controlled rate into the urethra. The pressure required to open the urethral sphincter is displayed on the device; urethral opening pressure is the pressure at which the measurement reading plateaus.

Efficacy

Preliminary data on the use of this procedure in women with stress urinary incontinence found that there was a weak relationship between the readings of this test and other standard tests. The correlation coefficient between URP and maximum urethral closing pressure (MUCP) was 0.31 (95% confidence interval [CI], 0.19 to 1, $p < 0.0001$), and between URP and leak point pressure (LPP) was 0.28 (95% CI, 0.21 to 1, $p = 0.003$)[1]. Mean URP was 71 cm H_20 with mean values for URP being significantly different across symptom severity and decreasing with increasing severity. In another study that included some of the same centres but reported on asymptomatic women, the mean URP was found to be 112.6 cm H_20 [2]. However, given the preliminary nature of the data and the differences between studies, caution should exercised when interpreting and comparing results of these two studies.

It is also unclear at this stage the impact of this procedure on patient outcomes.

The Specialist Advisors were cautious in their comments on efficacy given the preliminary nature of this procedure.

Safety

In a study in which 258 women had both the new procedure and a standard procedure, pain (1.9%) and dysuria (1.6%) were the two most commonly reported events[1]. A total of 12 events were noted in a study of 61

asymptomatic women who had the new procedure; this included lower back pain (1.6%), discomfort (1.6%), pain (3.3%), dysuria (3.3%), urinary urgency (3.3%), urinary frequency (3.3%) and transient urine loss (3.3%)[2].

The Specialist Advisors had few safety concerns. Urinary tract infection and mild discomfort were listed by the Specialist Advisors as potential adverse events following the procedure.

Literature review

Rapid review of literature

The medical literature was searched to identify studies and reviews relevant to urethral retro-resistance pressure measurement. Searches were conducted via the following databases, covering the period from their commencement to April 2005: 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 (Table 1) 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.

Table 1 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 who have undergone the procedure.
Intervention/test	Urethral retro-resistance pressure measurement.
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 two studies; one including women with stress urinary incontinence[1], the other reporting on asymptomatic women[2].

Existing reviews on this procedure

No systematic reviews were identified.

Table 2 Summary of key efficacy and safety findings on urethral retro-resistance pressure measurement for urethral function testing

Abbreviations: SUI, stress urinary incontinence; MUCP, maximum urethral closing pressure; LPP, leak point pressure; CI, confidence interval, SST – standing stress test

Study Details	Key efficacy findings	Key safety findings	Comments
Slack et al (2004)[1] Randomised controlled trial, multicentre (22 centres) 258 women 79 women were premenopausal 171 women were postmenopausal Group 1: Test procedure followed by mulitchannel urodynamics Group 2: Mulitchannel urodynamics followed by test procedure Mean age: 56.2 years Follow-up: 1 week Inclusion criteria: Patients were at least 18 years old and complained of SUI Exclusion criteria: History of SUI surgery in the past 6 months; a history of bulking agent injection within the past 12 months; current pregnancy; active infection demonstrated by catheterised urine dipstick analysis; a known active lesion or present injury to the perineum or urethra; or a know urethral obstruction. Conflict of interest/funding source: research was organised, data managed, analysed and financially sponsored by Gynecare.	**Outcomes assessed**: Mean URP, MUCP and LPP. Mean MUCP at 100 ml = 57 cm H_20 Mean LPP at 250 ml = 87cm H_20 Mean URP was 71 cm H_20 Correlation between URP and MUCP was 0.31 (95% CI, 0.19 to 1, $p < 0.0001$) Correlation between URP and LPP was 0.28 (95% CI, 0.12 to 1, $p = 0.003$) Correlation between MUCP and LPP was 0.14 (95% CI, 0.04 to 1, $p = 0.101$). The mean values for URP across symptom severity categories were significantly different and decreased with increasing severity. Premenopausal women had a mean URP of 77 cm H_20 Postmenopausal women had a mean URP of 67 cm H_20 Menopausal status had a significant effect on URP ($p = 0.0068$)	**Complications:** Centres collected adverse events during the study visit and for a period of 1 week after testing. The two most frequent events reported after any procedure were pain (1.9% 5/258) and dysuria (1.6% 4/258). Authors note that the centres reported no serious adverse events. Other adverse events, that may or may not have been related to either procedure, included abdominal bloating, discomfort, pain, dysuria, cramping, frequency, hematura, vaginal spotting, light headedness and transient urinary retention (all < 0.8%). All adverse events resolved quickly.	Randomisation was according to a computer generated sequence. Sample size was based on power calculations. Before randomisation, patients underwent a 24-hour pad test with bladder diary; an incontinence quality of life (I-QOL) questionnaire, a visual analogue score and an incontinence severity score questionnaire. Authors note that there were no statiscally significant differences between the groups. Since the data showed no statiscally significant positive linear relationship between MUCP and LPP, the authors did not perform sensitivity and specificity analysis. The authors note that patients in the study would have had more severe incontinence and perhaps would not be representative of the total SUI population. Authors conducted a subgroup analysis on postmenopausal women.

Abbreviations: SUI, stress urinary incontinence; MUCP, maximum urethral closing pressure; LPP, leak point pressure; CI, confidence interval, SST – standing stress test

Study Details	Key efficacy findings	Key safety findings	Comments
Slack et al (2004)[2] Case series (cohort) 4 study centres (UK/US) 61 asymptomatic women after 1 visit: 58 women had three URP values 2 women had two URP values 1 woman had no reading 57 women were premenopausal 4 women were postmenopausal Retest: 32 women had retest procedures Mean age: 33 years Inclusion criteria: At least at 18 years old and did not have leakage on SST with a full bladder; complaints or urinary incontinence; any prior history of SUI surgery; prior history of urethral bulking agent injection; known active lesions or present injury to perineum or urethra; any degree of anterior wall prolapse; known urethral obstruction; current pregnancy; or active urinary tract infection. Conflict of interest/funding source: research was organised, data managed analysed and financially sponsored by Gynecare.	**Outcomes assessed**: Mean URP Mean URP at 1 visit was 112.6 ± (39.2) cm H20 The lower limit of the one-sided 90% CI for URP was 62 cm H_20. Comparing the mean from this study to the earlier study of symptomatic women[1] found them to be statistically significant. Analysis of premenopausal women: Mean URP for premenopausal asymptomatic women was 111.9 cm H_20 (n = 56) Mean URP for premenopausal symptomatic women was 76.7 cm H_20 (n = 79)	**Complications:** Lower back pain: 1 (1.6%) Discomfort: 1 (1.6%) Pain: 2 (3.3%) Dysuria: 2 (3.3%) Urgency: 2 (3.3%) Frequency: 2 (3.3%) Transient urine loss: 2 (3.3%)	Two of the centres were selected to perform additional URP measurements. At these centres 32 of 33 women returned for retest. The authors wanted to conduct comparisons between asymptomatic and symptomatic groups, but looked at the premenopausal groups only. Note that the differences in mean age, menopausal status and sample size limit the appropriateness of a direct comparison between the asymptomatic and symptomatic populations.

Validity and generalisability of the studies

- This is a procedure in its infancy, so data on efficacy and safety outcomes are lacking.
- The paper by Slack et al (2004)[1] is very explicit in terms of methodological approach and the approach taken by the authors has sought to minimise bias or potential operator variation.
- The study is a key paper; however, it should be noted that not all study objectives were met because one of the assumptions was not established.
- Sample size was calculated on the assumption that there would be a moderate correlation ($p > 0.40$) between two parameters. This was not found. However, the authors note that the relationship was appropriate when assessing a positive linear relationship ($p > 0$)
- Comparisons were made between studies; that is, between the results of asymptomatic and symptomatic women. However, conclusions are difficult to draw given that it is a comparison of unlike groups[2].
- Patient outcomes have not yet been addressed in the literature

Specialist advisors' opinions

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

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- There is little evaluation of the role of this procedure in the clinical evaluation of symptoms.
- Efficacy outcomes are yet to be established.
- Research is currently underway which will hopefully address these issues. However, until this time, the procedure should not be introduced into clinical practice.
- The procedure has the potential to be used prior to surgery.
- It is simple and requires limited training.

Issues for consideration by IPAC

There are several ongong studies looking at this procedure and it is likely, given the involvement of the manufacturer in this procedure, that further research will be published in the near future.

NICE Guidance: The Interventional Procedures Advisory Committee has previously issued guidance on transobturator foramen procedures for stress urinary incontinence (IPG107). There are also several pieces of interventional procedures guidance in development that will examine treatments for stress urinary incontinence. Development of a clinical guideline for urinary incontinence is also underway.

References

1 Slack M, Culligan P, Tracey M et al (2004) Relationship of urethral retro-resistance pressure to urodynamic measurements and incontinence severity.[see comment]. *Neurourology & Urodynamics* 23(2):109-114.

2 Slack M, Tracey M, Hunsicker K et al. (2004) Urethral retro-resistance pressure: a new clinical measure of urethral function.[see comment]. *Neurourology & Urodynamics* 23(7):656-661.

Appendix A: Additional papers on urethral retro-resistance pressure measurement not included in the summary tables

Article title	Number of patients/ follow-up	Comments	Reasons for non-inclusion
Peters GJ, McKinney T, Rezapour M et al. (2003) Multicenter study of gynecare MoniTorr urethral resistance pressure versus standard urodynamic MEA. *Obstetrics and Gynecology* 101:114S.	150 women with stress urinary incontinence	Abstract - limited information	These results are from one of the centres involved in the multicentre trial described in the above table[1]

Appendix B: Literature search for urethral retro-resistance pressure measurement

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.

Search strategy used in Medline

1 (urethra$ adj3 retro-resistance pressure).tw
2 URP.tw.
3 Monitorr.tw.
4 (retro$ adj3 filling adj3 urethra$).tw.
5 retro$ sphincterometry.tw.
6 or/1-5
7 leak point pressure.tw
8 (urethra$ resistance adj3 (profile or pressure or test$ or measur$ or system$ or assess$)).tw.
9 urethra$ closure pressure.tw.
10 (urodynamic$ adj3 measur$ adj3 system$).tw.
11 (urethra$ function$ adj3 (profile or pressure or test$ or measur$ or system$ or assess$)).tw. (
12 or/7-11
13 retro$.tw.
14 12 and 13
15 6 or 14
16 Stress urinary incontinence.tw.
17 exp Urinary Incontinence, Stress/pp [Physiopathology]
18 (urinary tract adj (dysfunction$ or function$)).tw.
19 detrusor instability.tw.
20 (sphincter adj (deficiency or dysfunction$ or function$)).tw.
21 or/16-20
22 15 and 21
23 limit 22 to humans

Procedure number: 296	Procedure Name: Urethral retro-resistance pressure measurement	
Databases	**Version searched (if applicable)**	**Date searched**
Cochrane	2005 Issue 1	13.4.2005
CRD Databases	March 2005	13.4.2005
Embase	1980 to 2005 week 15	11.4.2005
Medline	1966 to March week 5 2005	11.4.2005
Premedline	April 08, 2005	11.4.2005
CINAHL	1982 to April week 1 2005	11.4.2005
British Library Inside Conferences (limited to current year only)	2004 to current	13.4.2005
National Research Register	2005 Issue 1	11.4.2005
Controlled Trials Registry	N/A	13.4.2005