The Regulation and Quality Improvement Authority

Regional Audit of the Use of Mid-Urethral Tapes for Stress Urinary Incontinence in Northern Ireland

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Assurance, Challenge and Improvement in Health and Social Care

Preface

The audit of mid-urethral tape surgery for the management of stress urinary incontinence in Northern Ireland commenced following the recommended suspension of mesh surgery in Scotland pending an Independent Review commissioned by the Scottish Government in June 2014.

Within Northern Ireland, clinicians (surgeons, physiotherapists and continence advisers) were concerned that problems experienced by women elsewhere required evaluation in their own region. There was a desire to establish the quality of care provided locally and use this information to assist in a strategy for continence services in the future.

My thanks to the project team, who assisted in the development of the audit proforma and provided feedback from the draft reports. The medical students and O&G Trainees, despite their examinations and assessments, were enormously helpful in the collection of data throughout Northern Ireland over a period of time much longer than anticipated. I do hope that benefit will accrue to them in their careers having had experience at first hand of a major audit process. They were greatly assisted by the audit staff within each Trust and staff and managers in Independent Hospitals.

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Executive Summary

Background

Recent concerns from patient groups who have suffered complications associated with mid-urethral tape surgery have resulted in worldwide and United Kingdom (Scotland and England) inquiries. The focus has been on the safety of devices used to treat Stress Urinary Incontinence (SUI).

Clinicians in Northern Ireland with the assistance of the Regulation and Quality Improvement Authority's (RQIA) Clinical Audit programme (formerly Guidelines and Audit Implementation Network) wished to investigate the preparation for mid-urethral tape surgery (pre-operative therapy, investigation and consent), operative technique and immediate post-operative care/review, as a first step towards understanding the apparent mismatch between the clinicians' perception of the procedure as being effective and safe and patients' distressing experiences of complications.

Aims and Objectives

To assess the quality of care provided for patients who have had mid-urethral tape surgery for the management of stress urinary incontinence (SUI) carried out in Northern Ireland (NI) during the calendar year of 2013. This includes the use of conservative measures before surgery, consent, surgical technique/workload, and complications of the procedure.

Key Findings

The overall conclusion of the audit was that the use of mid-urethral tape appeared to be effective and safe in the short term for the management of SUI in Northern Ireland.

- *Mean age at the date of the procedure was 50.9yrs and two-thirds (67%) were undertaken in the age group between 40 – 60 yrs.*
- *77% (215/279) of women for whom BMI was measured were overweight (BMI 25 – 29.9) or obese (BMI 30 – 34.9). This was compared with the NI adult female population in 2013/2014 of whom 56% were overweight or obese.*
- *Pelvic Floor Physiotherapy was offered to at least 73% (248/340) of the sample population. This figure must be regarded as a failure of compliance with the NICE Guidelines (2006)* [(6)] *in which physiotherapy is regarded as a first line therapy in the management of stress urinary incontinence.*
- *Urodynamic investigation was carried out in 90% (305/340) of the sample population. Information obtained about availability of urodynamics in all Trusts has established that all women potentially have access to appropriate assessment of their lower urinary tract.*
- *The quality of information given to women during the consent process was variable: advice on the risk of infection, bladder trauma and voiding disorder was provided in 95% (313/331), 92% (304/331) and 88% (291/331) of cases respectively whereas information on the risk of failure of the technique (60%,*

199/331) and de novo urge and urge incontinence (59% 195/331) was recorded less frequently.

- *A Consultant or Specialty doctor undertook the operative procedure in 86% (293/340) of cases and was present at surgery in 99% (337/340) of cases. These figures indicate a high level of input by senior medical staff.*
- *78% (32/41) of Consultants who undertook the operative procedure were not compliant with the NICE recommendation* [6] *on workload of completing at least 20 procedures in 2013. Within NI, 63% (26/41) of Consultants undertook between 5 and 20 procedures in 2013, with 15% (6/41) performing fewer than five mid urethral tape surgeries in that year.*
- *55% (188/340) of mid-urethral tapes were inserted by the transobturator route and 44% (148/340) retropubically in 2013. The surgical technique was unknown in four women. This predominance of the transobturator technique was higher than in other parts of the United Kingdom (UK). Repeat mid-urethral tape procedures were undertaken across all Trusts in NI in 21/340 cases (6%).*
- *80% (214/268) of women reported an overall improvement of stress incontinence symptoms at initial review (based on the number of patients where review information was available).*
- *79% (268/340) of women attended for a post-operative review. Methods of review included attendance at an outpatient clinic, telephone call or ward attendance. The majority of reviews (85%, 229/268) occurred within 6 months of surgery for the study cohort. Evidence of follow up was not available for 13% (43/340) of women.*
- *Most complications of the procedure were in line with those described in the literature. De novo urge and urge incontinence had a higher incidence (14%) than expected.*

Recommendations

- It should be mandatory for Trusts multidisciplinary teams to implement pre-operative care in line with NICE CG171. Consent should be primarily a detailed one to one discussion with a patient about a procedure and should be supplemented with appropriate information documents e.g. a patient leaflet or/and 'sticker' for the consent form which outlines the risks, benefits and potential complications.

- Only practitioners with appropriate training and who undertake an agreed number of cases annually (NICE CG40, 2006[6] states 'at least 20') should undertake mid-urethral tape surgery.

- Repeat surgery for stress urinary incontinence following a mid-urethral tape procedure, should only be undertaken within a setting that provides specialised Consultant care in urogynaecology.

- All practitioners who undertake mid-urethral tape surgery should submit data to a recognised national audit database to facilitate monitoring of results e.g. British Society of Urogynaecology (BSUG) or British Association of Urological Surgeons (BAUS).

- Formal post-operative follow up in an outpatient setting by staff with clinical expertise in the management of mid-urethral tape surgery is important to identify any deleterious effects of mid-urethral tape surgery. Women require advice on possible long term sequelae and how to seek assistance.

- Review of OPCS-4 codes is required to facilitate audit of repeat mid-urethral tape procedures and surgical operations undertaken in response to tape complications (e.g. tape division, trimming, partial or complete excision).

- An audit of long term outcomes (e.g. five years) should be undertaken.

Clinical Audit Report

Background

Mid-urethral tapes[i]* were described for the treatment of stress urinary incontinence (SUI) in 1996[(1)]. Predominantly, polypropylene mesh was inserted through the retropubic space with the further development of an alternative technique through the obturator foramen initiated by Delorme in 2001[(2)]. The mesh is placed at mid-urethral level, without tension, to prevent hypermobility of the urethra during exertion such as coughing or exercise. This has been a successful minimally invasive procedure in the management of a debilitating condition in the short and medium term [(3)]. A number of different synthetic and biological mesh materials are now available. The predominant synthetic material used in 2013 within Northern Ireland was polypropylene with polyvinylidene fluoride (PVDF, Dynamesh®) being used in a small number of procedures.

Polypropylene mesh may also be used for the management of vaginal prolapse. Its use in this context is not addressed within this audit.

Adverse outcomes for mid-urethral tapes have been reported, such as post-operative pain, dyspareunia, tape erosion, voiding disorders and recurrent incontinence. Research shows that these complications occur in a low percentage of cases against a background of a reported effective operation for the management of SUI [(3)].

Communications issued by Regulators over a number of years have advised clinicians of evolving problems with mesh procedures. In 2008, the United States Food and Drug Administration (FDA) warned that the deleterious effects of mesh were 'rare'. However, in 2011[(28)], this warning was upgraded, stating that these deleterious effects were 'more common' than previously thought. However these complications were associated with mesh that was used in prolapse repair. Mid-urethral tape procedures for SUI were not the subject of the FDA safety communication.

In June 2014, the Acting Chief Medical Officer for Scotland recommended that Health Boards consider the suspension of all mesh procedures used for both prolapse and urinary incontinence, pending an Independent Review commissioned by the Scottish Government. This followed a request put before the Scottish Government Petitions Committee by patients adversely affected by vaginal mesh complications.

During 2015, NHS England set up a Mesh Working Group with the support of the Department of Health and the European Regulatory Authority the Medicines and

[i] * *The term 'mid-urethral tape' refers to the insertion of mesh material (predominantly polypropylene in this audit) sub urethrally using a retropubic, transobturator or 'mini sling' technique.*

Healthcare Products Regulatory Agency (MHRA). This group was established to address concerns about the safety and efficacy of mesh use for vaginal prolapse and stress urinary incontinence.

In 2014, the MHRA published a report on the safety and adverse effects of the use of vaginal mesh for stress urinary incontinence and prolapse which states that "for the majority of women, vaginal implant surgery is safe and effective" [(4)].

Also in 2014, the International Urogynaecological Association (IUGA) issued a position statement outlining the value of mid-urethral tape in the management of SUI, having assessed evidence from 2,000 publications [(5)].

Notwithstanding the apparent sound research base for the value of mid-urethral tapes (mesh) there still appears to be a mismatch between the clinician's perception of outcome and experiences expressed by some patients. This issue is now of prime importance, due to rising public concern in the USA, UK and other countries about the complication rates and safety of the technique. As a result in 2014, clinicians in NI requested the assistance of RQIA to conduct a regional audit of the use of mid-urethral tapes for the management of SUI in NI.

Audit Aim

To assess the quality of care against the standards for mid-urethral tape surgery for the management of SUI in Northern Ireland

Audit Objectives

To undertake an assessment of care in the following specific areas of practice:

- Preoperative management of the patient with SUI – appropriate conservative measures in advance of surgery;
- Use of urodynamic investigation;
- Proper consent procedures;
- Surgery to be undertaken by surgeons familiar with the technique with an appropriate training and workload in this type of operation;
- An assessment of the complications of surgery as compared to the literature; and
- Outcome following surgery, at first review, in terms of improvement in incontinence from clinicians' and patients' perspective.

Audit Standards

The standards used were taken from National Institute for Health and Care Excellence (NICE) documentation:

- NICE (2006), *Urinary Incontinence: the management of urinary incontinence in women. Clinical guideline* (CG40, 2006) [(6)].

NICE Guideline CG40 was replaced by NICE CG171 *Urinary incontinence in women: management.* However its publication in September 2013 and subsequent issue in Northern Ireland in December 2013 meant that these changes occurred in the year chosen for the regional audit. It was regarded as more appropriate to use the earlier NICE Guideline (2006) as the Standard of Practice against which outcomes should be measured. The following audit criteria drawn from the NICE Guideline on Urinary Incontinence (CG40, 2006) demonstrate the core principles of practice in the use of mid-urethral tapes for SUI.

Audit Criteria (100% target to be achieved)

1. Offer a trial of supervised pelvic floor muscle training of at least 3 months duration as first-line treatment to women with stress or mixed urinary incontinence**.** (NICE CG40, 2006) [(6)]
2. In making the decision to use mid-urethral tape, the patient should be fully informed of the advantages and drawbacks of the relevant surgical procedures.
3. The procedure should be performed only by surgeons who have received appropriate training in the technique, and who regularly carry out surgery for stress incontinence in women. An annual workload of at least 20 cases per procedure is recommended (NICE CG40, 2006) [(6)]

Methodology

A retrospective audit of cases was undertaken for women who had undergone mid-urethral tape surgical procedures in Northern Ireland during the period January 1st – December 31st, 2013. A letter was sent to the Chief Executives of all HSC Trusts and Independent Sector Hospitals advising them of the regional audit. All agreed to participate. Data access and/or confidentiality agreements were signed before the start of data collection.

All women in NI undergoing a bladder procedure involving the use of mid-urethral tapes were coded using any of the following OPCS Classification of Interventions and Procedures Codes (OPCS-4). OPCS-4 codifies operations, procedures and interventions performed during in-patient stays, day case surgery and some out-patient treatments in NHS hospitals. Though the code structure is different, as a code set, OPCS-4 is comparable to the American Medical Association's Current Procedural Terminology. M53.3 (vaginal operations to support outlet of female bladder - introduction of Tension Free Vaginal Tape, TVT) or M53.6 (vaginal operations to support outlet of female bladder - introduction of Transobturator tape, TOT) (either as the primary operation or secondary operation in any position) between 1st January and 31st December 2013 were included in the audit population.

This included a number of women referred to Health and Social Care (HSC) Trusts who underwent such procedures within Independent Sector Hospitals as these were being commissioned for HSC Trust patients at that time. Private patients were excluded from the scope of the audit.

In total, 691 patients were identified as having undergone these procedures in NI in 2013. The initial intention was to study all 691 patients. However delays as a result of the time taken to secure individual HSC Trust and Independent Sector approval to examine the data and the limited time availability of auditors to examine the case-notes required a change to the methodology. Subsequently, an audit sample of 50% was identified rather than the entire 2013 cohort.

The 340 cases were selected using stratified sampling methodology, based on the overall identified populations within each HSC Trust/Independent Sector Hospital. Simple randomisation was subsequently applied and random numbers generated using an online tool accessed via Graph Pad software.

Audit staff working within HSC Trusts across Northern Ireland assisted with patient identification and co-ordinated retrieval of the case-notes required for the audit.

Senior medical students (Years 4 and 5), Foundation Year 1 doctors and a Specialist Trainee in Obstetrics & Gynaecology were recruited for data collection. Data collection was also undertaken by the Assistant Trust Governance Manager in the Northern Health and Social Care Trust along with the Project Lead (also a Specialist Trainee in Obstetrics & Gynaecology).

Before the start of the audit, data collectors received training on terminology, techniques of surgery, case-note review and common abbreviations used. Guidance notes were also provided to assist with completion of the audit proforma (see Appendix 2). Information was recorded using an audit proforma (see Appendix 1) that had been piloted in a preliminary study. No patient or clinician identifiable information was recorded.

The initial audit proforma content was based on information supplied to the British Society of Urogynaecology Audit Database and following the preliminary audit the content of the audit proforma was amended. Members of the Ulster Gynae-Urology Society (UGUS) multidisciplinary team were consulted during the audit proforma design.

As part of initial data validation, 20% of cases in the first HSC Trust to be audited were double-audited (i.e. the same case was audited by two different auditors), to measure the consistency of the data collection.

Data from the proformas were entered onto Microsoft Excel by audit staff in the Northern Health and Social Care Trust. Data validation then involved a double check of 7% of the dataset content for accuracy (25 proformas). This was followed by additional quality assurance/validation and subsequent analysis by the Assistant Trust Clinical and Social Care Governance Manager in the Northern Health and Social Care Trust.

Please note that due to the rounding rule not all totals will equal 100%.

Exclusions

Private patients undergoing mid-urethral tape surgical procedures were excluded from the audit.

Review/outcome information was not available for some patients included in the audit sample as either no review was apparently planned, the patient failed to attend or no review information was available within the case-notes.

The statistical significance of the difference in outcomes referred to in the discussion has been calculated using the *z* score test for two population samples, where the null hypothesis is that there is no difference in outcome between the two groups. A z score less than 1.64 indicates that the null hypothesis can be accepted with 95% confidence.

As there is no reason to believe that there would be any difference in outcomes for the patients who returned for review compared with those who didn't, given the similarity of the age, BMI, parity and type of procedure, of both groups, analysis of patient outcomes has been calculated using complete cases only as the denominator.

Population

In total, 691 mid-urethral tape procedures were performed in Northern Ireland in 2013. A sample size of 340 (49%) was used.

The predominant synthetic material used in 2013 within Northern Ireland was Type 1 mesh constructed from polypropylene. Of the 340 cases audited, only 17 cases (5%) used polyvinylidene fluoride (PVDF, Dynamesh®).

Table 1 (overleaf) provides a breakdown of the number of procedures performed and the sample size for each HSC Trust and within the Independent Sector (HSC Trust patients only). Due to the small number of procedures undertaken within individual Independent Sector Hospitals, the number of procedures has been combined.

Table 1: Number of Procedures Performed

Organisation Name	Total population (*Total Mid-urethral Tape procedures performed in 2013 audit time period*)	Sample size *(Number included in audit)*
Northern HSC Trust	137	68
Southern HSC Trust	137	68
Western HSC Trust	120	58
Belfast HSC Trust	102	51
South Eastern HSC Trust	99	47
North West Independent Hospital/ Ulster Independent Clinic	96	48
Total	**691**	**340**

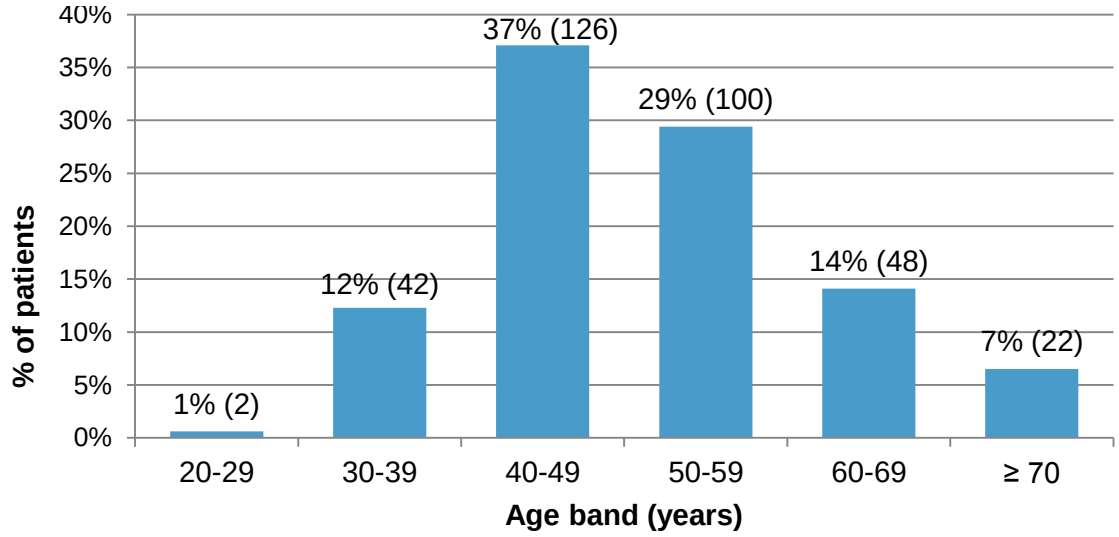
Clinical Audit Findings

Demographics

Age at date of procedure

The mean age was 50.9 (range 29-86 years). The majority of procedures 226/340 (67%) were undertaken in the 40 – 49 years and 50 – 59 years age groups. Noteworthy is that two women were <30 years.

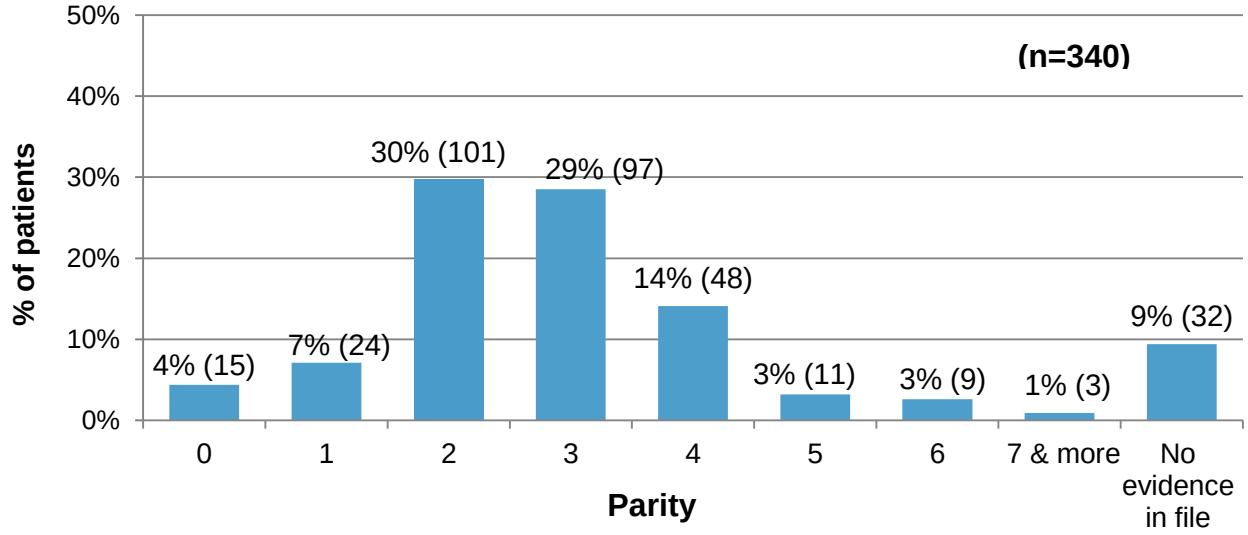
Graph 1: Age at procedure **(n=340)**



Parity

Parity ranged from 0-10 with a median parity of 3. Fifteen nulliparous women had the operative procedure.

Graph 2: Parity at procedure

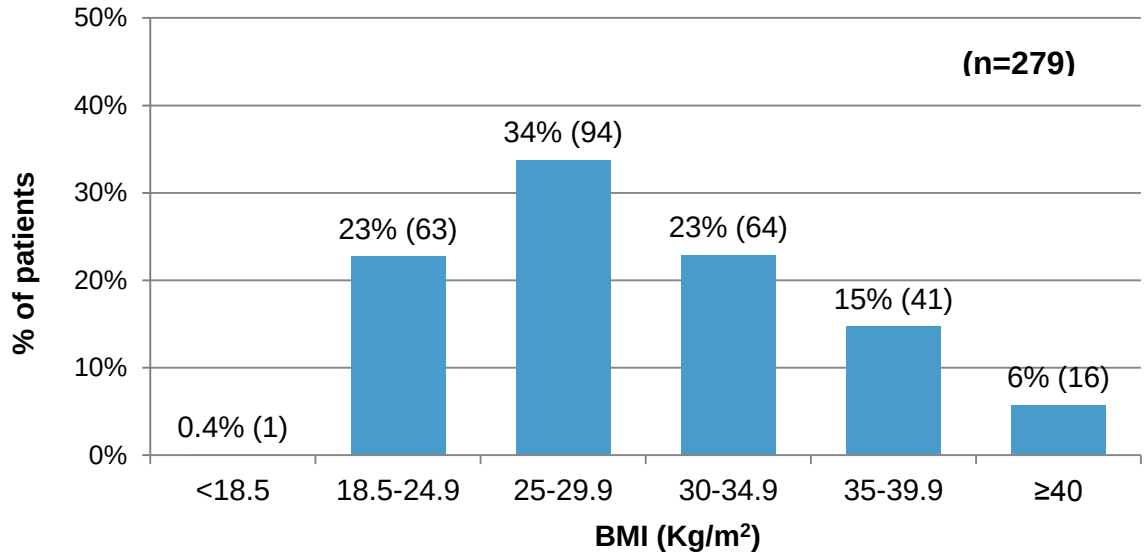


Note: 7 & more (3 women) – 7, 9, and 10

Body Mass Index (BMI)

The sample mean BMI was 29.9 (range: 18-54.7 Kg/m^2). At least 77% (215/279) of this cohort of women undergoing mid-urethral tape procedures were overweight or obese. Information on BMI was unavailable for 61/340 (18%) women.

Graph 3: BMI of women undergoing procedures



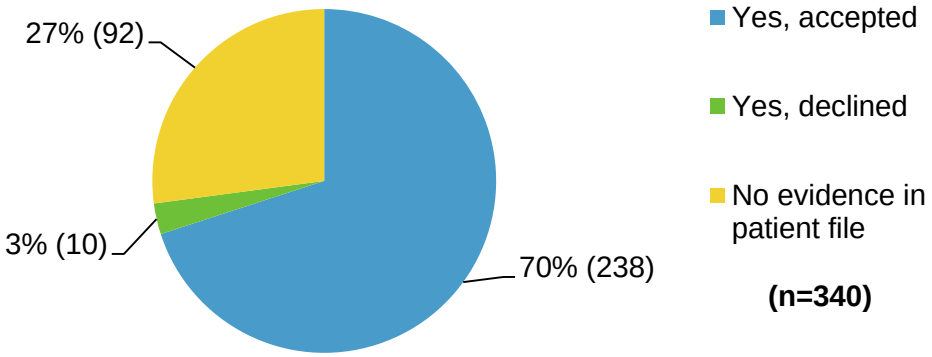
BMI (Kg/m2) Descriptor (Ref: NICE 2014 CG189 Obesity: Identification, Assessment and Management)

18.5 or less Underweight; 18.5 to 24.9 Healthy Weight; 25 to 29.9 Overweight; 30 to 34.9 Obesity I; 35 – 39.9 Obesity II; and 40 or more Obesity III

Pre-operative preparation

Pelvic floor exercises

Figure 1: Pelvic Floor Exercises Offered?



In 92/340 women (27%) no record was present in the patients' case-notes as to whether or not pelvic floor exercises had been offered. Within Figure 1 there were administrative difficulties that hindered the audit; in some cases, patients had a number of case-notes relating to the same gynaecological complaint of SUI and had their appointments, procedures or reviews at different sites and not all charts from all sites were available for audit. However, at least 73% (248/340) of women were offered pelvic floor exercises. The term 'at least' is in recognition of patients who attended for surgery but whose full details of preoperative care (to include physiotherapy) were unavailable to the auditors.

Graph 4: Supervision of pelvic floor exercises

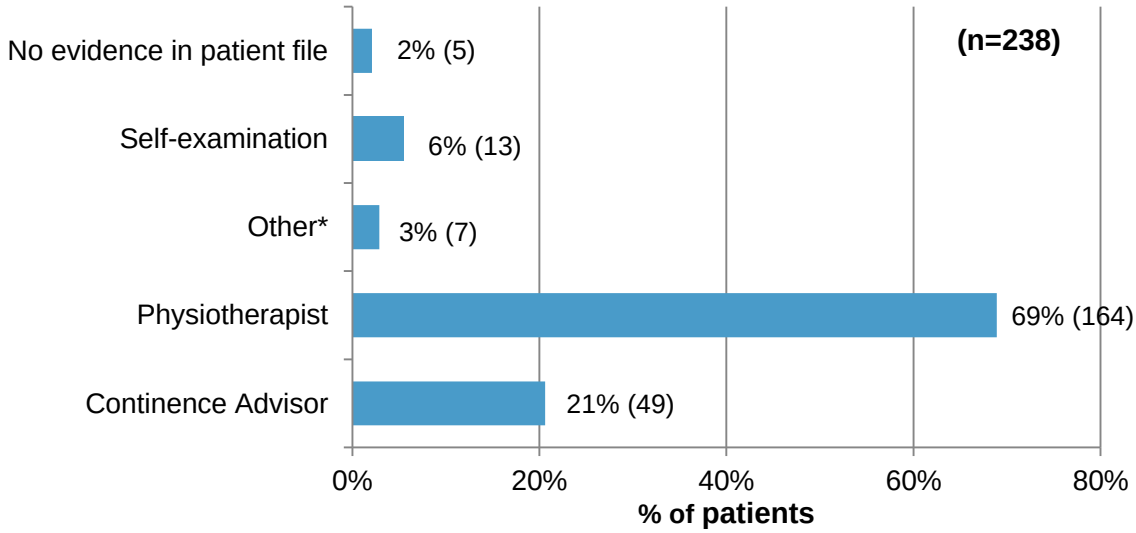


Figure 2: Completed pelvic floor exercises

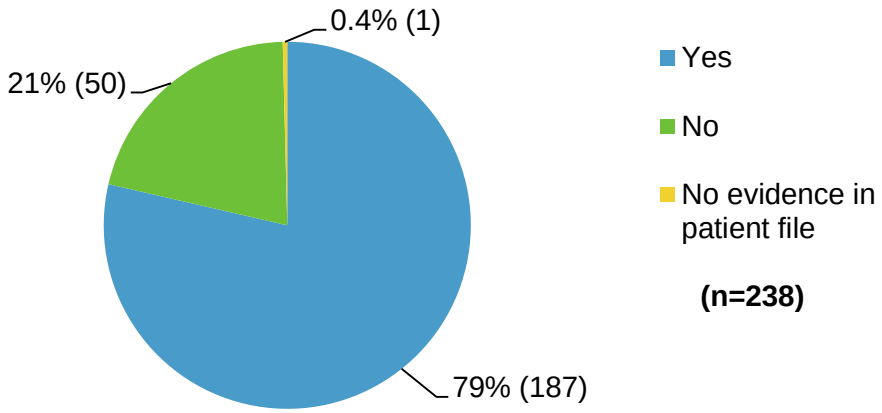
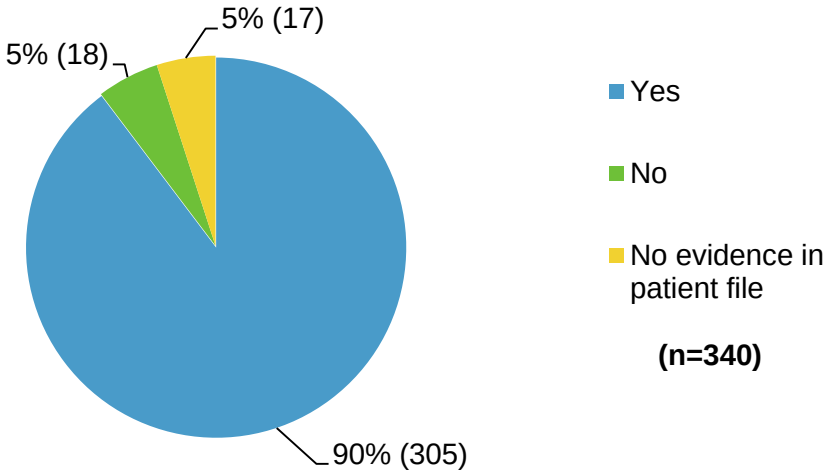
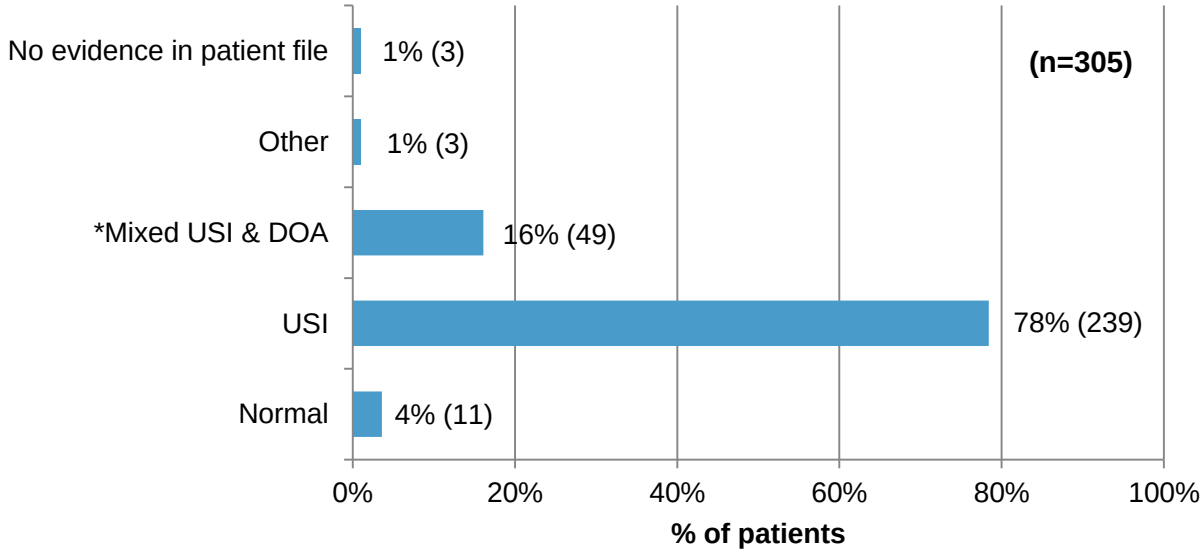


Figure 3: Pre-operative urodynamics performed?

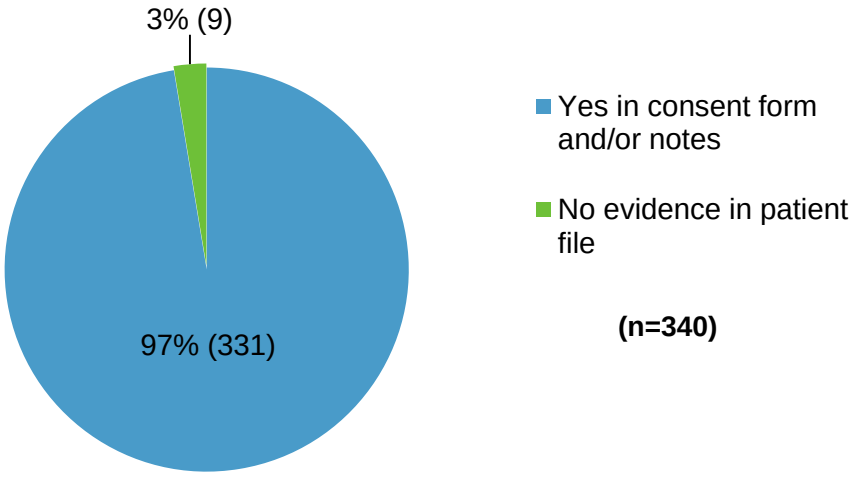


Graph 5: Urodynamic diagnosis



*Note: *Mixed USI (Urinary Stress Incontinence) & DOA (Detrusor Overactivity)*

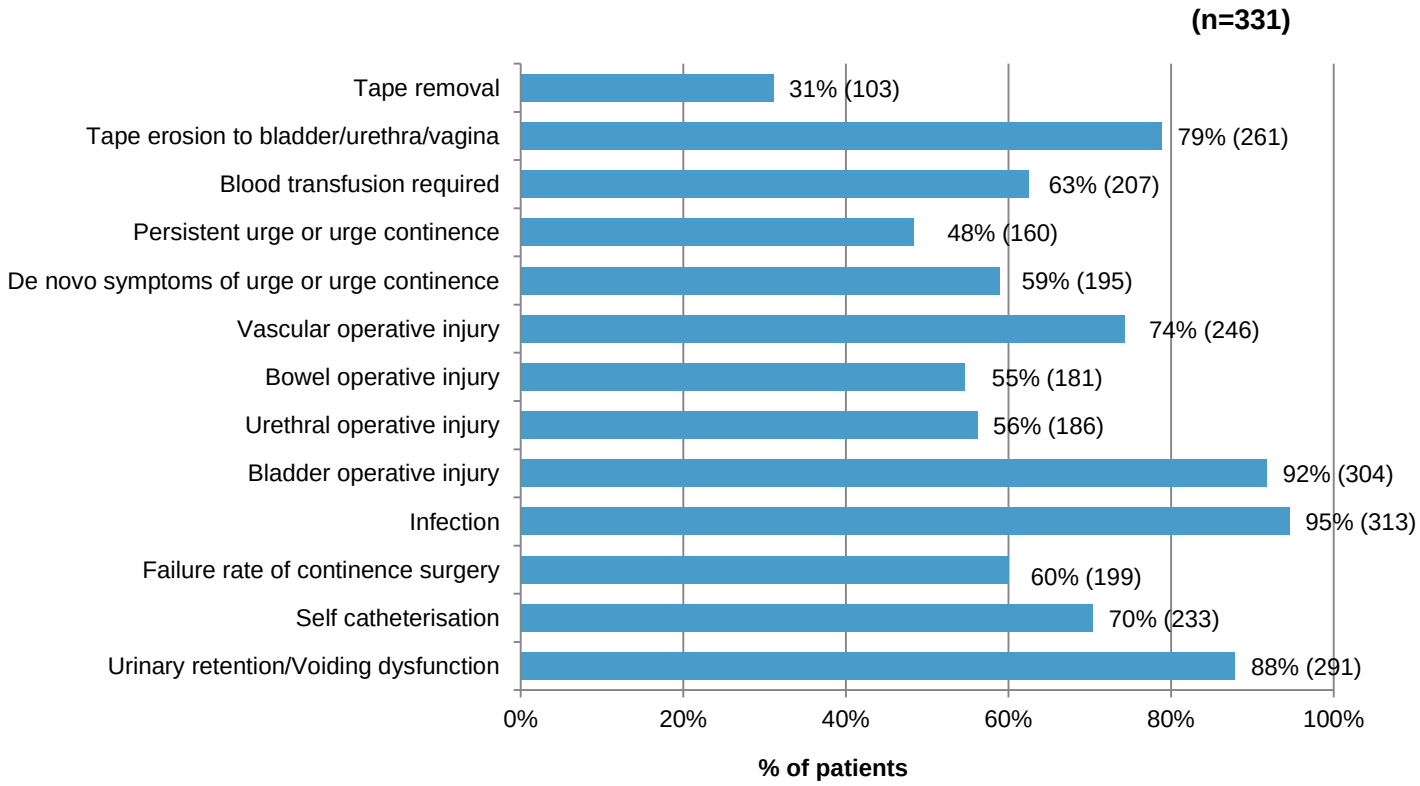
Figure 4: Evidence of written patient consent?



In 331/340 women (97%) consent was obtained in written form and was present within the case-notes. Three of these women (1%) had evidence of written consent within the case notes but without a formal consent form.

In 9/340 women (3%) no record of consent for surgery was in the patient record.

Graph 6: Information provided at consent on complications

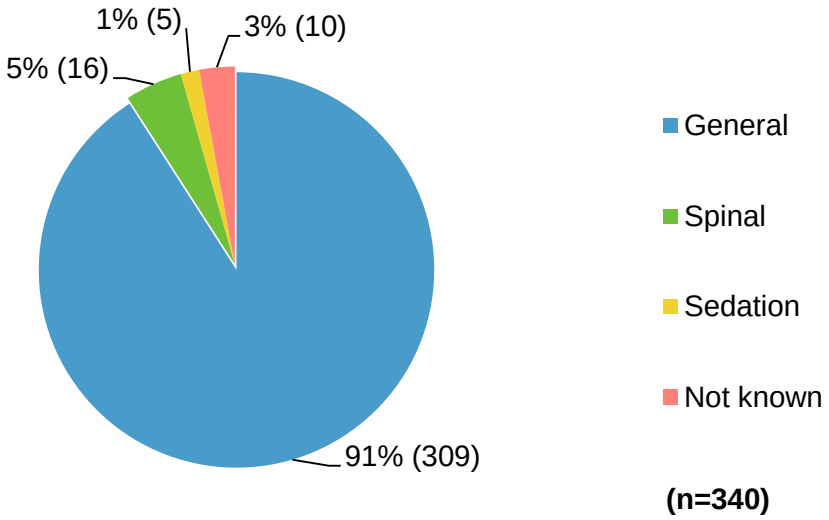


Of those women who had a consent form filed in their clinical notes in advance of surgery (331/340), information was given on the risk of infection, bladder trauma and voiding disorder in 95%, 92% and 88% of cases respectively. Evidence of advice on

tape erosion (79%) and failure of surgery to improve incontinence (60%) in addition to the frequency of information on other accepted surgical complications at consent is set out in Graph 6 (see previous page).

Procedure-related information

Figure 5: Anaesthetic type



General anaesthesia was the technique of choice in 91% (309/340) women. This is at variance with the original intention for the use of mid-urethral tape as being a minimally invasive operation under local anaesthesia.

Graph 7: Grade of most senior surgeon at procedure

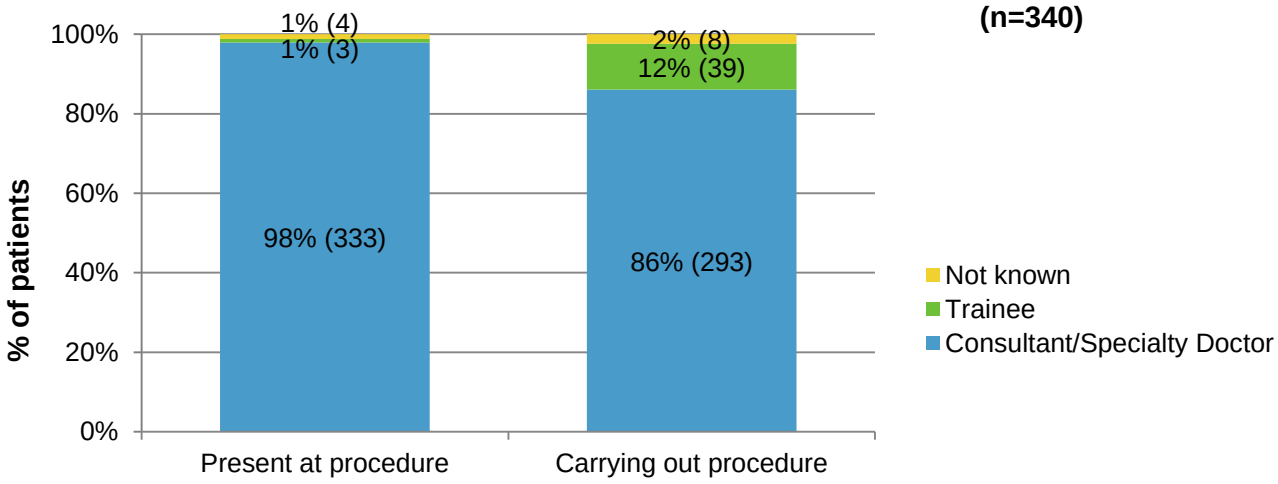
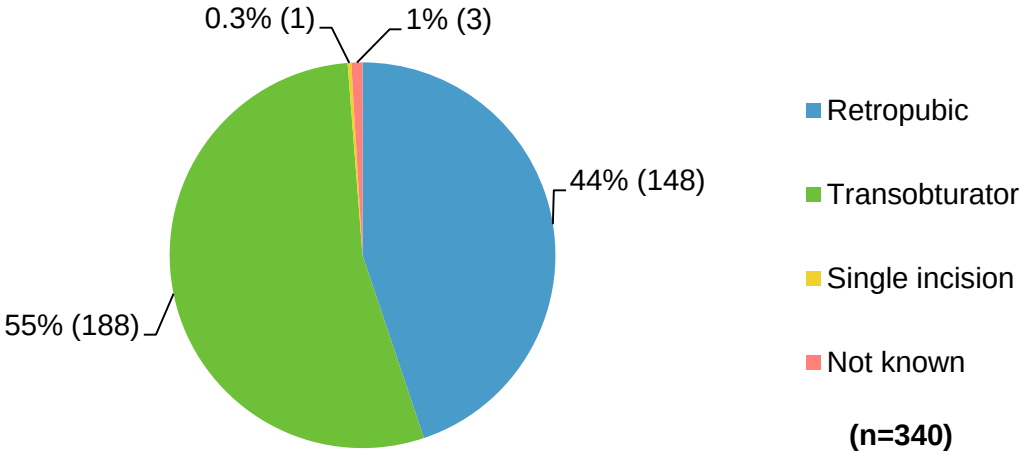


Figure 6: Surgical technique



A transobturator approach was used in 188/340 (55%) and the retropubic method in 148/340 (44%). The prevalence of the transobturator approach is greater than elsewhere in the UK. In one case a single incision technique was used. The surgical approach was not documented in three cases (1%).

Cases per Consultant in 2013 calendar year (HSC Trusts only)*

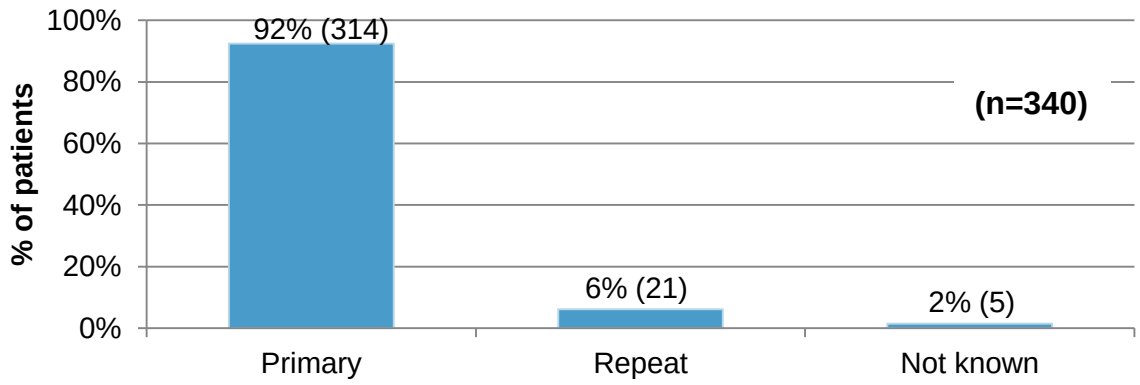
**Some Consultants may have had additional cases as part of their work within Independent Sector Hospitals*

Table 2: Cases per Consultant

	% of Consultants (n=41)
Less than 5 cases	15% (6)
5 - 20 cases	63% (26)
More than 20 cases	22% (9)

The NICE Urinary Incontinence guideline (CG40, 2006) recommends that at least 20 cases per annum per surgeon are required to maintain their skills.

Graph 8: Incontinence surgery type (primary or repeat surgery)



Of the 21 women undergoing a repeat mid-urethral tape procedure, nine had previously had one or more transobturator procedures. In the 12 additional cases the procedure type could not be determined.

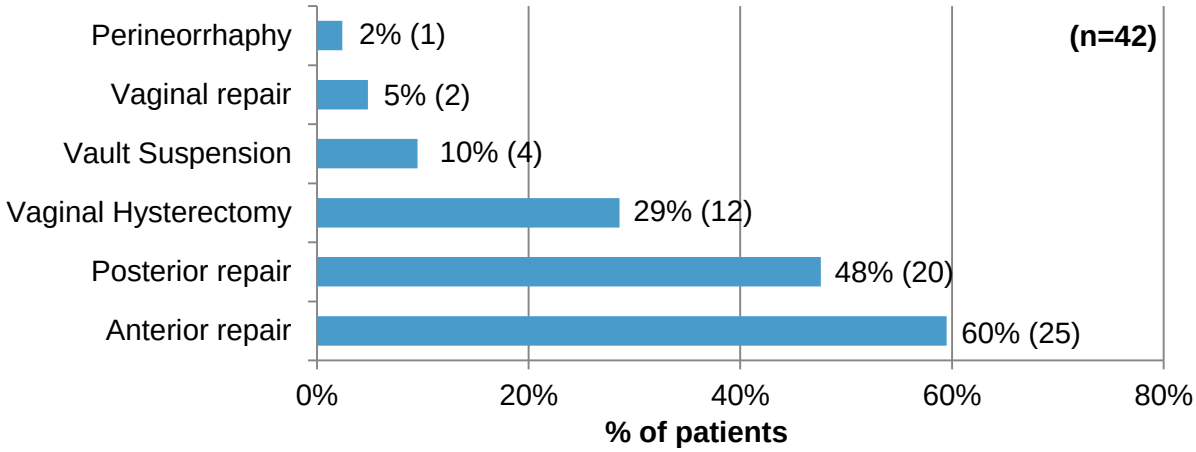
Concomitant Surgery

Other surgery was performed in addition to mid-urethral tapes in 77/340 (23%) women. This included procedures such as:

- insertion or replacement of Mirena coil
- laparoscopic sterilisation
- oophorectomy
- excision of labial cyst
- hysteroscopy
- removal of ring pessary
- excision of bladder lesion
- salpingo-oophorectomy
- salpingectomy
- vesical botulinum toxin injection.

In 42/340 women (12%), concomitant pelvic organ prolapse surgery was undertaken.

Graph 9: Concomitant pelvic organ prolapse surgery



Note: Some women had more than one procedure

Length of stay

The length of stay for the whole audit sample varied depending on whether concomitant procedures were performed or not. In those patients who had a mid-urethral tape procedure only (263/340), 89% (235) were either day cases or had an inpatient stay of 1-2 days*

*Note: *Day Case: Admission and discharge on the same date*
1-2 days: Indicates an overnight stay

Complications

Intraoperative complications

In 320/340 cases (94%) there were no intraoperative complications. Seventeen women (5%) experienced intraoperative complications. In the remaining three cases (1%) information on complications was not available.

Intraoperative Complications by Surgical Technique (n=17 of 336* women)

* *In three cases the technique of surgery was unknown and in one further case the surgical technique was 'single incision' (with no complications)*

Table 3: Intraoperative complications as percentage of total number of known transobturator and retropubic procedures undertaken

		Surgical technique	
		Retropubic	**Transobturator**
Number of procedures		**148**	**188**
% of intraoperative complications	**Bladder perforation**	6% (9)	2% (3)
	Vaginal button holing	0% (0)	2% (3)
	Blood loss >500 mls intraoperatively	1% (1)	0 (0%)
	Urethral injury	1% (1)	0 (0%)

Post-op morbidity by surgical technique (n=35 of 336 women*)

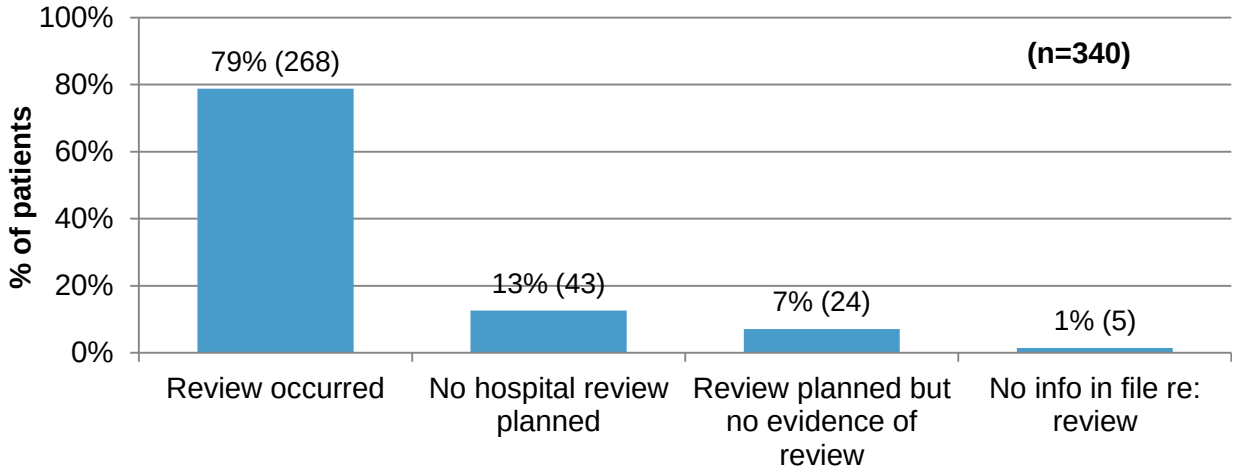
* *Please note that women may have had more than one complication*

* *In three cases the technique of surgery was unknown and in one further case the surgical technique was 'single incision' (with no post-op morbidity)*

Table 4: Post-op morbidity as proportion of total number of known Transobturator and Retropubic procedures undertaken

		Surgical technique	
		Retropubic	Transobturator
Number of procedures		**148**	**188**
% of post-operative complications	Tape complication	2% (3)	5% (10)
	Blood transfusion	0% (0)	1% (1)
	Self-catheterisation >10 days	7% (10)	2% (3)
	Groin pain	1% (2)	3% (6)
	Hospital re-admission within 30 days	3% (4)	3% (5)
	Return to theatre within 72 hours	0% (0)	1% (1)

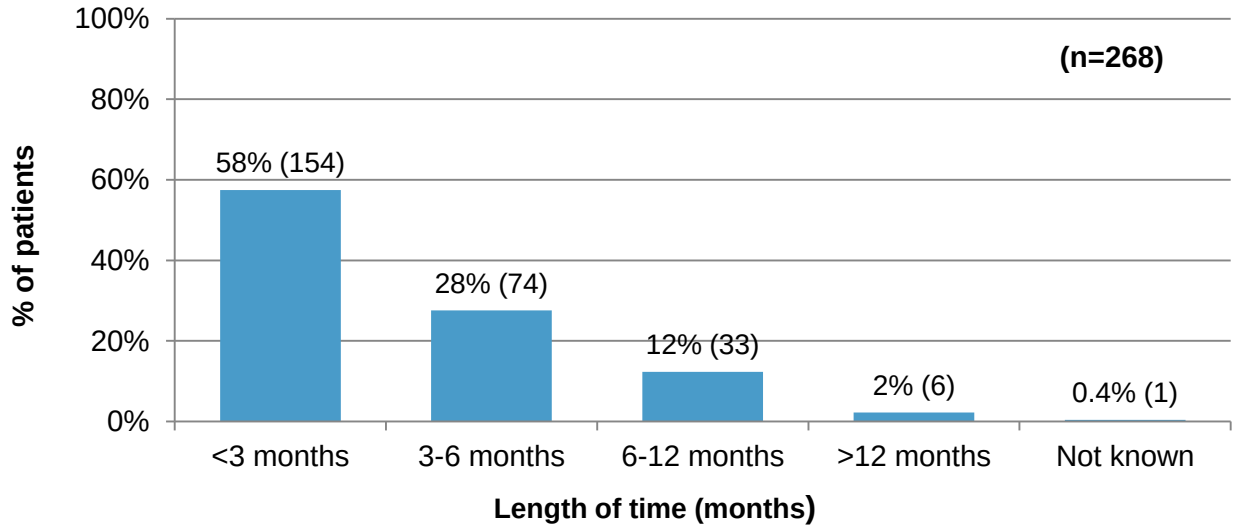
Graph 10: Post-operative follow-up (First Review)



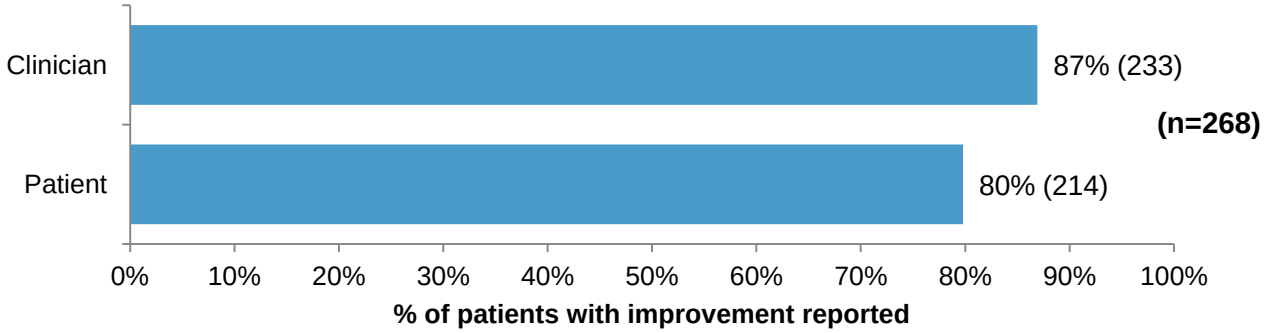
There was evidence of post-operative review in 268/340 (79%) cases. The methods of review included hospital outpatient appointment, telephone review, and ward attendance. In a further 43/340 (13%) cases no specific hospital review or follow-up was planned. All HSC Trusts had some cases where no review was planned.

* Consists of tape loosening or cutting for urinary retention / excision for mesh erosion / tape cutting or loosening for pain.

Graph 11: Interval to first review



Graph 12: Impression of improvement in stress urinary incontinence at first review by patient and clinician



214/268 (80%) women reported an overall improvement in stress incontinence symptoms at initial review (based on the number of patients where review information was available). Thirty-eight women (14%) reported no improvement in symptoms and in 15/268 (6%) cases the case-notes did not contain explicit patient feedback regarding symptoms. In one remaining case the tape had been removed before review.

In 233/268 cases (87%) the clinician's impression at initial review was that the patient's stress urinary incontinence was 'better' than prior to the procedure. In 12 cases (4% of 268 patients where review information was available) patient feedback regarding recovery differed from the clinician's impressions; the clinician had stated 'better' in terms of improvement for stress urinary incontinence and the patient stated 'not improved'.

Table 5: Relationship of clinical factors with success at first review

		Number of procedures	% Improved (± 95% C.I.)	% Not improved (± 95% C.I.)
Age	< 65 years	219	85% (± 5%)	15% (± 5%)
	>= 65 years	33	85% (± 12%)	15% (± 12%)
BMI	<=29.9	114	88% (± 6%)	12% (± 6%)
	>=30	82	77% (± 9%)	23% (± 9%)
	Not known	56	91% (± 7%)	9% (± 7%)
Surgical Technique	Retropubic	112	85% (± 7%)	15% (± 7%)
	Transobturator	136	85% (± 6%)	15% (± 6%)
	Single Incision	1	100%	0%
	Not known	3	100%	0%
Pre-op urodynamics diagnosis	USI[1]	185	87% (± 5%)	13% (± 5%)
	Mixed USI & DOA[2]	38	79% (± 13%)	21% (± 13%)
Nature of surgery	POP surgery	33	82% (± 13%)	18% (± 5%)
	Concomitant surgery	24	79% (± 16%)	21% (± 16%)
	Mid-urethral surgery only[3]	195	86% (± 5%)	14% (± 5%)
Surgery Type	Primary Procedure	237	86% (± 4%)	14% (± 4%)
	Repeat Procedure	12	67% (± 27%)	33% (± 27%)
	Not known	3	100%	0%
Grade of surgeon	Consultant/Specialty Doctor	214	84% (± 5%)	16% (± 5%)
	Non Consultant	33	94% (± 8%)	6% (± 8%)
	Not known	5	80% (± 35%)	20% (± 35%)

[1] 239 patients had a pre-op urodynamics diagnosis of USI however there is only SUI improvement patient feedback data available relating to 185 patients

[2] Following pre-op urodynamics 49 patients had a diagnosis of mixed USI & DOA. Not all were reviewed or attended for review - information was only available for 40 patients and only 38 had patient feedback available on SUI improvement

[3] Mid-urethral tape surgery only* i.e. no Pelvic Organ Prolapse (POP) or other Concomitant Surgery

Table 6: Complications* at first review (n=55 of 268 women)**

* *Please note that women may have had more than one complication.*

***In three cases the technique of surgery was unknown and in one further case the surgical technique was 'single incision' (with no complications)*

	Surgical technique	
	Retropubic	**Transobturator**
Number of procedures	**120**	**144**
Persistent pain without erosion	6 (5%)	2 (1%)
Dyspareunia (painful sexual intercourse) without erosion	4 (3%)	2 (1%)
Groin Pain (at review)	2 (2%)	4 (3%)
Vaginal tape erosion	2 (2%)	1 (1%)
De novo development of frequency and urge (5 of these women had a combination of urge and pain)	19 (16%)	18 (13%)

Pain at review was assessed by identifying those women with dyspareunia and groin pain in addition to persistent pain since surgery.

There was no evidence from case-notes if pain was sought as a symptom at review in 71/268 cases (26.5%). However it might be expected that such an important symptom would be volunteered by the patient.

There was no evidence from case notes whether or not painful intercourse had been investigated as a symptom in 200/268 (75%) of women at first review. In one additional case (0.4%) the tape had been removed before review. Of those asked, 60/67 (90%) of women had no painful intercourse; 7/67 women (10%) expressed symptoms of painful intercourse (in one case this patient also experienced tape erosion). Of the six women who were experiencing painful intercourse without erosion four had retropubic procedures and two transobturator procedures.

Tape erosion occurred in three women, one woman complained of dyspareunia and persistent pain and the other persistent pain.

Numbers are small but both retropubic and transobturator techniques contribute to the finding of pain at first review.

Information was sought for the incidence of de novo frequency or urgency - in 192/268 women (72%) there was no evidence of de novo frequency or urgency whereas 37/268 women (14%) noted these symptoms. 19 of these 37 women had retropubic procedures compared with 18 undergoing the transobturator approach. Importantly there was no evidence that de novo development of frequency and urgency was sought in 38 women (14%). In one remaining case (0.4%) the tape had been removed before review.

Discussion

This audit of mid-urethral tapes in Northern Ireland was undertaken because of evolving concerns expressed by patient groups and Governments in various countries throughout the world (Scotland/USA/England/Australia [7,8] . Clinicians in NI wished to establish compliance with standards of practice for surgery involving the use of mid-urethral tapes, as set out in the NICE Guideline Urinary Incontinence: The Management of Urinary Incontinence in Women (CG40, 2006).

The audit has demonstrated that the use of mid-urethral tapes appears to be effective and safe in the short term (at time of initial review) for the management of stress urinary incontinence in NI. Overall, initial symptomatic outcomes as an indication of success of the procedure compare well with the literature. The audit establishes that 87% (233/268) of those seen at the initial review (range <3 months to >12 months) had an improvement in symptoms of stress urinary incontinence according to the clinician, for all techniques of the procedure. The difference in numbers of patients who had improved for a retropubic (85%, 95/112) versus transobturator procedure (85%, 115/136) at early review was not significant.

A recent systematic review in the Cochrane database [3] compared 55 trials examining subjective cure (patient reported improvement) of transobturator and retropubic procedures and established 'moderate evidence' that the rates of cure were similar in the short term ranging from 62 – 98% in the transobturator group and 71 – 97% in the retropubic group. The audit outcomes for improvement in stress urinary incontinence fall within these ranges for NI.

Demography

The mean age at the date of the procedure was 50.9 years and two-thirds of procedures (67%, 226/340) were undertaken in the 40 – 60 years age group. This is in line with prevalence studies in NI which indicated a peak of urinary incontinence in the perimenopausal age group (45 – 54 years) [9].

The majority of women within this audit had one or more children which indicate that parity is a risk factor for stress urinary incontinence. This is particularly so for the fertile age group in addition to the perimenopausal years [10].

77% (215/279) of patients for whom BMI was measured were overweight (BMI 25 – 29.9) or obese (BMI greater than or equal to 30). This was compared with the NI adult female population in 2013/2014 which established that 56% of adult females were overweight or obese [11]. The finding that a substantially higher percentage of the audit cohort were overweight/obese supports previous findings that urinary incontinence [12] is related to increased BMI.

Pelvic Floor Physiotherapy

The first criterion set for the audit was in relation to offering a trial of supervised pelvic floor muscle training (PFMT) of at least three months' duration as first-line treatment to women

with stress or mixed urinary incontinence. This intervention has been established as a worthwhile conservative treatment [13]. Various modalities of treatment were used depending on the HSC Trust. Most physiotherapy units would combine PFMT with bladder training, education on lifestyle and may include electrical stimulation or/and biofeedback. The audit did not examine these other forms of therapy.

PFMT as outlined was offered to at least 73% (248/340) of the sample population. This figure must be regarded as a failure of compliance with the NICE Urinary Incontinence Guideline (CG40, 2006) whereby physiotherapy is regarded as the first line therapy in the management of stress urinary incontinence. Difficulties in the collection of data may have contributed to the seemingly lower numbers of women being offered PFMT. In some cases, women had their appointments, procedures or reviews at different sites and as a result had a number of different case notes relating to the same gynaecological complaint. Thus relevant paper work was not available in a number of charts used for audit to demonstrate to auditors that PFMT had been offered. However, even allowing for these difficulties, the use of such conservative therapy compares to the British Society of Urogynaecology database review where 79% had preoperative physiotherapy [14].

Urodynamics

The audit shows that undertaking urodynamic investigation in advance of surgery seems to have become embedded within practice in Northern Ireland with 89% (305/340) of women undergoing pre-operative investigation. This finding is in line with results from the British Society of Urogynaecology (BSUG) Audit Database where 97% had urodynamic investigation in advance of surgery [14]. It is part of routine clinical practice.

NICE CG40[6] states that urodynamic investigation is not essential before primary surgery in women with pure stress urinary incontinence. However, it is acknowledged that the majority of women are 'likely to require urodynamic testing because they have some symptoms of OAB (overactive bladder).

Doubt is now being cast in the literature on the value of this test in terms of improving outcomes following surgery [15,16].

Rachaneni[15] summarises: "In women undergoing primary surgery for SUI or stress-predominant mixed urinary incontinence (MUI) without voiding difficulties, urodynamics does not improve outcomes – as long as the women undergo careful office evaluation." The important phrase is 'as long as the women undergo careful office evaluation'. Before any further evaluation of the efficacy of urodynamics in established medical practice in NI is undertaken standards need to be set for 'careful office evaluation'. This would include history, examination with assessment of bladder neck descent, visualisation of SUI and assessment of post void residuals to make a diagnosis.

In this audit, 94.4% of the sample had pure USI or mixed urinary incontinence. The dataset is incomplete due to lack of follow up in some cases but the subjective outcome (patient reported improvement) for success of surgery with a diagnosis of 'USI alone' is

87% (161/185). This compares with outcomes for a mixed diagnosis of USI and Detrusor Overactivity (DOA) where surgery success is 79% (30/38). This difference is not significant and is at variance with the literature that indicates that DOA is an adverse risk factor in surgery for USI [17] [18]. However numbers in this audit are small and therefore care must be exercised with any conclusions that may have been reached.

Consent

The second criterion set for the audit relates to whether adequate consent processes were in place in advance of surgery. The audit did not examine the general risks of surgery such as anaesthetic mishap or thromboembolism. Common (1/10 – 1/100) complications that would be expected to be discussed with a patient undergoing this type of surgery include

- risk of infection
- mesh erosion
- bladder or urethral trauma
- failure of the procedure
- persistent or de novo urge
- temporary bladder emptying problems
- groin pain (particularly with a transobturator procedure).

Information on the risk of infection, bladder trauma and bladder emptying problems (voiding disorder) was given to the patient in 95%, 92% and 88% of cases respectively. Advice on tape erosion (79%) and failure of surgery to improve incontinence (60%) was less consistent and persistent urge (48%)/de novo urge (59%) were discussed in approximately only one half of the sample. Thus information given on the common complications was variable with some areas being well covered and others being included in consent discussions less often. The audit omitted, in error, to request information on whether or not 'groin or pelvic pain' as a complication was included within consent. The variability in the quality of consent discussions has encouraged some HSC Trusts to use an Operation Specific Consent Form which assists the process by listing specific complications that must be discussed with patients. This may be particularly helpful when considering the frequent turnaround of doctors in training within the Health Service.

Anaesthesia

General anaesthesia was the anaesthetic of choice in 91% (309/340) of cases, spinal in 5% (16/340), sedation in 2% (5/340) and unknown technique in 3% (10/340). This is perhaps surprising considering that Ulmsten's original paper described the technique of mid-urethral tape insertion as 'an ambulatory surgical procedure under local anaesthesia' [19]. However, no apparent explanation exists for the high percentage of this procedure being undertaken under general anaesthesia in Northern Ireland. 23% (77/340) had concomitant pelvic floor surgery and would therefore have been expected to have a general anaesthetic. It is possible that patients declined the offer of regional or local anaesthesia and there may well also have been a preference on the part of the surgeon or anaesthetist for the procedure to be undertaken with the patient fully anaesthetised.

Appropriate Training/Expertise

'Appropriate training' was included as the third criterion of practice set for the audit and was determined by the identification of the most senior surgeon present at the operation. The audit however was not designed to identify whether or not a particular surgeon had formal training in the technique. A Consultant or Specialty doctor either undertook the procedure in 86% (293/340) of cases or was present at surgery in all but 1% (3/340) cases – in 1% (4/340) cases the surgeon is unknown. The high percentage of cases where senior clinicians either performed or were present during surgery would be in line with good practice.

Workload was compared with the NICE (CG40, 2006) [(6)] criterion. The recommendation from NICE is that a practitioner should be performing at least 20 cases of each primary procedure per year. Surgeons undertaking fewer than five cases per year should only do so with the support of their relevant Governance Committee.

Within NI, in 2013, 78% (32/41) of Senior Clinicians undertook less than 20 cases in 2013. Only 22% (9) complied with the NICE recommendation of performing at least 20 procedures yearly. 15% (6) performed less than five mid-urethral tape surgical procedures per year.

In the context of NI with a small population (1.8 million) and with the majority of Gynaecologists being trained as generalists, the NICE (CG40, 2006) recommendation of each surgeon performing 'at least 20 surgical procedures per annum' is difficult to attain. In the future there would need to be considerable narrowing of the field by limiting performance of these procedures to subspecialist gynaecologists or generalists with an interest in urogynaecology. Difficulties in attaining sufficient numbers will be further exacerbated following recent concerns about mesh usage. The procedure itself of mid-urethral tape insertion is not technically difficult. Instead of concentrating on number of procedures it is perhaps more important that the operation is undertaken within the confines of good governance – preoperative preparation and consent, multidisciplinary assessment and adequate post-operative review. However, the standard set by NICE CG40 (2006) whereby a practitioner should be performing at least 20 cases each year was not met in 2013 in Northern Ireland.

Small numbers do not allow meaningful conclusions to be reached when considering the grade of surgeon undertaking surgery. However results of the audit show that when the operation is undertaken by a trainee under supervision of senior medical personnel, 94% (31/33) of patients who had the procedure reported an improvement in SUI at their first review.

Surgical Technique

The transobturator technique was the most commonly performed surgical method for SUI during 2013 with 55% (188/340) of cases being performed by this route. 44% (148) were undertaken using the retropubic route. Within this audit, no significant difference in the outcome (improvement in stress urinary incontinence) was present in the short term

whether the operation was undertaken by the retropubic or transobturator route. The audit outcome is supported by the most recent Cochrane review[3] which indicates that both procedures are equally efficacious in the short (1-2 years) and medium term (3-5 years).

For transobturator procedures, mesh complications including excision, cutting or loosening of mid-urethral mesh for urinary retention are the most frequent form of post-operative morbidity (Table 4). The incidence of these complications is lower for retropubic procedures. However numbers are small making statistical comparisons inappropriate. Self catheterisation indicating voiding dysfunction is more common following the retropubic approach – 7% (10/148) of cases against 2% (3/188) for the transobturator procedure. Both the incidence of voiding disorder and its more frequent occurrence when using the retropubic as opposed to the transobturator approach are comparable with the literature [3].

This preference for use of the transobturator technique is higher than in other parts of the UK and at variance with the 2010 BSUG Database results in which 67% of procedures UK-wide used the retropubic route and only 23% were performed using the transobturator technique [14].

The recent Scottish Independent Review of mesh surgery has demonstrated a substantially higher repeat SUI surgery rate when using the transobturator approach. This has led to a recommendation for the adoption of the retropubic approach as the preferred procedure [7]. This is further supported by the Cochrane review also finding higher re-operation rates for the transobturator approach in medium and long term studies [3].

Repeat mid-urethral tape procedures were undertaken across all Trusts in Northern Ireland in 21/340 cases (6%). Unfortunately in 12/21 cases it was not possible to identify whether the initial procedure had used a transobturator or retropubic approach. 9/21 of repeat surgical cases definitely had a previous transobturator procedure.

There has been some debate about whether or not complex cases requiring repeat procedures involving a wide range of disease/conditions should be undertaken in all Trusts. The Department of Health document on ‘Good Practice in Continence Services’ recommended almost 20 years ago an integration of services such that local units would have access to national, regional or sub regional specialist units[20]. Evidence from other fields has accumulated to suggest that the best outcomes for specialist surgery are achieved when surgical teams operate on a critical volume to maintain expertise [29]. The recommendation included within NICE CG40 (2006) is unequivocal and states that complex stress incontinence surgery requires a higher level of training and should be carried out in surgical centres that have adequate volume to maintain expertise and best outcomes[6].

It may be reasonable to surmise that intense media scrutiny will do more to change practice such that the use of mesh for incontinence will in the future be confined to specialists with a particular interest in urogynaecology.

Concomitant Prolapse Surgery

A mid-urethral tape procedure was also used in 12% (42/340) of patients with urodynamically proven USI and who also required concomitant prolapse surgery. The most common procedures undertaken were an anterior or posterior colporrhaphy (repair). Of those reviewed post-operatively (33/268) no significant difference was observed in outcome in terms of improvement in stress urinary incontinence between those who had concomitant surgery (82% +/-13%) and those with mid-urethral tape surgery alone (87%+/-5%). This is in agreement with the literature with particular reference to the use of colporrhaphy and mid-urethral tape [21]. Concomitant colporrhaphy does not affect outcome when undertaken in conjunction with mid-urethral tape surgery.

Initial (First) Review

Methods of post-operative review identified within the case-notes included attendance at outpatient clinics, use of telephone calls or ward attendance. Post-operative review took place in 268/340 (79%) of women. The majority of reviews (85%) occurred within six months of surgery for the study cohort. A number of planned reviews took place at >6 months (15%, 39/268). Explanations for these timescales were not present in patients' case-notes. Review NHS appointments were under considerable strain during 2013 and this may also have had an influence on the variable timescale [30].

A number of patients (43/340, 13%) had no planned review and it is difficult to understand this approach in such a specialised area of practice. No guidelines exist [6] as to either the necessity for or the method of follow up after mid-urethral tape surgery, other than the requirement for surgeons to audit their results. It is not certain how this can be achieved considering the lack of a targeted approach to outpatient review appointments (as distinct from a first Consultant appointment) in NI [30].

Complications

Happily no major complications of surgery were identified in the case-notes of the cohort of patients who were part of the audit – thus there were no major vascular/thromboembolic or neurological sequelae identified during the period of the study.

The most common intraoperative complications were bladder perforation and vaginal 'button holing'. Bladder perforation was more common in retropubic procedures in 9/148 (6%) of cases as compared to 3/188 (2%) in the transobturator approach. Vaginal button holing was confined to the transobturator technique occurring in 3/188 (2%) of cases. Neither complication has been identified as having any long term sequelae and their low incidence within the audit also compares with the literature [3, 22].

A poorly defined complication identified by the audit as being associated with both techniques is the finding of 'persistent pain', present in 3% (8/268) of women at review. Such pain, which was distinct from groin pain or dyspareunia, is not confined to a single technique – 6 women with persistent pain had undergone a retropubic procedure and 2 had transobturator procedures. 2% (6/268) of women had dyspareunia without erosion and 2% (6/268) had groin pain. Again these complaints were not confined to a particular

technique of surgery. Although groin pain is reported as being more common in transobturator procedures, this was not the case in this audit. The incidence of pain of all types at review is comparable with the literature [3].

The audit demonstrates that the vast majority of women (200/268) had not apparently been asked about painful intercourse at their first review. When a procedure is successful in dealing with the primary complaint there may be a tendency in practice to reduce the relevance of certain other associated complaints that may be more difficult to address [23]. Further follow up of this group of patients with persistent pain/groin pain and dyspareunia may or may not have taken place in this cohort. Nothing was reported in the case-notes. As a result of the number of women who have presented to Independent Reviews with complaints of 'chronic pain' it is important to pay particular attention to those who present with pain in the early months following surgery. Those who do not have pain at review require to be advised to seek medical advice following the onset of suprapubic, groin or vaginal pain in the future. This observation is very much using hindsight following recent publicity but the audit has been seeking to explore possible errors of omission, within practice, to try to explain why so many women in different countries have been reporting the deleterious effects of mesh with particular reference to pain.

De novo urge and frequency occurred in 14% (37/268) of those reviewed which is significantly higher than other literature reports [3]. Again caution is required when drawing conclusions from small numbers.

Outcome

The audit proforma collected data from the first review visit from both clinicians and patients, as to whether or not they considered that the patient's condition had improved following the mid-urethral tape procedure. 87% (233/268) were recorded as 'better' by the clinician following surgery. The result is in line with published literature [3] and seems to support the efficacy of the procedure for the treatment of SUI. 80% (214/268) of patients reported that their condition had 'improved'. The discrepancies between the clinician's view of outcomes and the patient's was not significant but did contain a number of interesting mismatches, where the doctor interpreted the procedure as being successful, despite expressions of troublesome complications being reported by the patient and recorded in the case-notes.

The audit results demonstrated no significant difference in the outcome of surgery (as measured by improvement in stress urinary incontinence reported by the patient and clinician) in the short term following surgery for the variables of age (<65 years or ≥65 years), whether the operation was undertaken by the retropubic or transobturator route or undertaken concomitantly with a pelvic organ prolapse procedure.

In this audit BMI did not affect the success (improvement in stress urinary incontinence) of the procedure significantly with a reported 88% success where the BMI was ≤29.9 as compared with 77% when ≥30. Evidence in the literature is inconsistent, with some studies finding that BMI had no effect on outcomes in the short term [24] whereas others reported

worse outcomes for women with a raised BMI compared with women of normal weight in long term follow up [25].

The success of a repeat mid-urethral tape procedure in terms of improvement of stress urinary incontinence was less than when undertaken as a primary operation (67% versus 86%). However numbers of repeat procedures are small and caution is required when drawing conclusions. It is relevant to note that all repeat surgeries are undertaken throughout all Trusts in Northern Ireland. Presently a referral pathway for complex urogynaecological surgery does not exist. The literature does have indications that results can be better with a lower risk of complications when repeat surgery is undertaken by experienced urogynaecological surgeons in a unit providing specialised Consultant care in urogynaecology [26]. The NICE guideline recommendation (CG40, 2006) states that complex stress incontinence surgery requires a higher level of training and should be carried out in surgical centres that have adequate volume to maintain expertise and best outcomes[6].

Limitations of the Audit

- Collection of data was affected by the need to establish individual Data Access Agreements with each HSC Trust. This was an administrative challenge that resulted in the delay in completion of data collection in late March 2017. It also resulted in a reduction in the sample size as the original intention was to assess the total number of procedures undertaken during 2013.

- Some patients in the audit sample had a number of different case-notes from different hospital sites. A patient may have been assessed or reviewed in one hospital but operated upon in another. Auditors were on a number of occasions supplied with a single case-note which may or may not have contained all relevant data from all assessments or subsequent reviews in all units. This increased the number of 'not known' responses and may have affected the recording of the use of pre-operative physiotherapy in particular.

- When assessing consent processes only written data was collected. The patient may have been orally informed of certain complications of surgery or received written information but this is not recorded.

- As with any retrospective work, not all information was available in the case-notes. Detail on the presence or absence of e.g. dyspareunia, de novo urge, frequency, or voiding problems was patchy with no evidence that these symptoms had been discussed.

- It was not possible to determine the level of training which surgeons had undertaken. The recommendation contained within the NICE (CG40, 2006) Urinary Incontinence guideline whereby at least 20 cases per annum per surgeon is recommended to maintain expertise was used.

- Follow up was limited to the first visit following surgery. It would be preferable to have more long term outcomes as recommended within the Scottish Independent Review [7].

Recommendations

- It should be mandatory for Trust multidisciplinary teams to implement pre-operative care in line with NICE CG171. Consent should be primarily a detailed one to one discussion with a patient about a procedure and should be supplemented with appropriate information documents e.g. a patient leaflet or/and 'sticker' for the consent form which outlines the risks, benefits and potential complications.

- Only practitioners with appropriate training and who undertake an agreed number of cases annually (NICE CG40, 2006 states 'at least 20') should undertake mid-urethral tape surgery.

- Repeat surgery for stress urinary incontinence following a mid-urethral tape procedure should only be undertaken within a setting that provides specialised Consultant care in urogynaecology.

- All practitioners who undertake mid-urethral tape surgery should submit data to a recognised audit national database to facilitate monitoring of results (e.g. BSUG or BAUS).

- Formal post-operative follow up in an outpatient setting by staff with clinical expertise in the management of mid-urethral tape surgery is important to identify deleterious effects of mid-urethral tape surgery. Women require advice on possible long term sequelae and how to seek assistance.

- Review of OPCS-4 codes is required to easily facilitate audit of repeat mid-urethral tape surgical procedures and surgical operations undertaken in response to tape complications (e.g. tape division, trimming, partial or complete excision).

- An audit of long term outcomes (e.g. five years) should be undertaken.

Learning Points

- Too much detail within audit proforma for auditors unfamiliar with surgical procedure.

- Data Access agreements across Trusts and Independent Sector Hospitals should be ascertained in advance.

- An outcome measure such as 'pain' requires more detail and is difficult to define using a retrospective chart audit.

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List of Abbreviations used

BAUS	British Association of Urological Surgeons
BHSCT	Belfast Health and Social Care Trust
BSUG	British Society Of Urogynaecology
CI	Confidence Interval
DOA	Detrusor Overactivity
FDA	Food and Drug Administration
HSC	Health and Social Care
IUGA	International Urogynaecological Association
MHRA	Medicines And Healthcare Products Regulatory Agency
MUI	Mixed Urinary Incontinence
NHSCT	Northern Health and Social Care Trust
NI	Northern Ireland
NICE	National Institute for Health and Care Excellence
OPCS	Operating Procedure Codes
PFMT	Pelvic Floor Muscle Training
POP	Pelvic Organ Prolapse
RQIA	Regulation and Quality Improvement Authority
SEHSCT	South Eastern Health and Social Care Trust
SHSCT	Southern Health and Social Care Trust
SUI	Stress Urinary Incontinence
UGUS	Ulster Gynae-Urology Society
UK	United Kingdom
USA	United States of America
USI	Urinary Stress Incontinence
WHSCT	Western Health and Social Care Trust

Glossary

Anterior repair	An anterior (front) vaginal wall repair corrects a cystocele (bladder prolapse) by reinforcement of fascial supports
Concomitant	At the same time
De novo urge	New symptom resulting following mid urethral tape surgery
Dyspareunia	Pain during or after sexual intercourse
Mid-urethral tape	Tape placed underneath the urethra (the tube that goes from the bladder to outside the body) to correct stress urinary incontinence
Mixed urinary incontinence	Mixed incontinence occurs when symptoms of both stress and urgency types of incontinence are present
Nulliparous	Nulliparous is the medical term for a woman who has never given birth
Parity	Parity or ‘para’ indicates the number of births (live or stillborn) reaching viable gestational age (24+0 weeks)
Pelvic organ prolapse	Pelvic organ prolapse results from weakness of the pelvic floor supports which results in descent or bulging of one or more of the pelvic organs into the vagina
Perineorrhaphy	A surgical procedure in which an incision, tear, or defect in the perineum (between anus and vagina) is repaired by suturing
Posterior repair	A posterior (back) vaginal wall repair corrects a rectocele (bowel/rectal prolapse)
Retropubic procedure	A technique to insert a mid-urethral tape where the tape is inserted vaginally adjacent to the urethra on either side and comes out through two small incisions at the level of the pubic hair line
Single incision mini-sling procedure	A technique involving a single small incision inside the vagina just under the urethra. The mini-sling is tunnelled into this incision and anchored to pelvic side wall tissue.

Specialty Doctor	A Specialty Doctor is a senior career grade doctor working within the NHS
Stress urinary Incontinence	Leakage of urine from the urethra with an increase in intra-abdominal pressure (e.g. cough or laugh)
Transobturator procedure	A technique to insert a mid-urethral tape where the tape is inserted vaginally adjacent to the urethra on either side and comes out through two small incisions at the groin
Urodynamics	Urodynamic testing or urodynamics is a study that assesses how the bladder and urethra are performing their job of storing and releasing urine
Vault suspension	A vaginal vault suspension restores the vaginal cavity by reinforcing supportive structures within the vagina, elevating structures back into place
Vaginal hysterectomy	Removal of the uterus (womb) through the vagina
Vaginal button holing	Inadvertent perforation of the vaginal wall, due to operator error, resulting in tape exposure during mid-urethral tape insertion
Vaginal repair	An operation for women to correct prolapse (descent) of one or both vaginal walls by reinforcement of fascial supports
Voiding disorder	Inability to empty the bladder satisfactorily

Project Team

Name	Job Title/Specialty	HSC Trust	Role within Project (data collection, Supervisor etc.)
Dr RG Ashe	Consultant	NHSCT	Project Chairman
Dr A Abdelrahman	ST6	NHSCT	Project Lead
Mrs R McDonald	Assistant Trust Governance Manager	NHSCT	Project Manager
Dr L Dolan Dr M Casement Ms S Woolsey	Consultant Consultant Consultant	BHSCT BHSCT BHSCT	Clinical Advisor Clinical Advisor Clinical advisor
Dr G McCracken Dr H de Courcy-Wheeler Dr K Loane W Brown	Consultant Consultant Consultant Chartered Physio	SHSCT SHSCT SHSCT SHSCT	Clinical Advisor Clinical Advisor Clinical Advisor Clinical Advisor
Dr O Conlon Dr S McNeill	Consultant Consultant	WHSCT WHSCT	Clinical Advisor Clinical Advisor
Ms T Ayton	Chartered Physio	SEHSCT	Clinical Advisor
Dr S Tuhamy	Consultant	NHSCT	Clinical Advisor

Acknowledgments

Name	Designation	Role in Project
Lee Marshall	Medical Student	Data Collection
Sarah Brown		
Sophie Stezaker		
Patrick Farrell		
Mohit Inani		
Ashleigh Moore		
Kathryn Shields		
Meenu Sharma	ST4 Trainee Obs & Gynae	
Lyndsay Cresswell	FY1 Trainee	
Northern Health & Social Care Trust		
Ruth McDonald Deborah Doole Heather Bonar	Assistant Governance Manager Governance Support Officer Governance Support Assistant	Project co-ordination, sample identification, chart retrieval, data collection, input, validation and analysis
Regulation & Quality Improvement Authority (RQIA)		
Siobhan Crilly Robert Mercer Nicola Porter	RQIA Clinical Audit Facilitator RQIA Clinical Audit Facilitator RQIA Audit Manager	Project funding and advice
Western Health & Social Care Trust		
Teresa Murray Deirdre Kelly Charlene Cooke	Assistant Governance Manager QI & Audit Manager QI & Audit Department	Sample identification, chart retrieval and arrangements for auditors' visits
Southern Health & Social Care Trust		
Raymond Haffey	Senior Effectiveness & Evaluation Facilitator	Sample identification, chart retrieval and arrangements for auditors' visits
Belfast Health & Social Care Trust		
Fintan McErlean Verdi Jarvis	QI & Audit Manager QI & Audit Manager	Sample identification, chart retrieval and arrangements for auditors' visits
South Eastern Health & Social Care Trust		
Carol Lutton Sharon Thompson	QI & Audit Manager QI & Audit Manager	Sample identification, chart retrieval and arrangements for auditors' visits
Independent Sector		
Diane Graham	Matron/Chief Executive, Ulster Independent Clinic	Sample identification, chart retrieval and arrangements for auditors' visits
Shirley Baird	Head of Clinical Governance & IPC, North West Independent Hospital	Sample identification, chart retrieval and arrangements for auditors' visits
Others		
Ulster Gynae Urology Society		Expert multidisciplinary input by Committee into project design and review of draft report
Paul Hilton	Consultant Urogynaecologist (Retired)	Independent Assessor

Declaration of Interest for Project Team

Dr Robin Ashe has no current financial interests to declare.
He received expenses for travel to urogynaecological conferences in the late 1990s and up to 2010 (Gynecare, American Medical Services, Pfizer, Endosurgical, Astellas). He was a co-investigator in 2014 in a multicentre trial to evaluate the safety and effectiveness of Polyvinyl Fluoride (Dynamesh) in the treatment of stress urinary incontinence. Kebomed did not proceed with the trial. No financial reimbursement was involved.

He presently undertakes medicolegal work for the Directorate of Legal Services in Northern Ireland, the Health Service Executive in the Republic of Ireland and acts as an assessor for the Royal College of Obstetrics and Gynaecology for Obstetric and Gynaecological units in the UK.

Mr Paul Hilton has no current or recent financial interests to declare.
He was the chief investigator for a randomised comparative trial of a mid-urethral tape (*TVT*™) and colposuspension (1989-2003) funded by *Gynecare*, a Johnson & Johnson company. He was also the chief investigator for studies into a single incision tape (*MiniTape*™) (2001-2003) and for studies on a light-weight mesh for the treatment of pelvic organ prolapse (2001-2003) funded by *GyneIdeas Ltd* (previously *Mpathy Medical,* now *Coloplast*). During this time he received reimbursement of expenses associated with meetings at which research was presented, but received no other personal funding. He has had no dealings of any sort with either of these companies, or any other company in the medical devices or pharmaceutical industries, for 14 years.

He was a member of the NICE Interventional Procedures Advisory Committee (2002-2007) and chaired the NICE development group for the clinical guideline on urinary incontinence in women (2004-2007). He was a faculty member of the first five International Consultations on Incontinence (1997-2013), in particular the 'Surgery in women' committee of the 4th consultation (2007-2009). He has also been involved in research prioritisation as a member of NETSCC Health Technology Assessment (HTA) - Therapeutic Procedures Panel (2007-2008), HTA-Clinical Evaluations and Trials Prioritisation Group (2008-2010), and the James Lind Alliance Working Partnership on research priorities on urinary incontinence (2007-2009). He was a member of the Scottish Independent Review of the Use, Safety and Efficacy of Transvaginal Mesh Implants in the Treatment of Stress Urinary Incontinence and Pelvic Organ Prolapse in Women, and is presently commissioned by the NHS National Services Scotland Central Legal Office, to provide expert advice in relation to legal claims relating to the use of mesh in gynecological surgery. He is married to a Subspecialist Urogynaecologist who previously worked in Scotland, and currently works in Northern Ireland.

Dr Lucia Dolan has no financial interests to declare.
In 2002 as a trainee in urogynaecology, she received travel expenses to attend 2 urogynaecology conferences (Eli Lilley). Since then she has not received any sponsorship from industry and has had no involvement in commercially sponsored research. She was a

Consultant Gynaecologist and subspecialist in urogynaecology in Scotland, Lothian Health Board (2004-2011). There is litigation pending against Lothian Health Board which includes patients that will have been seen by Dr Dolan. She was the clinical representative on the data monitoring committee for 2 surgical RCTs on pelvic organ prolapse, namely PROSPECT and VUE. She is currently a clinical representative on the Project Steering Committee for the NIHR funded project on urinary incontinence with the London School Hygiene & Tropical Medicine. She is currently the urogynaecology clinical representative on RCOG Lindsay Stewart Committee for audit and informatics. She is a member of the PHA workstream on MDT working for mesh complications in NI and the lead for the mesh centre in Belfast. She has undertaken medicolegal work for the Directorate of Legal Services in NI. She is married to Mr Paul Hilton retired Consultant Urogynaecologist who was an independent advisor to the clinical lead (Dr Robin Ashe) for this project.

Dr Geoff McCracken has no current financial interests to declare.
He has received expenses for travel to urogynaecological conferences from 2008-2016 (Gynecare, American Medical Services, Pfizer, Endosurgical, Astellas, Baxter). He has also received payment for presentations on behalf of Pfizer and Astellas at local teaching sessions.

Dr Horace de Courcy-Wheeler has no current financial or other conflicts of interest.
He has received financial support to travel to conferences and speak at educational meetings from Pfizer and Astellas.

Dr Maire Casement - None

Ms Siobhan Woolsey - None

Dr Abdelmageed Abdelrahman – None

Dr Sandra Mc Neill – None

Dr Orla Conlon - None

Mrs Ruth McDonald - None

Dr Sayed Tuhamy - None

Ms Thamra Ayton - None

Dr Katharine Loane - None

Ms Wendy Brown - None

Appendix 1 – Audit Proforma

GAIN
GUIDELINES AND AUDIT IMPLEMENTATION NETWORK

03/09/2015 v2

Audit of Mid-Urethral Tapes for Stress Urinary Incontinence

Refer to aid notes to assist with completion of this data collection proforma

Organisation code: ____ Hospital code: ____ Patient code: ____

Patient demographics

Age at date of procedure: ____ years
Parity: ____
Weight: ____ kgs
Height: ____ m
BMI =

Pre-op preparation

1a. Pelvic floor exercises offered?

Yes, accepted ☐ No ☐
Yes, declined ☐ Missing/not recorded ☐

1b. Who supervised the pelvic floor exercises?

Continence Advisor ☐ Self-examination ☐
Specialist Nurse ☐ GP ☐
Physiotherapist ☐ Not applicable *(not offered or declined)* ☐

1c. Evidence of completed pelvic floor treatment?

Yes ☐ No ☐ Not applicable ☐

2a.Pre-op urodynamics performed? Yes ☐ No ☐

2b. Pre-op urodynamic diagnosis:

Normal USI ☐ Mixed USI & DOA ☐ Not applicable ☐ Missing/not recorded ☐ Voiding dysfunction ☐

Consent for Surgery (TVT)

3a. Evidence of patient consent for surgery?

Yes, consent form ☐
Yes, recorded in notes ☐
No ☐

3b. Was information given on the following complications?
(NB: Check consent form, continuation sheets and outpatient correspondence)

Common complications	Yes	No
Urinary retention/voiding dysfunction	☐	☐
Self-catheterisation	☐	☐
Failure rate of continence surgery (or success rate of surgery)	☐	☐
Urinary infection	☐	☐

1

3b. Was information given on the following complications? *(cont'd)*

(NB: Check consent form, continuation sheets and outpatient correspondence)

	Yes	No
Operative injury to bladder	☐	☐
Operative injury to urethra	☐	☐
Operative injury to bowel	☐	☐
Operative injury - vascular	☐	☐
New symptoms of urge or urge incontinence	☐	☐
Persistent urge or urge incontinence	☐	☐
Blood transfusion required	☐	☐
Tape erosion to bladder/urethra/vagina	☐	☐
Tape removal	☐	☐
Infection	☐	☐
Sepsis	☐	☐

Surgery *(Surgery Date must be between 1.1.2013 and 31.12.2013)*

4. Date of surgery: ___/___/___

5a. Surgical technique used:

Retropubic	☐	Top down	☐	Bottom up	☐
Transobturator *(TOT or TVTO)*	☐	Outside in	☐	Inside out	☐
Single incision	☐	Not known	☐		

5b. Device name: _____

6. Incontinence surgery type: Primary ☐ Repeat ☐

If 'Repeat' surgery please specify name of previous device name/tape used:

_____

7a. Other concomitant procedures/surgery

Yes ☐ No ☐

If Yes, specify: _____

_____

7b. Concomitant prolapse implant used?

Not used ☐ Used ☐

Name of Device: _____

_____

_____

2

Anaesthetic and Surgeon

8. Anaesthetic used: *Tick all applicable*

Local Anaesthetic (LA)	☐	Spinal	☐
General Anaesthetic (GA)	☐	Caudal	☐
Sedation	☐	Epidural	☐

9a. Senior Surgeon Present?

Consultant ☐ Non-Consultant ☐

If Non-Consultant specify grade: _____

If grade unclear, document doctor's name here: _____

9b. Grade of operator:

Consultant ☐ Non-Consultant ☐

If Non-Consultant specify grade: _____

If grade unclear, document doctor's name here: _____

9c. Consultant code: ☐

Intra-operative Information

10. Intra-operative injury or complication: *Tick all applicable*

Ureteric injury	☐	Vascular injury	☐
Bladder injury	☐	Blood loss >500ml	☐
Vaginal button-holing	☐	Death	☐
Urethral injury	☐	None	☐

Length of Stay

11. Length of stay:

Day case	☐	4 days	☐
1 - 2 days	☐	More than 4 days	☐
3 days	☐		

If 'More than 4 days', number: _____

Post-Op Morbidity

12. Did any of the following occur?

	Yes	No
Groin pain post op	☐	☐
Specify duration of groin pain: _____ weeks		
Return to theatre for procedure related event within 72 hrs	☐	☐
Re-admitted to hospital within 30 days for procedure related event	☐	☐
Indwelling urethral catheter inserted	☐	☐
Self catheterisation	☐	☐
Self catheterisation >10 days	☐	☐
Blood transfusion	☐	☐
Neurological injury	☐	☐
Thromboembolism	☐	☐

3

Stress Incontinence Tape Complication

13. Were there tape complications? Yes ☐ No ☐

If Yes, type of complication: _____

Post-Op/Follow-Up

14a. How was follow-up carried out?

Outpatient visit ☐ Telephone response ☐
Postal questionnaire ☐ GP Practice ☐
Online ☐

14b. Interval to first follow-up:

<3 months ☐ 6 - 12 months ☐
3 - 6 months ☐ >12 months ☐
Patient DNA'd ☐ Other please state: _____

If patient DNA'd or was followed-up elsewhere questions 14c - 15d cannot be completed

14c. Persistent pain present at time of patient follow-up?

Yes ☐ No ☐ Not known ☐

14d. Painful intercourse at time of patient follow-up?

Yes ☐ No ☐ Not known ☐

14e. De novo development of frequency and urge symptoms?

Yes ☐ No ☐ Not known ☐

Global Impression of Improvement for Incontinence at follow-up

15a. Impression of Improvement for Stress Urinary Incontinence:

Better ☐ No change ☐
Worse ☐

15b. Impression of Improvement of OAB:

Better ☐ No change ☐
Worse ☐ Not applicable ☐

15c. Voiding difficulty? Yes ☐ No ☐ Not known ☐

15d. Global impression from patient feedback re: progress/recovery

Improved ☐
Not improved ☐
No feedback ☐

PLEASE CHECK YOU HAVE ANSWERED ALL QUESTIONS 4

Appendix 2

Aid/Guidance Notes to assist with completion of the Audit of Mid-Urethral Tapes for Stress Urinary Incontinence proforma

Organisation code – use relevant code from master coding sheets. **Do not record** Trust/organisation name on the proforma

Hospital code – use relevant code from master coding sheets. **Do not record** Hospital name on the proforma.

Patient code – record the relevant patient details on the Master coding sheets and use the patient code generated. **Do not record** any patient identifiable information on the proforma

Patient demographics

- Record **patient age** (will be freely available throughout case notes) at time of procedure
- Record **patient weight and height** (should be available in nursing information on admission or within continuation sheets (handwritten notes) or operation/procedure record/notes). If not found state N/R. Height if recorded may be in feet/inches or cm/m – record height measurement, if appropriate
- **BMI** should be available where patient weight and height are recorded. **If BMI is not recorded then leave blank *(and data input clerk will calculate at time of analysis)***
- **Parity** will be documented in the case notes; this will usually be in the first gynae clinic consultation (outpatient) letter or in the continuation sheets containing handwritten notes made during any consultations and indicates the number of >24-week births (including viable and non-viable; i.e., stillbirths)

Pre-operative preparation

- **(Q1a, 1b, 1c) Offer and uptake of pelvic floor exercises, who supervised the exercises and evidence of completion** should be documented in the gynae clinic consultation (outpatient) letters or in the continuation sheets (handwritten notes) made during any medical gynae clinic consultations prior to booking the patient for the mid-urethral tape procedure. Pelvic floor exercise is the initial conservative method of managing patients with stress urinary incontinence. If pelvic floor exercises were not offered or declined record answer to Q1b and 1c as not applicable

  1c Case notes should contain attendance record at physio or continence adviser. 'No' refers to Did Not Attend (DNA) / Could Not Attend (CNA), reference to non-completion of pelvic floor exercises or no written evidence of completion

- **(Q2a, 2b) Urodynamics** is a special test performed to help with diagnosis pre-op. Evidence that this test was performed along with the results should be documented in the gynae clinic consultation (outpatient) letter or in the continuation sheets (handwritten notes) made during any medical gynae clinic consultations or the urodynamics results/report should be filed within the case notes. Some of the terms used in urodynamics diagnosis include: **USI** - short for urodynamic stress incontinence; **DOA** or **DO** - short for detrusor over-activity; and **voiding dysfunction**

Consent for surgery

- **(Q3a) Evidence of patient consent for surgery** will be found on the consent form or on the continuation sheets (hand written notes).
- **(Q3b) Information provided on complications as part of patient consent for surgery** – these should be recorded on the consent form, continuation sheets (handwritten notes) or may be mentioned in the gynae clinic consultation (outpatient) letters. **Check all sources.** Infection/Sepsis may have been explained as pyrexia, tachycardia requiring IV antibiotics. Any advice provided to patient about 'erosion' is sufficient for a 'Yes'.

Surgery

- **(Q4)** Only include patients whose surgery date falls between **1.1.2013 and 31.12.2013. Record date of surgery**
- **(Q5a) Surgical technique used – retropubic, transobturator** (TOT or TVTO. TOT stands for transobturator tape and is performed 'outside in', TVTO means TVT Obturator and is performed 'inside out') **or single incision** should be recorded on the operation/procedure record/notes. Record how the technique was applied in the case of retropubic or transobturator techniques only. Record not known if how technique was applied is unclear
- **(Q5b) Device name** (detailed in italic font below) should be recorded on operation/procedure record/notes:
    - Retropubic MUS - *TVT*
    - Retropubic MUS - *TVT exact*
    - Retropubic MUS - *Sparc*
    - Retropubic MUS - *IVS*
    - Retropubic MUS - *Uretex*
    - Retropubic MUS - *Safyre*
    - Retropubic MUS - *Advantage*
    - Retropubic MUS - *Advantage Fit*
    - Retropubic MUS - *Align*
    - Retropubic MUS - *Pelvilace*
    - Retropubic MUS – *I-Stop*
    - Retropubic MUS - *Kim*
    - Retropubic MUS - *Bioarc SP*
    - Retropubic MUS - *Lynx*
    - Retropubic MUS - *Other*
    - TVT – *Obturator (written as TVTO)*
    - TVT - *Abbrevo*
    - TOT - *Monarc*
    - TOT - *Aris*
    - TOT - *Uretex TO*
    - TOT - *Pelvilace TO*

- TOT - *Safyre-t*
- TOT - *Obtryx*
- TOT - *Align TO*
- TOT - *I-Stop*
- TOT - *KIM*
- TOT - *Other*
- TOT - *Bioarc*
- Single Incision tape: *TVT - Secur*
- Single Incision tape: *MiniArc*
- Single Incision tape: *MiniArc Precise*
- Single Incision tape: *Adjust*
- Single Incision tape: *Needleless*
- Single Incision tape: *Solyx*
- Single Incision tape: *Zippere*
- Single Incision tape: *Other*

- **(Q6) Incontinence surgery type: primary** (this means the first occasion the patient has had a Mid-Urethral Tape procedure – terms such as TVT, sling, tape, mesh may have been used or **repeat** when a similar procedure was undertaken previously). **If repeat procedure** state name of previous device name/tape used. This should be recorded in earlier continuation sheets (handwritten notes), previous operation/procedure records/notes or in earlier GP letters
- **(Q7a) 'Other' concomitant procedures/surgery** – this should be recorded on the operation/procedure record/notes or in the GP letter post-procedure. See list of concomitant procedures below. <u>Be sure to indicate procedure type including all patients with cystoscopy performed</u>

  Incontinence
  - Anterior repair (AR) + BNB
  - Artificial Urinary Sphincter
  - Cystoscopic BNI – Macroplastique
  - Cystoscopic BNI – collagen
  - Cystoscopic BNI – contigen
  - Cystoscopic BNI – tegress
  - Cystoscopic BNI – bulkamid
  - Cystoscopic BNI – other
  - Cystoscopic Botulinum Injection
  - Coaptite Injectable Inplant
  - Periurethral BNI
  - Non-cystoscopic BNI – zuidex
  - Non-cystoscopic BNI – durasphere
  - Non-cystoscopic BNI – MIS
  - Non-cystoscopic BNI – other
  - Colposuspension – open
  - Colposuspension – Laparoscopic
  - MMK
  - Laparoscopic Urethropexy
  - Sling – Bioarc Suprapubic
  - Sling – Infast Ultravagina
  - Sling – Rectus Sheath
  - Sling – Combined A/V (Aldridge)
  - Sling – Cadaveric
  - Sling – Adjustable TRT/Remeex
  - Sling- Adjustable AMI/TOA
  - Sling – Adjustable AMI/TVA
  - Sling – Autologous Spiral

- Sling – Synthetic Spiral
- Urethral Diverticulectomy
- Vaginal closure fistula
- Abdominal closure fistula
- Insertion Long Term Suprapubic Catheter
- Adjustable Continence Therapy (ACT)
- Discontinued: TOT – Needleness
- Discontinued: Stamey Procedure
- Discontinued: Flexible Cystoscopy

Prolapse

- Anterior repair (AR)
- AR + graft
- Manchester Repair
- Vaginal Hysterectomy
- Vaginal Hysterectomy + AR
- LAVH
- LAVH + BSO
- TOAR - (Transobturator AR) – Perigee
- TOAR - Avaulta (solo)
- TOAR - Avaulta (plus)
- TOAR: Elevate
- TOAR: Uphold
- TOAR: Pinnacle
- TOAR: Other
- Needleless Repair – Pinnacle (Anterior)
- Posterior Repair (PR)
- PR + graft
- PR + Perineorrhaphy
- PR + Perineorrhaphy + graft
- Recto-enterocoele repair
- Recto-enterocoele repair + graft
- MPR (MeshPosterior Repair) – Apogee
- MPR - Avaulta
- MPR - other
- Needleless Repair – Pinnacle (Posterior)
- Needleless Repair – Elevate
- Uphold Vaginal Support System
- Posterior IVS
- Infracoccygeal mesh hysteropexy
- Infracoccygeal vault mesh suspension
- TVM - Apogee + Perigee
- TVM - Avaulta (solo)
- TVM - Avaulta (plus)
- TVM - Other
- Paravaginal Repair – vaginal
- Paravaginal Repair – Abdominal
- Paravaginal Repair – Laparoscopic
- Sacrocolpopexy – Open
- Sacrocolpopexy – Laparoscopic
- Sacrospinous Fixation
- Sacrospinous Fixation - Capio
- Sacrospinous Hysteropexy
- Sacrospinous Hysteropexy – Capio
- Iliococcygeal fixation

- Iliococcygeal fixation – Capio
- Sacrocolpohysteropexy – Open
- Sacrocolpohysteropexy – Laparoscopic
- Sacrocolpocervicopexy – Open
- Sacrocolpocervicopexy – Laparoscopic
- Laparoscopic Suture Hysteropexy
- Laparoscopic Uterosacral Plication
- Vaginal Uterosacral Plication
- Moscowitz
- Halban
- Colpoclesis
- Total Colpectomy
- Discontinued: Total Vaginal Mesh (TVM) – Prolift
- Discontinued: TVM-Prolift-M
- Discontinued: Needleness Repair – Prosima
- Discontinued: IMPR-Prolift-M
- Discontinued: IMPR-Prolift
- Discontinued: TOAR-Prolift M
- Discontinued: TOAR-Prolift M
- Discontinued: TOAR-Prolift

Other Procedures

- Cystoscopy – Rigid
- Cystoscopy – Flexible
- Insertion of S/P Catheter
- Laparoscopy
- Hysteroscopy/D+C
- Endometrial ablation
- Endometrial resection
- TAH
- TAH+USO
- TAH+BSO
- Subtotal TAH
- Subtotal AH+USO
- Subtotal AH+BSO
- Unilateral salpingo-oopherectomy
- Bilateral salpingo-oophorectomy
- Ovarian Cystectomy
- Therapeutic Laparoscopy – Endometriosis
- Therapeutic Laparoscopy – other
- Laparoscopic Hysterectomy
- Laparoscopic Hysterectomy + BSO
- Laparoscopic STAH
- Laparoscopic STAH+BSO
- Myomectomy
- Fenton's Procedure

(Q7b) Concomitant prolapse implants refers to implants used at time of procedure. This should be recorded on the operation/procedure record/notes if used. See list of implants below and device name:

- TOAR - (Transobturator AR) – *Perigee*
- TOAR - *Avaulta (solo)*
- TOAR - *Avaulta (plus)*
- TOAR: *Elevate*

- TOAR: *Uphold*
- TOAR: *Pinnacle*
- TOAR: *Other*
- Needleless Repair – *Pinnacle (Anterior)*
- MPR (MeshPosterior Repair) – *Apogee*
- MPR **-** *Avaulta*
- MPR - *other*
- Needleless Repair – *Pinnacle (Posterior)*
- Needleless Repair – *Elevate*
- *Uphold Vaginal Support System*
- TVM - *Apogee* + *Perigee*
- TVM - *Avaulta (solo)*
- TVM - *Avaulta (plus)*
- TVM - *Other*
- Discontinued: Total Vaginal Mesh (TVM) – *Prolift*
- Discontinued: TVM - *Prolift-M*
- Discontinued: Needleness Repair – *Prosima*
- Discontinued: IMPR - *Prolift-M*
- Discontinued: IMPR - *Prolift*
- Discontinued: TOAR - *Prolift M*
- Discontinued: TOAR - *Prolift M*
- Discontinued: TOAR – Prolift

Anaesthetic and surgeon

- **(Q8) Anaesthetic type used** - this should be recorded on the operation/procedure record/notes
- **(Q9a) Senior surgeon present** - this should be recorded on the operation/ procedure record/notes. State grade if non-Consultant. If grade is unclear, document doctor's name so that this can be clarified at a later date by the data input clerk
- **(Q9b) Grade of operator** - this should be recorded on the operation/ procedure record/notes. State grade if non-Consultant. If grade is unclear, document doctor's name so that this can be clarified at a later date by the data input clerk
- **(Q9c) Consultant code** – use relevant code from master coding sheet. This is the Consultant with responsibility for the patient's care

Intraoperative information

- **(Q10)** Look for **intraoperative injuries or complications** – these should be recorded on the operation/procedure record/notes, continuation sheets (handwritten notes) or in the GP letter post-procedure. The injury may for example be: ureteric, bladder, urethral, vascular – see proforma for full list

Length of stay

- **(Q11) Length of stay** - day case (patient had procedure and went home same day) or record length of stay if patient admitted. <u>If the procedure was initially planned as a day case and the patient needed admitted, tick both 'day case' and also specify length of stay/number of days admitted.</u> This information should be recorded on continuation sheets (handwritten notes), or in the GP letter post-procedure

Length of stay:

1-2 days – one night in hospital

3 days – 2 nights in hospital
4 days - 3 nights in hospital etc.

Count both date of admission and discharge

Post-op morbidity

- **(Q12) Evidence of post-op morbidity** should be recorded on the continuation sheets (handwritten notes) or in any GP letters post-procedure. Post-op morbidity types are detailed on the proforma

Stress incontinence tape complication

- **(Q13) Complications from the tape -** terms such as 'exposure', 'migration', 'erosion' may be used to indicate break in the epithelial surface. These terms are used to describe graft complications. Any complications should be recorded in the continuation sheets (handwritten notes)

Post-op follow-up

- **(Q14a, Q14b)** State **method of post-op follow-up** and **length of time between procedure and follow-up** – this should be found in review notes on continuation sheets (handwritten notes) or in review letter to GP. If patient Did Not Attend (DNA'd) follow-up then tick appropriate box at Q14b
- **(Q14c) Persistent pain present** at time of patient follow-up - this should be found in review notes on continuation sheets (handwritten notes) or in review letter to GP. If no mention of persistent pain being present or not then state not known. Also record 'not known' if patient DNA'd or was followed up elsewhere
- **(Q14d) Painful intercourse** at time of patient follow-up - this should be recorded in review notes on continuation sheets (handwritten notes) or in review letter to GP. If no mention of painful intercourse or not then state not known. Also record 'not known' if patient DNA'd or was followed up elsewhere
- **(Q14e) De novo development of frequency and urge symptoms** at time of patient follow-up - this should be recorded in review notes on continuation sheets (handwritten notes) or in review letter to GP. If no mention of de novo development of frequency and urge symptoms or not then state not known. Also record 'not known' if patient DNA'd or was followed up elsewhere

Global impression of improvement

- **(Q15a) Impression of improvement for Stress Urinary Incontinence** (SUI). Look for some mention of whether improvement, no change or worsening of condition. This should be found in review notes on continuation sheets (handwritten notes) or in review letter to GP. Also record 'not known' if patient DNA'd or was followed up elsewhere
- **(Q15b) Impression of improvement of OAB**. OAB is short for overactive bladder. This should be found in review notes on continuation sheets (handwritten notes) or

in review letter to GP. Not all patients will have had OAB – in such instances not applicable should be recorded. Record 'not known' if patient DNA'd or was followed up elsewhere

- **(Q15c) Voiding difficulty** indicates a problem with normal micturition. This may be described as 'poor flow', 'hesitancy' or 'sensation of incomplete bladder emptying'. Reference should be found in review notes on continuation sheets (handwritten notes) or in review letter to GP. If no mention of voiding difficulty or not then state not known. Also record 'not known' if patient DNA'd or was followed up elsewhere
- **(Q15d) Global impression from patient feedback regarding progress/recovery** - this may be found in review notes on continuation sheets (handwritten notes) and may be a general mention of the patient's impression of progress/recovery since procedure undertaken. For example, improved, not improved, no feedback. Also record 'no feedback' if patient DNA'd or was followed up elsewhere

PLEASE REMEMBER TO CHECK YOU HAVE ANSWERED ALL THE QUESTIONS ON COMPLETION OF EACH PROFORMA

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