

Using routinely available health data to examine the provision of, and outcomes following, surgery for SUI and POP in Scotland

Technical report

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1 PURPOSE

1.1 Aim

To investigate the relative safety and effectiveness of specific mesh and non-mesh procedures provided for stress urinary incontinence (SUI) and pelvic organ prolapse (POP) in Scotland from 1997/98 to 2013/14 inclusive to inform the Scottish Government Independent Review of Transvaginal Mesh Implants¹.

1.1.1 Objectives

For each of SUI and POP, during the period 1997/98 to 2013/14, in Scotland:

- a) To determine the frequency of performance of different mesh and non-mesh surgical procedures and how this has changed over time.
- b) To determine the characteristics of women undergoing the different procedures (age, comorbidity, deprivation)
- c) To determine the characteristics of providers delivering the different procedures (surgeon volume, hospital type)
- d) To determine the relative frequency of adverse events between different procedure types, including: i) immediate procedural complications; ii) late procedural complications; iii) requirement for further surgery; iv) pain (referral to NHS pain management clinics, prescription of opiate containing medication); v) readmission to hospital for any reason; and vi) mortality.

1.2 Preliminary work

In order to meet the above aim and objectives initial work included the identification of all surgical procedures likely to have been undertaken for SUI and POP in Scotland over the period 1997/98 to 2013/14. Procedure codes were defined in conjunction with clinical expertise and

¹ <http://www.gov.scot/About/Review/Transvaginal-Mesh-Implants>

defined using the coding in the Office of Population Censuses and Surveys *Classification of Interventions and Procedures*, current revision 4 (OPCS-4).

The recording of the different surgical treatments for SUI and POP in Scottish routine hospital discharge data was examined over the study period to ensure all procedures were identified, allowing for new code introduction and changes in coding practice.

Following identification of procedures (mesh and non-mesh) the frequency of procedure events was examined to decide on procedures to include in the analysis given sufficient numbers to allow a comparative analysis.

Notes on the decision making process for included and excluded index procedures, and the specific OPCS4 codes used to define included index procedures, are described in Appendices A and B.

2 DATA AVAILABILITY & LIMITATIONS;

Information Services Division (ISD) Scotland holds NHS health and health related data for over 5 million people in Scotland, which in some cases span an individual's whole life: from before birth, with the mothers antenatal records, through to that individual's death registration record. Data is stored within a number of different datasets and patients are identified through their unique Community Health Index (CHI) number. For the purposes of this study data was extracted from four national datasets: SMR00 outpatient records; SMR01 hospital discharge records; the Prescribing Information System (PIS) prescribing records and NRS statutory death registration records. Information about the national datasets used in this project is included in Appendix C.

2.1 Limitations of the datasets

SMR01 returns are subject to stringent validation: ISD undertakes extensive data quality assurance, with high return rates, and a high level of accuracy of recording of key variables^{2 3}. Additionally, all routine records held by ISD contain a Community Health Index (CHI) number, a unique identifier for each patient in Scotland, which allows records belonging to individual patients to be linked across different datasets.

Outpatient data

Whilst detailed information is held for all inpatient stays (SMR01) the outpatient data (SMR00) is significantly more limited and as such holds no diagnostic information. In the context of this study this means that only the type of clinic referred to (e.g. gynaecology, urology, pain, anaesthetics) can be identified with no information about the purpose or outcome of the consultation. It is known that some women undergo minor uro-gynaecological procedures in outpatient clinic (e.g. trimming of mesh) – this information is not available for this study.

² <http://www.isdscotland.org/Products-and-Services/Hospital-Records-Data-Monitoring/>

³ <http://www.isdscotland.org/Products-and-Services/Data-Quality/Assessments/>

Mesh coding

Following the introduction of a new surgical procedure, a new identifying code is added to the OPCS catalogue – although there can be a lag in this occurring. For example, retropubic and transobturator tape procedures for SUI were introduced into routine clinical practice in Scotland in the late 1990s and early 2000s respectively but specific OPCS4 codes for these procedures were not introduced until 2006. Prior to 2006, tape procedures were coded to a non-specific code, so that retropubic and transobturator tapes cannot be distinguished using routinely available SMR01 data. Delay in the introduction of codes denoting mesh procedures is less of an issue for POP. Mesh colporrhaphies were introduced into clinical practice in Scotland in the mid 2000s and specific OPCS4 codes for these procedures were introduced in 2007.

Specific OPCS4 codes denoting repair/revision procedures required for complications of prior surgery may or may not be available. For example, specific codes for the removal of SUI tapes were introduced alongside the codes for tape insertion in 2006. However, there are as yet no specific codes for the removal of POP mesh. It should be noted that OPCS4 allows for the coding of any and all surgical procedures; for example relatively non-specific codes can be used to denote POP mesh removal. However, the availability of specific codes increases the confidence with which particular procedures of interest can be accurately identified using routine SMR01 data.

3 DATA EXTRACTION – DEFINITIONS, INCLUSIONS AND EXCLUSIONS;

3.1 Definitions

All surgical procedures likely to be undertaken for SUI and POP in Scotland over the period 1997/98 to 2013/14 were agreed in conjunction with expert clinicians. The OPCS4 (and ICD10) codes likely to identify each procedure on SMR01 were then agreed in conjunction with both clinicians and the national clinical coding team

3.1.1 Index procedures

Episodes recording the defined codes for the period 1997/98 to 2013/14, in any position, were extracted from the SMR01 dataset in order to identify the *first single index procedures* of interest.

Procedures were grouped as follows:

SUI procedures: colposuspension (open); urethral injection therapy; suprapubic sling; unspecified tape procedures; retropubic tape procedures; and transobturator tape procedures.

POP procedures: anterior colporrhaphy; anterior colporrhaphy with mesh; posterior colporrhaphy; posterior colporrhaphy with mesh; sacrospinous fixation of the vagina (+/- concurrent non-mesh colporrhaphy); infracoccygeal colpopexy (+/- concurrent non-mesh colporrhaphy); open sacrocolpopexy (+/- concurrent non-mesh colporrhaphy) and vaginal hysterectomy for uterine prolapse.

Full details of the OPCS-4 coding of each procedure group are available in Appendix B.

3.1.2 Inclusion/exclusion

Women aged ≥ 20 years and undergoing single, first procedures were included in the comparative analysis. This was to ensure homogeneous categories and therefore a fairer comparison between mesh and non-mesh procedures as adverse outcomes are likely to be more common

following combination and/or repeat procedures, and the proportion of procedures done in combination with other procedures, and that are repeats, varies by procedure type.

'First' procedures were defined as qualifying index procedure codes with no prior SUI or POP procedure within the previous 5 years.

'Single' procedures were defined as the procedure of interest not combined with any other SUI or POP procedure (except for sacrospinous fixation and colpexy procedures which rarely occur as single procedures and were allowed in combination). SMR01 records including additional procedure codes indicating other (ie not a specific SUI or POP) procedures are therefore included as 'single' procedures however review of the other codes used on such records showed that the vast majority indicate minor interventions that would be expected as an integral part of the SUI/POP procedure, for example urinary catheterisation.

Detailed information regarding the decision process for inclusion and exclusion of combined procedures and other procedures is available in Appendix A.

3.1.3 Adverse event outcomes

Eight adverse event outcomes were identified and are defined below. Table 1 summarises key information on the outcomes. Full details of the OPCS-4 and ICD-10 coding of each outcome is provided in Appendix D.

Table 1. Summary of complication outcome definitions

Outcome	Rationale	Source	Period studied	Complication occurring within time of index event	Response	
Primary outcomes						
1	Immediate procedural complication	Complications likely to be related to the index event, for example urinary tract infection, pain, sepsis	SMR01	1997/98-2013/14	Within index admission and <90 days	Yes/no
2	Readmission with late procedural complication	Complications likely to be related to the index event but occurring after the index admission	SMR01	1997/98-2013/14	After index admission and within 5 years	Count of admissions
3	Readmission for further SUI or POP surgery	An indicator of, for example, initial surgery failure	SMR01	1997/98-2013/14	After index admission and within 5 years	Count of admissions
Secondary outcomes						
1	Readmission with late procedural complication or for further SUI or POP surgery	Combination of primary outcomes 2 and 3	SMR01	1997/98-2013/14	After index admission and within 5 years	Count of admissions
2	Referral to outpatient pain clinic	Identification of chronic pain through new referrals to pain and anaesthetics clinics.	SMR00	1997/98-2013/14	Within 5 years	Count of referrals
3	Prescription for opiate containing medication	Identification of severe and/or chronic pain through the prescription of opiate containing medication	PIS	2009/10-2013/14	Within 3 years	Yes/no
4	Readmission for any reason	Indication of wider impact on health status and/or check to ensure adjustment has adequately accounted for pre-existing health status	SMR01	1997/98-2013/14	After index admission and within 5 years	Count of admissions
5	Death	Indication of wider impact on health status and/or check to ensure adjustment has adequately accounted for pre-existing health status	Statutory death registration records	1997/98-2013/14	Within 5 years	Dead/alive

PIS Prescribing Information System; **SMR** Scottish Morbidity Record.

3.1.4 Confounding variables

Potential confounding variables/covariates were identified as described in Table 2 (full details in Appendix E). A further potential confounder – severity of underlying condition prior to index surgery – was not quantifiable.

Table 2 Covariates included in the multivariable analyses

Covariate	Definition
Age	Age at admission for index procedure
Deprivation	SIMD quintile at admission for index procedure (using SIMD version appropriate to index procedure year)
Co-morbidity	Presence of ischaemic heart disease, diabetes or chronic obstructive pulmonary disease recorded in hospital discharge records in the 5-years prior to the index procedure
Hospital type	Indicator of the wider clinical environment that the surgery was provided in. Categorized as teaching hospital, large general hospital, general hospital and community or other hospital
Consultant volume	Indicator of surgeon experience. High volume consultants identified as those performing 20 or more SUI or POP procedures in any given year

POP pelvic organ prolapse; **SIMD** Scottish Index of Multiple Deprivation; **SUI** stress urinary incontinence.

4 ANALYTIC APPROACH;

Data were analysed using SPSS v21.0 (SPSS Inc, Illinois, USA).

Index POP and index SUI procedures were analysed separately.

4.1 Descriptive analyses

We report: the frequency of performance of different first single SUI/POP procedures over the study period (1997/98-2013/14); the characteristics of women undergoing the different procedures (mean (sd) age, co-morbidity (% with COPD, IHD or DM in the preceding 5-years) and deprivation (SIMD quintile at the time of the index operation); and, provider characteristics for the different procedures (hospital type and consultant volume (% low volume, <20 procedures/year)).

We report the frequency of adverse event outcomes in terms of both the number of women experiencing the outcome and the total number of outcomes (where a woman can record ≥ 1). For outcomes with 5-year follow-up the percentage of outcomes occurring within 1- and 3-years is reported. For outcomes with 3-year follow-up the percentage of outcomes occurring within 1-year is reported.

The total person-years of exposure following each procedure are reported alongside a crude incidence rate for each outcome.

4.2 Multivariable analyses

Poisson regression analysis was used to calculate the rate ratio (RR – for immediate procedural complications) or incidence rate ratio (IRR – all other outcomes) between the different SUI or POP procedures compared to a non-mesh reference category. Analyses were undertaken both unadjusted and adjusted for age, deprivation (SIMD quintile), patient co-morbidity, hospital size and surgeon volume. For late procedural complications, repeat SUI or POP surgery, any admission and referral to pain clinic multiple events were counted and patient time was censored at 5 years or death. For opiate prescription and death, time to first event was calculated and patient time was censored at first event, 5 years (3 years for opiate prescriptions) or death.

For SUI analyses the reference category was open colposuspension. Additionally, subgroup analyses were undertaken to compare transobturator tape procedures to retropubic tape procedures for the period 2006/07 onwards.

For POP analyses the reference category was anterior colporrhaphy without mesh. Additionally, subgroup analyses were undertaken to compare mesh to non-mesh procedures for: anterior colporrhaphy with mesh vs anterior colporrhaphy without mesh (for the period 2007/08 onwards) posterior colporrhaphy with mesh vs posterior colporrhaphy without mesh (for the period 2007/08 onwards, and each of infracoccygeal colpopexy with mesh and open sacrocolpopexy with mesh vs sacrospinous fixation (for the period 2006/07 onwards).

5 RESULTS - SUI

5.1 Numbers of procedures and patient characteristics

Nearly 26,000 SUI procedures were undertaken in Scotland during the period April 1997 to end March 2014. Non-qualifying index procedures comprised 14.0% of the total and were excluded. Combination procedures comprised 24.3% of included procedures and were excluded from the study cohort, as were a further 0.9% for having had a previous similar procedure within 5-years. Of the study cohort 0.7% (n=123) were excluded from the multivariable analyses due to missing deprivation data or having no follow-up due to death on the day of the index procedure (Figure 1).

Figure 1. Flow chart of patients undergoing stress urinary incontinence surgery in Scotland, 1997-2014.

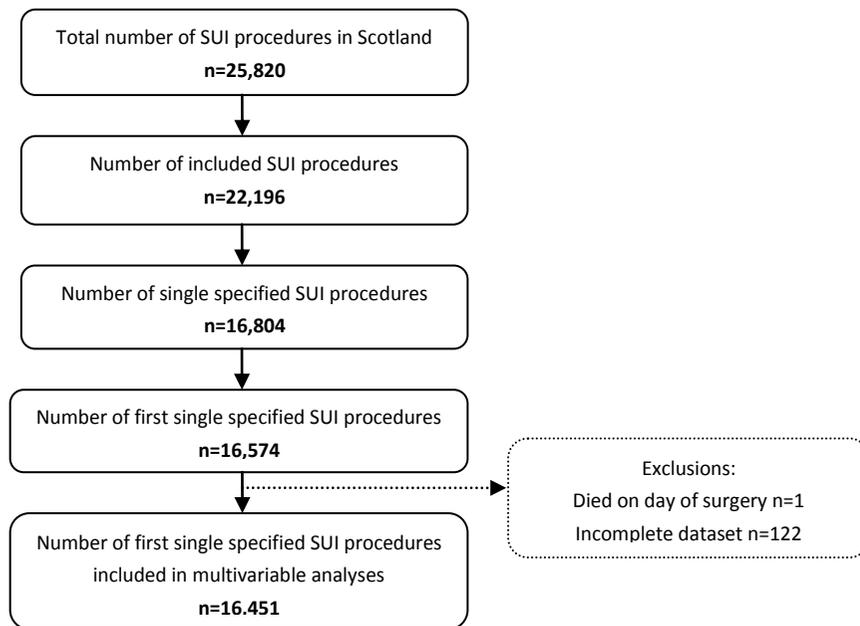
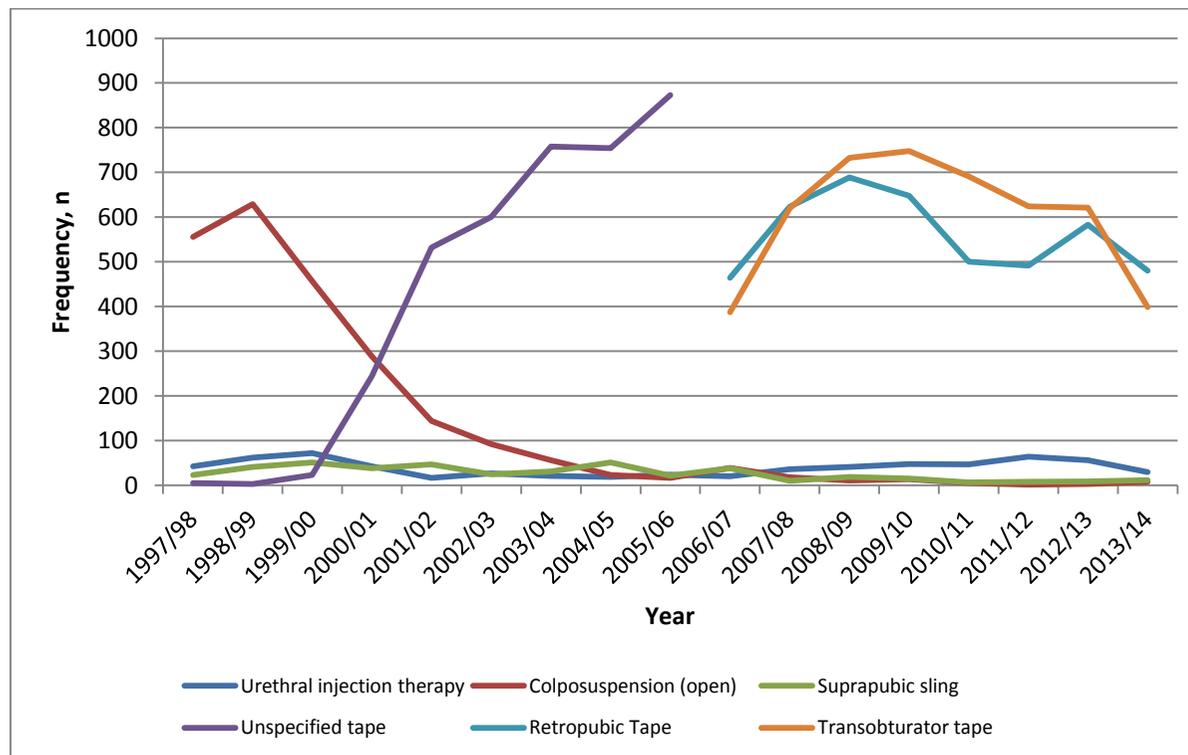


Figure 2 and Table 3 show by procedure type the frequency of first single SUI procedures performed in Scotland during the period 1997-2014.

Overall the number of SUI procedures performed rose to a peak of nearly 1500 in 2008/09 before a clear reduction.

Mesh procedures were introduced in 2000/2001 with the introduction of procedure specific coding in 2006/07. Overall 79% of procedures involved the use of mesh, however there was a marked increase from 39.7% in 2000/01 to 94.7% in 2012/13. This shows a clear replacement of the previous most commonly performed procedure – colposuspension – with retropubic and transobturator tapes (mesh procedures) constituting 89.2% of all procedures performed from 2006-2014.

Figure 2. Numbers of first single SUI procedures performed in Scotland, 1997-2014.



Coding for unspecified tapes was replaced with specific procedure codes (retropubic and transobturator tapes) in 2006/07

Table 3 First single SUI procedure frequency in Scotland, 1997-2014.

	97/98	98/99	99/00	00/01	01/02	02/03	03/04	04/05	05/06	06/07	07/08	08/09	09/10	10/11	11/12	12/13	13/14	Total
Colposuspension (open)	556	629	457	289	144	92	56	23	17	39	18	11	14	5	2	3	8	2363
Urethral injection therapy	43	62	72	43	17	27	21	19	24	20	36	41	48	47	64	56	30	670
Suprapubic sling	23	41	51	38	47	25	31	51	22	38	10	19	15	7	8	9	12	447
Unspecified tape	5	3	23	244	532	600	758	754	873	-	-	-	-	-	-	-	-	3792
Retropubic tape	-	-	-	-	-	-	-	-	-	464	623	689	648	500	492	583	480	4479
Transobturator tape	-	-	-	-	-	-	-	-	-	387	620	733	748	691	624	621	399	4823
Total	627	735	603	614	740	744	866	847	936	948	1307	1493	1473	1250	1190	1272	929	16574

Patients undergoing the different types of SUI procedure were broadly similar (visual examination, Table 4). Exceptions included: patients undergoing urethral injection therapy were slightly older than those in other procedure groups; higher levels of deprivation in patients undergoing suprapubic sling surgery compared to the other procedure groups; and there was more co-morbidity at the time of index procedure in those undergoing urethral injection therapy or suprapubic sling surgery compared to the other procedure groups.

The hospital setting for SUI procedures varied by procedure with urethral injection therapy and suprapubic sling surgery most commonly performed in teaching hospitals and the other procedures more likely to be performed in a general or community hospital. Similarly the consultant volume (surrogate for experience) varied by procedure with urethral injection therapy, open colposuspension and suprapubic sling procedures frequently carried out by surgeons providing a low volume (<20 procedures/year) of included SUI procedures.

Table 4. Characteristics of patients undergoing first single SUI procedures in Scotland, 1997-2014.

	Colposuspension (open)	Urethral inj. therapy	Suprapubic sling	Unspecified tape	Retropubic tape	Transobturator tape
Number	2363	670	447	3792	4479	4823
Age, years, mean (sd)	51.0 (10.6)	56.8 (16.0)	53.6 (10.9)	52.1 (11.2)	51.2 (10.9)	51.3 (10.9)
Most deprived quintile, %	23.2	21.6	33.4	16.6	17.9	18.8
Co-morbidity, %	5.9	14.0	11.2	7.5	5.1	7.0
Teaching hospital, %	36.0	59.0	70.2	29.7	25.0	22.5
Low volume consultant, %	63.0	63.0	45.0	29.5	17.5	14.7

Inj. Injection.

5.2 Adverse events

5.2.1 Immediate procedural complications

Table 5 shows the different types of immediate procedural complication experienced by women during their index procedure hospital stay. Column percentages sum more than 100% as women could experience more than one type of complication. Infection was the most common complication affecting all procedure types.

Table 5 Types of immediate complication, as a proportion of all immediate complication admissions, by SUI procedure in Scotland, 1997-2014

	Colposuspension (open)	Urethral inj. Therapy	Suprapubic sling	Unspecified tape	Retropubic tape	Transobturator tape
Number of patients with a complication	106	7	14	138	78	41
Haemorrhage, % patients experiencing	17.3	14.3	35.7	20.8	13.8	19.9
Infection, % patients experiencing	67.9	85.7	42.9	55.9	55.6	65.9
Pain, % patients experiencing	3.1	14.3	10.7	4.2	5.3	10.6
Procedural, % patients experiencing	58.2	28.6	60.7	50.7	46.8	37.4

Inj. Injection.

Comparisons were made with the risk of experiencing an immediate procedural complication in women undergoing open colposuspension, where the proportion experiencing a complication was 4.5%.

After adjustment, all procedures with the exception of suprapubic sling had significantly lower risks than open colposuspension of immediate complications, with retropubic and transobturator tapes having complication incidence rates 62% and 81% lower respectively (Table 6 and Appendix F).

When compared to retropubic tapes, patients receiving transobturator tapes were 0.50 (95%CI 0.34-1.74) less likely to have immediate complications (Appendix G).

Table 6. Risk of an immediate complication, by SUI procedure type, following first single SUI procedure in Scotland, 1997-2014.

	Colposuspension (open) n=2353	Urethral inj. Therapy n=667	Suprapubic sling n=446	Unspecified tape n=3781	Retropubic tape n=4449	Transobturator tape n=4755
Number of patients with a complication	106	7	14	138	78	41
% with a complication	4.5	1.0	3.1	3.6	1.8	0.9
Unadjusted RR	1.00 (Ref)	0.23 (0.11,0.50)	0.70 (0.40,1.22)	0.81 (0.63,1.05)	0.39 (0.29,0.52)	0.19 (0.13,0.27)
Adjusted RR	1.00 (Ref)	0.24 (0.11,0.52)	0.72 (0.41,1.27)	0.74 (0.56,0.97)	0.38 (0.28,0.52)	0.19 (0.13,0.27)

Inj. Injection; RR rate ratio.

Adjusted for: age, deprivation, co-morbidity, hospital type and consultant volume

5.2.2 Admission with late procedural complications

Table 7 shows the different types of complication experienced by women during the later post-operative period (after their index admission). Column percentages sum more than 100% as women could experience more than one type of complication during the period. Direct procedure related complications were the most common complication affecting all procedure types. Small numbers of patients had mesh removal recorded following a non-mesh procedure – this is likely to reflect a complication of a further SUI or POP procedure occurring within the five year follow-up period and involving mesh.

Table 7 Types of late complication, as a proportion of all late procedural complication admissions, by SUI procedure in Scotland, 1997-2014

	Colposuspension (open)	Urethral inj. Therapy	Suprapubic sling	Unspecified tape	Retropubic tape	Transobturator tape
Total number of complication admissions	357	184	89	541	580	598
Haemorrhage, % patients experiencing	10.3	5.9	5.3	6.6	3.7	4.8
Infection, % patients experiencing	45.9	36.3	36.8	35.5	29.9	22.9
Procedural, % patients experiencing	68.2	72.5	64.2	69.7	71.9	72.5
Pain, % patients experiencing	10.8	4.9	11.6	10.6	9.3	9.8
Mesh removal, % patients experiencing	0.8	1.5	10.5	8.1	24.7	15.4

Inj. Injection.

Comparisons were made with IR of experiencing a late procedural complication in women undergoing open colposuspension, where the overall crude IR was 30.7 /1000 person years. Individual patients experienced up to 34 readmissions with late complications.

After adjustment, all procedures (with the exception of unspecified tapes) had significantly higher incidence rates than open colposuspension for late procedural complications. Retropubic and transobturator tapes had complication incidence rates 30% and 20% higher than open colposuspension respectively (Table 8 and Appendix F).

There was no difference in the rates of late procedural complications for transobturator tapes compared to retropubic tapes (Appendix G).

Table 8. Relative incidence of admission for late procedural complications, by SUI procedure type, following first single SUI procedure in Scotland, 1997-2014.

	Colposuspension (open) n=2353	Urethral inj. Therapy n=667	Suprapubic sling n=446	Unspecified tape n=3781	Retropubic tape n=4449	Transobturator tape n=4755
Number of patients with ≥1 admission*	255	98	60	370	409	389
Total number of admissions	357	184	89	541	580	598
Person-years of follow-up	11614	2651	2081	18755	15785	17058
% admissions within 1 year	60.5	34.3	54.7	50.0	51.1	41.2
% admissions within 3 years	81.0	72.5	69.5	78.3	80.0	76.9
Unadjusted IRR	1.00 (Ref)	2.26 (1.89,2.70)	1.39 (1.10,1.76)	0.94 (0.82,1.07)	1.20 (1.05,1.36)	1.14 (1.00,1.30)
Adjusted IRR	1.00 (Ref)	2.27 (1.89,2.71)	1.41 (1.12,1.79)	0.98 (0.85,1.13)	1.30 (1.13,1.50)	1.20 (1.05,1.38)
Crude IR /1000 person-years	30.7	69.4	42.7	28.9	36.8	35.0

Inj. Injection; IRR incidence rate ratio.

Adjusted for: age, deprivation, co-morbidity, hospital type and consultant volume

*Range 1-34 readmissions with late procedural complications per patient

5.2.3 Admission for further SUI or POP surgery

Table 9 shows the different types of repeat SUI or POP surgery experienced by women during the later post-operative period (after their index admission). There was variety in the types of procedures performed, for example following urethral injection therapy nearly all further procedures were further SUI operations, whereas, following an open colposuspension only 45% were further SUI procedures. Procedures following suprapubic sling or tape operations were similar with around 70% attributable to a further SUI procedure.

Table 9 Types of repeat surgery, as a proportion of further SUI or POP surgery admissions, by SUI procedure in Scotland, 1997-2014

	Colposuspension (open)	Urethral inj. Therapy	Suprapubic sling	Unspecified tape	Retropubic tape	Transobturator tape
Number of further surgery admissions	309	290	82	419	314	361
Further SUI procedure, %	44.7	96.4	75.6	69.9	65.8	74.0
Further POP procedure, %	50.9	3.3	20.7	28.2	32.6	24.3
Further SUI and POP procedures, %	4.4	0.3	3.7	1.9	1.7	4.1

Inj. Injection; POP pelvic organ prolapse; SUI stress urinary incontinence.

Comparisons were made with the incidence of requiring a further SUI or POP procedure in women undergoing open colposuspension, where the overall crude IR was 26.6 /1000 person years.

After adjustment, urethral injection therapy and suprapubic sling procedures had a higher incidence, and retropubic and transobturator tapes had a lower incidence, of requiring a further SUI or POP procedure than open colposuspension (Table 10 and Appendix F).

There was no difference in the rates of further SUI or POP surgery for transobturator tapes compared to retropubic tapes (Appendix G).

Table 10. Relative incidence of admission for further SUI or POP surgery, by SUI procedure type, following first single SUI procedure in Scotland, 1997-2014.

	Colposuspension (open) n=2353	Urethral inj. Therapy n=667	Suprapubic sling n=446	Unspecified tape n=3781	Retropubic tape n=4449	Transobturator tape n=4755
Number of patients with admission*	256	216	61	336	272	302
Number of admissions	309	290	82	419	314	361
Person-years of follow-up	11614	2651	2081	18755	15785	17058
% admissions within 1 year	24.1	41.6	35.4	40.2	39.0	49.2
% admissions within 3 years	71.5	87.3	68.3	78.2	76.7	83.0
Unadjusted IRR	1.00 (Ref)	4.11 (3.50,4.83)	1.48 (1.16,1.89)	0.84 (0.73,0.97)	0.75 (0.64,0.88)	0.80 (0.68,0.93)
Adjusted IRR	1.00 (Ref)	4.20 (3.57,4.95)	1.52 (1.18,1.94)	0.88 (0.75,1.02)	0.80 (0.68,0.95)	0.83 (0.71,0.98)
Crude IR /1000 person-years	26.6	109.3	39.4	22.3	20.0	21.3

Inj. Injection; IRR incidence rate ratio.

Adjusted for: age, deprivation, co-morbidity, hospital type and consultant volume

*Range 1-6 readmissions for further SUI or POP surgery per patient.

5.2.4 Admission with late complication or for further SUI or POP surgery

Comparisons were made with the incidence of experiencing a late procedural complication or requiring a further SUI or POP procedure in women undergoing open colposuspension, where the overall crude IR was 56.9 /1000 person years. Comparison with the two prior outcome categories suggests some, but little overlap between the two.

After adjustment, urethral injection therapy and suprapubic sling procedures had higher incidence rates of experiencing a late procedural complication or requiring a further SUI or POP procedure than open coloposuspension (Appendix H).

There was no difference in the rates of late procedural complications or requiring further SUI or POP surgery for transobturator tapes compared to retropubic tapes (Appendix G).

5.2.5 New referral to pain clinic

Comparisons were made with incidence of experiencing a new referral to an NHS pain clinic in women undergoing open colposuspension, where the overall crude IR was 7.2 /1000 person years.

After adjustment, urethral injection therapy had a higher incidence of referral than open colposuspension. There was no difference in the incidence rate for any other procedure compared to open coloposuspension (Appendix H).

There was no difference in the rates of referral to pain clinic for patients receiving transobturator tapes compared to retropubic tapes (Appendix G).

5.2.6 Prescription of opiate containing medication

Comparisons were made with IR of receiving a first prescription for opiate containing medication in women undergoing open colposuspension, where the overall crude IR was 433.4 /1000 person years.

There were smaller numbers of patients included in this analysis due to patient identifiable community prescribing data only becoming available in 2009/10.

No analyses reached statistical significance (Appendices G and H).

5.2.7 Admission for any reason

Comparison of procedure types (multivariable analyses)

Comparisons were made with the incidence of hospital admission for any reason in women undergoing open colposuspension, where the overall crude IR was 457.5 /1000 person years.

After adjustment (which had a relatively high impact), urethral injection therapy, suprapubic sling and transobturator tapes procedures had a higher incidence of hospital admission for any reason than open colposuspension with unspecified TVTs having a lower incidence rate (Appendix H).

When compared to retropubic tapes, patients receiving transobturator tapes were 1.10 times (95%CI 1.06-1.14) more likely to experience readmission for any reason (Appendix G).

5.2.8 Mortality

Comparison of procedure types (multivariable analyses)

Comparisons were made with the mortality rate of women undergoing open colposuspension, where the overall crude mortality rate was 5.0 /1000 person years.

After adjustment, only urethral injection therapy had a higher mortality rate, and only retropubic tapes had a lower mortality rate than open coloposuspension (Appendix H).

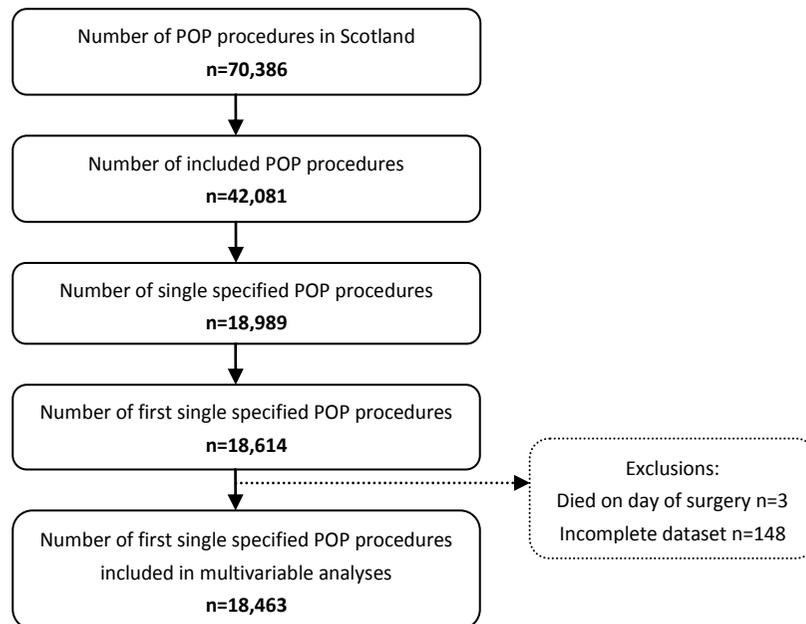
There was no difference in the mortality rates for patients receiving transobturator tapes compared to retropubic tapes (Appendix G).

6 RESULTS – POP

6.1 Numbers of procedures and patient characteristics

Just over 67,000 POP procedures were undertaken in Scotland during the period April 1997 to end March 2014. Non-qualifying procedures comprised 59.8% of all procedures and were excluded. Combination procedures comprised 45.1% of included procedures and were excluded from the study cohort, as were a further 0.9% for having had a previous similar procedure within 5-years. Of the study cohort 0.8% (n=151) were excluded from the multivariable analyses due to missing deprivation data or having no follow-up due to death on the day of the index procedure (Figure 3).

Figure 3. Flow chart of patients undergoing pelvic organ prolapse surgery in Scotland, 1997-2014.



Overall the number of POP procedures performed rose to a peak of nearly 1500 in 2009/10 before remaining broadly similar. There was a slight increase in both anterior and posterior colporrhaphy (non-mesh) procedures over time, with a marked increase in sacrospinous fixation procedures performed during the study period (Table 11 and Figure 4).

Mesh colporrhaphy procedure coding was introduced in 2007/2008. Overall 9% of procedures involved the use of mesh, with the use of mesh remaining constant since 2007/08.

Figure 4. Numbers of first single POP procedures performed in Scotland, 1997-2014.

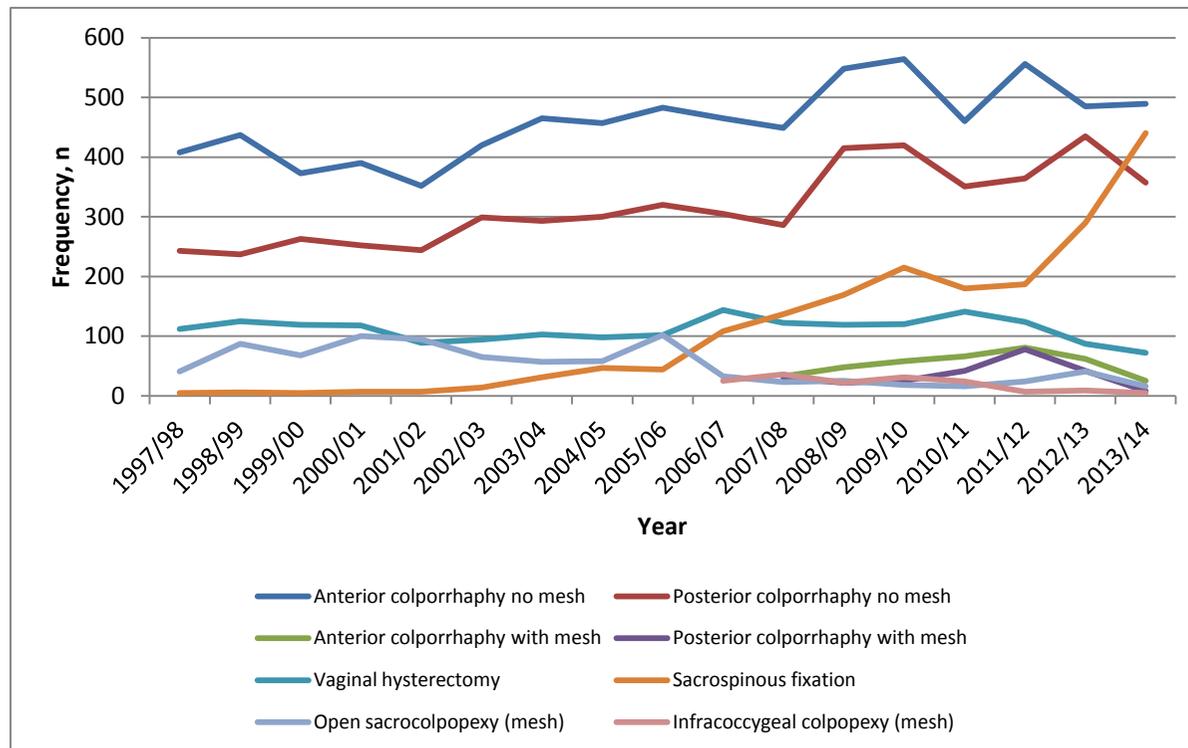


Table 11 First, single POP procedure frequency in Scotland, 1997-2014.

	97/98	98/99	99/00	00/01	01/02	02/03	03/04	04/05	05/06	06/07	07/08	08/09	09/10	10/11	11/12	12/13	13/14	Total
Ant. Col. (no mesh)	408	437	373	390	352	420	465	457	483	465	449	548	564	460	556	485	489	7801
Ant. Col. (mesh)	-	-	-	-	-	-	-	-	-	-	33	48	58	66	81	62	25	373
Post. Col. (no mesh)	243	237	263	252	244	299	293	300	320	305	286	415	420	351	364	435	357	5384
Post. Col. (mesh)	-	-	-	-	-	-	-	-	-	-	30	22	25	42	78	42	8	247
Sacrosp. Fix.	5	6	5	7	7	14	31	47	44	108	137	169	215	180	187	290	440	1892
Infracoc. Colpopexy (mesh)	-	-	-	-	-	-	-	-	-	25	36	22	31	24	7	9	5	159
Open Sacrocol. (mesh)	41	87	68	100	95	65	57	58	102	33	23	25	18	16	24	41	16	869
Vag. Hyst.	112	125	119	118	89	94	103	98	102	144	122	119	120	141	124	87	72	1889
Total	809	892	828	867	787	892	949	960	1051	1080	1116	1368	1451	1280	1421	1451	1412	18614

Ant. Col. anterior colporrhaphy; Infracoc. infracoccygeal ; Post. Col. posterior colporrhaphy; Sacrocol sacrocolpopexy; Sacrosp. Fix. Sacrospinous fixation of the vagina; Vag. Hyst. vaginal hysterectomy.

The characteristics of women undergoing POP procedures are shown in Table 12. The average age of women undergoing POP procedures was 60.7 years (sd 11.7). It was similar at 61-64 years for all procedure types with the exception of posterior colporrhaphy (non-mesh) and vaginal hysterectomy where patients were slightly younger (58.2 and 56.8 years respectively). The prevalence of co-morbidity was lowest in those undergoing vaginal hysterectomy (5.7%) and highest in those undergoing infracoccygeal colpopexy procedures (14.5%). For most procedure types 30-50% of procedures were carried out in teaching hospitals with the majority of the remainder in large general hospitals. A notable exception to this is infracoccygeal colpopexy procedures where a large majority were performed in large general hospitals (74.2%). There was wide variety in the proportion of procedures carried out by low/high volume surgeons, in general, with mesh procedures being carried out by high volume surgeons (except open sacrocolpopexy).

Table 12. Characteristics of patients undergoing first single POP procedures in Scotland, 1997-2014.

	Ant. Col.	Ant. Col. (mesh)	Post. Col.	Post. Col. (mesh)	Sacrosp. Fix.	Infracoc. Colpopexy (mesh)	Open Sacrocol. (mesh)	Vag. Hyst.
Number	7801	373	5384	247	1892	159	869	1889
Mean (sd) age, years	62.1 (10.9)	61.8 (10.2)	58.2 (12.0)	58.9 (10.2)	64.6 (11.0)	62.9 (11.1)	63.3 (10.9)	56.8 (13.0)
Most deprived quintile, %	17.3	16.4	15.9	22.7	16.8	16.4	12.4	19.9
Co-morbidity, %	8.3	8.8	7.5	11.3	11.6	14.5	9.4	5.7
Teaching hospital, %	30.7	50.7	34.7	43.7	37.6	18.2	42.9	39.2
Low volume consultant, %	55.7	12.3	55.1	15.0	22.5	8.8	47.9	61.1

Ant. Col. anterior colporrhaphy; Infracoc. infracoccygeal; Post. Col. posterior colporrhaphy; Sacrocol. sacrocolpopexy; Sacrosp. Fix. Sacrospinous fixation of the vagina; Vag. Hyst. vaginal hysterectomy

6.2 Adverse events

6.2.1 Immediate procedural complications

Table 13 shows the different types of immediate procedural complication experienced by women during their index procedure hospital stay. Column percentages sum more than 100% as women could experience more than one type of complication. Infection was the most common complication affecting anterior and posterior colporrhaphies (non-mesh), sacrospinal fixation and open sacrocolpopexy, with procedure related complications most common in mesh anterior and posterior colporrhaphies, infracoccygeal colpopexy and vaginal hysterectomy procedures.

Table 13 Types of immediate complication, as a proportion of all immediate complication admissions, by POP procedure in Scotland, 1997-2014

	Ant. Col.	Ant. Col. (mesh)	Post. Col.	Post. Col. (mesh)	Sacrosp. Fix	Infracoc. Colpopexy (mesh)	Open Sacrocol. (mesh)	Vag. Hyst.
Number of patients with a complication	105	8	66	2	29	6	27	57
Haemorrhage, % patients experiencing	10.5	21.4	19.3	20.0	14.9	8.3	31.6	47.2
Infection, % patients experiencing	79.1	50.0	57.8	40.0	74.3	8.3	53.9	35.2
Pain, % patients experiencing	1.9	0	9.1	20.0	3.0	16.7	7.9	7.2
Procedural, % patients experiencing	33.2	64.3	41.7	40.0	30.7	83.3	46.1	64.0

Ant. Col. anterior colporrhaphy; Infracoc. infracoccygeal; Post. Col. posterior colporrhaphy; Sacrocol. sacrocolpopexy; Sacrosp. Fix. sacrospinous fixation of the vagina; Vag. Hyst. vaginal hysterectomy

Comparisons were made with the risk of experiencing an immediate procedural complication in women undergoing anterior colporrhaphy without mesh, where the overall crude proportion experiencing a complication was 1.3%.

After adjustment, vaginal hysterectomy, infracoccygeal colpopexy (mesh) and sacrocolpopexy (mesh) had higher risks than anterior colporrhaphy of immediate complications (Table 14 and Appendix I).

Comparisons of mesh procedures and their non-mesh equivalents were undertaken for the period 2006/07 onwards. The risk of immediate procedural complications in women undergoing specific procedure with mesh were around 3 times higher than their non-mesh equivalent (Appendix J).

Table 14. Risk of an immediate complication, by POP procedure type, following first single POP procedure in Scotland, 1997-2014.

	Ant. Col. n=7738	Ant. Col. (mesh) n=372	Post. Col. n=5322	Post. Col. (mesh) n=247	Sacrosp. Fix. n=1880	Infracoc. colpopexy (mesh) n=159	Open Sacrocol. (mesh) n=866	Vag. Hyst. n=1879
Number of patients with a complication	105	8	66	2	29	6	27	57
% with a complication	1.3	2.1	1.2	0.8	1.5	3.8	3.1	3.0
Unadjusted RR	1.00 (ref)	1.59 (0.77,3.27)	0.91 (0.67,1.24)	0.60 (0.15,2.44)	1.14 (0.76,1.72)	2.80 (1.23,6.38)	2.31 (1.51,3.52)	2.24 (1.63,3.10)
Adjusted RR	1.00 (ref)	1.33 (0.64,2.74)	0.89 (0.65,1.22)	0.49 (0.12,1.98)	1.01 (0.66,1.53)	2.55 (1.11,5.88)	2.20 (1.43,3.38)	2.22 (1.60,3.08)

Ant. Col. anterior colporrhaphy; Infracoc. infracoccygeal; Post. Col. posterior colporrhaphy; RR rate ratio; Sacrocol. sacrocolpopexy; Sacrosp. Fix. sacrospinous fixation of the vagina; Vag. Hyst. vaginal hysterectomy
Adjusted for: age, deprivation, co-morbidity, hospital type and consultant volume

6.2.2 Admission with late procedural complication

Table 15 shows the different types of complication experienced by women during the later post-operative period (after their index admission). Column percentages sum more than 100% as women could experience more than one type of complication during the period. Direct procedure related complications were the most common complication affecting all procedure types. Small numbers of patients had mesh removal recorded following a non-mesh procedure – this is likely to reflect a complication of a further SUI or POP procedure occurring within the five year follow-up period and involving mesh.

Table 15 Types of late complication, as a proportion of all late procedural complication admissions, by POP procedure in Scotland, 1997-2014

	Ant. Col. n=7738	Ant. Col. (mesh) n=372	Post. Col. n=5322	Post. Col. (mesh) n=247	Sacrosp. Fix. n=1880	Infracoc. colpopexy (mesh) n=159	Open Sacrocol. (mesh) n=866	Vag. Hyst. n=1879
Total number of complication admissions	647	76	459	65	194	34	127	180
Haemorrhage, % patients experiencing	16.4	2.6	19.1	10.6	12.0	11.8	11.6	21.7
Infection, % patients experiencing	26.3	11.8	21.7	13.6	24.5	11.8	19.9	24.4
Procedural, % patients experiencing	77.0	88.2	75.1	86.4	72.5	97.1	83.6	75.6
Pain, % patients experiencing	11.3	6.6	18.7	6.1	13.5	2.9	8.9	18.9
Mesh removal, % patients experiencing	4.5	19.7	4.6	37.9	6.5	38.2	11.6	2.2

Ant. Col. anterior colporrhaphy; **Infracoc.** infracoccygeal; **Post. Col.** posterior colporrhaphy; **RR** rate ratio; **Sacrocol.** sacrocolpopexy; **Sacrosp. Fix.** sacrospinous fixation of the vagina; **Vag. Hyst.** vaginal hysterectomy

Comparisons were made with incidence rate of late procedural complications in women undergoing anterior colporrhaphy without mesh, where the overall crude IR was 19.1 /1000 person-years.

After adjustment, all procedures involving mesh and sacrospinous fixation without mesh had higher incidence rates of late procedural complications (Table 16 and Appendix I).

The incidence rate of late procedural complications in women undergoing anterior colporrhaphy with mesh was 2.80 times (95%CI 2.14-3.68) that of women undergoing similar procedures without the use of mesh, after full adjustment. Results were similar for the incidence of late procedural complications following posterior colporrhaphy with mesh versus non-mesh procedures (adjusted IRR 3.23, 95%CI 2.38-4.38). There was no significant difference for suspension procedures with mesh versus non-mesh procedure (Appendix J).

Table 16. Relative incidence of admission for late procedural complications, by POP procedure type, following first single POP procedure in Scotland, 1997-2014.

	Ant. Col. n=7738	Ant. Col. (mesh) n=372	Post. Col. n=5322	Post. Col. (mesh) n=247	Sacrosp. Fix. n=1880	Infracoc. colpopexy (mesh) n=159	Open Sacrocol. (mesh) n=866	Vag. Hyst. n=1879
Number of patients with ≥1 admission*	462	51	363	40	154	25	87	124
Total number of admissions	647	76	459	65	194	34	127	180
Person-years of follow-up	32268	1200	21807	781	5499	663	3908	8105
% admissions within 1 year	41.0	36.8	47.2	60.6	53.5	35.3	42.5	56.1
% admissions within 3 years	76.0	80.3	75.3	86.4	84.5	73.5	76.7	76.7
Unadjusted IRR	1.00 (Ref)	3.32 (2.61,4.21)	1.10 (0.98,1.24)	4.36 (3.38,5.63)	1.85 (1.57,2.17)	2.69 (1.90,3.79)	1.70 (1.41,2.06)	1.08 (0.91,1.28)
Adjusted IRR	1.00 (Ref)	3.26 (2.56,4.16)	1.04 (0.92,1.17)	3.80 (2.92,4.93)	1.80 (1.53,2.13)	2.45 (1.72,3.49)	1.77 (1.45,2.15)	1.01 (0.85,1.20)
Crude IR, /1000 person-years	20.1	63.4	21.0	83.3	35.3	51.4	32.5	22.2

Ant. Col. anterior colporrhaphy; **Infracoc.** infracoccygeal; **IRR** incidence rate ratio; **Post. Col.** posterior colporrhaphy; **Sacrocol.** sacrocolpopexy; **Sacrosp. Fix.** sacrospinous fixation of the vagina; **Vag. Hyst.** vaginal hysterectomy

Adjusted for: age, deprivation, co-morbidity, hospital type and consultant volume

*Range 1-7 readmissions for late procedural complications per patient.

6.2.3 Admission for further SUI or POP surgery

Table 17 shows the different types of repeat SUI or POP surgery experienced by women during the later post-operative period (after their index admission). The majority of instances of further surgery were for further POP surgery for all index procedure types.

Table 17 Types of repeat surgery, as a proportion of all further SUI or POP surgery admissions, by POP procedure in Scotland, 1997-2014

	Ant. Col.	Ant. Col. (mesh)	Post. Col.	Post. Col. (mesh)	Sacrosp. Fix.	Infracoc. colpopexy (mesh)	Open sacrocol. (mesh)	Vag. Hyst.
Total number of admissions	1148	100	604	43	328	37	222	272
Further SUI procedure, %	18.0	27.0	19.3	16.3	12.2	13.5	11.2	14.7
Further POP procedure, %	78.7	69.0	76.1	81.4	84.1	86.5	82.0	80.1
Further SUI and POP procedures, %	3.3	4.0	4.7	2.3	3.7	0	6.8	5.1

Ant. Col. anterior colporrhaphy; **Infracoc.** infracoccygeal; **POP** pelvic organ prolapse; **Post. Col.** posterior colporrhaphy; **Sacrocol.** sacrocolpopexy; **Sacrosp. Fix.** sacrospinous fixation of the vagina; **SUI** stress urinary incontinence; **Vag. Hyst.** vaginal hysterectomy.

Comparisons were made with incidence rates of further SUI or POP procedure in women undergoing anterior colporrhaphy without mesh, where the overall crude IR was 35.0 /1000 person-years.

After adjustment posterior colporrhaphy without mesh had a significantly lower incidence rate than anterior colporrhaphy. Anterior colporrhaphy with mesh, sacrospinous fixation and open sacrocolpopexy all had higher incidence rates of further SUI or POP than anterior colporrhaphy without mesh (Table 18 and Appendix I).

Anterior colporrhaphy with mesh had a higher rate of requiring further SUI or POP surgery than anterior colporrhaphy without mesh. Posterior colporrhaphy and suspension procedures had similar rates whether performed with or without mesh (Appendix J).

Table 18. Relative incidence of admission for further SUI or POP surgery, by POP procedure type, following first single POP procedure in Scotland, 1997-2014.

	Ant. Col. n=7738	Ant. Col. (mesh) n=372	Post. Col. n=5322	Post. Col. (mesh) n=247	Sacrosp. Fix. n=1880	Infracoc. colpopexy (mesh) n=159	Open sacrocol. (mesh) n=866	Vag. Hyst. n=1879
Number of patients with ≥1 admission*	958	82	528	34	286	30	172	231
Total number of admissions	1148	100	604	43	328	37	222	272
Person-years of follow-up	32268	1200	21807	781	5499	663	3908	8105
% admissions within 1 year	28.1	39.0	23.9	23.3	43.0	40.5	34.4	26.8
% admissions within 3 years	77.8	88.0	75.9	81.4	86.3	81.1	77.6	78.3
Unadjusted IRR	1.00 (Ref)	2.38 (1.94,2.92)	0.79 (0.72,0.87)	1.57 (1.16,2.13)	1.70 (1.51,1.93)	1.59 (1.15,2.21)	1.62 (1.40,1.87)	0.95 (0.83,1.08)
Adjusted IRR	1.00 (Ref)	2.04 (1.66,2.51)	0.76 (0.69,0.84)	1.28 (0.94,1.74)	1.56 (1.38,1.77)	1.33 (0.95,1.85)	1.71 (1.48,1.98)	0.92 (0.80,1.05)
Crude IR, /1000 person-years	35.6	83.3	27.7	55.0	59.5	55.7	56.7	33.6

Ant. Col. anterior colporrhaphy; Infracoc. infracoccygeal; IRR incidence rate ratio; Post. Col. posterior colporrhaphy; Sacrocol. sacrocolpopexy; Sacrosp. Fix. sacrospinous fixation of the vagina; Vag. Hyst. vaginal hysterectomy

Adjusted for: age, deprivation, co-morbidity, hospital type and consultant volume

*range 1-5 readmissions for further SUI/POP surgery per patient.

6.2.4 Admission with late procedural complication or for further SUI or POP surgery

Comparisons were made with incidence rates of late procedural complications or further SUI or POP procedure in women undergoing anterior colporrhaphy without mesh, where the overall crude IR was 54.6 /1000 person-years. All uterine suspension procedures had higher incidence rates of further SUI or POP surgery, as did anterior colporrhaphy with mesh (adjusted IRRs 1.57-2.21, Appendix K).

The incidence rate of late procedural complications or further SUI or POP surgery in women undergoing anterior colporrhaphy with mesh was 1.96 times (95%CI 1.64-2.34) that of women undergoing similar procedures without the use of mesh, after full adjustment. Similarly the rate in women undergoing posterior colporrhaphy with mesh was 2.09 times (95%CI 1.67-2.63) that of women undergoing the non-mesh comparator.

There was no significant difference for suspension procedures with mesh versus non-mesh (Appendices I).

6.2.5 New referral to pain clinic

Comparisons were made with incidence rates of referral to pain clinic in women undergoing anterior colporrhaphy without mesh, where the overall crude IR was 5.6 /1000 person-years. After adjustment, only anterior colporrhaphy with mesh and posterior colporrhaphy with mesh had higher referral rates than the reference procedure (adjusted IRRs 2.16 and 2.25 respectively, Appendix K).

There was no significant difference in the incidence rates of referral to pain clinic for anterior colporrhaphy, posterior colporrhaphy or suspension procedures with mesh when compared to their non-mesh equivalents (Appendices I).

6.2.6 Prescription of opiate containing medication

Comparisons were made with incidence rates of first opiate prescriptions in women undergoing anterior colporrhaphy without mesh, where the overall crude IR was 309.7 /1000 person-years. After adjustment only posterior colporrhaphy with mesh had a higher rate (IRR 1.24) and vaginal hysterectomy a lower rate (IRR 0.79) than anterior colporrhaphy (non-mesh) (Appendix K).

There was no significant difference in the incidence rates of opiate prescription for anterior colporrhaphy, posterior colporrhaphy or suspension procedures with mesh when compared to their non-mesh equivalents (Appendices I).

6.2.7 Admission for any reason

Comparisons were made with incidence rates of readmission for any reason in women undergoing anterior colporrhaphy without mesh, where the overall crude IR was 425.7 /1000 person-years. After adjustment all procedure types considered had significantly higher incidence rates for readmission for any reason compared to the rate for anterior colporrhaphy (without mesh) with the exception of vaginal hysterectomy where the rate was significantly lower than the reference procedure (Appendix K).

Women undergoing both anterior colporrhaphy with mesh and posterior colporrhaphy with mesh had significantly higher incidence rates for admission to hospital for any reason compared to their non-mesh comparator (IRR 1.21, 95%CI 1.12-1.32 and IRR 1.22 95%CI 1.11-1.34

respectively). Open sacrocolpopexy with mesh had an overall readmission rate lower than sacrospinous fixation (IRR 0.88, 95%CI 0.78-0.99, Appendix I).

6.2.8 Mortality

Comparisons were made with the mortality rate of women undergoing anterior colporrhaphy without mesh, where the overall crude mortality rate was 7.6 /1000 person-years. After adjustment, posterior colporrhaphy (without mesh), open sacrocolpopexy and vaginal hysterectomy all had higher mortality rates than the reference procedure (Appendix K).

There was no significant difference in the adjusted mortality rates for anterior colporrhaphy, posterior colporrhaphy or suspension procedures with mesh when compared to their non-mesh equivalents (Appendix I)

7 INTERPRETATION

This study has examined the frequency of performance of different mesh and non-mesh surgical procedures for SUI and POP and how this has changed over time. Additionally, it has determined the relative frequency of adverse events between different procedure types, including: i) immediate procedural complications; ii) late procedural complications; iii) requirement for further surgery; iv) pain (referral to NHS pain management clinics, prescription of opiate containing medication); v) readmission to hospital for any reason; and vi) mortality.

7.1 Key findings

7.1.1 Numbers of procedures and patient characteristics

Over time the total numbers of both SUI and POP procedures performed increased. For SUI, the introduction of newer (mesh) procedures almost totally replaced use of non-mesh procedures. For POP, use of mesh remained at a constant low level following its introduction.

7.1.2 Primary outcomes

The risk of immediate complications, later complications, and needing further surgery for SUI or POP differs between the different types of operation examined. A specific type of operation can carry a relatively high risk of one of these problems (for example immediate complications) but a relatively low risk of a different problem (for example longer term complications).

More extensive operations, for example those involving operating through the abdomen or a hysterectomy, tend to carry the highest risk of immediate complications.

Compared to open colposuspension, tape (mesh) operations for SUI tend to carry a somewhat higher risk of later complications but a somewhat lower risk of needing further incontinence or prolapse surgery.

Compared to open colposuspension, urinary injection therapy carries a much higher risk of needing further surgery and an associated higher risk of later complications.

Comparing transobturator with retropubic tapes, the risk of immediate complications was lower in transobturator compared to retropubic tapes with no significant differences between the two tape types for later complications or requiring further surgery.

Mesh colporrhaphies carry a substantially higher risk of later complications than non mesh colporrhaphies. Anterior mesh colporrhaphy also carries a higher risk of needing further surgery for incontinence or prolapse than non mesh anterior colporrhaphy.

Sacrospinous fixation, open sacrocolpopexy, and infracoccygeal colpopexy for prolapse of the top of the vagina all carry a higher risk of later complications than anterior colporrhaphy. Sacrospinous fixation and open sacrocolpopexy also carry a higher risk of needing further incontinence or prolapse surgery than anterior colporrhaphy.

Comparing mesh vault suspension procedures (infracoccygeal colpopexy and sacrocolpopexy) to non-mesh vault suspension procedures (sacrospinous fixation), the risk of immediate complications was higher with no significant differences between the procedures for later complications or requiring further surgery.

7.2 Strengths and limitations

7.2.1 Strengths

This unique population based study included women in the whole of Scotland over an extensive time period (1997/98 to 2013/14).

We have been able to explore the information held in high quality national datasets containing records of all routine NHS care performed during the study period.

We have included a wide range of different procedure types and followed them for 5-year adverse event outcomes.

7.2.2 Limitations

Our choice of primary outcomes focussed on diagnoses/procedures severe enough to require hospital admission. Additionally, there is a paucity of information on the exact nature and severity of complications, and it is not possible to ensure the outcome of interest is in fact a consequence of the index procedure and not related to an alternative event.

A problem that we were unable to address directly is the influence of the severity of the underlying clinical condition of a woman on both procedure choice and resultant adverse events. However given the size of the effects observed we think this is unlikely to alter our conclusions.

Whilst the coding of SMR01 records is of high quality, it is limited by the timing of introduction of codes for new procedures, with a lag between the introduction of a procedure in clinical practice and the provision of a related code.

The lack of specific codes for some outcomes of interest (e.g. POP mesh removal) make it difficult to determine their exact frequency however we have extensively validated our coding of outcomes to try and avoid any bias from this.

7.3 Conclusion

This is the first study to compare complication rates following a range of SUI and POP procedures undertaken in routine clinical practice. These findings add to a growing body of evidence reminding us that no surgery is without risk and that the use of mesh in SUI and POP surgery needs to be carefully considered and patients adequately counselled about potential risks and benefits.

8 APPENDICES

8.1 Appendix A - Index procedure inclusion and exclusion criteria decision making process

Excluded procedures

Procedures that were considered but rejected for inclusion in the comparative analysis due to insufficient numbers of procedures being performed in Scotland during 1997/98-2013/14 were:

- Laparoscopic colposuspension
- Creation of artificial urinary sphincter
- Colpocleisis
- Laparoscopic sacrocolpopexy
- Sacrohysteropexy (open or laparoscopic)
- Infracoccygeal hysteropexy

Vaginal buttressing of urethra was also excluded as this is very rarely carried out as a single procedure for SUI. It is generally done in combination with colporrhaphy for women with both POP and SUI and is therefore not a valid comparison for other SUI or POP procedures

Finally, combined AP colporrhaphies and colporrhaphies in conjunction with cervical amputation or vaginal hysterectomy without and with mesh were considered. Large numbers of non-mesh procedures but very few involving mesh are recorded on SMR01. As the primary focus of this analysis is on the relative safety and effectiveness of comparable mesh versus non-mesh approaches, these categories were therefore excluded.

Excluding combination procedures

A small number of records for included contained both a SUI and a POP procedure. A high proportion of index POP records (particularly for some procedure types) include a code indicating a second concurrent POP procedure. Inclusion of POP+POP combinations would contaminate the POP categories and potentially introduce bias if these combinations are more common for some POP procedure types than others.

The exception is women undergoing apical suspension procedures (sacrospinous fixation, infracoccygeal colpopexy and sacrocolpopexy). These procedures are very uncommonly recorded as single procedures. The substantial majority of all 3 procedure types are done in conjunction with another procedure, most commonly a colporrhaphy.

Single and combination procedures including a non mesh anterior, posterior, or anterior/posterior colporrhaphy were therefore included together in the analysis of these procedure types.

Combination procedures including any mesh colporrhaphies (or any other SUI or POP procedures) will be excluded as it would not be clear, for example, which mesh any subsequent mesh removal related to.

Records containing a potential index SUI or POP procedure alongside a related (non-index) procedure code were included. This was because many records indicating a SUI or POP procedure also contain other codes in other operation positions that record relatively minor issues such as concurrent cystoscopy or catheter insertion/removal and exclusion of these records would be unnecessarily wasteful (and may introduce bias if these 'combinations' are more often recorded for some procedure types than others).

Excluding repeat procedures

Repeat or revision surgery is known to carry different risks to first surgery. Procedures where there had been a prior SUI or POP procedure within the previous 5 years were therefore excluded.

8.2 Appendix B – Index procedure coding

Index SUI procedures: defined as the following OPCS-4 codes:

Colposuspension (open)	M52.3 (not paired with Y50.8 to 31.3.06 or Y75 from 1.4.06)
Urethral injection therapy	M56.3
Suprapubic sling	M52.1
Unspecified tape procedures	M53.8 to 31.3.06
Retropubic tape procedures	M53.3 from 1.4.06
Transobturator tape procedures	M53.6 from 1.4.06

Index POP procedures: defined as the following OPCS-4 codes:

Anterior colporrhaphy	P23.2 or P23.4 or P23.5 (not paired with Y02, Y36 or Y37) (not paired with Q01 or Q08), (Q01 or Q08 not recorded in any other Op positions) (P23.5 available from 1.4.06)
Anterior colporrhaphy with mesh	P23.6 available from 1.4.07 (Not paired with Q01 or Q08) (Q01 or Q08 not recorded in any other Op positions)
Posterior colporrhaphy	P23.3 (Not paired with Y02, Y36 or Y37) (Not paired with Q01 or Q08) (Q01 or Q08 not recorded in any other Op positions)
Posterior colporrhaphy with mesh	P23.7 available from 1.4.07 (Not paired with Q01 or Q08) (Q01 or Q08 not recorded in any other Op positions)
Sacrospinous fixation of vagina (+/- concurrent non-mesh colporrhaphy)	P24.4 to 31.3.06 or P24.7 from 1.4.06
Open sacrocolpopexy (+/- concurrent non-mesh colporrhaphy)	P24.2 or P24.5 from 1.4.06 (Not paired with Y50.8 to 31.3.06 or Y75 from 1.4.06)
Infracoccygeal colpopexy (+/- concurrent non-mesh colporrhaphy)	P24.6 from 1.4.06
Vaginal hysterectomy for uterine prolapse	Q08 (Paired with ICD10 diagnostic code N81)

8.3 Appendix C – National datasets

SMR01 – Inpatient hospital records

A SMR01 record is returned to ISD every time a patient is discharged following an episode of acute general inpatient or day case care. All SMR01 records contain information on the patient treated (e.g. Community Health Index number, sex, date of birth), administrative aspects of the care provided (e.g. admission and discharge dates, responsible consultant, specialty, hospital), and clinical details (coded information on the diagnosis that necessitated the admission and any surgical procedures provided during the episode of care). Diagnoses are coded according to the *International Classification of Diseases and Related Health Problems* (version 10 implemented in Scotland in 1997). Surgical procedures are coded according to the Office of Population Censuses and Surveys *Classification of Interventions and Procedures* (version 4 implemented in Scotland in 1989). All coding is undertaken by specialist clinical coders. SMR01 records allow the recording of 6 diagnostic codes and 4 pairs of procedural codes.

SMR00 – Outpatient records

An SMR00 record is returned to ISD every time a patient has an appointment at an outpatient clinic (whether or not the patient attended the appointment). The definition of an outpatient clinic includes: a medical consultant outpatient clinic; meeting with a consultant or senior member of his/her team out with an outpatient clinic session (including the patient's home); attendance at a clinic run by a nurse or an allied health professional identified as the health care professional responsible for care for that clinic and who has legal and clinical responsibility for that patient.

All SMR00 records contain information on the patient (e.g. Community Health Index number, sex, date of birth) and administrative aspects of the appointment (e.g. date, responsible consultant, specialty, hospital). Information about a patient's diagnosis or any procedures undertaken in the outpatient setting are not routinely recorded.

Prescribing Information System – community prescribing records

Prescribing data are generated as a by-product of prescription processing by NSS Practitioner Services which reimburses community pharmacies and surgeries for prescriptions dispensed. The Prescribing Information System (PIS) stores information on all prescriptions dispensed in the community. All PIS records include information on administrative aspects of the prescription (e.g. prescriber, dispenser, date) and the item dispensed (e.g. British National Formulary (BNF) drug code, quantity). Over recent years, information on the patient receiving the prescription, specifically the CHI number, has also been included in PIS. This information is considered sufficiently complete to allow patient based analyses from April 2009.

National Records for Scotland – death registration records

Death records are collated by National Records for Scotland (NRS) and passed to ISD for analysis purposes on a weekly basis. Death records contain demographic details of the deceased person and the cause of death as notified by the certifying doctor coded by NRS using ICD10 codes. ISD adds the individual's CHI number to allow death records to be linked to patients' prior healthcare records such as SMR01.

8.4 Appendix D – Adverse event outcome coding

Primary adverse event outcomes

Immediate procedural complication

Identification of complications likely to be related to the index event, for example urinary tract infection, pain, sepsis.

‘Immediate procedural complication’ was defined as a qualifying ICD-10 code occurring during the index procedure hospital stay where the patient was discharged within 90 days of their operation. Patients were categorised as either having a complication during their initial hospital stay (regardless of how many separate complication codes were recorded) or not.

Admission with a late procedural complication (within 5 years)

Identification of complications likely to be related to the index event but occurring after the index admission.

‘Late procedural complication’ was defined as a qualifying ICD-10 or OPCS-4 code occurring during a hospital stay subsequent to, and with a discharge date within 5 years of, the index procedure date. Each of a patient’s subsequent admissions was categorised as indicating a complication or not (regardless of how many separate complication codes were recorded) and counted separately.

Admission for further SUI or POP surgery (within 5 years)

Identification of hospital admissions for further SUI or POP surgery – an indicator of initial surgery failure.

‘Readmission for further of SUI or POP surgery’ was defined as a qualifying OPCS-4 code occurring during a hospital stay subsequent to, and with a discharge date within 5 years of, the index procedure date. Each of a patient’s subsequent admissions was categorised as indicating a further surgery event or not (regardless of how many separate procedure codes were recorded) and counted separately.

Secondary adverse event outcomes

Admission with a late procedural complication OR for further SUI or POP surgery (within 5 years)

Identification of complications likely to be related to the index event occurring after the index admission or requirement for further SUI or POP surgery (a combination of the above two complications).

'Readmission with a late procedural complication or for further SUI or POP surgery' was defined as a qualifying ICD-10 or OPCS-4 code occurring during a hospital stay subsequent to, and with a discharge date within 5 years of, the index procedure date. Each of a patient's subsequent admissions was categorised as indicating a complication or revision surgery event or not (regardless of how many separate complication/procedure codes were recorded) and counted separately.

New referral to outpatient pain clinic (within 5 years)

Identification of new referrals to NHS pain clinics in Scotland. 'New referral to outpatient pain clinic' was defined as a new patient appointment at an anaesthetics or pain management specialty outpatient clinic, whether or not the patient attended the appointment, subsequent to, and within 5 years of, the index procedure date.

Prescription of opiate containing medication (within 3 years)

Identification of first prescription for an opiate containing medication, excluding the immediate post-operative period. 'Prescription of opiate analgesia' was defined as the first qualifying code with a prescription date >90 days after, and within 5 years of, the index procedure date.

Admission for any reason (within 5 years)

Any readmission following the index event. 'Any readmission' was defined as any SMR01 record with a discharge date within 5 years of, the index procedure date, regardless of the diagnostic or procedural codes included.

Mortality

'Death' was defined as a National Records of Scotland statutory death record occurring subsequent to, and within 5 years of, the index procedure date, regardless of the cause of death.

Adverse event outcome coding

Complication	Extract	Timing	Codes	Response
Immediate procedural complication	SMR01	During the index CIS and where the patient was discharged within 90 days of their operation	<p>ICD10 diagnostic codes:</p> <p>Haemorrhage related:</p> <p>T81.0 Haemorrhage and haematoma complicating a procedure, NEC</p> <p>T81.1 Shock during or resulting from a procedure, NEC</p> <p>R58 Haemorrhage, NEC</p> <p>Infection related:</p> <p>T81.4 Infection following procedure, NEC</p> <p>T83.5 Infection and inflammatory reaction due to prosthetic device, implant and graft in urinary system</p> <p>T83.6 Infection and inflammatory reaction due to prosthetic device, implant and graft in genital tract</p> <p>N30x Cystitis</p> <p>N39.0 Urinary tract infection, site not specified</p> <p>R57.2 Septic shock</p> <p>R65x Systemic inflammatory response syndrome</p> <p>A40x Streptococcal sepsis</p> <p>A41x Other sepsis</p> <p>Pain related:</p> <p>N94.1 Dyspareunia</p> <p>R10.2 Pelvic and perineal pain</p> <p>R30 Pain associated with micturition</p> <p>R52.1 Chronic intractable pain</p> <p>R52.2 Other chronic pain</p> <p>Procedure related:</p> <p>T81x <i>Complications of procedures, NEC</i></p> <p>T81.2 Accidental puncture and laceration during a procedure, not elsewhere classified</p> <p>T81.3 Disruption of operation wound, NEC</p> <p>T81.5 Foreign body accidentally left in body cavity or operation wound following a procedure</p> <p>T81.6 Acute reaction to foreign substance accidentally left during a procedure</p>	Yes or no

			<p>T81.7 Vascular complications following a procedure, NEC</p> <p>T81.8 Other complications of procedures, NEC</p> <p>T81.9 Unspecified complication of procedure</p> <p>T83x <i>Complications of genitourinary prosthetic devices, implants and grafts</i></p> <p>T83.0 Mechanical complication of urinary (indwelling) catheter</p> <p>T83.1 Mechanical complication of other urinary devices and implants</p> <p>T83.2 Mechanical complication of graft of urinary system</p> <p>T83.3 Mechanical complication of intrauterine contraceptive device</p> <p>T83.4 Mechanical complication of other prosthetic devices, implants and grafts in genital tract</p> <p>T83.8 Other complications of genitourinary prosthetic devices, implants and grafts</p> <p>T83.9 Unspecified complication of genitourinary prosthetic device, implant and graft</p> <p>T88.8 Other specified complications of surgical and medical care, NEC</p> <p>T88.9 Complication of surgical and medical care, unspecified</p> <p>T98.3 Sequelae of complications of surgical and medical care, not elsewhere classified</p> <p>Y60x Unintentional cut, puncture, perforation or haemorrhage during surgical and medical care</p> <p>Y73x Gastroenterology and urology devices associated with adverse incidents</p> <p>Y76x Obstetric and gynaecological devices associated with adverse incidents</p> <p>Y83x Surgical operation and other surgical procedures as the cause of abnormal reaction of the patient, or of later complication, without mention of misadventure at the time of the procedure</p> <p>Y88x Sequelae with surgical and medical care as external cause</p> <p>R33 Retention of urine</p> <p>R39.1 Other difficulties with micturition</p>	
Readmission with a late procedural complication	SMR01	During a subsequent CIS and with CIS discharge date within 5 years of the date of index procedure	<p>ICD10 diagnostic codes:</p> <p>Haemorrhage related:</p> <p>R58* Haemorrhage, NEC</p> <p>Pain related:</p> <p>N94.1 Dyspareunia</p> <p>R10.2 Pelvic and perineal pain</p> <p>R30* Pain associated with micturition</p> <p>R52.1 Chronic intractable pain</p> <p>R52.2 Other chronic pain</p> <p>Infection related:</p> <p>N30x* Cystitis</p> <p>N39.0* Urinary tract infection, site not specified</p> <p>R57.2* Septic shock</p> <p>R65x* Systemic inflammatory response syndrome</p>	Count

			<p>A40x* Streptococcal sepsis</p> <p>A41x * Other sepsis</p> <p>Procedure related:</p> <p>T81x Complications of procedures, NEC</p> <p>T83x Complications of genitourinary prosthetic devices, implants and grafts</p> <p>T88.8 Other specified complications of surgical and medical care, NEC</p> <p>T88.9 Complication of surgical and medical care, unspecified</p> <p>T98.3 Sequelae of complications of surgical and medical care, not elsewhere classified</p> <p>Y60x* Unintentional cut, puncture, perforation or haemorrhage during surgical and medical care</p> <p>Y73x* Gastroenterology and urology devices associated with adverse incidents</p> <p>Y76x* Obstetric and gynaecological devices associated with adverse incidents</p> <p>Y83x Surgical operation and other surgical procedures as the cause of abnormal reaction of the patient, or of later complication, without mention of misadventure at the time of the procedure</p> <p>Y88x Sequelae with surgical and medical care as external cause</p> <p>R33* Retention of urine</p> <p>R39.1* Other difficulties with micturition</p> <p>OPCS4 procedure codes:</p> <p>Mesh removal:</p> <p>M53.4 Total removal of tension-free vaginal tape</p> <p>M53.5 Partial removal of tension-free vaginal tape</p> <p>M53.7 Removal of transobturator tape</p> <p>P05, P20, P22.8, P23.8, or P29 paired with Y03 or Y26 Non specific vaginal prolapse repair or other procedure on lower genital tract paired with supplementary code indicating 'attention to prosthesis' or 'other repair of organ'</p> <p><i>*only applicable if admission date within 90 days of the index procedure date.</i></p>	
Readmission for further SUI or POP surgery	SMR01	During a subsequent CIS and with CIS discharge date within 5 years of the date of index procedure	<p>OPSC4 procedural codes:</p> <p>M51-M58 (excl. episodes with only code M53.4, M53.5 or M53.7) Any operation on outlet of female bladder</p> <p>P18, P22 (except P22.8 when paired with Y03 or Y26), P23 (except P23.8 when paired with Y03 or Y26), P24, P26, Q54</p> <p>Any procedure for pelvic organ prolapse</p> <p>Q08 (paired with ICD10 diagnostic code N81) Vaginal hysterectomy for prolapse</p> <p>Note the P22.8 and P23.8 codes have been excluded when paired with codes Y03 or Y26 as examination of the PROSPECT validation data suggested these codes may be being used to code POP mesh removal rather than (or possibly as well as) repeat colporrhaphy</p>	Count
Readmission with a late procedural complication or for further of SUI or POP surgery	SMR01	During a subsequent CIS and with CIS discharge date within 5 years of the date of index procedure	Any of the above two categories (readmission with a late procedural complication readmission or readmission for a further of SUI or POP surgery)	Count

New referral to outpatient pain clinic	SMR00	First	Referral type = new Specialty code = C3 or C31 (pain or anaesthetics)	Count
Prescription of opiate containing medication	PIS	A prescribed date >90 days and within 3 years of the index event date.	BNF sections 4.7.1 and 4.7.2	Yes or no
Readmission for any reason	SMR01	During a subsequent CIS and with CIS discharge date within 5 years of the date of index procedure	Any ICD-10 or OPCS-4 code	Count
Death from any cause	SMR01/NRS	Within 5 years of the date of index procedure	Any cause	Yes or no

NRS National records for Scotland; **PIS** Prescribing Information System; **POP** pelvic organ prolapse; **SMR** Scottish Morbidity Record; **SUI** stress urinary incontinence.

8.5 Appendix E – Confounding variable/covariate coding

Age

Defined as age in years at admission date for index procedure

Deprivation

Coded using the SIMD scoring appropriate to index procedure year and reported as quintiles.

- SIMD 2004 for index procedures in 1997-2005
- SIMD 2006 for index procedures in 2006-2008
- SIMD 2009 (v2) for index procedures in 2009-2011
- SIMD 2012 for index procedures in 2012-2014

Co-morbidity

Significant co-morbidity at the time of the index procedure was defined as any of diabetes, ischaemic heart disease or COPD recorded on the index procedure SMR01 record or a prior record with discharge date up to 5 years before the index procedure. The three conditions were identified using the following ICD-9/10⁴ codes:

- Diabetes – 250, E10-E14
- IHD – 410-414, I20-I25
- COPD - 490-492, 496, J40-J44

⁴ ICD-9 coding was used prior to 1997 with ICD-10 used for 1997 onwards

Consultant volume

Consultant volume was identified as a surrogate for consultant experience. The 'consultant responsible for care' was identified on included SUI index procedure records. Consultants performing <20 or ≥20 included SUI procedures in any year were categorised as low or high volume surgeons for that year respectively. Similarly, POP index procedure records were examined and surgeons performing <20/≥20 included POP procedures in any year were categorised as low/high volume surgeons for that year. The 20 procedure threshold was selected to reflect the NICE clinical guideline on urinary incontinence that recommends surgeons maintain an annual workload of at least 20 cases of each SUI procedure (<https://www.nice.org.uk/guidance/cg171>).

Hospital type

From the SMR01 extract the hospital where the index procedure was performed was identified and coded using the Scottish Health Service Costs (known as the Costs Book⁵) as:

1. Teaching hospital = "General" A1: Teaching hospitals - major teaching hospitals covering a full range of services and with special units.
2. Large general hospital = "General" A2: Large general hospitals - general hospitals with some teaching units, usually over 250 average staffed beds.
3. General hospital = "General" A3: General hospitals - mixed specialist hospitals (may have maternity units). Consultant type surgery undertaken, usually 250 and under average staffed beds.
4. Community and others = All other codes and hospitals with expired codes unable to be identified

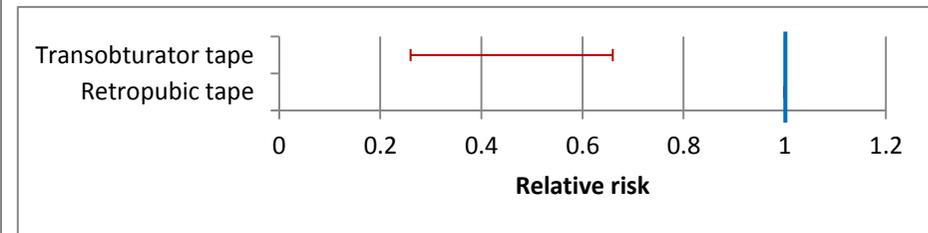
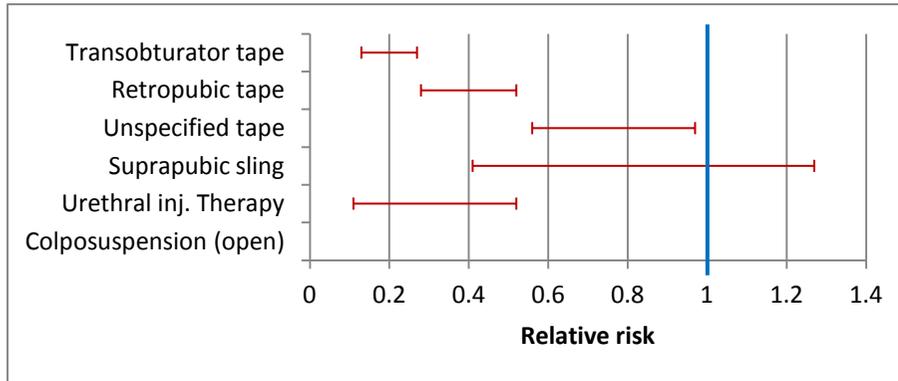
⁵ Costs Book available at <http://www.isdscotland.org/Health-Topics/Finance/Costs/>

8.6 Appendix F – SUI: Primary outcome figures

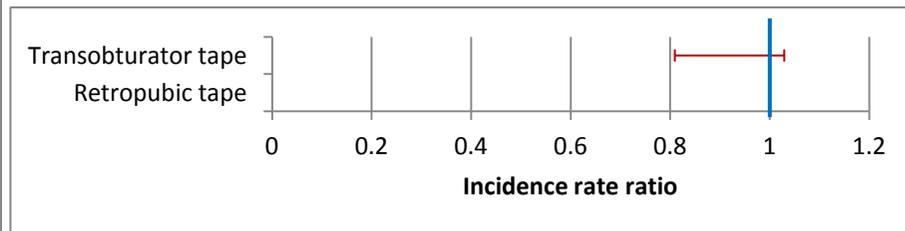
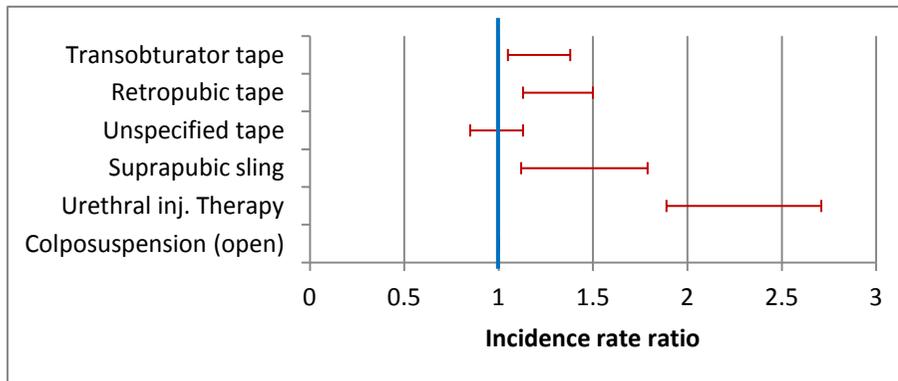
IRR incidence rate ratio; RR rate ratio.

Adjusted for: age, deprivation, co-morbidity, hospital type and consultant volume

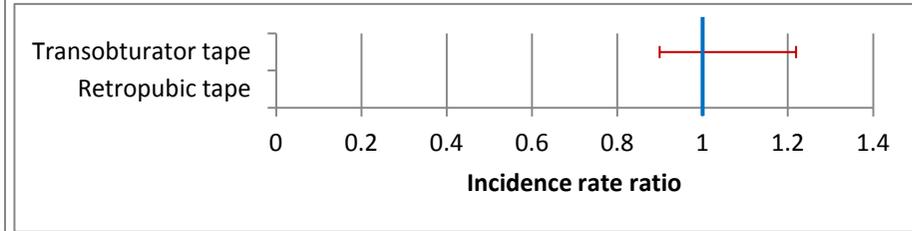
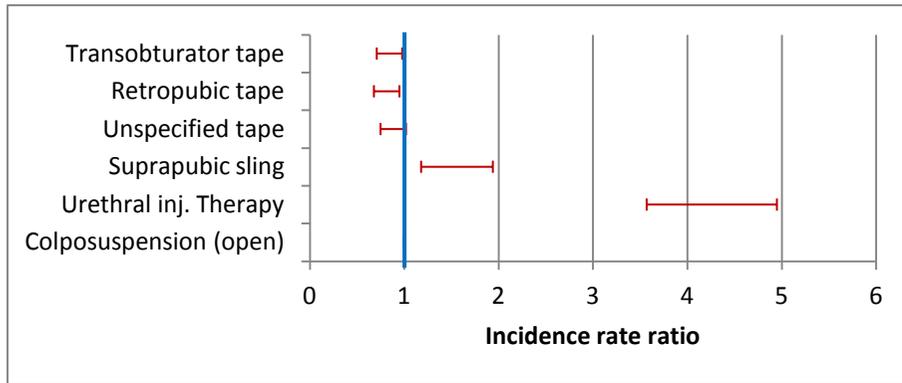
Risk of an immediate complication within 5-years



Risk of admission with a late procedural complication within 5-years



Risk of admission further SUI or POP surgery within 5-years



8.7 Appendix G – SUI: Results of transobturator vs retropubic tape analyses

Analysis for the period 2006/07-2013/14.

IRR incidence rate ratio; RR rate ratio.

Adjusted for: age, deprivation, co-morbidity, hospital type and consultant volume.

Risk of an immediate complication

	Retropubic tape N=4449	Transobturator tape N=4755
Unadjusted RR	1.00 (Ref)	0.49 (0.33,0.71)
Adjusted RR	1.00 (Ref)	0.50 (0.34,0.74)

Risk of admission with a late procedural complication within 5-years

	Retropubic tape N=4449	Transobturator tape N=4755
Unadjusted IRR	1.00 (Ref)	0.95 (0.85,1.07)
Adjusted IRR	1.00 (Ref)	0.91 (0.81,1.03)

Risk of admission further SUI or POP surgery within 5-years

	Retropubic tape N=4449	Transobturator tape N=4755
Unadjusted IRR	1.00 (Ref)	1.06 (0.92,1.24)
Adjusted IRR	1.00 (Ref)	1.05 (0.90,1.22)

Risk of admission with a late procedural complication or for further SUI or POP surgery within 5-years

	Retropubic tape N=4449	Transobturator tape N=4755
Unadjusted IRR	1.00 (Ref)	0.97 (0.88,1.07)
Adjusted IRR	1.00 (Ref)	0.94 (0.86,1.03)

Risk of referral to pain clinic within 5-years

	Retropubic tape N=4449	Transobturator tape N=4755
Unadjusted IRR	1.00 (Ref)	1.04 (0.83,1.30)
Adjusted IRR	1.00 (Ref)	1.03 (0.82,1.29)

Risk of opiate medication prescription within 3-years

	Retropubic tape N=4449	Transobturator tape N=4755
Unadjusted IRR	1.00 (Ref)	1.06 (0.98,1.15)
Adjusted IRR	1.00 (Ref)	1.06 (0.98,1.15)

Risk of admission for any reason within 5-years

	Retropubic tape N=4449	Transobturator tape N=4755
Unadjusted IRR	1.00 (Ref)	1.14 (1.10,1.18)
Adjusted IRR	1.00 (Ref)	1.10 (1.06,1.14)

Risk of death within 5-years

	Retropubic tape N=4449	Transobturator tape N=4755
Unadjusted IRR	1.00 (Ref)	1.24 (0.87,1.77)
Adjusted IRR	1.00 (Ref)	1.25 (0.87,1.80)

8.8 Appendix H - SUI: Results of secondary adverse event outcomes analyses

Inj. Injection; IRR incidence rate ratio; RR rate ratio.

Adjusted for: age, deprivation, co-morbidity, hospital type and consultant volume

Relative incidence of admission with late procedural complications or further SUI or POP surgery, by SUI procedure type, following first single SUI procedure in Scotland, 1997-2014.

	Colposuspension (open) n=2353	Urethral inj. Therapy n=667	Suprapubic sling n=446	Unspecified tape n=3781	Retropubic tape n=4449	Transobturator tape n=4755
Number of patients with ≥1 admission*	464	280	105	581	578	588
Total number of admissions	661	477	170	888	854	895
Person-years of follow-up	11614	2651	2081	18755	15785	17058
% admissions within 1 year	43.1	39.1	45.6	43.9	47.3	41.4
% admissions within 3 years	76.5	81.8	68.4	78.3	78.3	77.2
Unadjusted IRR	1.00 (Ref)	3.16 (2.81,3.56)	1.44 (1.21,1.70)	0.83 (0.75,0.92)	0.95 (0.86,1.05)	0.92 (0.83,1.02)
Adjusted IRR	1.00 (Ref)	3.17 (2.81,3.58)	1.45 (1.22,1.72)	0.87 (0.78,0.97)	1.03 (0.92,1.15)	0.97 (0.87,1.08)
Crude IR, /1000 person-years	56.9	179.8	81.9	47.2	54.1	52.3

*Range 1-34 admissions for late procedural complications or further SUI/POP surgery per patient.

Relative incidence of referral to pain clinic, by SUI procedure type, following first single SUI procedure in Scotland, 1997-2014.

	Colposuspension (open) n=2353	Urethral inj. Therapy n=667	Suprapubic sling n=446	Unspecified tape n=3781	Retropubic tape n=4449	Transobturator tape n=4755
Number of referrals*	84	39	22	116	147	165
Person-years of follow-up	11614	2651	2081	18755	15785	17058
% referrals within 1 year	15.9	31.0	11.1	18.8	19.0	15.2
% referrals within 3 years	63.6	64.3	66.7	62.4	74.8	70.9
Unadjusted IRR	1.00 (Ref)	2.03 (1.39,2.97)	1.46 (0.91,2.34)	0.86 (0.65,1.13)	1.29 (0.98,1.68)	1.34 (1.02,1.74)
Adjusted IRR	1.00 (Ref)	1.99 (1.35,2.92)	1.34 (0.83,2.18)	0.84 (0.63,1.12)	1.27 (0.95,1.69)	1.30 (0.98,1.73)
Crude IR, /1000 person-years	7.2	14.6	10.5	6.2	9.3	9.6

*no patient had more than 1 referral

Relative incidence of receiving opiate medication prescription, by SUI procedure type, following first single SUI procedure in Scotland, 2009-2014.

	Colposuspension (open) N=31	Urethral inj. Therapy N=242	Suprapubic sling N=51	Unspecified TVT -	Retropubic TVT N=2675	Transobturator TVT N=3030
Number of patients prescribed opiate containing medication	17	139	27	-	1145	1425
Person-years of follow-up	39	306	62	-	4004	4698
% prescriptions within 1 year	70.6	77.0	88.9	-	68.8	67.4
Unadjusted IRR	1.00 (Ref)	1.05 (0.63,1.73)	1.00 (0.55,1.84)	-	0.66 (0.41,1.07)	0.70 (0.43,1.13)
Adjusted IRR	1.00 (Ref)	0.94 (0.56,1.57)	0.95 (0.51,1.76)	-	0.78 (0.48,1.26)	0.82 (0.51,1.34)
Crude IR, /1000 person-years	433.4	453.8	433.5	-	286	303.3

Relative incidence of hospital readmission for any reason, by SUI procedure type, following first single SUI procedure in Scotland, 1997-2014.

	Colposuspension (open) n=2353	Urethral inj. Therapy n=667	Suprapubic sling n=446	Unspecified tape n=3781	Retropubic tape n=4449	Transobturator tape n=4755
Number of patients with ≥1 admission*	1587	555	338	2436	2291	2677
Total number of admissions	5314	2879	1299	7913	6654	8182
Person-years of follow-up	11614	2651	2081	18755	15785	17058
% admissions within 1 year	24.3	27.9	27.9	21.7	26.0	23.3
% admissions within 3 years	64.3	68.8	62.1	61.1	66.2	67.9
Unadjusted IRR	1.00 (Ref)	2.37 (2.27,2.48)	1.36 (1.28,1.45)	0.92 (0.89,0.96)	0.92 (0.89,0.96)	1.05 (1.01,1.09)
Adjusted IRR	1.00 (Ref)	2.07 (1.98,2.17)	1.24 (1.16,1.31)	0.95 (0.91,0.98)	0.99 (0.96,1.03)	1.10 (1.06,1.14)
Crude IR /1000 person-years	457.5	1086.0	624.2	421.9	421.5	479.7

*Range 1-119 readmissions for any reason per patient.

Relative five-year mortality, by SUI procedure type, following first single SUI procedure in Scotland, 1997-2014.

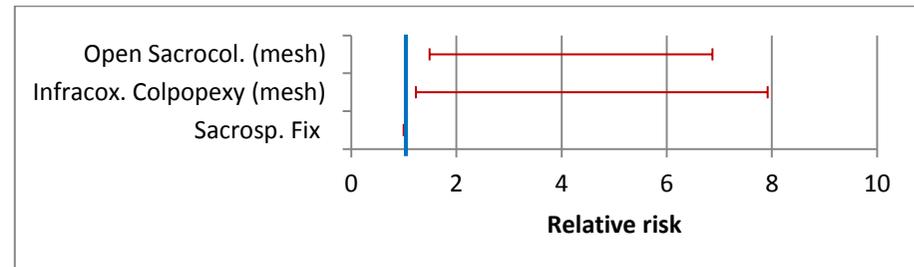
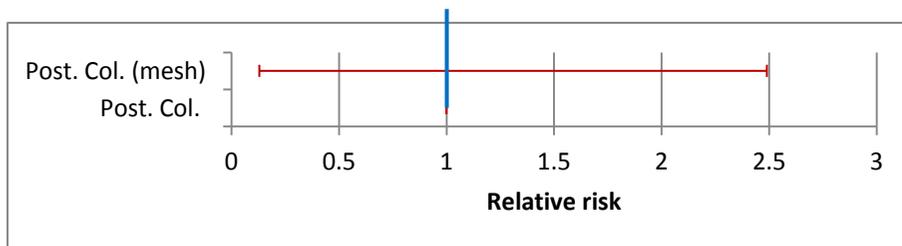
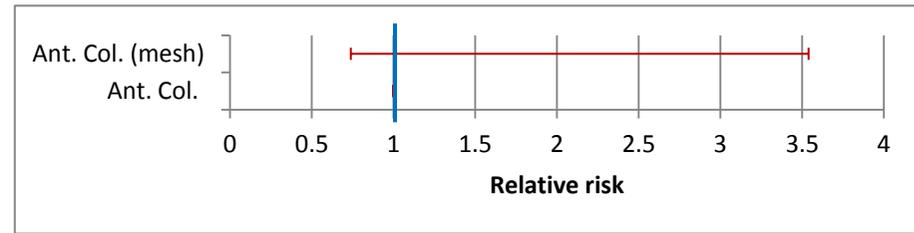
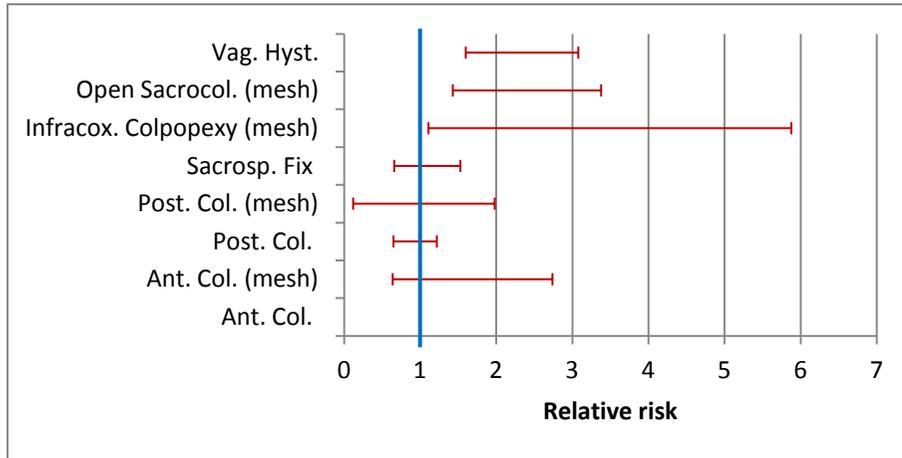
	Colposuspension (open) n=2353	Urethral inj. Therapy n=667	Suprapubic sling n=446	Unspecified tape n=3781	Retropubic tape n=4449	Transobturator tape n=4755
Number of deaths	58	63	12	97	53	71
Person-years of follow-up	11614	2651	2081	18755	15785	17058
% deaths within 1 years	9.7	18.8	14.3	12.1	20.8	15.5
% deaths within 3 years	54.8	56.3	50.0	51.5	64.2	59.2
Unadjusted IRR	1.00 (Ref)	4.75 (3.33,6.79)	1.16 (0.62,2.15)	1.04 (0.75,1.44)	0.67 (0.46,0.98)	0.83 (0.59,1.18)
Adjusted IRR	1.00 (Ref)	1.98 (1.36,2.91)	0.81 (0.43,1.52)	0.91 (0.65,1.28)	0.65 (0.44,0.96)	0.77 (0.53,1.12)
Crude IR /1000 person-years	5.0	23.7	5.8	5.2	3.4	4.2

8.9 Appendix I – POP: primary outcome figures

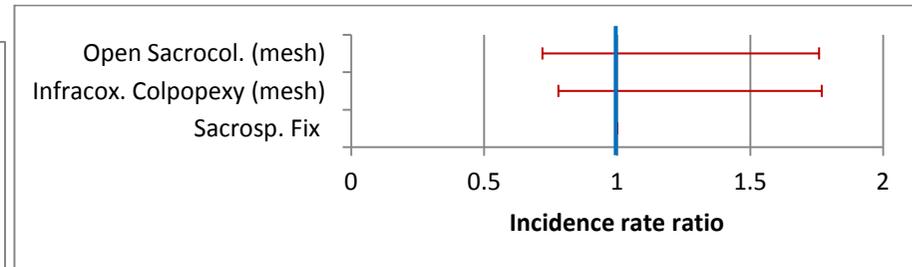
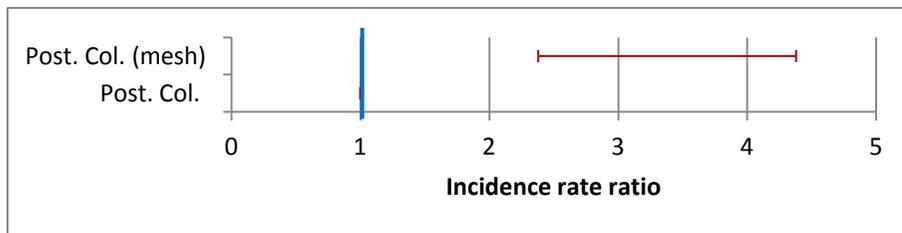
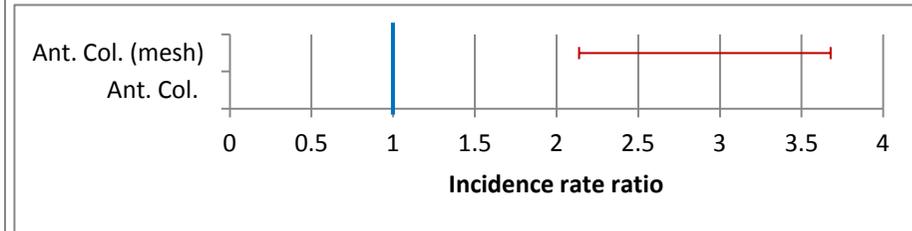
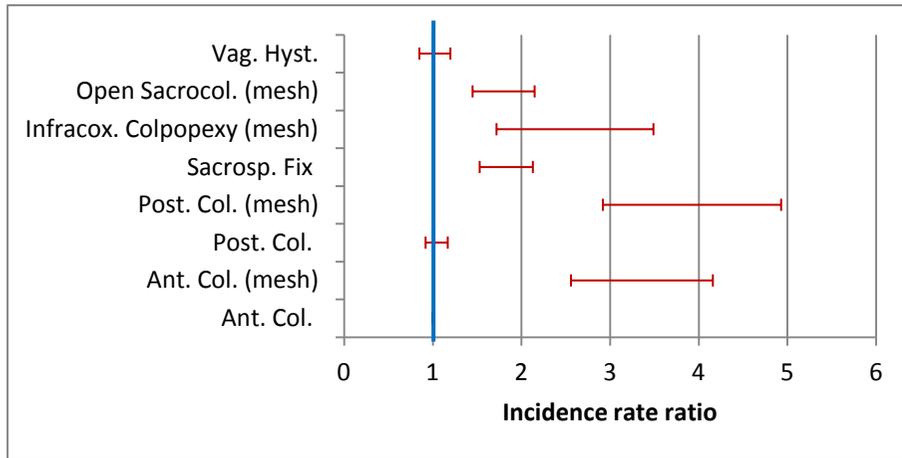
IRR incidence rate ratio; RR rate ratio.

Adjusted for: age, deprivation, co-morbidity, hospital type and consultant volume

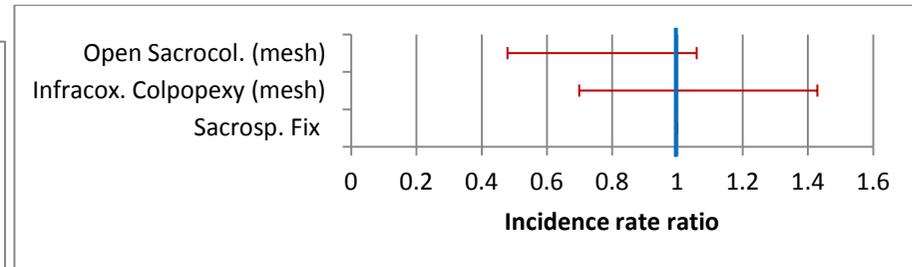
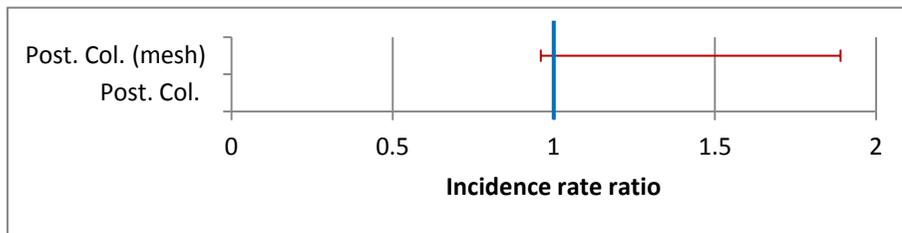
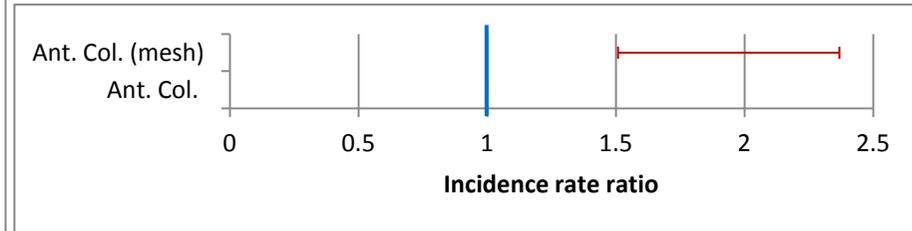
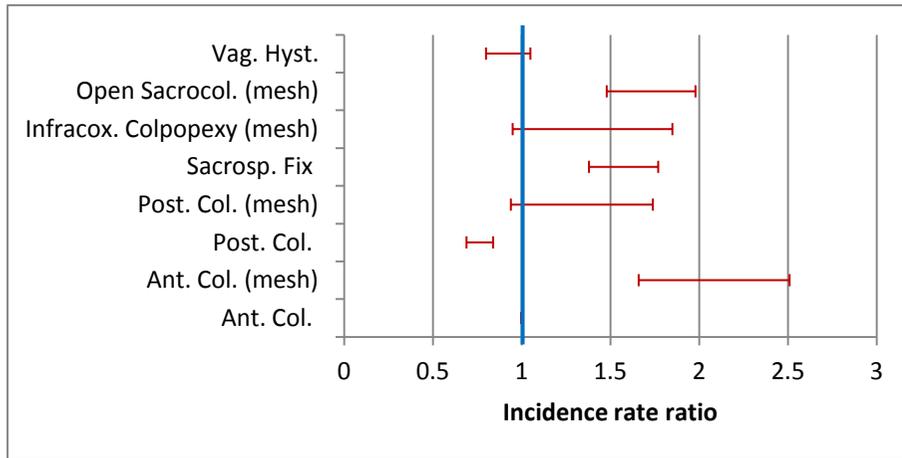
Risk of an immediate complication within 5-years



Risk of admission with a late procedural complication within 5-years



Risk of admission further SUI or POP surgery within 5-years



8.10 Appendix J - POP: Results of mesh vs non-mesh analyses

Analysis for the period 2006/07-2013/14 for suspension procedures and for 2007/08-2013/14 for colporrhaphy procedures.

Ant. Col. anterior colporrhaphy; **IRR** incidence rate ratio; **Post. Col.** posterior colporrhaphy; **RR** rate ratio; **Sacrosp. Fix.** Sacrospinous fixation of the vagina; **Infracoc.** Infracoccygeal; **Sacrocol.** sacrocolpopexy.

Adjusted for: age, deprivation, co-morbidity, hospital type and consultant volume

Risk of an immediate complication within 5-years

	Ant. Col. n=3506	Ant. Col. - mesh n=372	Post. Col. n=2583	Post. Col. - mesh n=247	Sacrosp. Fix. n=1714	Infracoc. Colpopexy – mesh n=159	Open sacrocol. – mesh n=193
Unadjusted RR	1.00 (Ref)	1.81 (0.85,3.86)	1.00 (Ref)	0.69 (0.16,2.87)	1.00 (Ref)	2.71 (1.11,6.64)	3.67 (1.76,7.67)
Adjusted RR	1.00 (Ref)	1.62 (0.74,3.54)	1.00 (Ref)	0.58 (0.13,2.49)	1.00 (Ref)	3.13 (1.23,7.92)	3.20 (1.49,6.87)

Risk of admission with a late procedural complication within 5-years

	Ant. Col. n=3506	Ant. Col. - mesh n=372	Post. Col. n=2583	Post. Col. – mesh n=247	Sacrosp. Fix. n=1714	Infracoc. Colpopexy – mesh n=159	Open sacrocol. – mesh n=193
Unadjusted IRR	1.00 (Ref)	2.80 (2.17,3.62)	1.00 (Ref)	3.49 (2.63,4.61)	1.00 (Ref)	1.49 (1.03,2.16)	1.06 (0.69,1.63)
Adjusted IRR	1.00 (Ref)	2.80 (2.14,3.68)	1.00 (Ref)	3.23 (2.38,4.38)	1.00 (Ref)	1.18 (0.78,1.77)	1.12 (0.72,1.76)

Risk of admission for further SUI or POP surgery within 5-years

	Ant. Col. n=3506	Ant. Col. - mesh n=372	Post. Col. n=2583	Post. Col. - mesh n=247	Sacrosp. Fix. n=1714	Infracoc. Colpopexy – mesh n=159	Open sacrocol. – mesh n=193
Unadjusted IRR	1.00 (Ref)	2.06 (1.66,2.55)	1.00 (Ref)	1.65 (1.20,2.27)	1.00 (Ref)	0.94 (0.67,1.32)	0.72 (0.49,1.05)
Adjusted IRR	1.00 (Ref)	1.89 (1.51,2.37)	1.00 (Ref)	1.35 (0.96,1.89)	1.00 (Ref)	1.00 (0.70,1.43)	0.71 (0.48,1.06)

Risk of admission with a late complication or for further SUI or POP surgery

	Ant. Col. n=3506	Ant. Col. - mesh n=372	Post. Col. n=2583	Post. Col. - mesh n=247	Sacrosp. Fix. n=1714	Infracoc. Colpopexy – mesh n=159	Open sacrocol. – mesh n=193
Unadjusted IRR	1.00 (Ref)	2.08 (1.75,2.47)	1.00 (Ref)	2.38 (1.92,2.94)	1.00 (Ref)	1.07 (0.82,1.38)	0.86 (0.65,1.15)
Adjusted IRR	1.00 (Ref)	1.96 (1.64,2.34)	1.00 (Ref)	2.09 (1.67,2.63)	1.00 (Ref)	1.00 (0.76,1.32)	0.87 (0.66,1.19)

Risk of referral to pain clinic within 5-years

	Ant. Col. n=3506	Ant. Col. - mesh n=372	Post. Col. n=2583	Post. Col. - mesh n=247	Sacrosp. Fix. n=1714	Infracoc. Colpopexy – mesh n=159	Open sacrocol. – mesh n=193
Unadjusted IRR	1.00 (Ref)	1.63 (0.97,2.72)	1.00 (Ref)	1.47 (0.80,2.68)	1.00 (Ref)	0.61 (0.19,1.97)	1.83 (0.88,3.80)
Adjusted IRR	1.00 (Ref)	1.43 (0.84,2.44)	1.00 (Ref)	1.36 (0.73,2.57)	1.00 (Ref)	0.47 (0.14,1.61)	1.88 (0.88,4.03)

Risk of opiate medication prescription within 3-years

	Ant. Col. n=2398	Ant. Col. – mesh n=286	Post. Col. n=1798	Post. Col. – mesh n=195	Sacrosp. Fix. n=1192	Infracoc. colpopexy – mesh n=75	Open sacrocol. – mesh n=110
Unadjusted IRR	1.00 (Ref)	0.96 (0.80,1.15)	1.00 (Ref)	1.35 (1.11,1.64)	1.00 (Ref)	0.84 (0.60,1.17)	0.91 (0.68,1.21)
Adjusted IRR	1.00 (Ref)	0.86 (0.71,1.03)	1.00 (Ref)	1.15 (0.94,1.41)	1.00 (Ref)	0.78 (0.56,1.10)	0.94 (0.69,1.27)

Risk of admission for any reason within 5-years

	Ant. Col. n=3506	Ant. Col. - mesh n=372	Post. Col. n=2583	Post. Col. - mesh n=247	Sacrosp. Fix. n=1714	Infracoc. Colpopexy – mesh n=159	Open sacrocol. – mesh n=193
Unadjusted IRR	1.00 (Ref)	1.28 (1.18,1.38)	1.00 (Ref)	1.45 (1.33,1.59)	1.00 (Ref)	1.08 (0.97,1.20)	0.79 (0.70,0.89)
Adjusted IRR	1.00 (Ref)	1.21 (1.12,1.32)	1.00 (Ref)	1.22 (1.11,1.34)	1.00 (Ref)	1.00 (0.89,1.12)	0.88 (0.78,0.99)

Risk of death within 5-years

	Ant. Col. n=3506	Ant. Col. - mesh n=372	Post. Col. n=2583	Post. Col. - mesh n=247	Sacrosp. Fix. n=1714	Infracoc. Colpopexy – mesh n=159	Open sacrocol. – mesh n=193
Unadjusted IRR	1.00 (Ref)	0.54 (0.22,1.33)	1.00 (Ref)	0.40 (0.10,1.65)	1.00 (Ref)	0.72 (0.31,1.67)	0.96 (0.46,2.02)
Adjusted IRR	1.00 (Ref)	0.56 (0.23,1.04)	1.00 (Ref)	0.29 (0.07,1.22)	1.00 (Ref)	0.77 (0.32,1.84)	1.39 (0.66,2.94)

8.11 Appendix K - POP: Results of secondary adverse event outcomes analyses

Ant. Col. anterior colporrhaphy; **Infracoc.** infracoccygeal; **POP** pelvic organ prolapse; **Post. Col.** posterior colporrhaphy; **Sacrocol.** sacrocolpopexy; **Sacrosp. Fix.** sacrospinous fixation of the vagina; **SUI** stress urinary incontinence; **Vag. Hyst.** vaginal hysterectomy.

Adjusted for: age, deprivation, co-morbidity, hospital type and consultant volume

Relative incidence of admission for late procedural complications or further SUI or POP surgery, by POP procedure type, following first single POP procedure in Scotland, 1997-2014.

	Ant. Col. n=7738	Ant. Col. (mesh) n=372	Post. Col. n=5322	Post. Col. (mesh) n=247	Sacrosp. Fix. n=1880	Infracoc. colpopexy (mesh) n=159	Open Sacrocol. (mesh) n=866	Vag. Hyst. n=1879
Number of patients with ≥1 admission*	1345	107	836	66	405	46	221	332
Total number of admissions	1780	160	1063	104	512	66	322	448
Person-years of follow-up	32268	1200	21807	781	5499	663	3908	8105
% admissions within 1 year	32.9	36.3	35.0	43.3	46.9	36.4	38.4	38.6
% admissions within 3 years	77.2	85.6	75.5	82.7	86.5	78.8	76.9	78.1
Unadjusted IRR	1.00 (Ref)	2.44 (2.08,2.87)	0.89 (0.83,0.96)	2.44 (2.00,2.98)	1.71 (1.55,1.88)	1.82 (1.43,2.33)	1.51 (1.34,1.70)	1.00 (0.91,1.11)
Adjusted IRR	1.00 (Ref)	2.21 (1.87,2.60)	0.86 (0.79,0.93)	2.05 (1.68,2.51)	1.60 (1.45,1.77)	1.57 (1.22,2.02)	1.58 (1.40,1.78)	0.97 (0.87,1.07)
Crude IR, /1000 person-years	55.2	133.3	48.7	134.6	93.1	99.5	82.4	55.2

*Range 1-7 admissions for late procedural complications or further SUI/POP surgery per patient.

Relative incidence of referral to pain clinic, by POP procedure type, following first single POP procedure in Scotland, 1997-2014.

	Ant. Col. n=7738	Ant. Col. (mesh) n=372	Post. Col. n=5322	Post. Col. (mesh) n=247	Sacrosp. Fix. n=1880	Infracoc. colpopexy (mesh) n=159	Open Sacrocol. (mesh) n=866	Vag. Hyst. n=1879
Number of referrals*	182	17	162	12	37	3	27	39
Person-years of follow-up	32268	1200	21807	781	5499	663	3908	8105
% referrals within 1 year	20.7	17.6	25.7	0.0	24.3	66.7	32.3	23.1
% referrals within 3 years	72.3	76.5	66.5	41.7	91.9	66.7	32.3	59.0
Unadjusted IRR	1.00 (Ref)	2.51 (1.53,4.13)	1.32 (1.07,1.63)	2.73 (1.52,4.89)	1.19 (0.84,1.70)	0.80 (0.26,2.51)	1.23 (0.82,1.84)	0.85 (0.60,1.21)
Adjusted IRR	1.00 (Ref)	2.16 (1.30,3.57)	1.21 (0.98,1.50)	2.25 (1.25,4.08)	1.14 (0.79,1.63)	0.76 (0.24,2.39)	1.22 (0.81,1.83)	0.76 (0.53,1.07)
Crude IR, /1000 person-years	5.6	14.1	7.4	15.3	6.7	4.5	6.9	4.8

*no patient had more than 1 referral

Relative incidence of receiving opiate medication prescription, by POP procedure type, following first single POP procedure in Scotland, 2009-2014.

	Ant. Col. n=2398	Ant. Col. (mesh) n=286	Post. Col. n=1798	Post. Col. (mesh) n=195	Sacrosp. Fix. n=1192	Infracoc. Colpopexy (mesh) n=75	Open Sacrocol. (mesh) n=110	Vag. Hyst. n=514
Number of patients prescribed opiate containing medication	1118	133	842	117	515	37	49	209
Person-years of follow-up	3609	448	2695	278	1491	127	157	892
% prescriptions within 1 year	72.0	71.4	70.1	70.1	80.6	70.3	83.1	73.2
Unadjusted IRR	1.00 (Ref)	0.96 (0.80,1.15)	1.01 (0.92,1.10)	1.36 (1.12,1.65)	1.12 (1.01,1.24)	0.94 (0.68,1.30)	1.01 (0.76,1.34)	0.76 (0.65,0.88)
Adjusted IRR	1.00 (Ref)	0.88 (0.73,1.06)	1.07 (0.98,1.17)	1.24 (1.02,1.50)	1.01 (0.91,1.12)	0.77 (0.56,1.08)	0.97 (0.73,1.31)	0.79 (0.68,0.92)
Crude IR, /1000 person-years	309.7	297.3	312.8	421.2	346.9	291.1	312.8	235.4

Relative incidence of hospital readmission for any reason, by POP procedure type, following first single POP procedure in Scotland, 1997-2014.

	Ant. Col. n=7738	Ant. Col. (mesh) n=372	Post. Col. n=5322	Post. Col. (mesh) n=247	Sacrosp. Fix. n=1880	Infracoc. colpopexy (mesh) n=159	Open Sacrocol. (mesh) n=866	Vag. Hyst. n=1879
Number of patients with ≥1 admission*	4705	243	3248	163	1106	105	605	1055
Total number of admissions	13731	702	9711	554	3262	419	1904	2952
Person-years of follow-up	32268	1200	21807	781	5499	663	3908	8105
% admissions within 1 year	22.8	27.2	22.4	30.5	27.5	20.8	25.5	23.5
% admissions within 3 years	64.8	70.5	64.8	79.6	71.4	59.2	67.2	64.6
Unadjusted IRR	1.00 (Ref)	1.38 (1.27,1.48)	1.05 (1.02,1.07)	1.67 (1.53,1.82)	1.39 (1.34,1.45)	1.48 (1.35,1.64)	1.15 (1.09,1.20)	0.86 (0.82,0.89)
Adjusted IRR	1.00 (Ref)	1.32 (1.22,1.42)	1.10 (1.08,1.13)	1.55 (1.42,1.69)	1.27 (1.22,1.32)	1.32 (1.20,1.46)	1.13 (1.08,1.18)	0.92 (0.88,0.96)
Crude IR, /1000 person-years	425.7	587.5	447.0	710.9	591.7	630.0	489.6	366.1

*Range 1-89 admissions for any reason per patient.

Relative five-year mortality, by POP procedure type, following first single POP procedure in Scotland, 1997-2014.

	Ant. Col. n=7738	Ant. Col. (mesh) n=372	Post. Col. n=5322	Post. Col. (mesh) n=247	Sacrosp. Fix. n=1880	Infracoc. colpopexy (mesh) n=159	Open Sacrocol. (mesh) n=866	Vag. Hyst. n=1879
Number of deaths	246	5	170	2	66	6	57	70
Person-years of follow-up	32268	1200	21807	781	5499	663	3908	8105
% deaths within 1 year	13.4	20.0	13.5	0.0	22.7	0.0	10.5	12.9
% deaths within 3 years	52.4	80.0	54.7	0.0	57.6	33.3	61.4	48.6
Unadjusted IRR	1.00 (Ref)	0.55 (0.23,1.33)	1.02 (0.84,1.24)	0.34 (0.08,1.35)	1.57 (1.20,2.06)	1.19 (0.53,2.67)	1.91 (1.44,2.55)	1.13 (0.87,1.48)
Adjusted IRR	1.00 (Ref)	0.57 (0.23,1.37)	1.30 (1.07,1.58)	0.41 (0.10,1.66)	1.15 (0.87,1.53)	0.98 (0.43,2.22)	1.59 (1.19,2.14)	1.43 (1.20,1.89)
Crude IR, /1000 person-years	7.6	4.2	7.8	2.6	12.0	9.0	14.5	8.6