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EPIDEMIOLOGY OF PRIMARY AND REPEAT SURGICAL TREATMENT FOR FEMALE PELVIC ORGAN PROLAPSE AND INCONTINENCE

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Contributorship: MAF conceived the research idea, wrote the first draft of the paper and was responsible for the clinical interpretation of the findings. AF facilitated data linkage, cleaned the linked data and conducted initial analyses. SF conducted and supervised all statistical analyses. JF conducted initial literature searches. SB gave methodological support in the designing of the study and extraction and linkage of data. All authors contributed to the writing of the final draft of the paper. MAF is the guarantor of this paper.

Ethics: This research proposal was approved by the Steering Committee of the Aberdeen Maternity and Neonatal Databank and the Privacy Advisory Committee of the Information and Services Division NHS Scotland. Formal ethical approval was sought from the North of Scotland Research Ethics Service and was not considered necessary as only anonymised data were analysed in this study.

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Abstract

Objectives:

- To determine the lifetime risk of undergoing various types of pelvic floor surgery in a cohort of UK women.
- To determine the re-operation rates for various pelvic floor surgery, time intervals for repeat surgery and the independent risk factors for undergoing primary and repeat pelvic floor surgery.

Study design:
Retrospective register based cohort study.

Main outcome measures:
Primary outcome:

- Lifetime risk of parous women in UK undergoing any form of pelvic floor surgery and various sub groups: pelvic organ prolapse(POP)/ urinary incontinence(UI)/rectal prolapse or faecal incontinence (RP-FI)

Secondary outcomes:

- Re-operation rates and time interval for repeat surgery for POP/UI.
- Independent risk factors for undergoing primary and repeat pelvic floor surgery.

Results
34631 women identified from the AMND were linked with the Scottish Morbidity Records(SMR)databases of NHS Scotland to assess the relevant outcomes.

The lifetime risk for women by age of 80 years for undergoing any form of pelvic floor surgery was 12.2%. 2130(6.2%)women had at least one pelvic floor surgery, of which 407(19 %)had repeat operations. The median time interval between index and repeat UI and POP surgery were 2.80 (0.94 to 8.07)years and 3(1.00 to 8.25) years respectively.

There is a reduced life-time risk of pelvic floor surgery in women who had all deliveries by caesarean section only($p<0.001$) and those aged less than 20 years at first delivery($p=0.021$)while there is an increased risk in women who sustained at least one perineal laceration (in the absence of a classified perineal tear) during delivery($p<0.001$)and in women who had at least one instrumental delivery with the use of forceps ($p=0.015$).

Conclusions:
Our study reveals that more than one in ten parous women in UK, over their lifetime, will require at least one surgical procedure for pelvic floor disoders. The study also identifies independent risk and protective factors for pelvic floor surgery in parous women.

Article focus

- Lifetime risk of pelvic floor surgery in a cohort of UK women
- Re-operation rates,time interval for repeat surgery and risk factors for undergoing primary and repeat pelvic floor surgery.

Key messages:

- More than one in ten parous women in the UK will require at least one surgical procedure for pelvic floor dysfunction
- Re-operation rate for pelvic floor dysfunction is 19%
- Increased BMI and forceps delivery are risk factors for pelvic floor surgery (both of which are avoidable) while exclusive delivery by caesarean section is protective.

Strengths and limitations:
The main strengths include its large cohort size and long duration of follow-up; unless the study cohort is large there would be insufficient numbers of women having repeat surgery to be able to assess re-operation rates with adequate precision. Furthermore our study represents the general population rather than a selected population therefore we are confident that our findings are generalisable to the UK or indeed any European population.

Aberdeen city and district had a relatively stable population over the last century, minimising loss to follow up. Both AMND & SMR databases used in this study are subjected to quality control measures at regular intervals and there are numerous consistency checks in place to ensure validity of data entry. Good quality data relating to both exposure (AMND) and outcomes (SMR) added strength and validity to the findings.

Our study however had a number of limitations: Information was missing on smoking and BMI in a large proportion of women. We were unable to link 27% of women with the SMR databases. There is also a possibility, albeit small, of misclassification bias resulting from wrong linkage due to error in probability matching.

Introduction:

Female pelvic floor disorders such as urinary incontinence (UI) and pelvic organ prolapse (POP) are common and distressing conditions for women particularly over the age of 40 years (1) and are associated with negative impact on a woman's social, physical and psychological wellbeing. The true prevalence of these disorders is difficult to determine; but it is estimated that in this age group, in UK, around 6 million (40%) have clinically significant UI symptoms, of whom 1 million (6.2%) are bothered by these symptoms and 2.2% find them socially disabling (2). UI has significant cost implications to the individual and the health services; in the UK it accounts for 0.3% of the NHS budget (3) in-addition to costs borne by women (4). Similarly, POP is an increasingly prevalent condition as the elderly female population continues to rise (5).

Conservative management is usually the first line of treatment, although surgical treatment for UI/POP is quite common; Aparna et al (6) reported that 18/10,000 women in USA had undergone surgical treatment for POP in 2003 with rates rising with advancing age. In the UK, POP accounts for 20% of women on the waiting list for major gynecological surgery and is the indication for 15% of hysterectomies (7) while 11,000 mid-urethral sling (MUS) procedures were performed for stress UI in England alone in 2009-10 (8). In 1997, Olsen et al (9) in a widely quoted study showed that the lifetime risk for women to undergo a surgical operation for UI/POP by the age of 80 years was 11.1%. However, a recent study in the West of Australia reported a significantly higher risk (19%) for POP surgery by the age of 85 years (10). Re-operation rates for UI/POP widely varied in the literature between 43-56% in tertiary referral centers (11, 12) to 17% in the general population (13).

In the UK, the population is expected to increase from an estimated 61.4 million in 2008 to 71.6 million in 2033; the numbers in the older age groups will increase the fastest with the number of women over 75 years expected to almost double by 2033 (from 4.8 million to 8.7 million or 81%) (14). The life-time risk of surgically managed UI/POP has not been previously studied in a UK population despite its importance in planning medical services and the future allocation of health resources.

Research Questions:

In this study we aimed to determine the lifetime risk of parous women undergoing primary or repeat pelvic floor surgery i.e. surgical treatment for UI, POP and rectal prolapse/ faecal incontinence (RP-FI) in a cohort of women representing the "general population" in UK (primary outcome). We also aimed to determine re-operation rates for UI/POP, time intervals for repeat surgery and to assess independent risk factors for undergoing primary and repeat UI/POP surgery (secondary outcomes).

Methods

- **Identification of the cohort:**

The Aberdeen Maternity and Neonatal Databank (www.abdn.ac.uk/amnd) stores linked information on all obstetric related events occurring in women living in Aberdeen city and district since 1950 and currently contains data for 147,000 women; so it is possible to construct a complete reproductive history for each woman on the database. This database is therefore ideal for raising a cohort of UK parous women, up to the age of 80 years for linking them to the hospital discharge data (SMR01) in Scotland.

The Information and Services Division (ISD) is responsible for collating the morbidity

returns from all NHS hospitals in Scotland. The SMR 01/02 contain information on all outpatient/ in-patient hospital admissions and discharges with around one million new records added each year. A record linkage system is in place in Scotland using probability matching to link together general hospital discharge records, death registrations from the General Register Office for Scotland (GRO-S) and cancer registrations for individual patients. All these health related data sets are contemporaneously added to the system, which establishes a hospital career summary for individual patients in Scotland from 1975 to date. This linkage system therefore offers the ideal opportunity to assess the lifetime risk of POP and UI surgery in the cohort of women raised from the AMND.

Records of parous women who were born before 1st January 1968 identified on the AMND were linked by ISD to the SMR01 and the GRO-S death records using probability matching to generate an anonymised study database of "linked" women followed-up to 31 July 2010. The database contained information on episodes of diagnosis and surgical treatment for pelvic floor disorders and death records of women if available. The reproductive histories as recorded in the AMND database were extracted for these women.

- **Data available**

A number of variables were considered as potential risk factors for undergoing pelvic floor surgery and were grouped as follows: "*age of woman at 1st delivery*": < 20years; 20-29 years; ≥30 years, "*parity*": 1; 2 - 4; > 4, "*twin delivery*" , "*mode of delivery*": all spontaneous vaginal deliveries (SVD) or breech; all caesarean section (CS): instrumental with at least one forceps delivery; instrumental but no forceps; combination of SVD and CS, "*time interval between deliveries*": one delivery only; all intervals <2 years; all intervals ≥ 2years; mixture and "*type of perineal wound sustained at delivery*": intact perineum; all episiotomies; at least

one 3rd degree tear; lacerations but no actual tears. Reference groups were identified according with advice from specialist urogynaecologists. The age of 80 years was chosen based on information from "Office for National Statistics" (2009) showing that life expectancy of women in UK is 82 years and in Scotland is 80 years (14).

- **Statistical Analysis:**

Cox Regression was used to calculate lifetime risk for pelvic floor surgery; time was calculated from birth to date of operation (or censored at date of death/date of data extraction as appropriate). Unadjusted Cox regression models were carried out for various risk factors mentioned above; the adjusted models were then implemented to identify independent risk factors for primary surgery for UI, POP or RP-FI. Sub-group analysis for women who had at least one operation was performed to calculate re-operation rates and logistic regression was used to determine any associations between the risk factors and repeat surgery. The logistic regression for repeat UI included type of primary operation as a potential risk factor.

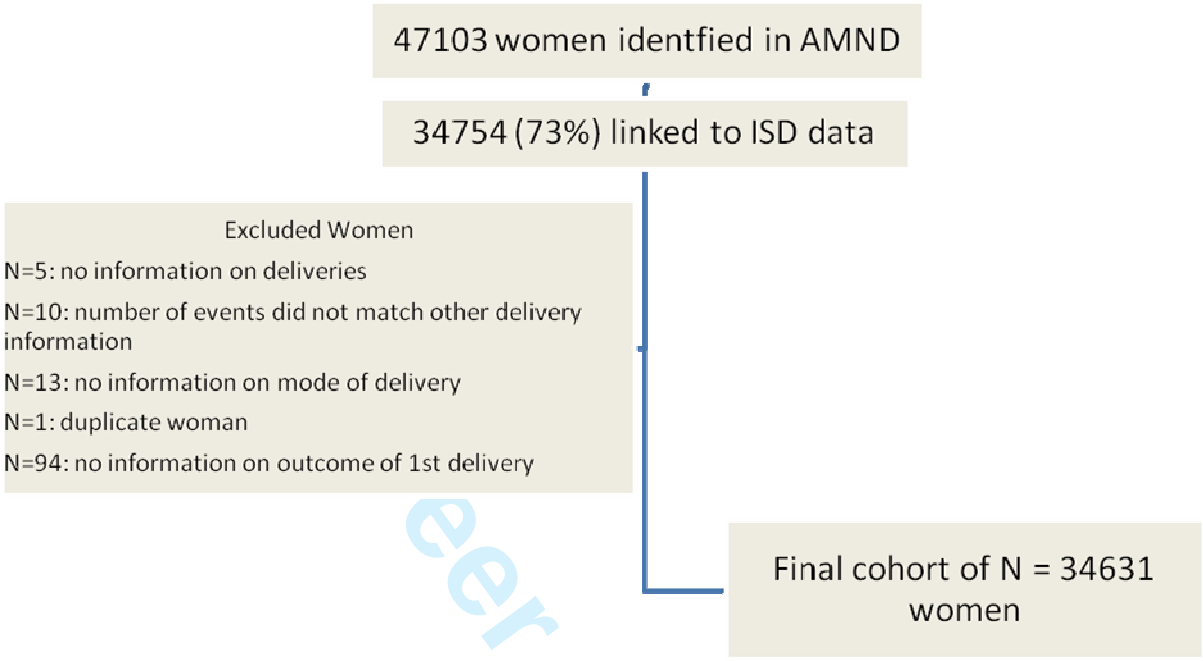
Results:

A total of 47103 women were identified in the AMND for initial linkage to the ISD database and 34754 (73%) of them were linked; 123 women were excluded leaving 34631 women in the cohort for analysis (**Figure 1**).

- **Life time risk for pelvic floor surgery (UI, POP and/or FI/RP):**

Within the cohort of women; 2130/34631 (6.2%) had surgical treatment for UI, POP and/or FI/RP; 762 women (2.2%) had an operation for UI; 1508 women (4.4%) had a POP repair and 98 women (0.3%) underwent an operation for RP-FI. The index surgery was for UI in 609 women (28.6%), POP in 1357 women (63.7%), combined UI and POP in 66 women

Figure 1: Flow diagram of participants in study

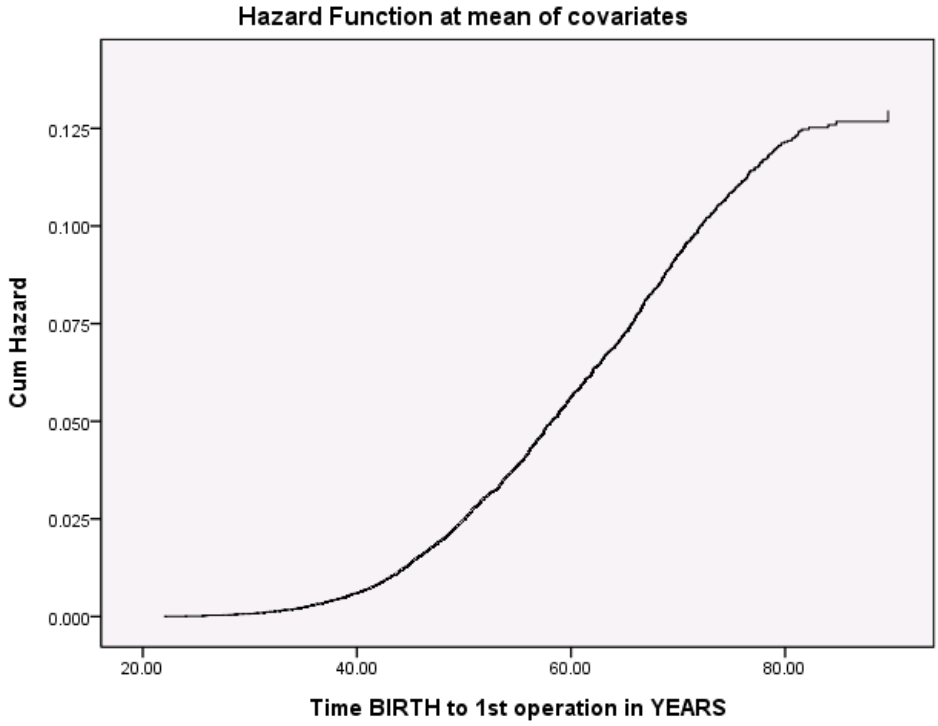


(3.1%) and RP-FI in 78 women (3.7%). **Figure 2** shows the cumulative hazard for women to undergo a pelvic floor surgery with age; the lifetime risk for women to undergo a pelvic floor surgery, by age 80, is **12.2%.** Further analysis showed the lifetime risk of undergoing UI operation is 3.6%, POP repair is 9.5% and RP-FI operation is 0.7%.

- **Risk factors for undergoing single pelvic floor surgery (UI, POP and/or RP-FI):**

Table 1 shows the Cox regression model for each potential risk factor; a reduced risk of pelvic floor surgery was seen if a woman had caesarean deliveries only ($p<0.001$) while the risk increased for women who sustained perineal lacerations in absence of classified perineal tears ($p<0.001$). BMI was considered to be an important risk factor however data on BMI was available for only 20054 (58%) of the women. Undertaking the same analysis in this subgroup, and including BMI showed that women with increased BMI had an increased risk of pelvic floor surgery ($p = 0.007$). With normal BMI as reference group, the adjusted HRs

Figure 2: Plot of cumulative risk of surgery for pelvic floor disorders (POP/ UI/ RP-FI)



(95% CI) for BMI were: underweight (HR = 0.60; 95% CI 0.34, 1.06; p = 0.078), overweight (HR = 1.22; 95% CI 1.06, 1.41; p = 0.007), obese (HR = 0.94; 95% CI 0.72, 1.22; p = 0.63).

Subgroup analyses of independent risk factors for undergoing UI, POP or RP-FI surgery separately are shown in **Table 2, 3 & 4**. Having at least one forceps delivery was an independent risk factor for undergoing POP/ RP-FI but not a UI operation. Similarly sustaining a third degree perineal tear was only a risk factor for a RP-FI operation. Delivering all siblings by CS was significantly protective against surgery for UI/ POP but not FI-RP.

Table 1: Cox Regression Results for Risks of Undergoing Pelvic Floor Surgery (POP, UI and/ or FI/RP)

	All Women (N=34631)	No Operation (N=32501)	Operation (N=2130)	Unadjusted			Adjusted		
Risk Factor	**N (%)**	**N (%)**	**N (%)**	**HR**	**95% CI**	**p-value**	**HR**	**95% CI**	**p-value**
Mode of delivery									
SVD/Breech only	21210 (61.2%)	19776 (60.8%)	1434(67.3%)	1.00					
CS only	2551 (7.4%)	2524 (7.8%)	27 (1.3%)	*0.25*	*(0.16, 0.36)*	*<0.001*	*0.27*	*(0.18, 0.39)*	*<0.001*
Instrumental (at least one forceps)	9022 (26.1%)	8433 (25.9%)	589 (27.7%)	*1.14*	*(1.03, 1.26)*	*0.007*	*1.13*	*(1.02, 1.25)*	*0.015*
Instrumental (at least one, but no forceps)	663 (1.9%)	639 (2.0%)	24 (1.1%)	1.42	(0.95, 2.13)	0.09	1.35	(0.90, 2.02)	0.15
SVD+CS	1185 (3.4%)	1129 (3.5%)	56 (2.6%)	0.92	(0.70, 1.20)	0.53	0.89	(0.68, 1.17)	0.40
Age at 1st delivery									
Under 20 years	5867 (16.9%)	5510 (17.0%)	357 (16.8%)	*0.88*	*(0.78, 0.99)*	*0.035*	*0.87*	*(0.78, 0.98)*	*0.021*
20-29 years	23751 (68.6%)	22221 (68.4%)	1530 (71.8%)	1.00			1.00		
30-49 years	5013 (14.5%)	4770 (14.7%)	243 (11.4%)	1.11	(0.97, 1.28)	0.12	*1.34*	*(1.16, 1.54)*	*<0.001*
Total number of deliveries									
Single	8699 (25.1%)	8306 (25.6%)	393 (18.5%)	1.00			1.00		
2 to 4	24986 (72.1%)	23323 (71.8%)	1663 (78.1%)	*1.41*	*(1.26, 1.58)*	*<0.001*	*1.30*	*(1.16, 1.46)*	*<0.001*
5+	946 (2.7%)	872 (2.7%)	74 (3.5%)	1.15	(0.90, 1.48)	0.27	1.10	(0.85, 1.41)	0.48
Twins at some point									
No	34148 (98.6%)	32044 (98.6%)	2104 (98.8%)	1.00					
Yes	483 (1.4%)	457 (1.4%)	26 (1.2%)	0.80	(0.54, 1.17)	0.25			
Time between deliveries									
One delivery	8699 (25.1%)	8306 (25.6%)	393 (18.5%)	1.00					
All < 2 years	4151 (12.0%)	3883 (11.9%)	268 (12.6%)	*1.40*	*(1.19, 1.63)*	*<0.001*			
All greater than or equal to 2 years	16510 (47.7%)	15463 (47.6%)	1047 (49.2%)	*1.40*	*(1.24, 1.57)*	*<0.001*			
Mixture	5271 (15.2%)	4849 (14.9%)	422 (19.8%)	*1.41*	*(1.23, 1.62)*	*<0.001*			
Type of perineal wound									
No wound	14365 (41.5%)	13601 (41.8%)	764 (35.9%)	1.00			1.00		
All Episiotomy	9457 (27.3%)	8852 (27.2%)	605 (28.4%)	*1.19*	*(1.07, 1.33)*	*0.001*	1.05	(0.94, 1.18)	0.37
At least one 3rd degree tear	162 (0.5%)	150 (0.5%)	12 (0.6%)	*1.99*	*(1.12, 3.53)*	*0.018*	1.68	(0.95, 2.97)	0.076
No Perineal Tears (lacerations only)	10647 (30.7%)	9898 (30.5%)	749 (35.2%)	*1.57*	*(1.41, 1.73)*	*<0.001*	*1.36*	*(1.22, 1.52)*	*<0.001*

Table 2: Cox Regression Results for Risk Factors of Undergoing Surgical Treatment for UI

	No Operation (N=32501)	SUI Operation (N=762)	Unadjusted			Adjusted		
Risk Factor	**N (%)**	**N (%)**	**HR**	**95% CI**	**p-value**	**HR**	**95% CI**	**p-value**
Mode of delivery								
SVD/Breech only	19776 (60.8%)	533 (69.9%)	1.00			1.00		
CS only	2524 (7.8%)	18 (2.4%)	*0.40*	*(0.25, 0.64)*	*<0.001*	*0.51*	*(0.32, 0.83)*	*0.007*
Instrumental (at least one forceps)	8433 (25.9%)	172 (22.6%)	0.86	(0.72, 1.02)	0.08	0.86	(0.72, 1.03)	0.10
Instrumental (at least one, but no forceps)	639 (2.0%)	12 (1.6%)	*1.72*	*(0.97, 3.05)*	*0.06*	1.65	(0.93, 2.94)	0.09
SVD+CS	1129 (3.5%)	27 (3.5%)	1.12	(0.76,1.65)	0.57	1.07	(0.73, 1.58)	0.72
Age at 1st delivery								
Under 20 years	5510 (17.0%)	182 (23.9%)	*1.28*	*(1.08, 1.52)*	*0.004*	*1.25*	*(1.05, 1.48)*	*0.011*
20-29 years	22221 (68.4%)	519 (68.1%)	1.00			1.00		
30-49 years	4770 (14.7%)	61 (8.0%)	0.82	(0.63, 1.07)	0.14	1.00	(0.76, 1.31)	0.98
Total number of deliveries								
Single	8306 (25.6%)	126 (16.5%)	1.00			1.00		
2 to 4	23323 (71.8%)	614 (80.6%)	*1.63*	*(1.35, 1.97)*	*<0.001*	*1.45*	*(1.18, 1.77)*	*<0.001*
5+	872 (2.7%)	22 (2.9%)	1.17	(0.74, 1.84)	0.51	0.98	(0.62, 1.56)	0.93
Twins at some point								
No	32044 (98.6%)	754 (99.0%)	1.00					
Yes	457 (1.4%)	8 (1.0%)	0.70	(0.35, 1.41)	0.32			
Time between deliveries								
One delivery	8306 (25.6%)	126 (16.5%)	1.00					
All < 2 years	3883 (11.9%)	97 (12.7%)	*1.57*	*(1.20, 2.04)*	*0.001*			
All greater than or equal to 2 years	15463 (47.6%)	393 (51.6%)	*1.63*	*(1.33, 1.99)*	*<0.001*			
Mixture	4849 (14.9%)	146 (19.2%)	*1.59*	*(1.25, 2.01)*	*<0.001*			
Type of perineal wound								
No wound	13601 (41.8%)	265 (34.8%)	1.00			1.00		
All Episiotomy	8852 (27.2%)	239 (31.4%)	*1.32*	*(1.11, 1.58)*	*0.002*	*1.22*	*(1.01, 1.46)*	*0.035*
At least one 3rd degree tear	150 (0.5%)	2 (0.3%)	0.90	(0.22, 3.62)	0.88	0.81	(0.20, 3.24)	0.76
No Perineal Tears (lacerations only)	9898 (30.5%)	256 (33.6%)	*1.53*	*(1.29, 1.82)*	*<0.001*	*1.31*	*(1.10, 1.57)*	*0.003*

Table 3: Cox Regression Results for Risk Factors of Undergoing Surgical Treatment for POP

	No Operation (N=32501)	POP Operation (N=1508)	Unadjusted			Adjusted		
Risk Factor	**N (%)**	**N (%)**	**HR**	**95% CI**	**p-value**	**HR**	**95% CI**	**p-value**
Mode of delivery								
SVD/Breech only	19776 (60.8%)	1021 (67.7%)	1.00			1.00		
CS only	2524 (7.8%)	7 (0.5%)	*0.09*	*(0.04, 0.19)*	*<0.001*	*0.10*	*(0.05, 0.21)*	*<0.001*
Instrumental (at least one forceps)	8433 (25.9%)	430 (28.5%)	*1.20*	*(1.07, 1.34)*	*0.002*	*1.19*	*(1.05, 1.33)*	*0.004*
Instrumental (at least one, but no forceps)	639 (2.0%)	16 (1.1%)	1.41	(0.86, 2.32)	0.17	1.34	(0.82, 2.21)	0.25
SVD+CS	1129 (3.5%)	34 (2.3%)	0.80	(0.57, 1.13)	0.20	0.79	(0.56, 1.12)	0.18
Age at 1st delivery								
Under 20 years	5510 (17.0%)	221 (14.7%)	*0.77*	*(0.67, 0.89)*	*<0.001*	*0.76*	*(0.66, 0.89)*	*<0.001*
20-29 years	22221 (68.4%)	1100 (72.9%)	1.00			1.00		
30-49 years	4770 (14.7%)	187 (12.4%)	*1.20*	*(1.02, 1.40)*	*0.023*	*1.48*	*(1.26, 1.73)*	*<0.001*
Total number of deliveries								
Single	8306 (25.6%)	285 (18.9%)	1.00			1.00		
2 to 4	23323 (71.8%)	1171 (77.7%)	*1.38*	*(1.21, 1.57)*	*<0.001*	*1.25*	*(1.09, 1.44)*	*0.001*
5+	872 (2.7%)	52 (3.4%)	1.08	(0.80, 1.45)	0.61	1.04	(0.77, 1.41)	0.81
Twins at some point								
No	32044 (98.6%)	1489 (98.7%)	1.00					
Yes	457 (1.4%)	19 (1.3%)	0.81	(0.52, 1.28)	0.37			
Time between deliveries								
One delivery	8306 (25.6%)	285 (18.9%)	1.00					
All < 2 years	3883 (11.9%)	196 (13.0%)	*1.42*	*(1.18, 1.70)*	*<0.001*			
All greater than or equal to 2 years	15463 (47.6%)	727 (48.2%)	*1.35*	*(1.18, 1.55)*	*<0.001*			
Mixture	4849 (14.9%)	300 (19.9%)	*1.37*	*(1.16, 1.61)*	*<0.001*			
Type of perineal wound								
No wound	13601 (41.8%)	527 (34.9%)	1.00			1.00		
All Episiotomy	8852 (27.2%)	412 (27.3%)	*1.19*	*(1.04, 1.35)*	*0.009*	1.03	(0.90, 1.17)	0.70
At least one 3rd degree tear	150 (0.5%)	6 (0.4%)	1.50	(0.67, 3.34)	0.33	1.23	(0.55, 2.76)	0.61
No Perineal Tears (lacerations only)	9898 (30.5%)	563 (37.3%)	*1.73*	*(1.53, 1.94)*	*<0.001*	*1.50*	*(1.32, 1.70)*	*<0.001*

Table 4: Cox Regression Results for Risk Factors of Undergoing Surgical Treatment for FI/RP

	No Operation (N=32501)	RAP or FI Operation (N=1508)	Unadjusted			Adjusted		
Risk Factor	N (%)	N (%)	HR	95% CI	p-value	HR	95% CI	p-value
Mode of delivery								
SVD/Breech only	19776 (60.8%)	56 (57.1%)	1.00			1.00		
CS only	2524 (7.8%)	2 (2.0%)	0.45	(0.11, 1.84)	0.26	0.41	(0.10, 1.71)	0.22
Instrumental (at least one forceps)	8433 (25.9%)	37 (37.8%)	*1.90*	*(1.25, 2.88)*	*0.003*	*1.81*	*(1.18, 2.77)*	*0.007*
Instrumental (at least one, but no forceps)	639 (2.0%)	1 (1.0%)	1.39	(0.19, 10.1)	0.75	1.35	(0.18, 9.87)	0.77
SVD+CS	1129 (3.5%)	2 (2.0%)	0.83	(0.20, 3.40)	0.79	0.83	(0.20, 3.39)	0.79
Age at 1st delivery								
Under 20 years	5510 (17.0%)	14 (14.3%)	0.77	(0.43, 1.36)	0.36			
20-29 years	22221 (68.4%)	73 (74.5%)	1.00					
30-49 years	4770 (14.7%)	11 (11.2%)	0.97	(0.52, 1.83)	0.93			
Total number of deliveries								
Single	8306 (25.6%)	16 (16.3%)	1.00					
2 to 4	23323 (71.8%)	77 (78.6%)	1.65	(0.96, 2.83)	0.067			
5+	872 (2.7%)	5 (5.1%)	1.86	(0.68, 5.09)	0.23			
Twins at some point								
No	32044 (98.6%)	96 (98.0%)	1.00					
Yes	457 (1.4%)	2 (2.0%)	1.32	(0.33, 5.34)	0.70			
Time between deliveries								
One delivery	8306 (25.6%)	16 (16.3%)	1.00					
All < 2 years	3883 (11.9%)	8 (8.2%)	1.05	(0.45, 2.45)	0.91			
All greater than or equal to 2 years	15463 (47.6%)	54 (55.1%)	1.82	(1.04, 3.19)	0.035			
Mixture	4849 (14.9%)	20 (20.4%)	1.66	(0.86, 3.21)	0.13			
Type of perineal wound								
No wound	13601 (41.8%)	43 (43.9%)	1.00			1.00		
All Episiotomy	8852 (27.2%)	26 (26.5%)	0.98	(0.60, 1.60)	0.94	0.80	(0.48, 1.33)	0.40
At least one 3rd degree tear	150 (0.5%)	7 (7.1%)	*21.8*	*(9.72, 48.7)*	*<0.001*	*16.9*	*(7.44, 38.3)*	*<0.001*
No Perineal Tears (lacerations only)	9898 (30.5%)	22 (22.4%)	0.83	(0.49, 1.38)	0.47	0.76	(0.45, 1.29)	0.31

- **Re-operation rate for UI and/or/POP:**

407 women had more than one operation for UI/POP giving a re-operation rate of 19%. 238 women had at least one repeat POP operation with a re-operation rate of 15.8% and median (IQR) time interval of 3.0 years (1.00, 8.25) between the index and repeat surgery. 67 women had at least one repeat UI surgery giving a re-operation rate of 8.8%. The median (IQR) time between index and repeat UI surgery was 2.80 (0.94, 8.07) years. The median time interval for repeat UI surgery varied according to the type of index operation; 0.93 years (0.27, 2.49) for mid-urethral slings compared to 4.20 years (1.73, 8.38) for retropubic abdominal procedures.

- **Risk factors for re-operation of UI/POP:**

Re-operation rate for UI was 3.2% (11/342) within the MUS group, 10.7% (34/319) within the abdominal retropubic surgery group, 17.5% (14/80) within the anterior colporraphy group and 50% (n=5/10) within the peri-urethral injectables group. **Table 5** shows the independent risk factors of re-operation for UI; using abdominal retropubic group as the reference group, women undergoing MUS had a significantly lower risk of repeat UI surgery.

Table 6 shows the unadjusted ORs for the different risk factors for repeat POP operation; only women with age at first delivery of 30-39 years were less likely to have a re-operation for POP. 72/814 women underwent repeat anterior repair at some point with a re-operation rate for the anterior compartment of 8.8%. Similarly, 57/775 women underwent a repeat posterior repair with a re-operation rate of 7.4% for the posterior compartment. The median (IQR) time interval for repeat surgery was 3 years (1, 9.25) and 4 years (1, 9) for those women whose initial POP operation was in the anterior and posterior compartments respectively.

Table 5: Results of Logistic Regression for Risk of Re-Operation for UI

	UI operation		Unadjusted Analysis			Adjusted Analysis		
Risk Factor	**One (N=695)**	**> 1 (N=67)**	**OR**	**95% CI**	**p-value**	**OR**	**95% CI**	**p-value**
Type of first SUI surgery								
Abdominal retropubic procedures	285 (41.0%)	34 (50.7%)	1.00			1.00		
Mid-urethral slings	331 (47.6%)	11 (16.4%)	*0.28*	*(0.14, 0.56)*	*<0.001*	*0.30*	*(0.15, 0.60)*	*0.001*
Anterior Colporrhapy	66 99.5%)	14 (20.9%)	1.78	(0.90, 3.50)	0.096	1.92	(0.97, 3.82)	0.063
Peri-urethral Injectables	5 (0.7%)	5 (7.5%)	*8.38*	*(2.31, 30.4)*	*0.001*	*9.05*	*(2.42, 33.8)*	*0.001*
Repair of Uro-genital Fistulae	8 (1.2%)	3 (4.5%)	3.14	(0.80, 12.4)	0.102	2.50	(0.58, 10.8)	0.22
Mode of delivery								
SVD only	488 (700.2%)	45 (67.2%)	1.00					
CS only	16 (2.3%)	2 (3.0%)	1.36	(0.30, 6.08)	0.69			
At least one forceps	158 (22.7%)	14 (20.9%)	0.96	(0.51, 1.80)	0.90			
At least one instrumental: no forceps	9 (1.3%)	3 (4.5%)	3.62	(0.95, 13.8)	0.06			
SVD+CS	24 (3.5%)	3 (4.5%)	1.36	(0.39 ,4.68)	0.63			
Age at 1st delivery								
Under 20 years	166 (23.9%)	16 (23.9%)	0.93	(0.51, 1.67)	0.80			
20-29 years	470 (67.6%)	49 (73.1%)	1.00					
30-49 years	59 (8.5%)	2 (3.0%)	0.33	(0.08, 1.37)	0.13			
Total number of deliveries								
One	116 (16.7%)	10 (14.9%)	1.00					
2 to 4	558 (80.3%)	56 (83.6%)	1.16	(0.58, 2.35)	0.67			
5+	21 (3.0%)	1 (1.5%)	0.55	(0.07, 4.55)	0.58			
Occurrence of twins								
No	687 (98.8%)	67 (100%)						
yes	8 (1.2%)	0 (0%)						
Time between deliveries								
One delivery	116 (16.7%0	10 (14.9%)	1.00					
All < 2 years	89 (12.8%)	8 (11.9%)	1.04	(0.40, 2.75)	0.93			
All greater than 2 years	354 (19.6%)	10 (14.9%)	1.28	(0.62, 2.64)	0.51			
Mixture	136 (19.6%)	10 (14.9%)	0.85	(0.34, 2.12)	0.73			
Type of perineal wound								
No Wound	239 (34.4%)	26 (38.8%)	1.00			1.00		
All Episiotomy	211 (30.4%)	28 (41.8%)	1.22	(0.69, 2.15)	0.49	1.22	(0.68, 2.19)	0.51
At least one 3rd degree tear	1 (0.1%)	1 (1.5%)	9.19	(0.56, 151)	0.12	4.83	(0.25, 92.8)	0.30
No Perineal tears (lacerations only)	244 (35.1%)	12 (17.9%)	*0.45*	*(0.22, 0.92)*	*0.028*	*0.46*	*(0.22, 0.95)*	*0.037*

Table 6: Results of Logistic Regression for Risk of Re-Operation for POP Repair.

	POP operation		Unadjusted		
Risk Factor	**One (N=1270)**	**> 1 (N=238)**	**OR**	**95% CI**	**p-value**
Mode of delivery					
SVD only	857 (67.5%)	164 (68.9%)	1.00		
CS only	7 (0.6%)	0 (0%)			
At least one forceps	365 (28.7%)	65 (27.3%)	0.93	(0.68, 1.27)	0.65
At least one instrumental: no forceps	15 (1.2%)	1 (0.4%)	0.35	(0.05, 2.66)	0.31
SVD+CS	26 (2.0%)	8 (3.4%)	1.61	(0.72, 3.61)	0.25
Age at 1st delivery					
Under 20 years	174 (13.7%)	47 (19.7%)	*1.44*	*(1.00, 2.06)*	*0.049*
20-29 years	926 (72.9%)	174 (73.1%)	1.00		
30-49 years	170 (13.4%)	17 (7.1%)	*0.53*	*(0.31, 0.90)*	*0.018*
Total number of deliveries					
One	246 (19.4%)	39 (16.4%)	1.00		
2 to 4	978 (77.0%)	193 (81.1%)	1.25	(0.86, 1.81)	0.25
5+	46 (3.6%)	6 (2.5%)	0.82	(0.33, 2.06)	0.68
Occurrence of twins					
No	1254 (98.7%)	235 (98.7%)	1.00		
yes	16 (1.3%)	3 (1.3%)	1.00	(0.29, 3.46)	0.99
Time between deliveries					
One delivery	246 (19.4%)	39 (16.4%0	1.00		
All < 2 years	167 (13.1%)	29 (12.2%)	1.10	(0.65, 1.84)	0.73
All greater than 2 years	608 (47.9%)	119 (50.0%)	1.24	(0.84, 1.83)	0.29
Mixture	249 (19.6%)	51 (21.4%)	1.29	(0.82, 2.03)	0.27
Type of perineal wound					
No Wound	442 (34.8%)	85 (35.7%)	1.00		
All Episiotomy	361 (28.4%)	51 (21.4%)	0.74	(0.51, 1.07)	0.11
At least one 3rd degree tear	5 (0.4%)	1 (0.4%)	1.04	(0.12, 9.01)	0.97
No perineal tears (lacerations only)	462 (36.4%)	101 (42.4%)	1.14	(0.83, 1.56)	0.43

Discussion:

Summary of findings: In this large longitudinal epidemiological study we have established the lifetime risk for women, in a UK parous population, to undergo a single pelvic floor surgery (UI/POP/RP-FI) as 12.2% by age of 80 years. Olsen et al (9) reported an 11.1% lifetime risk for women to undergo a single operation for UI/POP by age of 80 years. Their results were echoed by Fialkow et al (15) in 2008; they showed a similar 11.8% life-time risk for UI/POP surgery in a similar cohort of American women. The latter two studies were limited by the fact that they involved special poulation of health maintenance organisations which would generally exclude the elderly, socially disabled, lower social class and sick members of the public limiting the application of their results to the female general poulation both in the USA and European countries. Furthermore, they were cross-sectional studies and therefore suffered from a limited follow-up period. Our study is a longitudinal retrospective study spanning the life-time of a group of women representing the "general-population" in UK. We chose 80-years as our age limit as it represents the average life-span of women in UK (14). The poulation in Aberdeen city and district is predominetly caucasian however with a number of ethnic minority communities including Asian and Esatern Europe and therefore is deemed to be quite representative for the general UK poulation.

Unlike previous studies, we calculated the lifetime risk for surgical treatment of various pelvic floor disorders separately; the life-time risk of women to undergo a single UI operation in our study was 3.6%. The MRC Leicestershire study (2) showed that 33.6% of the population in the UK above age of 40 years describe UI symptoms however only 6.2% reported these symptoms to be bothersome. A recent French study showed similar findings with 29% prevalence of female UI although only 9% sought some form of medical help (16). Conservative measures such as pelvic floor muscle training (PFMT) can be quite successful

in management of 50-60% of women with UI (17) while surgical treatment is usually a second line management. The above facts would suggest that the life-time risk reported in our study is likely to be a true reflection of the current clinical practice.

Our study showed that the lifetime risk of women to undergo a single POP surgery was 9.5%; this was almost 50% lower than the risk of women in Western Australia! In 2010, Smith et al (10) conducted a cross-sectional study on female "general population" in Western Australia between 2001 and 2005 and they calculated a higher life-time risk for POP surgery of 19% by age of 85 years. It is difficult to explain the huge difference in the results between both population-based studies; the difference in design i.e. longitudinal vs. cross-sectional is unlikely to be of such a major influence. In a European study, Hove et al (18) assessed the whole population of a small town in Netherlands and reported that 40% of women aged 45-85 years, have POP ≥ stage II on examination however only 12% of women were symptomatic. We therefore believe that, with the current concept of only treating symptomatic and/or severe prolapse and knowing that a percentage of women will opt for conservative measures such as vaginal pessaries, the life-time surgical risk reported in our study is likely to be more representative for the clinical practice in UK and Europe.

The re-operation rate for UI/POP in our study was 19% and was comparable with 17% reported by Denman et al (13) in a 10 year follow-up prospective study. The re-operation rate in the latter study increased to 21% after adjustment for missing women in the follow-up. Olsen et al (9) reported 29% of cases to be re-operations for UI/ POP in their cross-sectional study; it is important to note that 50% of their population were smokers (current/former) with over 20% suffering of chronic lung disease which may have contributed to their relatively higher re-operation rates. The re-operation rates, in our study, for UI and POP separately

were 8.8% and 15.8% respectively; these were comparable to 8% and 13% re-operation rates for UI and POP respectively reported by Clarke et al (19) in their 5-year prospective study. Similarly, Fialkow et al (20) showed an 8.6% re-operation rate for UI over 8 years in a retrospective cohort study. The POP re-operation rates in the same compartment were not hugely different between the anterior and posterior compartments; similar results were reported by Clarke et al (19) who showed 8 and 11% re-operation rates for anterior and posterior compartments respectively within 5 years with higher re-operation rates (15% vs. 12% respectively) if associated with apical prolapse.

In our study, compared to women who had only SVDs, exclusive delivery by caesarean sections was found to be protective against pelvic floor surgery for each of UI, POP, and RP-FI (≈ 60%). This protective effect was not seen if a woman had a mixture of caesarian and vaginal deliveries. A single forceps delivery significantly increased the risk of surgery for POP and/or RP-FI but not for UI. Similar results were reported by MacArthur et al (21) in their 12 years prospective study and Larson et al (22) in their nested case-control study. In our study, the increased parity of 2-4 deliveries was an independent risk factor for POP/UI surgery compared to a single delivery. A Dutch group previously showed increased parity of 2-3 to be a risk factor for the development of POP; interestingly the risk was not further increased if parity was > 3 (5). Conversely, MacArthur et al (21) found parity ≥ 4 to be a risk factor for UI. The latter two studies assessed risk factors for development of symptomatic UI/POP rather than risk factors for undergoing surgical treatment. It is evident from our data that increased parity and vaginal forceps deliveries are risk factors for the development of UI/POP that warrant surgical management. As expected, sustaining a third degree perineal tear was a risk factor for undergoing RP-FI surgery and episiotomy was not found to be protective.

Analysis of potential risk factors for re-operation for UI/POP did not reveal specific independent risk factors apart from delayed age at first delivery (30-39 years) which seems to be of little clinical significance if any. These results were in agreement with other studies in the literature (9, 13); all of which failed to detect independent risk factors for repeat UI/POP surgery. However it was evident that women undergoing MUS had significantly reduced risk of re-operation for UI when compared to abdominal retropubic surgery. Conversely, peri-urethral injections were associated with significantly higher risk of repeat UI surgery. Fialkow et al (20) have previously reported a reduced risk of repeat UI surgery following Burch colposuspension compared to traditional slings.

Strengths and limitations:

To our knowledge, this is the first study to report the lifetime risk for women in UK to undergo surgical treatment for UI/ POP/ RP-FI. The main strengths include its large cohort size and long duration of follow-up; unless the study cohort is large there would be insufficient numbers of women having repeat surgery to be able to assess re-operation rates with adequate precision. Furthermore our study represents the general population rather than a selected population therefore we are confident that our findings are generalisable to the UK or indeed any European population. Aberdeen city and district had a relatively stable population over the last century, minimising loss to follow up. Both AMND & SMR databases used in this study are subjected to quality control measures at regular intervals and there are numerous consistency checks in place to ensure validity of data entry. Good quality data relating to both exposure (AMND) and outcomes (SMR) added strength and validity to the findings.

Our study however had a number of limitations: information was missing on smoking and BMI in a large proportion of women. We were unable to link 27% of women with the SMR

databases; there are a number of possible reasons for this: (a) failure to match the health records for these women with the data available on the AMND (b) these women are alive and have moved away from Scotland (c) they may have undergone further treatment on private basis. In the latter two situations their hospital admissions would not be recorded by the ISD in Scotland. As migration is highly correlated with socio-economic status, we cannot rule out any selection bias resulting from this. There is also a possibility, albeit small, of misclassification bias resulting from wrong linkage due to error in probability matching.

Clinical and research Implications:

We believe our results are essential to inform policy makers in the UK and Europe with regards healthcare planning for women and allocation of health resources and relevant staff training. Increased BMI and forceps deliveries were independent risk factors for undergoing surgery for pelvic floor disorders; both of which are potentially avoidable. Exclusive delivery by Caesarean sections was found to be protective against pelvic floor surgery although not 100% protective; and other risks associated with delivery by caesarean sections should be taken into consideration when making decisions regarding the mode of delivery.

Conclusion

Our study reveals that more than one in ten parous women in UK, over their lifetime, will require at least one surgical procedure for pelvic floor dysfunction with 19% requiring more than one procedure. Independent risk factors for pelvic floor surgery were forceps delivery and delayed initial child bearing. Protective factors included early initial delivery and delivery exclusively by caesarean section. This information is essential for clinicians, patients and policy makers with regards to counselling, decision making and allocation of health care resources.

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STROBE 2007 (v4) Statement—Checklist of items that should be included in reports of *cohort studies*

Section/Topic	Item #	Recommendation	Reported on page #
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	2
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	**2**
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	3 and 4
Objectives	3	State specific objectives, including any prespecified hypotheses	4
Methods			
Study design	4	Present key elements of study design early in the paper	2
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	4 and 5
Participants	6	(*a*) Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up	5
		(*b*) For matched studies, give matching criteria and number of exposed and unexposed	
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	4
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	*5 and 6*
Bias	9	Describe any efforts to address potential sources of bias	20
Study size	10	Explain how the study size was arrived at	5
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	5 and 6
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	6
		(*b*) Describe any methods used to examine subgroups and interactions	6
		(*c*) Explain how missing data were addressed	19 and 20
		(*d*) If applicable, explain how loss to follow-up was addressed	20
		(*e*) Describe any sensitivity analyses	
Results			

Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	6
		(b) Give reasons for non-participation at each stage	
		(c) Consider use of a flow diagram	7
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	
		(b) Indicate number of participants with missing data for each variable of interest	7
		(c) Summarise follow-up time (eg, average and total amount)	5
Outcome data	15*	Report numbers of outcome events or summary measures over time	
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	7-12
		(*b*) Report category boundaries when continuous variables were categorized	5,7-12
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	7-12
Discussion			
Key results	18	Summarise key results with reference to study objectives	16-19
Limitations			
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	19 and 20
Generalisability	21	Discuss the generalisability (external validity) of the study results	19
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	1

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

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PRIMARY AND REPEAT SURGICAL TREATMENT FOR FEMALE PELVIC ORGAN PROLAPSE AND INCONTINENCE IN PAROUS WOMEN IN UK: A REGISTER LINKAGE STUDY.

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PRIMARY AND REPEAT SURGICAL TREATMENT FOR FEMALE PELVIC ORGAN PROLAPSE AND INCONTINENCE IN PAROUS WOMEN IN UK: A REGISTER LINKAGE STUDY.

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Running Title: Surgery for pelvic organ prolapse and incontinence

Competing Interest: The authors declare that they have no conflict of interest.

Contributorship: MAF conceived the research idea, wrote the first draft of the paper and was responsible for the clinical interpretation of the findings. AF facilitated data linkage, cleaned the linked data and conducted initial analyses. SF conducted and supervised all statistical analyses. JF conducted initial literature searches. SB gave methodological support in the designing of the study and extraction and linkage of data. All authors contributed to the writing of the final draft of the paper. MAF is the guarantor of this paper.

Ethics: This research proposal was approved by the Steering Committee of the Aberdeen Maternity and Neonatal Databank and the Privacy Advisory Committee of the Information and Services Division NHS Scotland. Formal ethical approval was thought from the North of Scotland Research Ethics Service and was not considered necessary as only anonymised data were analysed in this study.

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Data Sharing: Data tables and summaries are available from corresponding author at m.abdelfattah@abdn.ac.uk.

Abstract

Objectives:

- To determine the lifetime risk of undergoing various types of pelvic floor surgery in a cohort of UK women.
- To determine the re-operation rates for various pelvic floor surgery, time intervals for repeat surgery and the independent risk factors for undergoing primary and repeat pelvic floor surgery.

Study design:
A register linkage study

Main outcome measures:
Primary outcome:

- Lifetime risk of parous women in UK undergoing any form of pelvic floor surgery: pelvic organ prolapse (POP)/ urinary incontinence (UI) / rectal prolapse or faecal incontinence (RP-FI)

Secondary outcomes:

- Re-operation rates and time interval of repeat surgery for POP/UI.
- Independent risk factors for undergoing primary and repeat pelvic floor surgery.

Results
34631 women identified from the AMND were linked with the Scottish Morbidity Records (SMR) databases of NHS Scotland to assess relevant outcomes.

The lifetime risk for women by age of 80 years, undergoing any form of pelvic floor surgery was 12.2%. 2130 (6.2%) women had at least one pelvic floor surgery, of which 407 (19 %) had repeat operations. The median time interval between index and repeat UI and POP surgery was 2.80 (0.94 to 8.07) years and 3 (1.00 to 8.25) years respectively.

There is a reduced life-time risk of pelvic floor surgery in women who had all deliveries by caesarean section only ($p<0.001$) and those aged less than 20 years at first delivery ($p=0.021$). Women who sustained at least one perineal laceration (in the absence of a classified perineal tear) during delivery or who had at least one instrumental delivery with the use of forceps were at increased risk ($p<0.001$ and $p=0.015$ respectively).

Conclusions:
Our study shows that in the UK more than one in ten parous women will require at least one surgical procedure for pelvic floor disorders over their lifetime. The study also identifies independent risk and protective factors for pelvic floor surgery in parous women.

Introduction:

Female pelvic floor disorders, such as urinary incontinence (UI) and pelvic organ prolapse (POP), are common and distressing conditions, particularly over the age of 40 years (1) and are associated with negative impact on a woman's social, physical and psychological wellbeing. The true prevalence of these disorders is difficult to determine.In this age group, in UK, approximately 6 million (40%) have clinically significant UI symptoms, of whom 1 million (6.2%) are bothered by these symptoms and 2.2% find them socially disabling (2). UI has significant cost implications to the individual and the health services; in the UK it accounts for 0.3% of the NHS budget (3) in-addition to costs borne by women (4). Similarly, POP is an increasingly prevalent condition especially as the elderly population continues to rise in UK (5).

Conservative management is usually the first line of treatment. However surgical treatment for UI/POP is common. Aparna et al (6) reported that 18/10,000 women in USA had undergone surgical treatment for POP in 2003, with rates rising with advancing age. In the UK, POP accounts for 20% of women on the waiting list for major gynecological surgery and is the indication for 15% of hysterectomies (7). In England alone, 11,000 mid-urethral sling (MUS) procedures were performed for stress UI in 2009-10 (8). Olsen et al (9) in a widely quoted study, in 1997, showed that the lifetime risk for American women to undergo a surgical operation for UI/POP by the age of 80 years was 11.1%. However, a recent study in the West of Australia reported a significantly higher risk (19%) of POP surgery by the age of 85 years (10). Re-operation rates for UI/POP vary widely in the literature from 43-56% in tertiary referral centers (11, 12) to 17% in the general population (13).

In the UK, the population is expected to increase from an estimated 61.4 million in 2008 to 71.6 million in 2033.Older age groups will increase fastest, with the number of women over 75 years expected to almost double by 2033 (from 4.8 million to 8.7 million or 81%) (14).The lifetime risk of surgically managed UI/POP has not been previously studied in a UK population despite its importance in medical services planning and health resources allocation.

Research Questions:

In this study we aimed to determine the lifetime risk of parous women undergoing primary or repeat pelvic floor surgery, i.e. surgical treatment for UI, POP and rectal prolapse/ faecal incontinence (RP-FI) in a cohort of women representing the "general population" in UK (primary outcome). We also aimed to determine re-operation rates for UI/POP, time intervals for repeat surgery and independent risk factors for undergoing primary and repeat UI/POP surgery (secondary outcomes).

Methods

- **Identification of the cohort:**

The Aberdeen Maternity and Neonatal Databank (www.abdn.ac.uk/amnd) stores linked information on all obstetric related events occurring in women living in Aberdeen city and district since 1950 and currently contains data for 147,000 women. Therefore it is possible to construct a complete reproductive history for each woman on the database. This database is therefore ideal for identifying a cohort of UK parous women, up to the age of 80 years, to link to hospital discharge data (SMR01) in Scotland.

The Information and Services Division (ISD) is responsible for collating the morbidity returns from all NHS hospitals in Scotland. The SMR 01/02 contain information on all outpatient/ in-patient hospital admissions and discharges with around one million new records added each year. A record linkage system is in place in Scotland using probability matching to link together general hospital discharge records, death registrations from the General Register Office for Scotland (GRO-S) and cancer registrations for individual patients. All these health related data sets are contemporaneously added to the system, which establishes a hospital career summary for individual patients in Scotland from 1975 to date. This linkage system therefore offers an ideal opportunity to assess the lifetime risk of POP and UI surgery in the cohort of women raised from the AMND.

To generate an anonymised study database of "linked" women up to 31 July 2010, records of parous women who were born before 1st January 1968 identified on the AMND were linked by ISD to the SMR01 and the GRO-S death records using probability matching. The database contained information on episodes of diagnosis and surgical treatment for pelvic floor disorders and death records of women if available. The reproductive histories as recorded in the AMND database were extracted for these women.

- **Data available**

A number of variables were considered as potential risk factors for undergoing pelvic floor surgery and were grouped as follows: "*age of woman at 1st delivery":* < 20years, 20-29 years or ≥30 years*, "parity"*: 1, 2 – 4, or > 4, *"twin delivery"*, "*mode of delivery"*: all spontaneous vaginal deliveries (SVD) or breech, all caesarean section (CS), instrumental with at least one forceps, instrumental but no forceps or combination of SVD and CS, "*time interval between deliveries*": one delivery only, all intervals <2 years, all intervals ≥ 2years or mixture, and

"*type of perineal wound sustained at delivery*": intact perineum, all episiotomies, at least one 3rd degree tear or lacerations but no actual tears. Reference groups were identified according to advice from specialist urogynaecologist. The age of 80 years was chosen based on information from "Office for National Statistics" (2009) showing that life expectancy of women in UK is 82 years and in Scotland is 80 years (14).

- **Statistical Analysis:**

Cox Regression was used to calculate lifetime risk for pelvic floor surgery. Time was calculated from birth to date of operation (or censored at date of death/date of data extraction as appropriate). The proportional hazards assumption for each covariate in each model was assessed using the log survival time versus the negative log of the survivor distribution function. Each covariate showed parallel curves indicating the proportional hazards assumption was met. Unadjusted Cox regression models were carried out for various risk factors mentioned above. The adjusted models were then implemented to identify independent risk factors for primary surgery for UI, POP or RP-FI. Time for these models was calculated from date of first delivery to date of operation (or censored appropriately). Sub-group analysis for women who had at least one operation was performed to calculate re-operation rates and logistic regression was used to determine any associations between the risk factors and repeat surgery. Logistic regression for repeat UI included type of primary operation as a potential risk factor.

Results:

A total of 47103 women were identified in the AMND for initial linkage to the ISD database and 34754 (73%) of them were linked; 123 women were excluded leaving 34631 women in the cohort for analysis (**Figure 1**).

- **Lifetime risk for pelvic floor surgery (UI, POP and/or FI/RP):**

Within the cohort of women; 2130/34631 (6.2%) had surgical treatment for UI, POP and/or FI/RP, 762 women (2.2%) had an operation for UI, 1508 women (4.4%) had a POP repair and 98 women (0.3%) underwent an operation for RP-FI. The index surgery was for UI in 609 women (28.6%), POP in 1357 women (63.7%), combined UI and POP in 66 women (3.1%) and RP-FI in 78 women (3.7%). **Figure 2** shows the cumulative hazard function for women to undergo a pelvic floor surgery with age. Using this model the lifetime distribution function can be calculated. The probability of a woman undergoing pelvic floor surgery by age 80 was 0.115. Further analysis showed that the probability of undergoing UI surgery was 0.036, POP repair was 0.091 and RP-FI operation was 0.007.

In other words, the lifetime risk for women to undergo a pelvic floor surgery, by age 80, is **12.2%**, while the lifetime risk of undergoing UI operation is 3.6%, POP repair is 9.5% and RP-FI operation is 0.7%.

- **Risk factors for undergoing single pelvic floor surgery (UI, POP and/or RP-FI):**

Table 1 shows the Cox regression model for each potential risk factor. There was a reduced risk of pelvic floor surgery if a woman had caesarean deliveries only ($p<0.001$), while the risk increased for women who sustained perineal lacerations in absence of classified perineal tears ($p<0.001$). BMI was considered to be an important risk factor, however was only available for 20054 (58%) of the women. Undertaking the same analysis in this subgroup, and including BMI showed that women with increased BMI had an increased risk of pelvic floor surgery ($p = 0.007$). With normal BMI as reference group, the adjusted HRs (95% CI) for BMI were: underweight (HR = 0.60; 95% CI 0.34, 1.06; $p = 0.078$), overweight (HR = 1.22; 95% CI 1.06, 1.41; $p = 0.007$) and obese (HR = 0.94; 95% CI 0.72, 1.22; $p = 0.63$).

Table 1: Cox Regression Results for Risks of Undergoing Pelvic Floor Surgery (POP, UI and/ or FI/RP)

	All Women (N=34631)	No Operation (N=32501)	Operation (N=2130)	Unadjusted			Adjusted		
Risk Factor	**N (%)**	**N (%)**	**N (%)**	**HR**	**95% CI**	**p-value**	**HR**	**95% CI**	**p-value**
Mode of delivery									
SVD/Breech only	21210 (61.2%)	19776 (60.8%)	1434(67.3%)	1.00					
CS only	2551 (7.4%)	2524 (7.8%)	27 (1.3%)	*0.25*	*(0.16, 0.36)*	*<0.001*	*0.27*	*(0.18, 0.39)*	*<0.001*
Instrumental (at least one forceps)	9022 (26.1%)	8433 (25.9%)	589 (27.7%)	*1.14*	*(1.03, 1.26)*	*0.007*	*1.13*	*(1.02, 1.25)*	*0.015*
Instrumental (at least one, but no forceps)	663 (1.9%)	639 (2.0%)	24 (1.1%)	1.42	(0.95, 2.13)	0.09	1.35	(0.90, 2.02)	0.15
SVD+CS	1185 (3.4%)	1129 (3.5%)	56 (2.6%)	0.92	(0.70, 1.20)	0.53	0.89	(0.68, 1.17)	0.40
Age at 1st delivery									
Under 20 years	5867 (16.9%)	5510 (17.0%)	357 (16.8%)	*0.88*	*(0.78, 0.99)*	*0.035*	*0.87*	*(0.78, 0.98)*	*0.021*
20-29 years	23751 (68.6%)	22221 (68.4%)	1530 (71.8%)	1.00			1.00		
30-49 years	5013 (14.5%)	4770 (14.7%)	243 (11.4%)	1.11	(0.97, 1.28)	0.12	*1.34*	*(1.16, 1.54)*	*<0.001*
Total number of deliveries									
Single	8699 (25.1%)	8306 (25.6%)	393 (18.5%)	1.00			1.00		
2 to 4	24986 (72.1%)	23323 (71.8%)	1663 (78.1%)	*1.41*	*(1.26, 1.58)*	*<0.001*	*1.30*	*(1.16, 1.46)*	*<0.001*
5+	946 (2.7%)	872 (2.7%)	74 (3.5%)	1.15	(0.90, 1.48)	0.27	1.10	(0.85, 1.41)	0.48
Twins at some point									
No	34148 (98.6%)	32044 (98.6%)	2104 (98.8%)	1.00					
Yes	483 (1.4%)	457 (1.4%)	26 (1.2%)	0.80	(0.54, 1.17)	0.25			
Time between deliveries									
One delivery	8699 (25.1%)	8306 (25.6%)	393 (18.5%)	1.00					
All < 2 years	4151 (12.0%)	3883 (11.9%)	268 (12.6%)	*1.40*	*(1.19, 1.63)*	*<0.001*			
All greater than or equal to 2 years	16510 (47.7%)	15463 (47.6%)	1047 (49.2%)	*1.40*	*(1.24, 1.57)*	*<0.001*			
Mixture	5271 (15.2%)	4849 (14.9%)	422 (19.8%)	*1.41*	*(1.23, 1.62)*	*<0.001*			
Type of perineal wound									
No wound	14365 (41.5%)	13601 (41.8%)	764 (35.9%)	1.00			1.00		
All Episiotomy	9457 (27.3%)	8852 (27.2%)	605 (28.4%)	*1.19*	*(1.07, 1.33)*	*0.001*	1.05	(0.94, 1.18)	0.37
At least one 3rd degree tear	162 (0.5%)	150 (0.5%)	12 (0.6%)	*1.99*	*(1.12, 3.53)*	*0.018*	1.68	(0.95, 2.97)	0.076
No Perineal Tears (lacerations only)	10647 (30.7%)	9898 (30.5%)	749 (35.2%)	*1.57*	*(1.41, 1.73)*	*<0.001*	*1.36*	*(1.22, 1.52)*	*<0.001*

Subgroup analyses of independent risk factors for undergoing UI, POP or RP-FI surgery separately are shown in **Table 2, 3 & 4**. Undergoing at least one forceps delivery was an independent risk factor for requiring POP/ RP-FI surgery but not for a UI surgery. Similarly, sustaining a third degree perineal tear was only a risk factor for a RP-FI operation. Delivering all siblings by CS was significantly protective against surgery for UI/ POP but not RP-FI.

- **Re-operation rate for UI and/or POP:**

407 women had more than one operation for UI/POP giving a re-operation rate of 19%. 238 women had at least one repeat POP operation with a re-operation rate of 15.8% and median (IQR) 3.0 years (1.00, 8.25) between the index and repeat surgery. 67 women had at least one repeat UI surgery giving a re-operation rate of 8.8%. The median (IQR) time between index and repeat UI surgery was 2.80 (0.94, 8.07) years. The median time interval for repeat UI surgery varied according to the type of index operation; 0.93 years (0.27, 2.49) for mid-urethral slings compared to 4.20 years (1.73, 8.38) for retropubic abdominal procedures.

- **Risk factors for re-operation of UI/POP:**

Re-operation rate for UI was 3.2% (11/342) within the MUS group, 10.7% (34/319) within the abdominal retropubic surgery group, 17.5% (14/80) within the anterior colporraphy group and 50% (n=5/10) within the peri-urethral injectables group. **Table 5** shows the independent risk factors of re-operation for UI. Using abdominal retropubic group as the reference group, women undergoing MUS had a significantly lower risk of repeat UI surgery.

Table 2: Cox Regression Results for Risk Factors of Undergoing Surgical Treatment for UI

	No Operation (N=32501)	SUI Operation (N=762)	Unadjusted			Adjusted		
Risk Factor	**N (%)**	**N (%)**	**HR**	**95% CI**	**p-value**	**HR**	**95% CI**	**p-value**
Mode of delivery								
SVD/Breech only	19776 (60.8%)	533 (69.9%)	1.00			1.00		
CS only	2524 (7.8%)	18 (2.4%)	*0.40*	*(0.25, 0.64)*	*<0.001*	*0.51*	*(0.32, 0.83)*	*0.007*
Instrumental (at least one forceps)	8433 (25.9%)	172 (22.6%)	0.86	(0.72, 1.02)	0.08	0.86	(0.72, 1.03)	0.10
Instrumental (at least one, but no forceps)	639 (2.0%)	12 (1.6%)	*1.72*	*(0.97, 3.05)*	*0.06*	1.65	(0.93, 2.94)	0.09
SVD+CS	1129 (3.5%)	27 (3.5%)	1.12	(0.76,1.65)	0.57	1.07	(0.73, 1.58)	0.72
Age at 1st delivery								
Under 20 years	5510 (17.0%)	182 (23.9%)	*1.28*	*(1.08, 1.52)*	*0.004*	*1.25*	*(1.05, 1.48)*	*0.011*
20-29 years	22221 (68.4%)	519 (68.1%)	1.00			1.00		
30-49 years	4770 (14.7%)	61 (8.0%)	0.82	(0.63, 1.07)	0.14	1.00	(0.76, 1.31)	0.98
Total number of deliveries								
Single	8306 (25.6%)	126 (16.5%)	1.00			1.00		
2 to 4	23323 (71.8%)	614 (80.6%)	*1.63*	*(1.35, 1.97)*	*<0.001*	*1.45*	*(1.18, 1.77)*	*<0.001*
5+	872 (2.7%)	22 (2.9%)	1.17	(0.74, 1.84)	0.51	0.98	(0.62, 1.56)	0.93
Twins at some point								
No	32044 (98.6%)	754 (99.0%)	1.00					
Yes	457 (1.4%)	8 (1.0%)	0.70	(0.35, 1.41)	0.32			
Time between deliveries								
One delivery	8306 (25.6%)	126 (16.5%)	1.00					
All < 2 years	3883 (11.9%)	97 (12.7%)	*1.57*	*(1.20, 2.04)*	*0.001*			
All greater than or equal to 2 years	15463 (47.6%)	393 (51.6%)	*1.63*	*(1.33, 1.99)*	*<0.001*			
Mixture	4849 (14.9%)	146 (19.2%)	*1.59*	*(1.25, 2.01)*	*<0.001*			
Type of perineal wound								
No wound	13601 (41.8%)	265 (34.8%)	1.00			1.00		
All Episiotomy	8852 (27.2%)	239 (31.4%)	*1.32*	*(1.11, 1.58)*	*0.002*	*1.22*	*(1.01, 1.46)*	*0.035*
At least one 3rd degree tear	150 (0.5%)	2 (0.3%)	0.90	(0.22, 3.62)	0.88	0.81	(0.20, 3.24)	0.76
No Perineal Tears (lacerations only)	9898 (30.5%)	256 (33.6%)	*1.53*	*(1.29, 1.82)*	*<0.001*	*1.31*	*(1.10, 1.57)*	*0.003*

Table 3: Cox Regression Results for Risk Factors of Undergoing Surgical Treatment for POP

	No Operation (N=32501)	POP Operation (N=1508)	Unadjusted			Adjusted		
Risk Factor	**N (%)**	**N (%)**	**HR**	**95% CI**	**p-value**	**HR**	**95% CI**	**p-value**
Mode of delivery								
SVD/Breech only	19776 (60.8%)	1021 (67.7%)	1.00			1.00		
CS only	2524 (7.8%)	7 (0.5%)	*0.09*	*(0.04, 0.19)*	*<0.001*	*0.10*	*(0.05, 0.21)*	*<0.001*
Instrumental (at least one forceps)	8433 (25.9%)	430 (28.5%)	*1.20*	*(1.07, 1.34)*	*0.002*	*1.19*	*(1.05, 1.33)*	*0.004*
Instrumental (at least one, but no forceps)	639 (2.0%)	16 (1.1%)	1.41	(0.86, 2.32)	0.17	1.34	(0.82, 2.21)	0.25
SVD+CS	1129 (3.5%)	34 (2.3%)	0.80	(0.57, 1.13)	0.20	0.79	(0.56, 1.12)	0.18
Age at 1st delivery								
Under 20 years	5510 (17.0%)	221 (14.7%)	*0.77*	*(0.67, 0.89)*	*<0.001*	*0.76*	*(0.66, 0.89)*	*<0.001*
20-29 years	22221 (68.4%)	1100 (72.9%)	1.00			1.00		
30-49 years	4770 (14.7%)	187 (12.4%)	*1.20*	*(1.02, 1.40)*	*0.023*	*1.48*	*(1.26, 1.73)*	*<0.001*
Total number of deliveries								
Single	8306 (25.6%)	285 (18.9%)	1.00			1.00		
2 to 4	23323 (71.8%)	1171 (77.7%)	*1.38*	*(1.21, 1.57)*	*<0.001*	*1.25*	*(1.09, 1.44)*	*0.001*
5+	872 (2.7%)	52 (3.4%)	1.08	(0.80, 1.45)	0.61	1.04	(0.77, 1.41)	0.81
Twins at some point								
No	32044 (98.6%)	1489 (98.7%)	1.00					
Yes	457 (1.4%)	19 (1.3%)	0.81	(0.52, 1.28)	0.37			
Time between deliveries								
One delivery	8306 (25.6%)	285 (18.9%)	1.00					
All < 2 years	3883 (11.9%)	196 (13.0%)	*1.42*	*(1.18, 1.70)*	*<0.001*			
All greater than or equal to 2 years	15463 (47.6%)	727 (48.2%)	*1.35*	*(1.18, 1.55)*	*<0.001*			
Mixture	4849 (14.9%)	300 (19.9%)	*1.37*	*(1.16, 1.61)*	*<0.001*			
Type of perineal wound								
No wound	13601 (41.8%)	527 (34.9%)	1.00			1.00		
All Episiotomy	8852 (27.2%)	412 (27.3%)	*1.19*	*(1.04, 1.35)*	*0.009*	1.03	(0.90, 1.17)	0.70
At least one 3rd degree tear	150 (0.5%)	6 (0.4%)	1.50	(0.67, 3.34)	0.33	1.23	(0.55, 2.76)	0.61
No Perineal Tears (lacerations only)	9898 (30.5%)	563 (37.3%)	*1.73*	*(1.53, 1.94)*	*<0.001*	*1.50*	*(1.32, 1.70)*	*<0.001*

Table 4: Cox Regression Results for Risk Factors of Undergoing Surgical Treatment for FI/RP

	No Operation (N=32501)	RAP or FI Operation (N=1508)	Unadjusted			Adjusted		
Risk Factor	N (%)	N (%)	HR	95% CI	p-value	HR	95% CI	p-value
Mode of delivery								
SVD/Breech only	19776 (60.8%)	56 (57.1%)	1.00			1.00		
CS only	2524 (7.8%)	2 (2.0%)	0.45	(0.11, 1.84)	0.26	0.41	(0.10, 1.71)	0.22
Instrumental (at least one forceps)	8433 (25.9%)	37 (37.8%)	*1.90*	*(1.25, 2.88)*	*0.003*	*1.81*	*(1.18, 2.77)*	*0.007*
Instrumental (at least one, but no forceps)	639 (2.0%)	1 (1.0%)	1.39	(0.19, 10.1)	0.75	1.35	(0.18, 9.87)	0.77
SVD+CS	1129 (3.5%)	2 (2.0%)	0.83	(0.20, 3.40)	0.79	0.83	(0.20, 3.39)	0.79
Age at 1st delivery								
Under 20 years	5510 (17.0%)	14 (14.3%)	0.77	(0.43, 1.36)	0.36			
20-29 years	22221 (68.4%)	73 (74.5%)	1.00					
30-49 years	4770 (14.7%)	11 (11.2%)	0.97	(0.52, 1.83)	0.93			
Total number of deliveries								
Single	8306 (25.6%)	16 (16.3%)	1.00					
2 to 4	23323 (71.8%)	77 (78.6%)	1.65	(0.96, 2.83)	0.067			
5+	872 (2.7%)	5 (5.1%)	1.86	(0.68, 5.09)	0.23			
Twins at some point								
No	32044 (98.6%)	96 (98.0%)	1.00					
Yes	457 (1.4%)	2 (2.0%)	1.32	(0.33, 5.34)	0.70			
Time between deliveries								
One delivery	8306 (25.6%)	16 (16.3%)	1.00					
All < 2 years	3883 (11.9%)	8 (8.2%)	1.05	(0.45, 2.45)	0.91			
All greater than or equal to 2 years	15463 (47.6%)	54 (55.1%)	1.82	(1.04, 3.19)	0.035			
Mixture	4849 (14.9%)	20 (20.4%)	1.66	(0.86, 3.21)	0.13			
Type of perineal wound								
No wound	13601 (41.8%)	43 (43.9%)	1.00			1.00		
All Episiotomy	8852 (27.2%)	26 (26.5%)	0.98	(0.60, 1.60)	0.94	0.80	(0.48, 1.33)	0.40
At least one 3rd degree tear	150 (0.5%)	7 (7.1%)	*21.8*	*(9.72, 48.7)*	*<0.001*	*16.9*	*(7.44, 38.3)*	*<0.001*
No Perineal Tears (lacerations only)	9898 (30.5%)	22 (22.4%)	0.83	(0.49, 1.38)	0.47	0.76	(0.45, 1.29)	0.31

Table 6 shows the unadjusted ORs for the different risk factors for repeat POP operation. Only women with age at first delivery of 30-39 years were less likely to have a re-operation for POP. 72 of 814 women underwent repeat anterior repair at some point with a re-operation rate for the anterior compartment of 8.8%. Similarly, 57/775 women underwent a repeat posterior repair with a re-operation rate of 7.4% for the posterior compartment. For those women whose initial POP operation was in the anterior and posterior compartments, the median (IQR) time interval for repeat surgery was 3 years (1, 9.25) and 4 years (1, 9) respectively.

Table 5: Results of Logistic Regression for Risk of Re-Operation for UI

	UI operation		Unadjusted Analysis			Adjusted Analysis		
Risk Factor	**One (N=695)**	**> 1 (N=67)**	**OR**	**95% CI**	**p-value**	**OR**	**95% CI**	**p-value**
Type of first SUI surgery								
Abdominal retropubic procedures	285 (41.0%)	34 (50.7%)	1.00			1.00		
Mid-urethral slings	331 (47.6%)	11 (16.4%)	*0.28*	*(0.14, 0.56)*	*<0.001*	*0.30*	*(0.15, 0.60)*	*0.001*
Anterior Colporrhapy	66 99.5%)	14 (20.9%)	1.78	(0.90, 3.50)	0.096	1.92	(0.97, 3.82)	0.063
Peri-urethral Injectables	5 (0.7%)	5 (7.5%)	*8.38*	*(2.31, 30.4)*	*0.001*	*9.05*	*(2.42, 33.8)*	*0.001*
Repair of Uro-genital Fistulae	8 (1.2%)	3 (4.5%)	3.14	(0.80, 12.4)	0.102	2.50	(0.58, 10.8)	0.22
Mode of delivery								
SVD only	488 (700.2%)	45 (67.2%)	1.00					
CS only	16 (2.3%)	2 (3.0%)	1.36	(0.30, 6.08)	0.69			
At least one forceps	158 (22.7%)	14 (20.9%)	0.96	(0.51, 1.80)	0.90			
At least one instrumental: no forceps	9 (1.3%)	3 (4.5%)	3.62	(0.95, 13.8)	0.06			
SVD+CS	24 (3.5%)	3 (4.5%)	1.36	(0.39 ,4.68)	0.63			
Age at 1st delivery								
Under 20 years	166 (23.9%)	16 (23.9%)	0.93	(0.51, 1.67)	0.80			
20-29 years	470 (67.6%)	49 (73.1%)	1.00					
30-49 years	59 (8.5%)	2 (3.0%)	0.33	(0.08, 1.37)	0.13			
Total number of deliveries								
One	116 (16.7%)	10 (14.9%)	1.00					
2 to 4	558 (80.3%)	56 (83.6%)	1.16	(0.58, 2.35)	0.67			
5+	21 (3.0%)	1 (1.5%)	0.55	(0.07, 4.55)	0.58			
Occurrence of twins								
No	687 (98.8%)	67 (100%)						
yes	8 (1.2%)	0 (0%)						
Time between deliveries								
One delivery	116 (16.7%0	10 (14.9%)	1.00					
All < 2 years	89 (12.8%)	8 (11.9%)	1.04	(0.40, 2.75)	0.93			
All greater than 2 years	354 (19.6%)	10 (14.9%)	1.28	(0.62, 2.64)	0.51			
Mixture	136 (19.6%)	10 (14.9%)	0.85	(0.34, 2.12)	0.73			
Type of perineal wound								
No Wound	239 (34.4%)	26 (38.8%)	1.00			1.00		
All Episiotomy	211 (30.4%)	28 (41.8%)	1.22	(0.69, 2.15)	0.49	1.22	(0.68, 2.19)	0.51
At least one 3rd degree tear	1 (0.1%)	1 (1.5%)	9.19	(0.56, 151)	0.12	4.83	(0.25, 92.8)	0.30
No Perineal tears (lacerations only)	244 (35.1%)	12 (17.9%)	*0.45*	*(0.22, 0.92)*	*0.028*	*0.46*	*(0.22, 0.95)*	*0.037*

Table 6: Results of Logistic Regression for Risk of Re-Operation for POP Repair.

	POP operation		Unadjusted		
Risk Factor	**One (N=1270)**	**> 1 (N=238)**	**OR**	**95% CI**	**p-value**
Mode of delivery					
SVD only	857 (67.5%)	164 (68.9%)	1.00		
CS only	7 (0.6%)	0 (0%)			
At least one forceps	365 (28.7%)	65 (27.3%)	0.93	(0.68, 1.27)	0.65
At least one instrumental: no forceps	15 (1.2%)	1 (0.4%)	0.35	(0.05, 2.66)	0.31
SVD+CS	26 (2.0%)	8 (3.4%)	1.61	(0.72, 3.61)	0.25
Age at 1st delivery					
Under 20 years	174 (13.7%)	47 (19.7%)	*1.44*	*(1.00, 2.06)*	*0.049*
20-29 years	926 (72.9%)	174 (73.1%)	1.00		
30-49 years	170 (13.4%)	17 (7.1%)	*0.53*	*(0.31, 0.90)*	*0.018*
Total number of deliveries					
One	246 (19.4%)	39 (16.4%)	1.00		
2 to 4	978 (77.0%)	193 (81.1%)	1.25	(0.86, 1.81)	0.25
5+	46 (3.6%)	6 (2.5%)	0.82	(0.33, 2.06)	0.68
Occurrence of twins					
No	1254 (98.7%)	235 (98.7%)	1.00		
yes	16 (1.3%)	3 (1.3%)	1.00	(0.29, 3.46)	0.99
Time between deliveries					
One delivery	246 (19.4%)	39 (16.4%0	1.00		
All < 2 years	167 (13.1%)	29 (12.2%)	1.10	(0.65, 1.84)	0.73
All greater than 2 years	608 (47.9%)	119 (50.0%)	1.24	(0.84, 1.83)	0.29
Mixture	249 (19.6%)	51 (21.4%)	1.29	(0.82, 2.03)	0.27
Type of perineal wound					
No Wound	442 (34.8%)	85 (35.7%)	1.00		
All Episiotomy	361 (28.4%)	51 (21.4%)	0.74	(0.51, 1.07)	0.11
At least one 3rd degree tear	5 (0.4%)	1 (0.4%)	1.04	(0.12, 9.01)	0.97
No perineal tears (lacerations only)	462 (36.4%)	101 (42.4%)	1.14	(0.83, 1.56)	0.43

Discussion:

In this large longitudinal epidemiological study we have established the lifetime risk for parous women, in a UK population, to undergo a single pelvic floor surgery (UI/POP/RP-FI) as 12.2% by age of 80 years. Olsen et al (9) reported an 11.1% lifetime risk for women to undergo a single operation for UI/POP by age of 80 years. Their results were echoed by Fialkow et al (15) in 2008; showing a similar 11.8% lifetime risk for UI/POP surgery in a

similar cohort of American women. The latter two studies were limited because they sampled health miantenace organisations. Therefore the results may not be applied to European or wider USA populations, since generalisibility would have be poor through the exclusion of large groups, such as the elderly, socially disabled, lower social class and individuals with chronic illness.. Furthermore, both study designs were cross-sectional and therefore suffered from a limited follow-up period. Our study is a longitudinal retrospective study spanning the lifetime of a group of women representing the "general-population" in UK. We chose 80-years as our age limit as it represents the average life-span of women in UK (14). The poulation in Aberdeen city and district is predominetly caucasian however with a number of ethnic minority communities including Asian, African and Eastern Europe and therefore is deemed to be quite representative of the general UK poulation.

Unlike previous studies, we calculated the lifetime risk for surgical treatment of various pelvic floor disorders separately; the life-time risk of women to undergo a single UI operation in our study was 3.6%. The MRC Leicestershire study (2) showed that 33.6% of the population in the UK above age of 40 years describe UI symptoms, however only 6.2% reported these symptoms to be bothersome. A recent French study showed similar findings with 29% prevalence of female UI, although only 9% sought medical help (16). Conservative measures such pelvic floor muscle training (PFMT) can be quite successful in management of 50-60% of women with UI (17), while surgical treatment is usually a second line management. Therefore the lifetime risk reported in our study is likely to be a true reflection of the current clinical practice.

Our study showed that the lifetime risk of women undergoing a single POP surgery was 9.5%; this was almost 50% lower than the risk of women in Western Australia. In 2010,

Smith et al (10) conducted a cross-sectional study on female "general population" in Western Australia between 2001 and 2005 and they calculated a higher lifetime risk for POP surgery of 19% by age of 85 years. It is difficult to explain the difference in the results between both population-based studies. The difference in design, i.e. longitudinal vs. cross-sectional, is unlikely to be a major influence. In a European study, Hove et al (18) assessed the whole population of a small town in Netherlands and reported that 40% of women aged 45-85 years, to have POP ≥ stage II on examination, however only 12% of women were symptomatic. We therefore believe that, with the current concept of only treating symptomatic and/or severe prolapse and knowing that a percentage of women will opt for conservative measures such as vaginal pessaries, the life-time surgical risk reported in our study is likely to be more representative for the clinical practice in UK and European countries.

The re-operation rate for UI/POP in our study was 19% and was comparable with 17% reported by Denman et al (13) in a 10 year follow-up prospective study. The re-operation rate in the latter study increased to 21% after adjustment for missing women in the follow-up. Olsen et al (9) reported 29% re-operation rates for UI/ POP within 5 years time in their cross-sectional study. It is important to note that 50% of their population were smokers (current/former) and over 20% suffered from chronic lung disease which may have contributed to their higher re-operation rates. The re-operation rates, in our study, for UI and POP separately were 8.8% and 15.8% respectively; these were comparable to 8% and 13% re-operation rates for UI and POP respectively reported by Clarke et al (19) in their 5-year prospective study. Similarly, Fialkow et al (15) showed an 8.6% re-operation rates for UI over 8 years in a retrospective cohort study. The POP re-operation rates in the same compartment were not hugely different between the anterior and posterior compartments. Similar results were reported by Clarke et al (19) who found a five-year re-operation rates for

anterior of 8% and posterior compartments of 11%, with higher re-operation rates (15% vs. 12% respectively) if associated with apical prolapse.

In our study, exclusive delivery by caesarean sections, compared to women who had only SVDs, was found to be protective against pelvic floor surgery for each of UI, POP, and RP-FI (≈ 60%). This protective effect was not seen if a woman had a mixture of caesarian and vaginal deliveries. A single forceps delivery significantly increased the risk of surgery for POP and/or RP-FI but not for UI. Similar results were reported by MacArthur et al (20) in their 12 years prospective study and Larson et al (21) in their nested case-control study. In our study, the increased parity of 2-4 deliveries was an independent risk factor for POP/UI surgery compared to a single delivery. A Dutch group previously showed increased parity of 2-3 to be a risk factor for the development of POP; interestingly the risk was not further increased if parity was > 3 (5). Conversely, MacArthur et al (20) found parity ≥ 4 to be a risk factor for UI. The latter two studies assessed risk factors for development of symptomatic UI/POP rather than risk factors for undergoing surgical treatment. It is evident from our data that increased parity and vaginal forceps deliveries are risk factors for the development of UI/POP that warrant surgical management. As expected, sustaining a third degree perineal tear was a risk factor for undergoing RP-FI surgery. Episiotomy was not found to be protective.

Analysis of potential risk factors for re-operation for UI/POP did not reveal specific independent risk factors, except for delayed age at first delivery (30-39 years) which seems to be of little clinical significance. These results were in agreement with other studies in the literature (9, 13, 15); all of which failed to detect independent risk factors for repeat UI/POP surgery. However it was evident that women undergoing MUS had significantly reduced risk

of re-operation for UI when compared to abdominal retropubic surgery. It can be argued that MUS have not been used in surgical practice for as long as abdominal retropubic procedures and therefore the detected reduced risk may be subject to bias. However, the finding of the median time interval for repeat UI surgery as 1 year following MUS compared to 4 years following retropubic abdominal procedures is reassuring that repeat surgery following MUS is likely to have been captured within the time frame of this study. Conversely, peri-urethral injections were associated with significantly higher risk of repeat UI surgery. Fialkow et al (15), have previously reported a reduced risk of repeat UI surgery following Burch colposuspension compared to traditional slings.

Strengths and limitations:

- To our knowledge, this is the first study to report the lifetime risk for women in UK to undergo surgical treatment for UI/ POP/ RP-FI.
- Large cohort size and long duration of follow-up
- The study represents the general population rather than a selected population, therefore we are confident that our findings are generalisable to the UK or indeed any European population.
- Aberdeen city and district had a relatively stable population over the last century, minimising loss to follow up.
- Both AMND and SMR databases used in this study are subjected to quality control measures at regular intervals and there are numerous consistency checks in place to ensure validity of data entry.
- Good quality data relating to both exposure (AMND) and outcomes (SMR) added strength and validity to the findings.

Our study however had a number of limitations:

- Information was missing on smoking and BMI in a large proportion of women.
- We were unable to link 27% of women with the SMR databases. There are a number of possible reasons for this:

  (a) Failure to match the health records for these women with the data available on the AMND

  (b) These women are alive and have moved away from Scotland

  (c) They may have undergone further treatment on private basis.

  In the latter two situations their hospital admissions would not be recorded by the ISD in Scotland. As migration is highly correlated with socio-economic status, we cannot rule out any selection bias resulting from this.

  - There is also a possibility, albeit small, of misclassification bias resulting from wrong linkage due to error in probability matching.

Clinical and research Implications:

We believe our results are essential to inform policy makers in the UK and Europe with regards healthcare planning, resource allocation and staff training. Increased BMI and forceps deliveries were independent risk factors for undergoing surgery for pelvic floor disorders; both of which are potentially avoidable. Exclusive delivery by Caesarean sections was found to be protective against pelvic floor surgery, although not 100% protective. Other risks associated with delivery by caesarean sections should be taken into consideration when making decisions regarding the mode of delivery.

Conclusion

Our study reveals that more than one in ten parous women in UK, over their lifetime, will require at least one surgical procedure for pelvic floor dysfunction with 19% requiring more than one procedure. Independent risk factors for pelvic floor surgery were forceps delivery and delayed initial child bearing. Protective factors included early initial delivery and delivery exclusively by caesarean section. This information is essential for clinicians, patients and policy makers with regards to counselling, decision making and allocation of health care resources.

Competing Interests: The authors declare that they have no conflict of interest.

Data Sharing: Data tables and summaries are available from corresponding author at m.abdelfattah@abdn.ac.uk. Consent was not obtained from participants but the presented data are anonymised and risk of identification is low.

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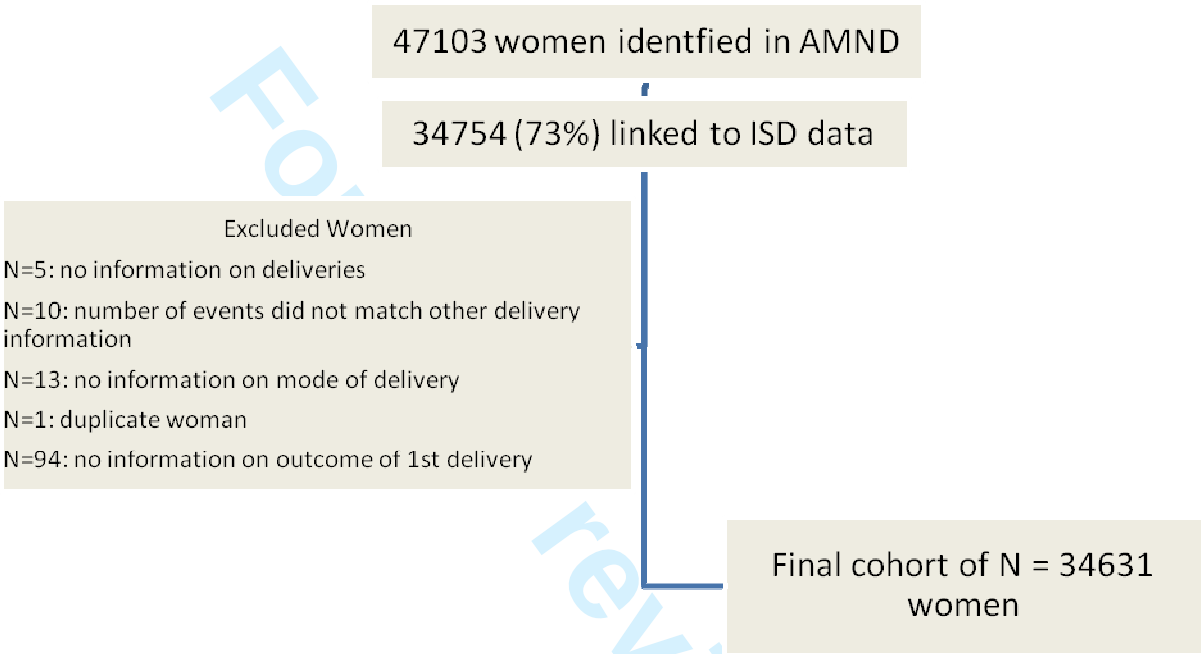
STROBE 2007 (v4) Statement—Checklist of items that should be included in reports of *cohort studies*

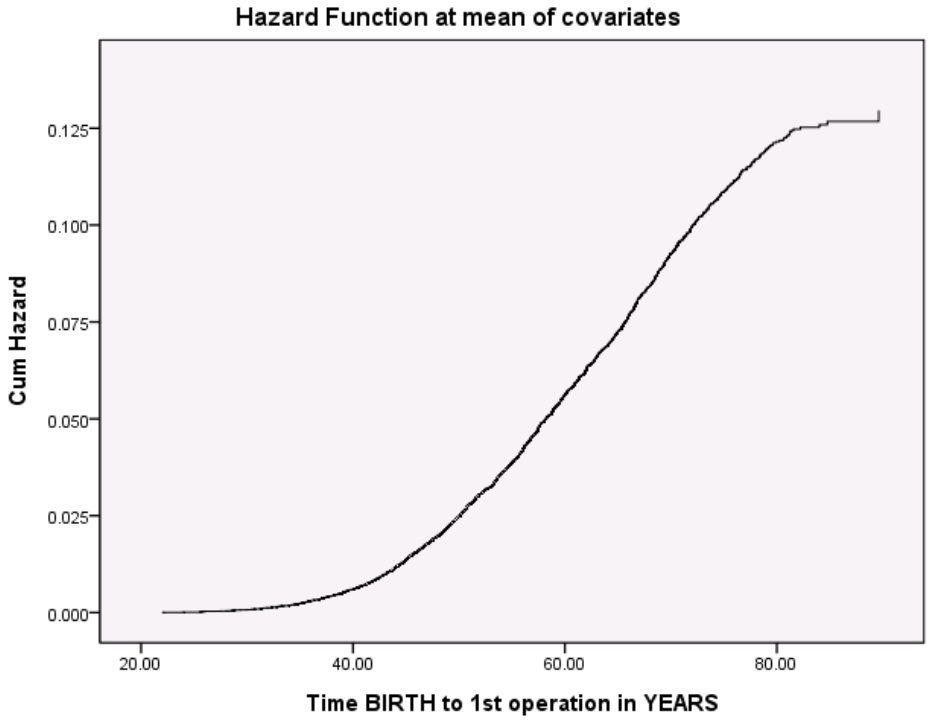
Section/Topic	Item #	Recommendation	Reported on page #
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	55
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	55
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	56 and 57
Objectives	3	State specific objectives, including any prespecified hypotheses	57
Methods			
Study design	4	Present key elements of study design early in the paper	55
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	57 and 58
Participants	6	(*a*) Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up	58
		(*b*) For matched studies, give matching criteria and number of exposed and unexposed	
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	58 and 59
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	58 and 59
Bias	9	Describe any efforts to address potential sources of bias	73
Study size	10	Explain how the study size was arrived at	58
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	58 and 59
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	59
		(*b*) Describe any methods used to examine subgroups and interactions	59
		(*c*) Explain how missing data were addressed	72 and 73
		(*d*) If applicable, explain how loss to follow-up was addressed	72 and 73
		(*e*) Describe any sensitivity analyses	
Results			

Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	80
		(b) Give reasons for non-participation at each stage	80
		(c) Consider use of a flow diagram	80
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	
		(b) Indicate number of participants with missing data for each variable of interest	80
		(c) Summarise follow-up time (eg, average and total amount)	58
Outcome data	15*	Report numbers of outcome events or summary measures over time	
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	59-66
		(*b*) Report category boundaries when continuous variables were categorized	59-66
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	59-66
Discussion			
Key results	18	Summarise key results with reference to study objectives	74
Limitations			
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	72-74
Generalisability	21	Discuss the generalisability (external validity) of the study results	72
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	54

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.




Hazard Function at mean of covariates
Cum Hazard
0.125
0.100
0.075
0.050
0.025
0.000
20.00
40.00
60.00
80.00
Time BIRTH to 1st operation in YEARS