BRITISH SOCIETY OF UROGYNAECOLOGY (BSUG)

MESH COMPLICATIONS SURGERY IN THE UK 2008-2019

1ST NATIONAL REPORT

BSUG AUDIT AND DATABASE COMMITTEE 2020

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Preface

The British Society of Urogynaecology (BSUG) database has been available online since 2007. Its users can record details and outcomes of procedures for urinary incontinence, pelvic organ prolapse and mesh complications.

Thanks to the commitment of BSUG members - and the patients who kindly allowed their data to be recorded - the database has been utilised widely. Its use is supported by the National Institute for Health and Care Excellence (NICE) and is a prerequisite for BSUG accreditation of urogynaecology units in the UK. The database currently holds information on more than 150 000 individual surgical episodes from across the UK. This wealth of information has generated national audits on operations for stress urinary incontinence and pelvic organ prolapse along with many publications which are listed on the BSUG website. At an individual level, consultants find the database useful for evaluating their own practice and for the purposes of annual appraisal and revalidation.

Continual improvements to the relevance and functionality of the database are being made, thanks to many consultants who have volunteered their time and expertise. Since November 2017, the database has been updated to capture more detailed information on surgery performed to treat mesh complications.

This is the first National Report on Surgery for Mesh Complications from the BSUG Audit and Database Committee and includes the first full 12 years of data collection (2008 – 2019). Mesh surgery has never been under more scrutiny and publication of this report comes at an opportune time. In writing the report a conscious decision was taken to not interpret or comment on the results apart from where an explanation was necessary.

BSUG Audit and Database Committee 2020

ABBREVIATIONS

British Society of Urogynaecology (BSUG)

International Continence Society (ICS)

International Urogynaecological Association (IUGA)

Medicines and Healthcare Products Regulatory Agency (MHRA)

Mid-urethral tape (MUT)

Multi-disciplinary team (MDT)

National Health Service (NHS)

National Institute for Health and Care Excellence (NICE)

Patient-reported global impression of improvement (PGI-I)

Pelvic organ prolapse (POP)

Patient-reported outcome measures (PROMs)

Royal College of Obstetricians and Gynaecologists (RCOG)

Stress Urinary Incontinence (SUI)

Urinary incontinence (UI)

CHAPTER 1: Introduction

1.1 BSUG DATABASE

The British Society of Urogynaecology (BSUG) database was established in 2004 and launched online in 2007. It collects data on operations for urinary incontinence (UI), pelvic organ prolapse (POP) and mesh complications. The database is held within the secure NHS N3 network and access to it is password protected. Patient consent is necessary for data entry. The database is accessible to BSUG members only and its use is voluntary.

1.2 AUDIT TIMEFRAME

The timeframe of the audit was from the start of 2008, the first full year of online data collection, to the end of 2019.

1.3 DATABASE USAGE

Data on mesh complication surgery was uploaded by 78 UK centres.

1.4 LIMITATIONS

The BSUG database is a voluntary database used by individual surgeons to record outcomes of their surgical procedures. Mesh complication operations are also undertaken by urologists, colorectal surgeons and consultants who have chosen not to be BSUG members. Therefore, not every operation performed for the treatment of mesh-related problems during the timeframe of the audit will be included in this analysis.

In addition, caution must be applied to the use and interpretation of this report because of missing data and the limited recording of long-term outcomes – both positive and negative. This is particularly the case for long-term complications which may arise after the initial period of follow-up, some of which will be treated in other units.

1.5 OPERATIONS INCLUDED

The database allows users to record prespecified mesh complication procedures. Not all these options were available throughout the timeframe of the audit as some were added to the database at different stages of its development. 'Excise mesh erosion' was the earliest available option. The list of options increased significantly in November 2017 when a separate section on surgery for mesh complications was introduced to the database.

The current options for mesh complication operations are:

1. Abdominal removal of sacrocolpopexy mesh (Open/laparoscopic/robotic)
2. Burial of mesh/graft exposure vaginally (No mesh removed)
3. Excision vaginal part of MUT (Not exposed/eroded)
4. Localised excision and closure of transvaginal mesh exposure
5. Excision of mesh erosion (Bladder)
6. Excision of mesh erosion (Bowel)
7. Excision of mesh erosion (Urethra)
8. Partial removal of retropubic tape (Open/laparoscopic/robotic)
9. Suburethral tape - divided
10. Suburethral tape - stretched
11. Total excision of vaginal mesh for pelvic organ prolapse
12. Total removal of retropubic tape (Open/laparoscopic/robotic)
13. Total removal of transobturator tape
14. Excise mesh erosion

CHAPTER 2: Numbers and trends

2.1 NUMBER OF SURGICAL PROCEDURES TO TREAT MESH COMPLICATIONS AND TRENDS

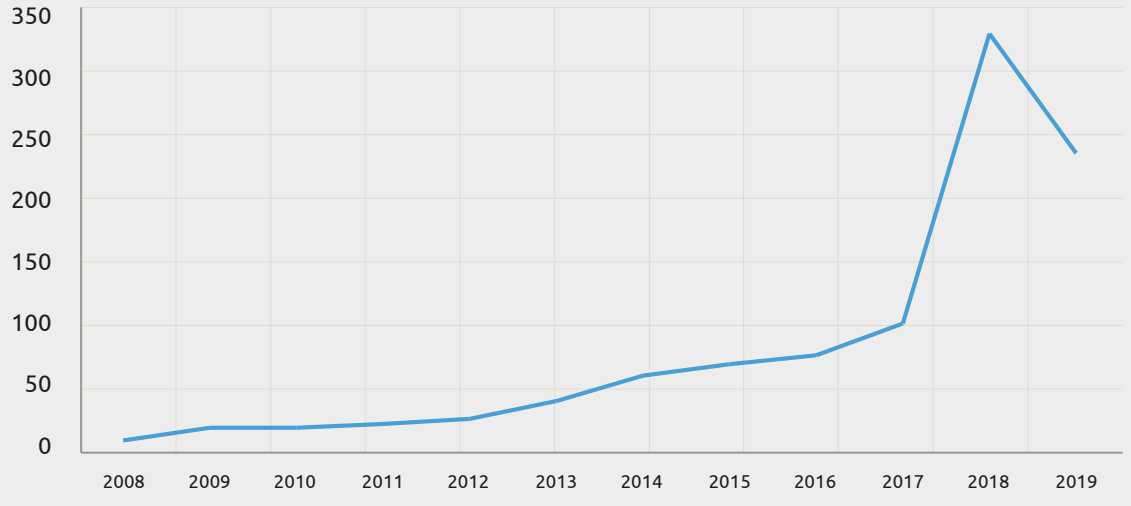
There were 1005 operations for mesh complications from 2008 to the end of 2019.

From 2008 to 2017 there was a gradual increase in the number of episodes entered into the database each year (*Table 1*, *Figure 1*). There was a sharp, 225.7%, increase in the number of episodes in 2018 most likely in response to the new more detailed section on mesh complication surgery which was introduced in November 2017. The number of episodes decreased in 2019 for reasons which are uncertain. This could be due to most patients having been treated already or possibly secondary to the introduction of the mesh 'pause' in July 2018 in the UK and the consequent reduction in mesh complications subsequently[1]. The reduction in 2019 was also seen in the number of mesh-related adverse incidents reported to the MHRA that year (*Table 2*).

Table 1: *Number of mesh complication surgical episodes 2008-2019*

Year	Mesh complication operations, n
2008	9
2009	19
2010	19
2011	22
2012	26
2013	40
2014	60
2015	69
2016	76
2017	101
2018	329
2019	235
Total	**1005**

Figure 1: *Number of mesh complication surgical episodes 2008-2019*



2.2 COMPARISON WITH MHRA DATA

Mesh-related adverse incidents reported to the MHRA from 2014-2019[2] were compared to figures for the corresponding years from the BSUG database (*Table 2*). MHRA incidents consist of mesh-related problems resulting from mesh operations for both POP and SUI and includes cases that may not have undergone surgery along with incidents of device malfunction. Whilst users of the BSUG database are healthcare professionals, MHRA incidents may be reported by both professionals and members of the public so each case is more likely to have been reported more than once. BSUG data is likely to underestimate the actual number of mesh-related problems in the UK.

Table 2: *Comparison of MHRA and BSUG data 2014-2019*

Year	MHRA incidents	BSUG episodes
2014	160	60
2015	271	69
2016	176	76
2017	689	101
2018	1066	329
2019	674	235

Detailed MHRA data and statements from the MHRA are in Appendix A

CHAPTER 3: Preoperative preparation

3.1 USE OF THE ICS/IUGA CLASSIFICATION FOR MESH COMPLICATIONS

The BSUG database allows the ICS/IUGA code for mesh complications to be recorded. A link in the database directs the user to an online code calculator. The code provides information regarding the category, timing, site and pain characteristics of the complication. This function was introduced in February 2012.

Since the introduction of this function, the ICS/IUGA mesh complication code was recorded in 124 (13.0%) episodes.

Since the introduction of the section on surgery for mesh complications to the database in November 2017, the ICS/IUGA mesh complication code was recorded in 119 (19.3%) episodes.

3.2 REPORTING MESH COMPLICATIONS TO THE MHRA

The database records whether a mesh complication episode has been reported to the MHRA through the Yellow Card Scheme. A link in the database directs the user to the MHRA website. This function was introduced in July 2017.

Since the introduction of this function, 174 (26.8%) episodes were recorded as having been reported to the MHRA.

3.3 MULTIDISCIPLINARY TEAM DISCUSSION

The database allows the user to record whether preoperative MDT review occurred. Since the introduction of the section on surgery for mesh complications to the database in November 2017, 476 (94.4%) episodes had an MDT review (*Table 3*).

Table 3: *Preoperative MDT review*

	n (%)
Unrecorded	113
No	28 (5.6)
Yes	476 (94.4)
Total	**617**

3.4 PROVISION OF PROCEDURE-SPECIFIC INFORMATION

Since the introduction of the section on surgery for mesh complications to the database in November 2017, procedure-specific information was provided prior to mesh complication surgery in 243 (66.4%) episodes (*Table 4*).

Table 4: *Provision of procedure-specific information*

	n (%)
Unrecorded	251
No	123 (33.6)
Yes	243 (66.4)
Total	**617**

CHAPTER 4: Surgical data

4.1 INDICATIONS FOR MESH COMPLICATION SURGERY

Prespecified indications for surgery can be entered into the database. These options were added to the database in November 2017 and were not available throughout the timeframe of the audit. They are:

1. Pain
2. Dyspareunia
3. Mesh erosion
4. Voiding dysfunction
5. Urgency
6. Urinary incontinence
7. Infection
8. Patient choice

Since November 2017, 41.8% (249) of episodes had one indication for surgery (*Table 5*). 58.2% (347) of episodes had more than one indication. Where multiple indications were present, it was not possible to determine the main indication.

Table 5: *Indications for surgery*

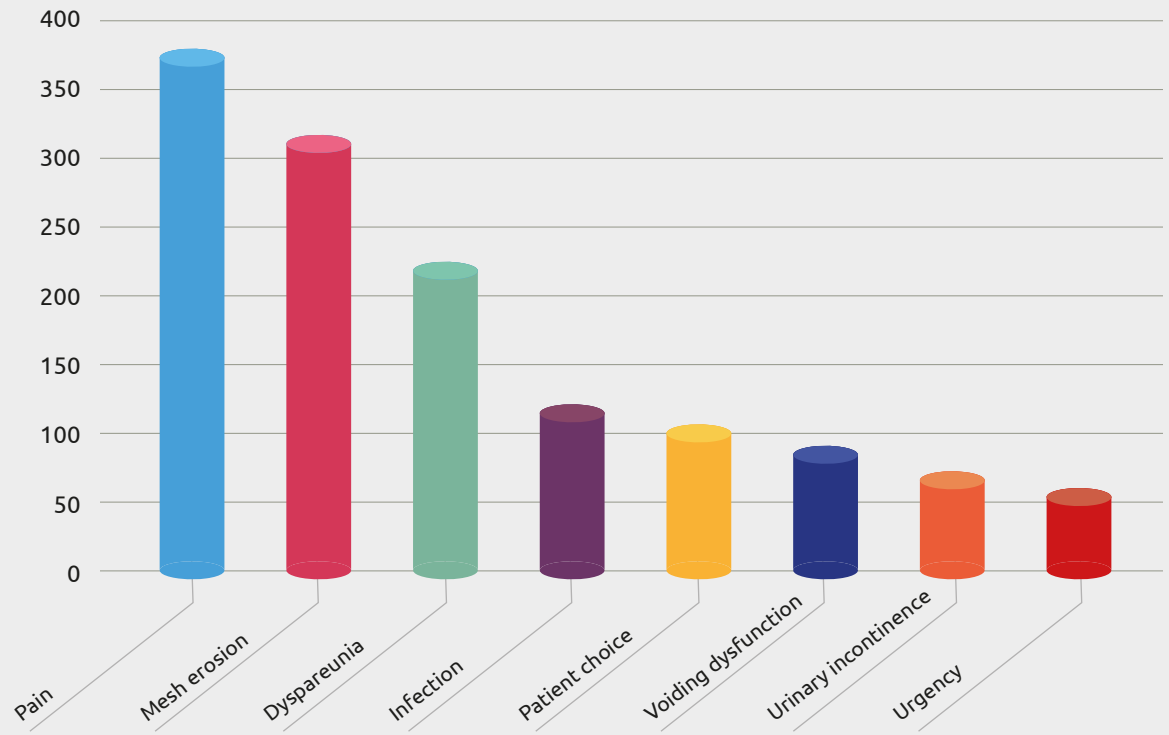
	n (%)
Unrecorded	21
1 indication	249 (41.8)
More than 1 indication	347 (58.2)
Total	**617**

The most common indications for surgery were pain (28.2%) followed by mesh erosion (23.4%) and dyspareunia (16.6%). It is not possible to ascertain the incidence of these mesh problems as the actual number of mesh complications and mesh implant operations during this timeframe is unknown. Patient choice comprised 7.6% of all indications for surgery (*Table 6*, *Figure 2*).

Table 6: *Individual indications for mesh complication surgery*

	n (%)
Pain	373 (28.2)
Mesh erosion	310 (23.4)
Dyspareunia	219 (16.6)
Infection	115 (8.7)
Patient choice	100 (7.6)
Voiding dysfunction	85 (6.4)
Urinary incontinence	66 (5.0)
Urgency	54 (4.1)
Total	**1322**

Figure 2: *Individual indications for mesh complication surgery*



4.2 PREVIOUS MESH OPERATIONS FOR UI AND POP

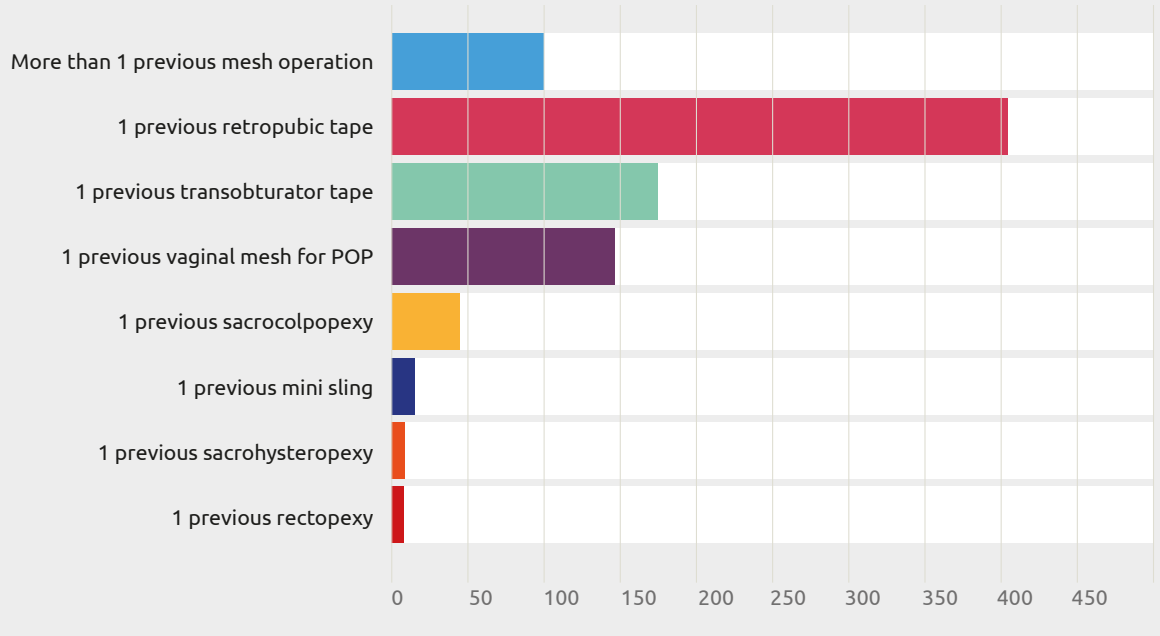
88.2 % (794) of episodes had 1 previous mesh operation for POP or UI. In this group, the commonest operations were retropubic tapes (45.2%) followed by transobturator tapes (19.5%) and transvaginal mesh operations for POP (16.3%) (*Table 7*, *Figure 3*). It was not possible to calculate the incidence of mesh complications of these procedures as the actual number of mesh complications and mesh implant operations during this timeframe is unknown.

11.2% (100) of episodes had more than 1 previous mesh operation for POP or UI (*Table 7*). In this group, it was not possible to ascertain which operation caused the mesh complication.

Table 7: *Previous mesh procedures*

	n (%)
Unrecorded	111
More than 1 previous mesh operation	100 (11.2)
1 previous retropubic tape	404 (45.2)
1 previous transobturator tape	174 (19.5)
1 previous vaginal mesh for POP	146 (16.3)
1 previous sacrocolpopexy	43 (4.8)
1 previous mini sling	14 (1.6)
1 previous sacrohysteropexy	7 (0.8)
1 previous rectopexy	6 (0.7)
Total	**1005**

Figure 3: *Previous mesh procedures*



4.3 TYPES OF MESH COMPLICATION OPERATIONS

The commonest operations for mesh complications were 'Localised excision and closure of vaginal mesh exposure' (23.5%) followed by 'Total removal of retropubic tape' (21.3%) and 'Excise mesh erosion' (19.1%) (*Table 8*).

8.4% of operations involved the excision of mesh from the bladder, bowel or urethra. In this group, 73.5% were for presence of mesh in the urethra.

Table 8: *Operations for mesh complications*

	n (%)
Localised excision and closure of transvaginal mesh exposure	191 (23.5)
Total removal of retropubic tape (open/laparoscopic/robotic)	173 (21.3)
Excise mesh erosion	192 (19.1)
Excision vaginal part of MUT (not exposed/eroded)	133 (16.4)
Total removal of transobturator tape	71 (8.7)
Total excision of vaginal mesh for pelvic organ prolapse	59 (7.3)
Partial removal of retropubic tape (open/laparoscopic/robotic)	52 (6.4)
Excision of mesh erosion (urethral)	50 (6.2)
Burial of mesh/graft exposure vaginally (no mesh removed)	36 (4.4)
Suburethral tape - divided	18 (2.2)
Excision of mesh erosion (bladder)	16 (2.0)
Suburethral tape - stretched	6 (0.7)
Abdominal removal of sacrocolpopexy mesh (open/laparoscopic/robotic)	6 (0.7)
Excision of mesh erosion (bowel)	2 (0.2)
Total	**1005**

4.4 PRIMARY AND REPEAT OPERATIONS

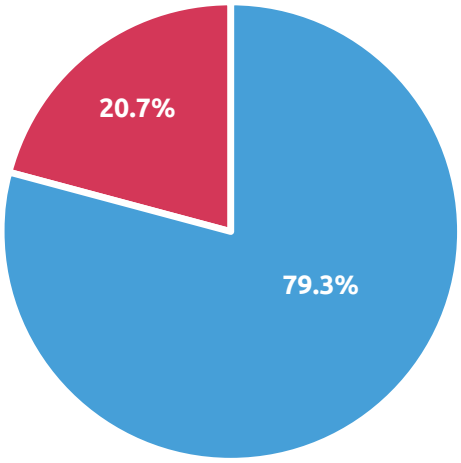
The database allows users to record whether an operation is for a patient's first mesh complication or for a recurrent problem.

79.3% (591) of episodes had first time surgery for mesh complications. 20.7% (154) were repeat operations (*Table 9*, *Figure 4*).

Table 9: *Primary and repeat mesh complication operations*

	n (%)
Primary mesh complication surgery	591 (79.3)
Repeat mesh complication surgery	154 (20.7)
Unrecorded	260
Total	**1005**

Figure 4: *Primary and repeat mesh complication operations*



4.5 SOLE PROCEDURES AND THOSE WITH CONCOMITANT OPERATIONS

12.5% (125) of mesh complication operations had concomitant operations for POP or UI. In this group, 68.0% (85) of these concomitant procedures were for UI and 32.0% (40) for POP (*Table 10*, *Figure 5*).

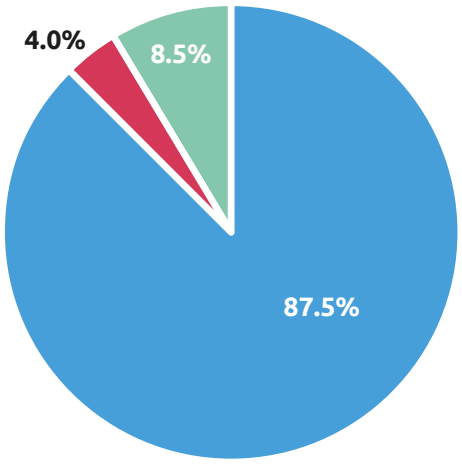
Concomitant procedures for POP were transvaginal repairs (64.8%, 81) and transabdominal repairs (3.2%, 4).

Concomitant procedures for UI were autologous fascial slings (18.4%, 23) and colposuspensions (13.6%, 17).

Table 10: *Sole procedures and procedures with concomitant operations*

	n (%)
Sole procedures	880 (87.5)
With concomitant UI surgery	40 (4.0)
With concomitant POP surgery	85 (8.5)
Total	**1005**

Figure 5: *Sole procedures and procedures with concomitant operations*



CHAPTER 5: Complications

5.1 COMPLICATIONS RECORDED

The database records prespecified intraoperative and postoperative complications. They are:

1. Ureteric injury
2. Bladder injury
3. Vaginal buttonhole
4. Urethral injury
5. Bowel injury
6 Vascular injury
7. Neurological injury
8. Estimated blood loss >500 ml
9. Perioperative blood transfusion
10. Thromboembolism
11. Return to theatre within 72 hours of the procedure
12. Catheterisation >10 days
13. Readmission within 30 days of the procedure
14. Death

5.2 ASSIGNMENT OF RISK FOR COMPLICATIONS

The incidence of each intraoperative and postoperative complication was assigned a level of risk based on guidance by the Royal College of Obstetricians and Gynaecologists[3] (*Table 11*).

Table 11: *RCOG assignment of risk*

Term	Equivalent numerical ratio	Colloquial equivalent
Very common	1/1 to 1/10	A person in a family
Common	1/10 to 1/100	A person in a street
Uncommon	1/100 to 1/1000	A person in a village
Rare	1/1000 to 1/10 000	A person in a small town
Very rare	Less than 1/10 000	A person in a large town

5.3 INCIDENCE OF COMPLICATIONS

The most common intraoperative complications were blood loss >500 ml (1.4%) followed by urethral injury (1.2%) and bladder injury (0.8%) (*Table 12*).

The most common postoperative complications were catheterisation >10 days (3.2%) followed by reoperation within 72 hours (0.6%) and readmission within 30 days (0.6%) (*Table 12*)

Table 12: *Intraoperative and postoperative complications*

Complication (recorded outcomes)	Incidence n (%)	Risk
Ureteric injury (966)	1 (0.1)	1 in 1000 Uncommon
Bladder injury (968)	8 (0.8)	1 in 125 Uncommon
Vaginal buttonhole (916)	3 (0.3)	1 in 333 Uncommon
Urethral injury (916)	11 (1.2)	1 in 83 Common
Bowel injury (967)	5 (0.5)	1 in 200 Uncommon
Vascular injury (966)	0	Very Rare
Neurological injury (966)	0	Very Rare
Estimated blood loss >500 ml (967)	14 (1.4)	1 in 71 Common
Perioperative blood transfusion (964)	3 (0.3)	1 in 333 Uncommon
Thromboembolism (956)	0	Very Rare
Death (956)	1 (0.1)	1 in 1000 Rare
Return to theatre within 72 hours (484)	3 (0.6)	1 in 167 Uncommon
Catheterisation >10 days (466)	15 (3.2)	1 in 31 Common
Readmission within 30 days (467)	3 (0.6)	1 in 167 Uncommon

CHAPTER 6: Follow-up

6.1 FOLLOW-UP METHOD AFTER SURGERY

Prespecified methods of follow-up can be recorded in the database. The follow-up method was recorded in 43% (442) of episodes. 97.5% (431) were followed-up in clinic (*Table 13*).

Table 13: *Follow-up method*

	n (%)
Unrecorded	563
Outpatient visit	431 (97.5)
Postal questionnaire	1 (0.2)
Telephone response	10 (2.3)
Total	**1005**

6.2 FOLLOW-UP INTERVAL AFTER SURGERY

The database records the interval to the 1st follow-up after surgery at 4 prespecified intervals: 6 weeks, 3 months, 6 months and 1 year.

438 (44%) episodes had the 1st follow-up interval recorded. The 1st follow-up occurred most frequently at 3 months (64.6%) (*Table 14*).

Table 14: *Follow-up interval after surgery*

	n (%)
Unrecorded	567
6 Weeks	88 (20.1)
3 Months	283 (64.6)
6 Months	59 (13.5)
12 Months	8 (1.8)
Total	**1005**

6.3 PATIENT-REPORTED OUTCOME MEASURES

The database allows the recording of PGI-I for urinary incontinence and pelvic organ prolapse after surgery (*Table 15*). Although they are relevant secondary outcome measures, they do not tell us whether the main mesh-related problems, such as pain and mesh erosion/exposure, have resolved. Improvement in incontinence was reported in 40% of episodes but it was not possible to determine if this was due to an improvement in urge leakage or concomitant continence procedures. A deterioration in UI was reported in 34%, possibly resulting from the loss of suburethral support after mesh excision.
The option of recording pre and postoperative pain on a visual analogue scale was introduced to the database at the end of 2019 to improve the capture of PROMs.

Table 15: *PGI-I for incontinence and prolapse*

	PGI-I UI	PGI-I POP
Unrecorded	755	879
Very much better	29 (11.6)	44 (34.9)
Much better	48 (19.2)	18 (14.3)
A little better	23 (9.2)	2 (1.6)
No change	65 (26.0)	56 (44.4)
A little worse	39 (15.6)	3 (2.3)
Much worse	30 (12.0)	2 (1.6)
Very much worse	16 (6.4)	1 (0.8)
Total	**1005**	**1005**

APPENDIX A: MHRA data

Table 16: *Mesh-related incidents reported to the MHRA from 2014-2019*

	For POP		For SUI		Indication unknown	
Year	**Reported by professional users**	**Reported by MOP**	**Reported by professional users**	**Reported by MOP**	**Reported by professional users**	**Reported by MOP**
2014	48	3	86	22	1	0
2015	61	24	85	89	6	6
2016	25	15	81	27	18	10
2017	57	50	184	115	52	231
2018	102	118	286	263	148	149
2019	88	34	248	47	227	30

MOP – members of public

Accompanying statement from the MHRA regarding above data

When using this data, is important to note the following:

- These figures cannot be used to estimate complication rates. While complication rates only form part of the picture, they have been a prominent part of the wider public debate. The rates will vary based on which source is examined.
- As always, these figures need to be interpreted with caution, consideration must be given to the individual procedures being undertaken, skill of the surgeon, the temporal relation to the procedure, the severity of the complication and what actions, if any, were required to address the complication.
- This data includes surgical mesh for SUI/POP by different surgical approaches, for example transvaginal, retropubic and abdominal. We are unable to break this down as this is not a mandatory field in the Yellow Card Scheme and may be unknown to the reporter. This is one of the reasons why adverse incident data is not solely relied on and other data is collected and analysed.
- These numbers are accurate at the time they are extracted from our database (January 2020) and minor changes in the numbers can occur if more details are provided later.
- A report does not necessarily represent an individual woman – people may report an incident at any time after the event and people can make multiple reports. Where possible, multiple reports for the same event are linked, however as reporters are not required to complete all fields, every duplicate cannot always be linked.
- These figures include a range of recognised complications related to this type of surgical procedure and do not necessarily indicate a fault with any particular device.
- The 2 conditions and treatment of SUI and POP are quite different. Therefore, the number of events by the indication of use have been separated.
- Some reports do not include the necessary information to determine what condition the mesh was used to treat – these are listed under 'unknown'.

REFERENCES

1) Letter from NHS England and NHS Improvement to trust medical directors regarding 'high vigilance restriction' procedures. July 2018.

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2) MHRA email communication. January 2020.

3) Understanding how risk is discussed in healthcare. Royal College of Obstetricians and Gynaecologists. 2015.

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