BRITISH SOCIETY OF UROGYNAECOLOGY (BSUG)

VAGINAL VAULT SUSPENSION SURGERY IN THE UK 2008-2017

SUMMARY REPORT

BSUG AUDIT AND DATABASE COMMITTEE 2019

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ABBREVIATIONS

British Society of Urogynaecology (BSUG)

National Institute for Health and Care Excellence (NICE)

Royal College of Obstetricians and Gynaecologists (RCOG)

National Health Service (NHS)

Hospital Episode Statistics (HES)

Global impression of improvement (GII)

Preface

The British Society of Urogynaecology (BSUG) database has been available online since 2007. It allows BSUG members to record details of procedures performed to treat urinary incontinence and pelvic organ prolapse. Although voluntary, use of the database is recommended by The National Institute for Health and Care Excellence (NICE). In addition, since July 2018, its use is required for 'high vigilance restriction' procedures [1].

The main aim of the BSUG database is to allow outcomes of individual operations to be studied in detail. Thanks to the commitment of BSUG members - and the patients who kindly allowed their data to be recorded – the database has been extremely successful. Currently more than 140 000 individual surgical episodes have been recorded by many consultants and centres. There have also been many publications which are listed on the BSUG website.

Individual consultants use the BSUG database to examine their own practice and for annual appraisal. It is also one of the requirements to become a BSUG accredited urogynaecology centre.

Continual improvements have been made to the BSUG database by many consultants who have worked in their own time without payment. While not perfect, the large number of cases entered by many consultants allows a valid assessment of the outcome of prolapse and incontinence procedures in the UK to be made.

This is the first National Report on Vaginal Vault Suspension Surgery from the BSUG Audit and Database Committee and includes the first full 10 years of data collection (2008 – 2017). We have included information on national trends and details about the four most commonly performed procedures for the treatment of apical prolapse: Sacrocolpopexy, sacrohysteropexy, sacrospinous colpopexy and sacrospinous hysteropexy. A conscious decision was taken to not interpret or comment on the results apart from where an explanation is necessary.

Thank you again to the patients and BSUG members who have contributed to this report which we hope you will find useful.

BSUG Audit and Database Committee 2019

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 and pelvic organ prolapse from the UK and is open to BSUG members. Access to the database is password-protected and the database is held within the secure NHS N3 network. Data entry is self-reported and voluntary but is recommended by NICE and is currently required for a centre to be accredited in urogynaecology by BSUG. Patient consent is required for data entry.

1.2 DATABASE USAGE

From 2008 to 2017, 116 037 procedures for urinary incontinence and prolapse were entered onto the database. There were 145 centres which entered data and these included teaching hospitals, district general hospitals and private hospitals. The cases entered also include operations carried out by trainees on patients under the care of consultants. These cases are included in the audit as they cannot be easily separated.

1.3 AUDIT TIMEFRAME AND OPERATIONS INCLUDED

The timeframe of the audit was from the start of 2008 (the first full year of online data collection) to the end of 2017. We have also shown the number of procedures undertaken in 2018 but have not analysed their outcomes because at the time of writing this report many patients had not completed their follow-up.

The 6 vaginal vault suspension operations which have been included in this audit are:

- Laparoscopic sacrocolpopexy (laparoscopic cervicopexy is included in this group)
- Open sacrocolpopexy (open cervicopexy is included in this group)
- Laparoscopic sacrohysteropexy
- Open sacrohysteropexy
- Sacrospinous colpopexy
- Sacrospinous hysteropexy

Vaginal vault suspension operations could be sole procedures or part of a combination of procedures, usually for pelvic organ prolapse but sometimes also for incontinence. Sole procedures cannot automatically be separated from procedures with concomitant operations using the current functions of the database and was done manually. Detailed reports on each vault suspension operation will be published separately.

1.4 OUTCOMES

1.4.1 FOLLOW-UP INTERVAL AFTER SURGERY

The database records the 1st follow-up after surgery at 4 prespecified intervals of 6 weeks, 3 months, 6 months and 1 year. How the follow-up was carried out can also be recorded *(Table 1)*.

Table 1: *Method of follow-up.*

Outpatient visit
Postal questionnaire
Online questionnaire
Telephone follow-up
Follow-up at the GP practice

1.4.2 GLOBAL IMPRESSION OF IMPROVEMENT (GII) AFTER SURGERY

The outcome of surgery was assessed by looking at the patient-reported global impression of improvement (GII). The scale has 7 outcome categories and is specific to an improvement in prolapse *(Table 2)*. Vaginal vault operations may have been carried out along with other concomitant procedures that may have a confounding effect on GII. Therefore, GII for both sole procedures and procedures with concomitant operations are reported separately. As the functions of the database only generate the overall GII automatically, data was analysed manually to obtain this information.

Table 2: *Global impression of improvement after surgery.*

Very much better
Much better
A little better
No change
A little worse
Much worse
Very much worse

1.4.3 SURGICAL COMPLICATIONS

The database records prespecified intraoperative and postoperative complications *(Table 3 & 4)*.

Table 3: *Intraoperative complications.*

Ureteric injury
Bladder injury
Bowel injury
Urethral injury
Nerve injury
Estimated blood loss > 500 ml

Table 4: *Postoperative complications.*

Graft complications (where relevant)
Blood transfusion
Thromboembolism
Return to theatre within 72 hours of the procedure
Catheterisation > 10 days
Readmission within 30 days of the procedure
Death

The database allows users to record the occurrence of postoperative 'graft complications'. It does not specify the exact nature of the complication and could encompass various mesh-related problems including pain, urinary symptoms, infection and mesh exposure or erosion. It was therefore not possible to categorise mesh complications more precisely for this report, but much more detailed assessments have now been added to the BSUG database.

It is important to note that vaginal vault operations may have been carried out along with other concomitant procedures that may have a confounding effect on the complication rate. Therefore, the rate for both sole procedures and procedures with concomitant operations are reported separately. As the functions of the database only generate the overall complication rate automatically, data was analysed manually to obtain this information.

1.4.4 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 (RCOG) [2] *(Table 5)*.

Table 5: *Assignment of risk for complications.*

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

CHAPTER 2: Summary of findings and general trends

2.1 VAGINAL VAULT SUSPENSION PROCEDURES 2008-2018

For the timeframe 2008 to 2017 inclusive, there were 17 572 procedures which have been included in this audit. Overall, sacrospinous colpopexy was the most frequently performed vault suspension procedure (9028, 51.4%).

We have also shown the number of vaginal vault suspension procedures added to the BSUG database in 2018 but have not included them in the overall analysis because at the time of writing this report many patients had not completed their follow-up. The 2018 numbers are of interest as sacrocolpopexies and sacrohysteropexies were classified as 'high vigilance restriction' procedures by NHS England in July 2018 [1]. *Figure 1* and *Table 6* show the number of procedures per year for each of the operations.

Figure1: *Number of vault suspension procedures added to the BSUG database per year 2008 – 2018.*

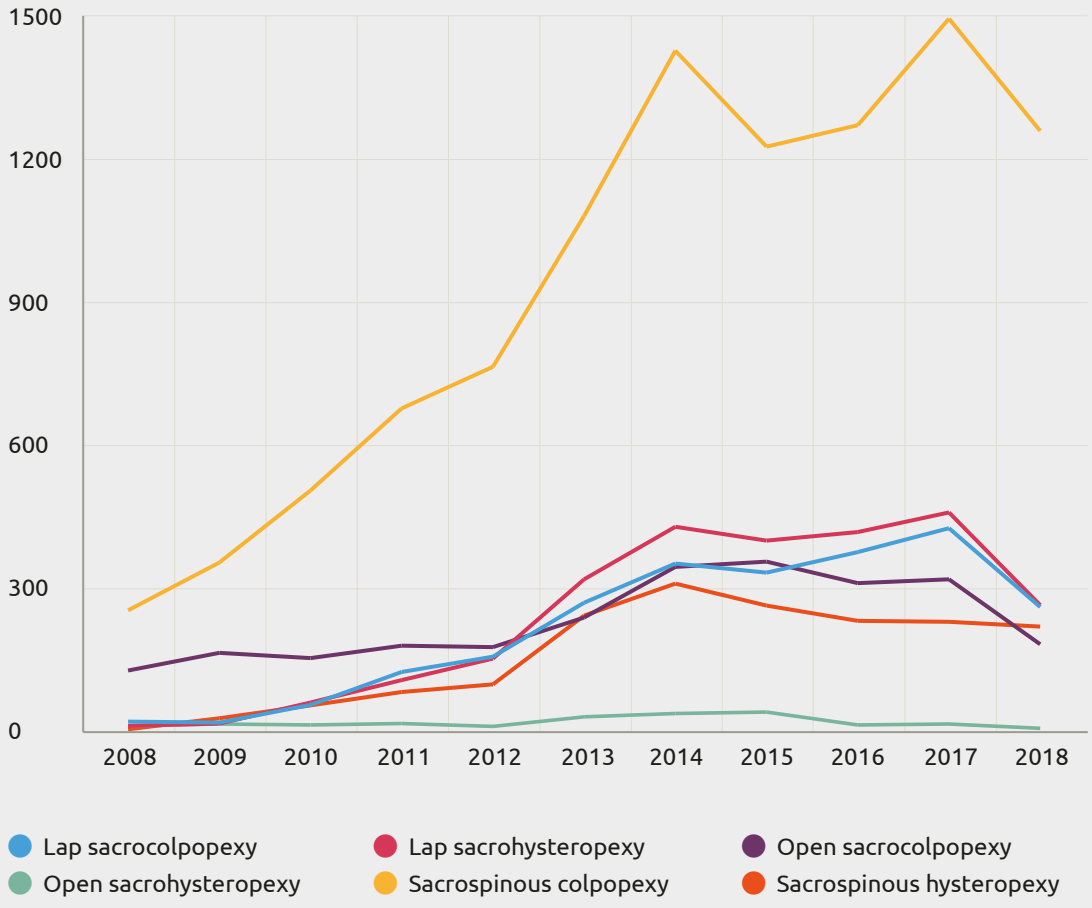

Table 6: *Number of vault suspension procedures added to the BSUG database per year 2008 – 2018.*

	Lap sacrocolpopexy	Lap sacrohysteropexy	Open sacrocolpopexy	Open sacrohysteropexy	Sacrospinous colpopexy	Sacrospinous hysteropexy
2008	19	10	126	10	252	3
2009	17	15	163	14	352	26
2010	54	59	152	12	503	53
2011	123	106	178	15	675	81
2012	155	151	175	9	762	97
2013	268	317	237	29	1078	241
2014	350	427	343	36	1424	308
2015	331	398	354	39	1223	262
2016	374	416	309	12	1268	230
2017	424	457	317	14	1491	228
2018	259	263	181	5	1256	218
Total	**2374**	**2619**	**2535**	**195**	**10284**	**1747**

Note: 2019 figures are not included in the audit analysis

2.2 CHANGES IN THE NUMBER OF VAGINAL VAULT PROCEDURES RECORDED 2017-2018

There was a fall in the number of all 6 vault suspension procedures added to the BSUG database in 2018 compared with 2017 *(Table 7)*. As expected, the falls were greatest in the procedures utilising mesh although a reduction in numbers for non-mesh procedures was also seen. We have not made a comparison with Hospital Episode Statistics (HES).

Table 7: *Fall in the number of vaginal vault suspension procedures added to the BSUG database in 2018 compared with 2017.*

	2017	2018	n	%
Lap sacrocolpopexy	424	259	-165	-38.9%
Lap sacrohysteropexy	456	263	-193	-42.3%
Open sacrocolpopexy	317	181	-136	-42.9%
Open sacrohysteropexy	14	5	-9	-64.3%
Sacrospinous colpopexy	1491	1256	-235	-15.8%
Sacrospinous hysteropexy	228	218	-10	-4.4%

CHAPTER 3: Surgery for recurrent prolapse

3.1 SURGERY FOR RECURRENT PROLAPSE

Open and laparoscopic sacrocolpopexy were the procedures performed most commonly for recurrent prolapse (45.3% and 46.4% respectively) *(Figure 2, Table 8)*.

Figure 2: *Surgery for recurrent prolapse.*

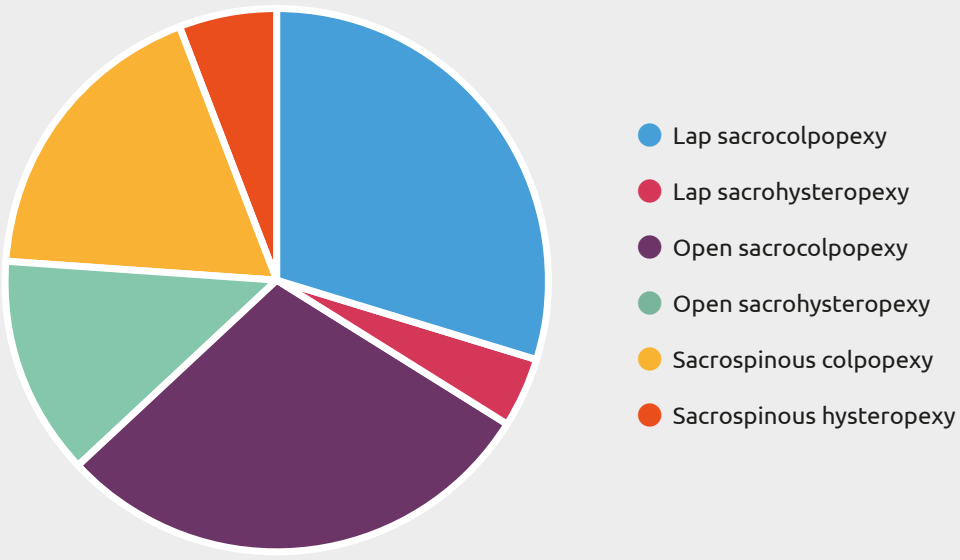

Table 8: *Surgery for recurrent prolapse.*

	Surgery for recurrent prolapse (%)
Lap sacrocolpopexy	46.4
Lap sacrohysteropexy	6.4
Open sacrocolpopexy	45.3
Open sacrohysteropexy	20.1
Sacrospinous colpopexy	27.8
Sacrospinous hysteropexy	8.9

CHAPTER 4: Outcomes of surgery

4.1 GLOBAL IMPRESSION OF IMPROVEMENT (GII) AFTER VAULT SUSPENSION PROCEDURES

GII was recorded at the first follow-up in:

- Lap sacrocolpopexy 64.4% of episodes (1363 of 2115)
- Lap sacrohysteropexy 64.2% of episodes (1512 of 2356)
- Open sacrocolpopexy 61.9% of episodes (1456 of 2354)
- Open sacrohysteropexy 66.8% of episodes (127 of 190)
- Sacrospinous colpopexy 59.6% of episodes (5381 of 9028)
- Sacrospinous hysteropexy 59.0% of episodes (902 of 1529)

For all 6 vault suspension procedures, more than 90% of first follow-ups occurred at or before 6 months. *Figure 3* and *Table 9* show episodes with Much Better (MB) or Very Much Better (VMB) GII for prolapse at the first follow-up.

Open sacrohysteropexy (97.6% MB or VMB) and open sacrocolpopexy (96.1% MB or VMB) were the most effective procedures overall. Non-mesh procedures, sacrospinous colpopexy (90.4% MB or VMB) and sacrospinous hysteropexy (90.2% MB or VMB) also appeared to have good success rates in the relatively short follow up period where data was available.

Figure 3: *Percentage of patients after vault suspension procedures reporting Much Better or Very Much Better GII.*

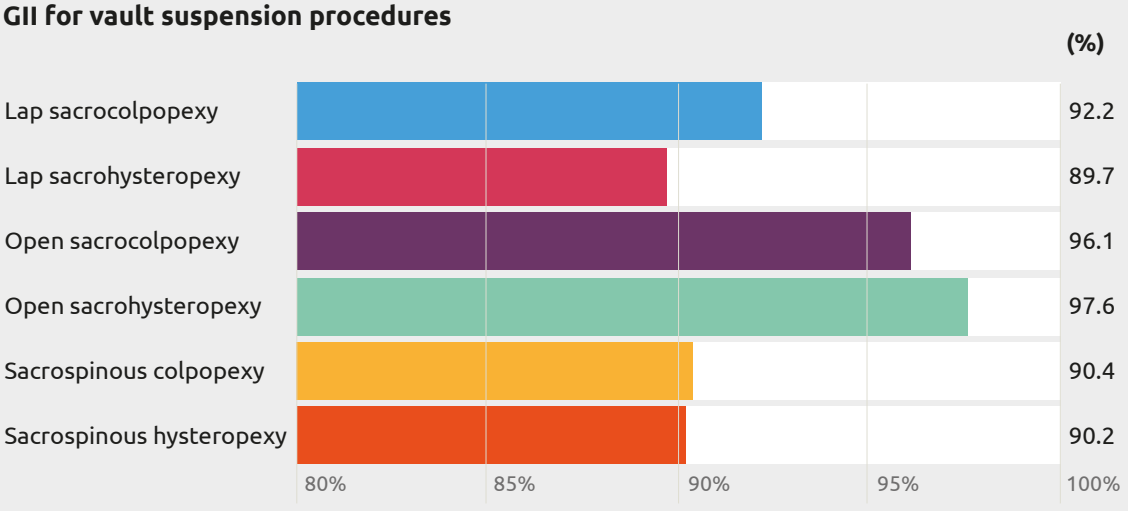

Table 9: *Percentage of patients after vault suspension procedures reporting Much Better or Very Much Better GII.*

	GII %	n
Lap sacrocolpopexy	92.2	1257
Lap sacrohysteropexy	89.7	1356
Open sacrocolpopexy	96.1	1400
Open sacrohysteropexy	97.6	124
Sacrospinous colpopexy	90.4	4865
Sacrospinous hysteropexy	90.2	814

CHAPTER 5: Complications

5.1 INTRA-OPERATIVE AND POST-OPERATIVE COMPLICATIONS

The intraoperative and postoperative complications for each procedure are shown in *Table 10.* The rates include vault suspension procedures with concomitant operations which may have a confounding effect. A much more detailed analysis of individual complications in procedures with and without concomitant operations will be shown in subsequent reports. 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 (RCOG) [2].

Overall, when the intraoperative and postoperative rates were combined, open sacrocolpopexy had the highest complication rate (11.4%) and laparoscopic sacrohysteropexy the lowest (5.1%).

Table 10: *Intraoperative and postoperative complications.*

	Incidence of complications (%)			
	Intraoperative	**Risk**	**Postoperative**	**Risk**
Lap sacrocolpopexy	2.4	Common	7.1	Common
Lap sacrohysteropexy	0.9	Uncommon	4.2	Common
Open sacrocolpopexy	2.3	Common	9.1	Common
Open sacrohysteropexy	2.6	Common	7.7	Common
Sacrospinous colpopexy	1.6	Common	8.3	Common
Sacrospinous hysteropexy	1.2	Common	6.2	Common

5.2 GRAFT COMPLICATIONS

The reported rate of postoperative graft complication for the procedures utilising mesh is shown in *Table 11*. The database allows the presence or absence of a 'graft complication' to be recorded. However, the term is non-specific and may refer to a variety of mesh-related problems. As such, it was not possible to categorise mesh complications more precisely.

Postoperative graft complications were less common after sacrohysteropexy compared with sacrocolpopexy. An exact incidence of postoperative graft complications was difficult to obtain due to the lack of long-term follow-up and missing values. In addition, use of the database is voluntary and can only be accessed by BSUG members. These factors are likely to result in an underestimation of the incidence.

Table 11: *Postoperative graft complication.*

	Postoperative graft complication (%)	Episodes with follow-up, n (%)
Lap sacrocolpopexy	1.4	1108 (52.4%)
Lap sacrohysteropexy	0.5	1313 (55.7%)
Open sacrocolpopexy	0.9	965 (41.0%)
Open sacrohysteropexy	0	83 (43.7%)

CHAPTER 6: Limitations of the audit

6.1 LIMITATIONS OF THE AUDIT

Not every operation performed for the treatment of vault prolapse over the last 10 years has been included in this analysis as use of the database is voluntary and open only to BSUG members. Some procedures will have been performed by surgeons who are not members of BSUG. A comparison to HES has not been made.

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 so for long-term complications which may arise after the initial period of follow-up and which may have been treated in other units.

REFERENCES

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

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