



BRITISH SOCIETY OF UROGYNAECOLOGY (BSUG)

STRESS URINARY INCONTINENCE SURGERY IN THE UK 2020-2021 TRENDS DURING PANDEMIC

3RD NATIONAL REPORT

BSUG AUDIT AND DATABASE COMMITTEE 2022

Contents

Abbreviations	3
Preface	4
Summary of report	5
CHAPTER 1 Introduction	6
1.1 BSUG database	6
1.2 Database usage	6
1.3 Audit timeframe and operations included	6
1.4 Pre-procedure work up	6
1.5 Length of stay	7
1.6 Outcomes	7
CHAPTER 2 General Trends	10
CHAPTER 3 Primary and Repeat Non-mesh Procedures for SUI	12
CHAPTER 4 Pre-procedure Work up for Non-mesh Continence Surgeries	13
CHAPTER 5 Length of Stay for Bladder Neck Injections	14
CHAPTER 6 Outcome of Non-mesh continence procedures	15
6.1 Follow up data	15
6.2 Global impression of improvement for incontinence at variable follow up interval	16
6.3 Change in urgency	17
6.4 Persistent pain	18
6.5 Needing catheters at the time of follow up	18
CHAPTER 7 Complications of Non-mesh continence procedures	19
7.1 Peri-operative complications	19
7.2 Postoperative complications	20

Abbreviations

- Autologous Fascial Sling (AFS)
- Bladder Neck Injection (BNI)
- British Society of Urogynaecology (BSUG)
- Pelvic Floor Exercises (PFE)
- Patient Reported Global Impression of improvement (PGI-I)
- Hospital Episode Statistics (HES)
- Mid-Urethral Tape (MUT)
- Multi-Disciplinary Team (MDT)
- National Health Services England (NHSE)
- Retropubic Mid-Urethral Tape (RP MUT)
- Royal College of Obstetricians and Gynaecologists (RCOG)
- Stress Urinary Incontinence (SUI)
- Transobturator Mid-Urethral Tape (TO MUT)
- Urodynamic Studies (UDS)

Preface

The British Society of Urogynaecology (BSUG) Audit Database has been available online since 2007. It enables BSUG members to record the details of surgical procedures for urinary incontinence and pelvic organ prolapse so that their outcomes can be evaluated. Although voluntary, use of the database is recommended by the National Institute for Health and Care Excellence (NICE) and is necessary for urogynaecology units to attain BSUG accreditation. Thanks to the commitment of BSUG members and the patients who kindly allowed their data to be recorded, the database has been very successful. Currently, more than 160000 surgical episodes have been recorded from a large number of consultants and centres. Information from the database has allowed numerous national audits on urogynaecological procedures to be produced by BSUG. It has also generated 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.

Improvements to the relevance and functionality of the database are continuously being made thanks to many consultants who have worked in their own time without payment. Despite its imperfections, the large number of cases allows a valid assessment of the outcome of prolapse and incontinence procedures in the UK to be made.

The 1st National Report on Stress Urinary Incontinence Surgery from the BSUG Audit Database was published in 2018 and included the first 10 years of data collection (2008 – 2017). Information on national trends and outcomes for the five most commonly performed procedures for stress incontinence were included. This was followed by two further national reports, the 2nd National Report on Stress Urinary Incontinence Surgery in UK (2018-2019) and report on Bladder Neck Injections (2018-2019). Both these reports highlighted the changing trends of continence surgery following the introduction of the high vigilance restriction period. We have followed on with this 3rd National Report which includes stress incontinence surgical procedures undertaken in 2020 and 2021. In March 2020, National Lockdown was started due to COVID-19 pandemic. Nationally, all non-urgent elective surgery was stopped in order to make resources available for managing the pandemic. This greatly affected the continence surgery. This report shows the change in trends due to the impact of the pandemic.

Summary of Report

In 2020 and 2021, 3030 stress incontinence procedures were recorded in BSUG database by 111 centres.

In the 2nd National Report, we had seen that due to the NHSE 'pause' on vaginal mesh procedures since July 2018, there had been a significant increase in the number of autologous fascial sling (AFS), colposuspension (open and laparoscopic) and bladder neck Injection (BNI) procedures. There had only been a very small number of retropubic mid-urethral tape (RP MUT) procedures recorded in the BSUG database since the 'pause' was introduced. Bladder neck injections (BNIs) had become the most commonly done continence procedure. The other non-mesh continence surgeries, that is, colposuspensions and fascial slings had continued to double each year in 2018 and 2019.

The 3rd National Report highlights the trend of continence procedures with the onset of the COVID-19 pandemic in 2020 and its impact on benign elective surgery. This report highlights that the number of stress incontinence procedures recorded in 2020 and 2021 decreased to about half of the previous two years. However, the proportion of each non-mesh procedure has remained comparable to 2019.

The proportion of procedures for primary vs recurrent incontinence has remained comparable to previous 2 years. In 2020-21, 13% of the colposuspensions, 21% of fascial slings and 27% of BNIs were undertaken for recurrent incontinence.

High vigilance requirements such as pre-operative pelvic floor exercises, urodynamic studies (UDS), multi-disciplinary team (MDT) discussion and provision of procedure specific information were fulfilled in 92-99% of cases.

In 2020 and 21, nearly 29% of BNIs were undertaken as outpatient procedures. This proportion has increased when compared to the previous 2 years when it was about 15%.

Outcome data was recorded in more than 50% of cases. The cure rate for AFS, open colposuspension and laparoscopic colposuspension was 94%, 91% and 83% respectively. For BNIs, the cure rate was 60%. Also, 20-34% of colposuspensions and fascial slings reported improved or cured urgency, whereas, it was reported to have worsened or appeared as a new symptom in 9-15% of these cases. For BNIs these numbers were smaller, being nearly 17% and 5% respectively. At the time of follow up, 5% of open colposuspensions and 8-9% of laparoscopic colposuspensions and fascial slings reported persistent pain while only 1% of BNIs had persistent pain. Need of catheters at the time of follow up was seen in less than 1% of BNIs and laparoscopic colposuspensions versus 3% of open colposuspensions and 9% of fascial slings. Follow up interval ranges from 6 weeks to 12 months, median being 3 months. Peri-operative and post-operative complication rate was low at less than 5%.

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 HSCN (previously called N3) network. Data entry is self-reported and voluntary 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

During the years 2020 and 2021, 3030 stress urinary incontinence (SUI) procedures were added by 111 centres and included teaching hospitals, district general hospitals and private hospitals.

1.3 AUDIT TIMEFRAME AND OPERATIONS INCLUDED

This report has looked at the number of stress incontinence procedures undertaken from the beginning of 2020 to the end of 2021. It was relevant to highlight changes in trends of surgery due to the onset of the COVID-19 pandemic in 2020 and its impact on elective benign surgery. The data was extracted from the BSUG database on 6/3/2022 and hence contains the information added till that date.

Similar to 2019, the MUTs undertaken in 2020-2021 were very few in number and hence were excluded from our subsequent data analysis. Detailed analysis of a large number of MUTs over a 10-year period was reported in BSUG's 1st National Report on Stress Urinary Incontinence Surgery 2008-2017.

The operations included in this report are:

- Bladder neck injection (BNI)
- Open Colposuspension
- Laparoscopic Colposuspension
- Autologous fascial sling (AFS)

1.4 PRE-PROCEDURE WORK UP

The BSUG database records information on presurgical processes. It includes information on whether pre-operative pelvic floor exercises, urodynamic studies, MDT discussion and provision of procedure specific information occurred. We have reported these outcomes as they are either high vigilance requirements or are accepted as components of best practice.

1.5 LENGTH OF STAY

BSUG database records the length of stay and the options available are:

Table 1: *Length of stay options*

Outpatient
Day Case
<24 hour stay
1 day
2 days
3 days
4 days or more

This analysis was undertaken for BNIs only for the purpose of this report as this procedure can be undertaken in a variety of settings varying from outpatient to in patient and it was worth reviewing if there was a change in practice in view of lack of theatre availability during the pandemic.

1.6 OUTCOMES

1.6.1 GLOBAL IMPRESSION OF IMPROVEMENT AFTER SURGERY

The outcome of non-mesh continence surgery was assessed using the patient-reported global impression of improvement (PGI-I). The scale has 7 outcome categories and is specific to an improvement in SUI (*Table 2*).

Table 2: *Global impression of improvement in incontinence after surgery*

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

1.6.2 SURGICAL COMPLICATIONS

The database records pre-specified peri-operative and postoperative complications (Tables 3 & 4).

Table 3: Peri-operative complications

Ureteric injury
Bladder injury
Bowel injury
Vaginal button-hole
Urethral injury
Neurological injury
Blood loss > 500 ml
Blood transfusion
Thromboembolism
Death

Table 4: Postoperative complications with sub-sections recording reason

Return to Theatre for procedure related event within 72 hours	Catheterised for longer than 10 days	Return to Hospital within 30 days for procedure related event	Readmitted to hospital within 30 days for procedure related event
Active Bleeding	Planned Catheterisation	Trial without catheter	Trial without catheter
Drainage of Haematoma	Failed Trial without Catheter	Voiding Difficulty	Voiding Difficulty
Bowel Injury	Indwelling catheter after Bladder Injury	Constipation	Constipation
Bladder Injury	Other	Infection	Infection
Ureteric Injury		Active Bleeding	Active Bleeding
Voiding Difficulty		Haematoma	Haematoma
Other		Bowel Injury	Bowel Injury
		Bladder Injury	Bladder Injury
		Ureteric Injury	Ureteric Injury
		Other	Other

1.6.3 PERSISTENT POST-OPERATIVE PAIN / CHANGE IN URGENCY / NEEDING CATHETER

The database also records additional outcomes following continence surgery and in this audit, the number of cases reporting change in urgency or needing catheter and reporting persistent post-operative pain at the time of follow up was also reviewed. Options for recording change in urgency are shown in *table 5*.

Table 5: *Change in urgency*

Cured
Improved
Never Present
No change
New Symptom
Worse

CHAPTER 2: Methods

2.1 TRENDS OVER LAST 5 YEARS

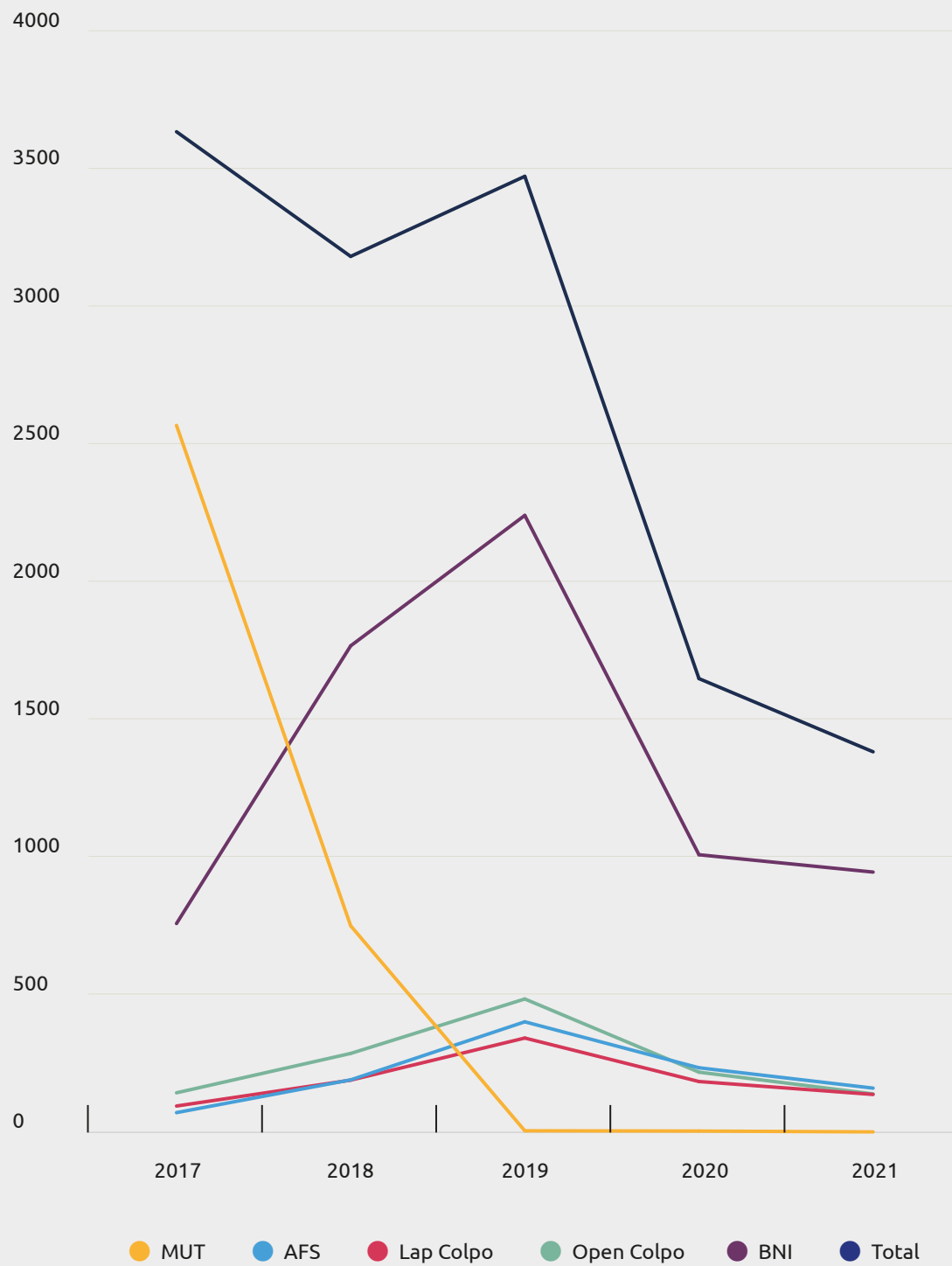
According to the data extracted on 6/3/2022, the total number of stress incontinence procedures recorded on the BSUG database in 2020 and 2021 was 3030.

Table 6: shows the number of continence procedures added to the BSUG database over the five year period from 2017 to 2021.

Year	MUT	AFS	Lap Colpo	Open Colpo	BNI	Total
2017	2568 (70%)	71	95	143	758	3635
2018	750	190	189	286	1767	3182
2019	5	401 (11.5%)	342 (10%)	484 (14%)	2241 (64%)	3473
2020	3	234 (14%)	184 (11%)	218 (13%)	1008 (61%)	1648
2021	1	160 (11.5%)	137 (10%)	139 (10%)	945 (68%)	1382

Since the onset of mesh pause in 2018, BNIs have become the most commonly done continence procedure. The other non-mesh continence surgeries, that is colposuspensions and fascial slings had continued to double each year in 2018 and 2019. With the onset of Covid-19 pandemic in 2020, with its significant impact on elective surgery, the total number of continence procedures decreased to half in 2020 and further decreased in 2021. However the proportion of each non-mesh procedure remained comparable to 2019.

Figure 1: The number of SUI procedures added to the BSUG database each year 2017-2021.



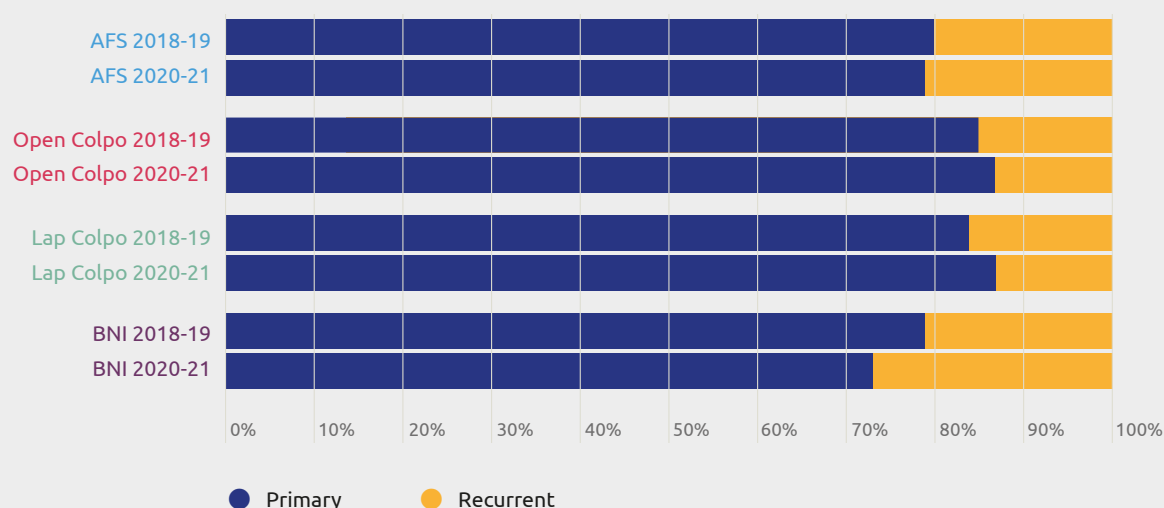
CHAPTER 3: Primary and Repeat Non-mesh Procedures for SUI

The number of procedures for primary and recurrent incontinence for 2018-2019 and 2020-2021 is shown in *Table 7* and *Figure 2*.

Table 7 – The number (%) of primary and repeat procedures for SUI - comparison with previous 2 years data

	Year	n (% excluding unanswered)			
		Unanswered	Primary	Repeat	Total
AFS	2018-2019	49	433 (80%)	109 (20%)	591
	2020-2021	19	297 (79%)	78 (21%)	394
Open Colposuspension	2018-2019	38	621 (85%)	111 (15%)	770
	2020-2021	8	305 (87%)	44 (13%)	357
Laparoscopic Colposuspension	2018-2019	34	418 (84%)	79 (16%)	531
	2020-2021	20	262 (87%)	39 (13%)	321
BNI	2018-2019	239	2978 (79%)	791 (21%)	4008
	2020-2021	120	1349 (73%)	484 (27%)	1953

Figure 2: Proportion of primary and repeat procedures for SUI - comparison with previous 2 years data



In the 2nd national report, we had compared the use of non-mesh procedures for primary and recurrent incontinence with the previous years and had seen that there was a significant increase in use of fascial slings for primary incontinence when compared to the previous years. This seemed to be due to the mesh pause. In the current audit period of 2020 and 2021, it was seen that the proportion of these procedures used for primary or recurrent incontinence remained comparable to the previous years following the mesh pause.

CHAPTER 4: Pre-procedure Work up for Non-mesh Continence Surgeries

The pre-procedure work up prior to undertaking surgery is shown in *Table 8*. Total number of cases in each section excludes the cases where the information was left unanswered. A high rate of compliance for all processes was seen.

Table 8: Pre-operative preparation – pelvic floor exercises, urodynamics, procedure specific information & pelvic floor MDT

		PFE offered and accepted	Pre-op UDS undertaken	Procedure specific information given	Pre-op MDT
AFS	Yes	340	351	356	365
	No. of cases	352	354	361	369
	%	96%	99%	98%	97%
Open Colposuspension	Yes	312	317	311	318
	No. of cases	327	324	316	326
	%	92%	98%	98%	96%
Laparoscopic Colposuspension	Yes	271	281	305	307
	No. of cases	282	295	306	312
	%	93%	97%	99.9%	96%
BNI	Yes	1561	1564	1617	1590
	No. of cases	1644	1694	1642	1706
	%	95%	92%	98%	93%

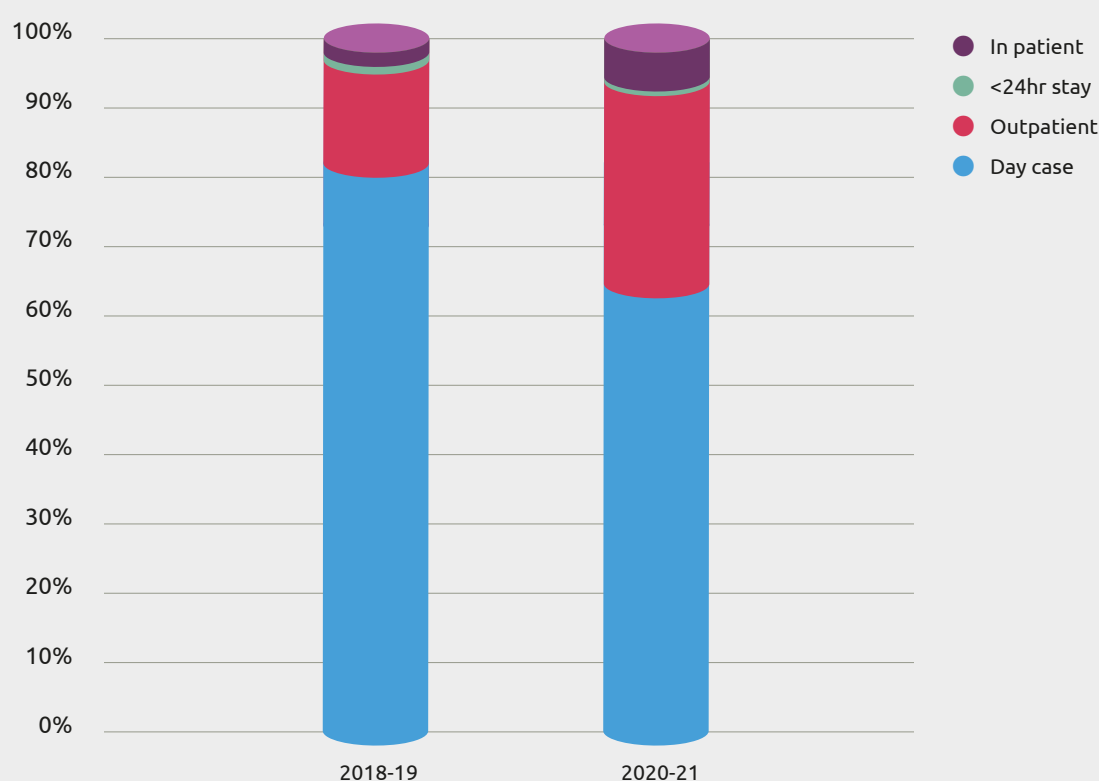
CHAPTER 5: Length of Stay for Bladder Neck Injections

As bladder neck injections can be undertaken in a variety of settings, comparison of the length of stay data for BNIs with the previous two years was undertaken. In the previous 2 years, 15% of BNIs were done as outpatient whereas in 2020 and 21, this proportion increased to 29%. (*Table 9 and Figure 3*). Proportion of inpatient procedures also increased, however it is difficult to say if they were intended to be inpatients or admitted from the out-patient or day case cohort.

Table 9: Length of stay for Bladder Neck Injections

	2018-19	2020-21
In patient 1 to >4 days	50 (2%)	89 (6%)
<24 hr stay	28 (1%)	8 (0.5%)
Day case	2093 (82%)	1011 (64.5%)
Outpatient	384 (15%)	460 (29%)
Total (answered)	2555 (100%)	1568 (100%)

Figure 3 – Comparing length of stay of BNIs with previous two years



CHAPTER 6: Outcome of Non-mesh continence procedures

6.1 FOLLOW UP DATA

The raw data for this report was extracted from the database on 6/3/2022. Follow-up data was recorded in more than 50% of cases. See *Table 10*.

Table 10: Follow up data recorded on database

Follow up outcome recorded	2020	2021	Overall
AFS	130 / 234 (55%)	86 / 160 (54%)	216 / 394 (55%)
Open Colposuspension	136 / 218 (62%)	72 / 139 (52%)	208 / 357 (58%)
Laparoscopic Colposuspension	99/184 (54%)	63 / 137 (46%)	162 / 321 (50%)
BNI	560 / 1008 (56%)	478 / 945 (50%)	1038 / 1953 (53%)

6.2 GLOBAL IMPRESSION OF IMPROVEMENT FOR INCONTINENCE AT VARIABLE FOLLOW UP INTERVAL

The follow-up interval recorded in the database varies from 6 weeks to 12 months. The median follow up interval at which the outcome was recorded was 3 months. The PGI-I for urinary incontinence for each procedure is shown in *Table 11* and *Figure 4*.

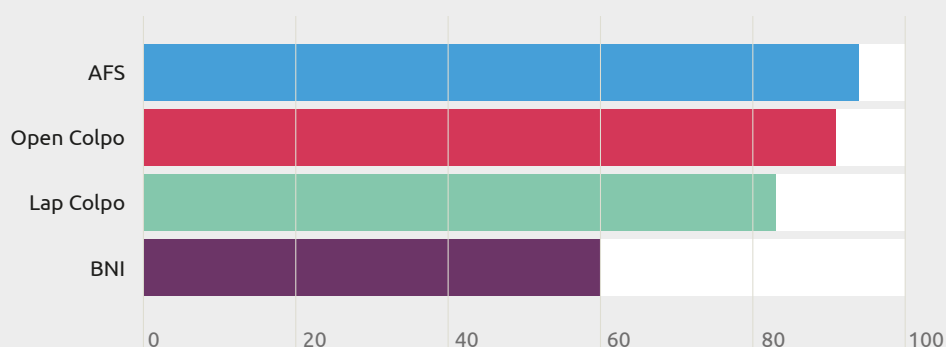
Table 11: PGI-I for incontinence after surgery

	AFS		Open Colpo		Lap Colpo		BNI	
	N	% (N=216)	Cases	% (N=208)	N	% (N=162)	N	% (N=1038)
Unanswered	178	-	149	-	159	-	915	-
Very Much Better	158	73%	140	67%	100	62%	342	33%
Much Better	45	21%	49	24%	35	22%	282	27%
Little Better	8	4%	7	3%	17	10%	206	20%
No Change	3	1.5%	10	5%	8	5%	191	18%
Little Worse	1	0.5%	1	0.5%	1	0.5%	10	1%
Much Worse	0	-	1	0.5%	0	-	5	0.5%
Very Much Worse	1	0.5%	0	-	1	0.5%	2	0.5%
Total	394	100%	357	100%	321	100%	1953	100%
VMB + MB*	203	94%	189	91%	135	83%	624	60%

*VMB + MB – Very much better + much better

Cure was taken to be a PGI-I of 'very much better' and 'much better'. The cure rate for AFS and open colposuspension was high, being more than 90%. The cure rate after laparoscopic colposuspension was slightly lower at 83%. BNIs had a cure rate at 60%.

Figure 4: Percentage of patients reporting Much Better (MB) and Very Much Better (VMB) PGI-I after surgery.



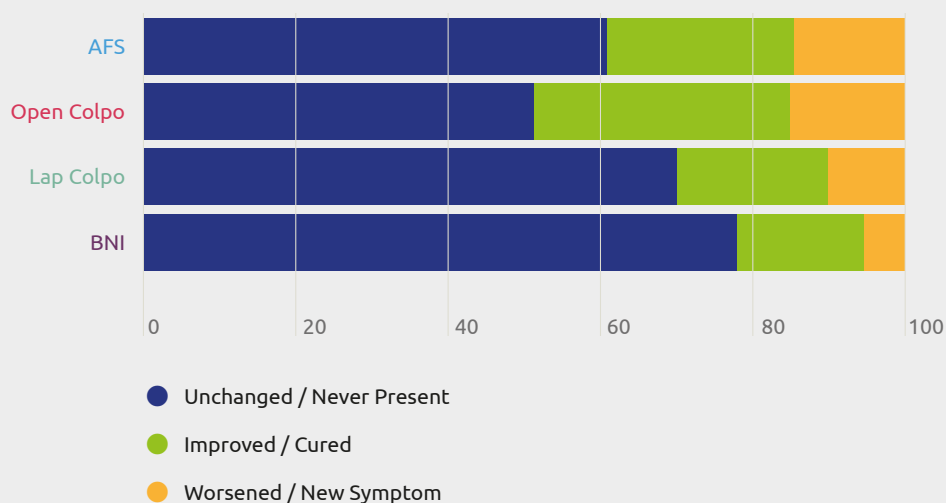
6.3 CHANGE IN URGENCY

BSUG database records change in urgency as one of the outcomes after continence surgery. 9-15% of colposuspensions and fascial slings had worsened or new urgency, while 20-34% reported improved or cured urgency. For BNIs these numbers were smaller, being nearly 5% and 17% respectively (*Table 12*).

Table 12: Change in urgency following continence surgery

Change in Urgency	AFS N=208 (answered)	Open Colpo N=195 (answered)	Lap Colpo N=142 (answered)	BNI N=862 (answered)
Cured	32 (15%)	25 (13%)	11 (8%)	31 (4%)
Improved	20 (9.5%)	40 (21%)	17 (12%)	111 (13%)
Never Present	69 (33%)	61 (31%)	52 (36%)	418 (48%)
No Change	56 (27%)	40 (20%)	48 (34%)	261 (30%)
New Symptom	20 (9.5%)	9 (5%)	7 (5%)	14 (2%)
Worse	11 (5%)	20 (10%)	7 (5%)	27 (3%)

Figure 5: Change in urgency following continence surgery



6.4 PERSISTENT PAIN

Another outcome recorded on the database at the time of follow up is 'Persistent Pain'. In order to exclude any other concomitant procedures that could lead to persistent pain, cases where any concomitant major surgery, prolapse surgery, endometriosis surgery, abdominal mesh insertion or mesh excision was undertaken were manually excluded, however, the overall proportion of patients reporting persistent pain at follow up remained unchanged. 5% of open colposuspensions and 8-9% of laparoscopic colposuspensions and fascial slings reported persistent pain. Persistent pain was reported in only 1% of BNIs (*Table 13*).

Table 13: Persistent Pain at follow up

	AFS	Open Colpo	Lap Colpo	BNI
Persistent Pain	9% 18/209	4.5% 9/196	9% 12/134	1% 11/865
After excluding cases with concomitant mesh excision / endometriosis surgery / a major surgery	8% 16/193	5% 9/179	8% 9/112	1% 9/829

6.5 NEEDING CATHETERS AT THE TIME OF FOLLOW UP

At follow up, if the patient is requiring catheter, it can be recorded in the database and this was looked at as well. 3% of open colposuspensions and 9% of fascial slings required catheter at the time of follow up, whereas, less than 1% of BNIs and lap colposuspensions needed a catheter at this stage (*Table 14*).

Table 14: Needing Catheters at the time of follow up

	AFS	Open Colpo	Lap Colpo	BNI
Needing Catheter	9% 19/213	3% 7/197	0.7% 1/144	0.7% 7/905

CHAPTER 7: Complications

7.1 PERI-OPERATIVE COMPLICATIONS

The peri-operative complications for each procedure are shown in *Table 15*. Total number of cases for each procedure excludes the cases where the information had been left unanswered. Overall intra-operative complication rate for any of these surgeries was recorded to be less than 5%.

Table 15: Intraoperative complications for continence procedures

	AFS			Open Colpo			Lap Colpo			BNI		
	Cases	N	%	Cases	N	%	Cases	N	%	Cases	N	%
Ureteric injury	-	-	-	-	-	-	-	-	-	-	-	-
Bladder injury	17	388	4%	7	353	2%	14	308	4%	1	1911	0.05%
Vaginal buttonhole	2	386	0.5%	-	-	-	-	-	-	-	-	-
Urethral injury	1	386	0.2%	-	-	-	-	-	-	-	-	-
Bowel injury	-	-	-	-	-	-	-	-	-	-	-	-
Vascular injury	-	-	-	-	-	-	-	-	-	-	-	-
Neurological injury	-	-	-	-	-	-	-	-	-	-	-	-
Blood loss >500ml	-	-	-	6	353	2%	-	-	-	-	-	-
Blood transfusion	-	-	-	-	-	-	-	-	-	-	-	-
Thrombo-embolism	-	-	-	-	-	-	-	-	-	-	-	-
Death	-	-	-	-	-	-	-	-	-	-	-	-

7.2 POSTOPERATIVE COMPLICATIONS

The postoperative complications for each procedure are shown in *Table 16*. Total number of cases for each procedure excludes the cases where the information had been left unanswered.

Table 16: Postoperative complications for all continence procedures, sole continence procedures and procedures with concomitant operations

	AFS			Open Colpo			Lap Colpo			BNI		
	Cases	N	%	Cases	N	%	Cases	N	%	Cases	N	%
Return to Theatre <72hrs	2	239	1%	3	228	1%	-	-	-	1	1123	0.1%
Catheterised >10days	24	242	10%	21	229	5%	8	177	4.5%	7	1122	0.6%
Return to hospital <30days	24	240	10%	27	230	12%	8	172	4.5%	14	1119	1%
Readmission <30 days	9	241	4%	6	229	2.5%	1	172	0.5%	1	1118	0.1%

The comments and reasons for each of the complications were manually evaluated. 1 open colposuspension went back to theatre due to kinking of ureter, and 2 went back for problems with wound drain. In addition to the above mentioned numbers, during manual review of other comments, 1 open colposuspension was recorded as having gone back to theatre on day 4, to relieve ureteric obstruction with a stent. Out of the two fascial slings that went back to theatre within 72 hours, one was for rectus sheath haematoma and another was for voiding difficulty. Again reviewing the other comments manually, two other cases of fascial slings were recorded to have gone back to theatre few weeks after surgery for loosening the sling. 1 BNI was reported as gone back to theatre within 72 hours due to voiding dysfunction.

Other complications had overlapping reasons. All the cases were included in the group of return to hospital within 30 days and the reasons varied from voiding difficulty, infection, haematoma, seroma, pain and constipation.

REFERENCES

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

https://i.emlfiles4.com/cmpdoc/9/7/2/8/1/1/files/47633_mesh-letter-to-acute-ceos-and-mds.pdf