



BRITISH SOCIETY OF
UROGYNAECOLOGY (BSUG)

**STRESS URINARY INCONTINENCE SURGERY
IN THE UK 2018-2019**

2ND NATIONAL REPORT

BSUG AUDIT AND DATABASE COMMITTEE 2020

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ABBREVIATIONS

Autologous Fascial Sling (AFS)
Bladder Neck Injection (BNI)
British Society of Urogynaecology (BSUG)
Hospital Episode Statistics (HES)
Mid-Urethral Tape (MUT)
Multi-Disciplinary Team (MDT)
National Health Services England (NHSE)
Patient Reported Global Impression of improvement (PGI-I)
Pelvic Floor Exercises (PFE)
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 150 000 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. We have followed on with this 2nd National Report which includes stress incontinence surgical procedures undertaken in 2018 and 2019. On 10th July 2018, the Secretary of State for Health and Social Care and the Chief Medical Officer announced a 'pause' in the use of synthetic tapes to treat stress urinary incontinence (SUI). In addition, all other continence operations were classified as 'high vigilance' procedures requiring specific preoperative criteria to be met. This report shows the changing trends of continence surgery since the introduction of the high vigilance restriction period. It also provides an indication of whether the specified high vigilance requirements are being met.

Summary of Report

In 2018 and 2019, 6171 stress incontinence procedures were recorded on the BSUG database by 134 centres.

There has been a significant increase in the number of autologous fascial sling (AFS), colposuspension (open and laparoscopic) and bladder neck injection (BNI) procedures undertaken, so much so that the number of procedures recorded in the last 2 years exceed that of the previous 10 years. This trend appears to have started even before the National Health Services England (NHSE) 'pause' on vaginal mesh procedures was introduced in July 2018¹ and has clearly continued. After July 2018, midurethral tape (MUT) operations could only be carried out when there was no suitable alternative treatment and a delay in treatment was unacceptable - subject to high vigilance scrutiny and clearly defined governance arrangements. Since the 'pause' was implemented there have only been a very small number of MUT procedures added to the BSUG database (5 RP MUT procedures and no TO MUT procedures in 2019).

In last 2 years nearly 80% of the non-mesh continence procedures were undertaken for primary stress incontinence, in contrast to the previous 10 years where only 40% of autologous fascial sling (AFS) procedures were undertaken for primary 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 86-99% of cases. The exception was pre-operative pelvic floor exercises for BNI which occurred in 74% of cases.

The cure rate for AFS, open colposuspension and laparoscopic colposuspension was 89%, 88% and 80% respectively. The lower cure rate for laparoscopic colposuspension was found to be statistically significant (p value 0.01). For BNI, the cure rate was 56%.

There was a trend towards continence procedures being less successful when undertaken at the same time as concomitant operations. However, this was only statistically significant for laparoscopic colposuspension, where success rate was seen to be 85% when performed as a sole procedure compared to 70% when performed with another concomitant procedure (p value 0.02).

The risk of intra-operative complications with AFS or colposuspensions was no more than 5%, the commonest complication being bladder injury. The next most common complication was blood loss >500 ml, which was highest in cases where AFS was carried out with concomitant procedures. Other complications such as urethral injury, bowel injury and ureteric injury were seen in less than 1% of cases. BNI cases did not result in any intra-operative complications.

Post-operatively, catheterisation for >10 days was required in 15% of AFS. It occurred in about 5% of colposuspensions and 1% of BNI.

Re-admission within 30 days of the procedure was seen after 13% of AFS and 9% of open colposuspension procedures. Readmissions occurred in less than 5% of cases after BNI and sole laparoscopic colposuspensions.

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

During the years 2018 and 2019, 6171 stress urinary incontinence (SUI) procedures were added by 134 centres and included teaching hospitals, district general hospitals and private hospitals. *Table 1* shows the number of centres reporting each individual continence procedure:

Table 1: Number of centres undertaking each continence procedure

Incontinence Procedure	Number of reporting centres
Retropubic mid-urethral tape (RP MUT)	85
Transobturator mid-urethral tape (TO MUT)	38
Autologous Fascial sling (AFS)	48
Open colposuspension	77
Laparoscopic colposuspension	33
Bladder neck Injection (BNI)	107

1.3 AUDIT TIMEFRAME AND OPERATIONS INCLUDED

This report has looked at the number of stress incontinence procedures undertaken from the beginning of 2018 to the end of 2019. Despite the short timeframe, it was relevant to highlight changes in practice amongst UK urogynaecologists since the mesh 'pause' and the introduction of high vigilance requirements for continence operations in July 2018. Looking at the trend of all stress incontinence surgeries, the MUTs undertaken in 2018-2019 were very few in number as compared to the previous years and hence were excluded from our 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 OUTCOMES

1.5.1 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*). SUI operations may have been carried out along with other concomitant procedures that may have a confounding effect. To mitigate this, the overall PGI-I (inclusive of both sole procedures and those with concomitant operations), PGI-I for sole SUI procedures and PGI-I for SUI procedures with concomitant operations are reported separately. The functions of the database only generate the overall PGI-I automatically. As such, PGI-I for sole procedures was obtained by analysing the data manually.

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

1.5.2 SURGICAL COMPLICATIONS

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

Table 3: *Intraoperative complications.*

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

Table 4: Postoperative complications.

Blood transfusion
Thromboembolism
Return to theatre within 72 hours of the procedure
Catheterisation >10 days
Readmission within 30 days of the procedure
Death

It is important to note that SUI operations may have been carried out along with other concomitant procedures that may have a confounding effect on the complication rate. To mitigate this, the overall complication rate (inclusive of both sole procedures and those with concomitant operations), the complication rate for sole SUI procedures and the complication rate for SUI procedures with concomitant operations are reported separately. The functions of the database only generate the overall complication rate automatically. As such, complication rates for sole procedures were obtained by analysing the data manually.

CHAPTER 2: General Trends

2.1 TRENDS COMPARED TO PREVIOUS REPORT 2008 - 2017

Table 5 shows the number of continence procedures added to the BSUG database during the timeframe of the 1st National Report on SUI Surgery (2008-2017) compared to the last 2 years (2018-2019). It is notable that there have been more non-mesh procedures undertaken in the last 2 years compared to the previous 10 years combined.

Table 5: The number of procedures for SUI added to the BSUG database during the timeframe of the 1st National Report on SUI Surgery (2008-2017) compared to the current study period (2018-2019).

	Number of procedures (% of total continence procedures)					Total
	RP MUT	TO MUT	AFS	Colpo (Open + lap)	BNI	
Total 2008-2017	26765 (67%)	9411 (23.5%)	252 (0.6%)	912 (2.3%)	2621 (6.6%)	39961 (100%)
Total 2018-2019	624 (10%)	182 (3%)	489 (8%)	1186 (19%)	3690 (60%)	6171 (100%)

2.2 CONTINENCE PROCEDURES 2008 - 2019

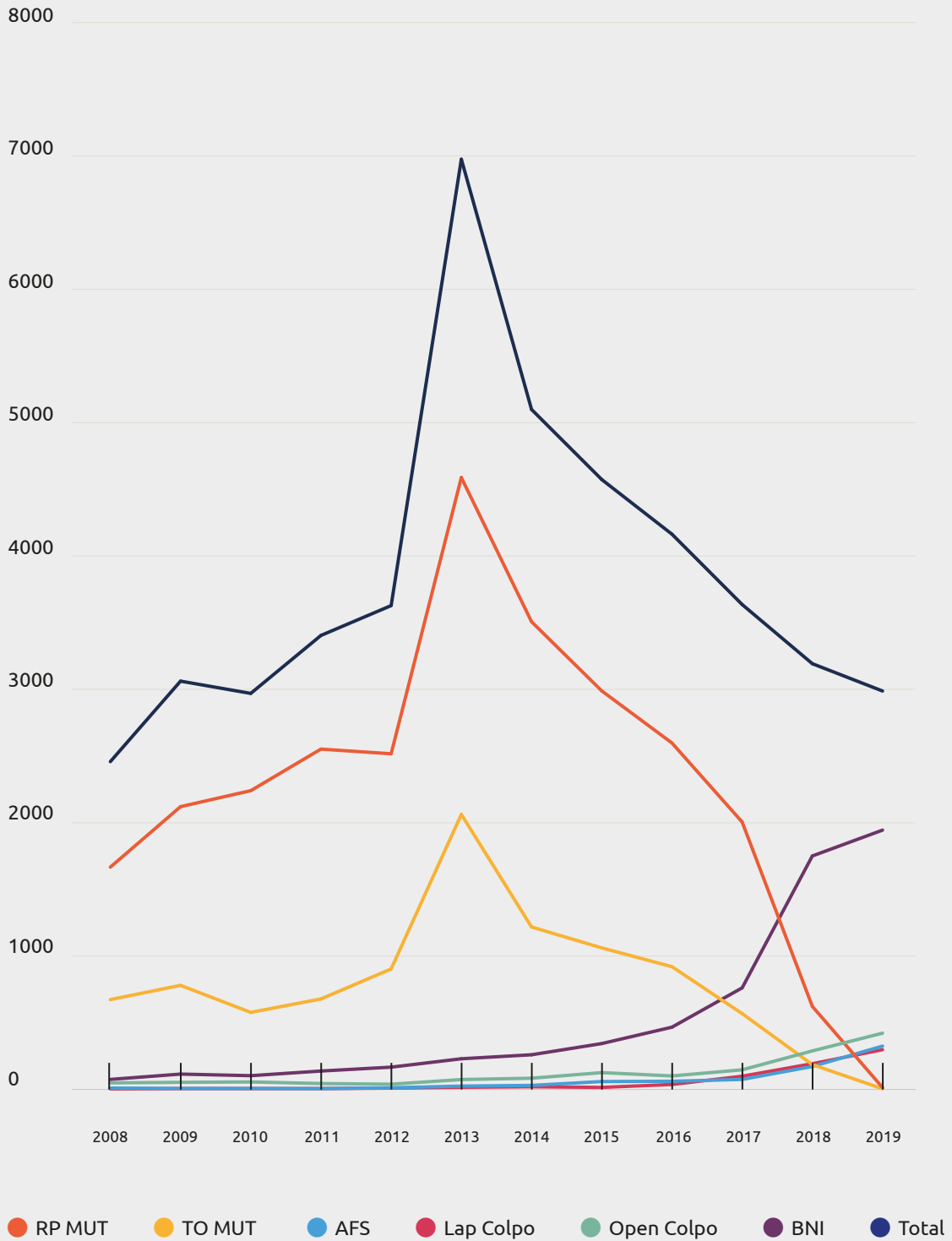
Table 6 and Figure 1 have combined the data from the 1st National Report with the current data to show the trend for each continence procedure. With the introduction of the mesh 'pause', the number of non-mesh procedures more than double in 2018 compared to 2017. In 2019 the numbers increased further. Overall, the total number of incontinence procedures has declined steadily since the peak in 2013.

Bladder Neck Injections have been the most commonly performed procedures in the last two years. Bulkamid has been the most commonly used BNI (92%).

Table 6: The number of SUI procedures added to the BSUG database each year 2008-2019

Year	RP MUT	TO MUT	AFS	Lap colpo	Open colpo	BNI	Total
2008	1664	670	6	0	45	71	2456
2009	2118	777	3	2	49	111	3060
2010	2238	574	3	2	52	99	2968
2011	2550	675	2	2	40	134	3403
2012	2515	900	8	6	35	163	3627
2013	4588	2060	21	12	70	226	6977
2014	3506	1215	26	16	80	256	5099
2015	2987	1058	55	11	122	340	4573
2016	2596	917	57	33	97	463	4163
2017	2003	565	71	95	143	758	3635
2018	619 (19%)	182 (6%)	168 (5%)	189 (6%)	285 (9%)	1748 (55%)	3191 (100%)
2019	5 (0.2%)	0	321 (10.8%)	294 (10%)	418 (14%)	1942 (65%)	2980 (100%)
Total	27389	9593	741	662	1436	6311	46132

Figure 1: The number of SUI procedures added to the BSUG database each year 2008-2019.



CHAPTER 3: Report Validity and Comparison with Hospital Episode Statistics (HES)

The BSUG database allows voluntary reporting of procedures by BSUG members only. SUI procedures carried out in both the NHS and private sector can be entered into the database. It should be noted that continence procedures during this time were also undertaken by urologists and gynaecologists with an interest in continence surgery who may have chosen not to become a BSUG member.

Hospital Episode Statistics (HES) data only includes NHS hospital admissions for SUI procedures in England from all specialties. It excludes procedures carried out in Wales and Scotland and those carried out in the private sector. It should be noted that the description of continence procedures used for HES is not identical to that used in the BSUG database. There are also other differences in the data recorded by HES and the BSUG database which limits direct comparisons.

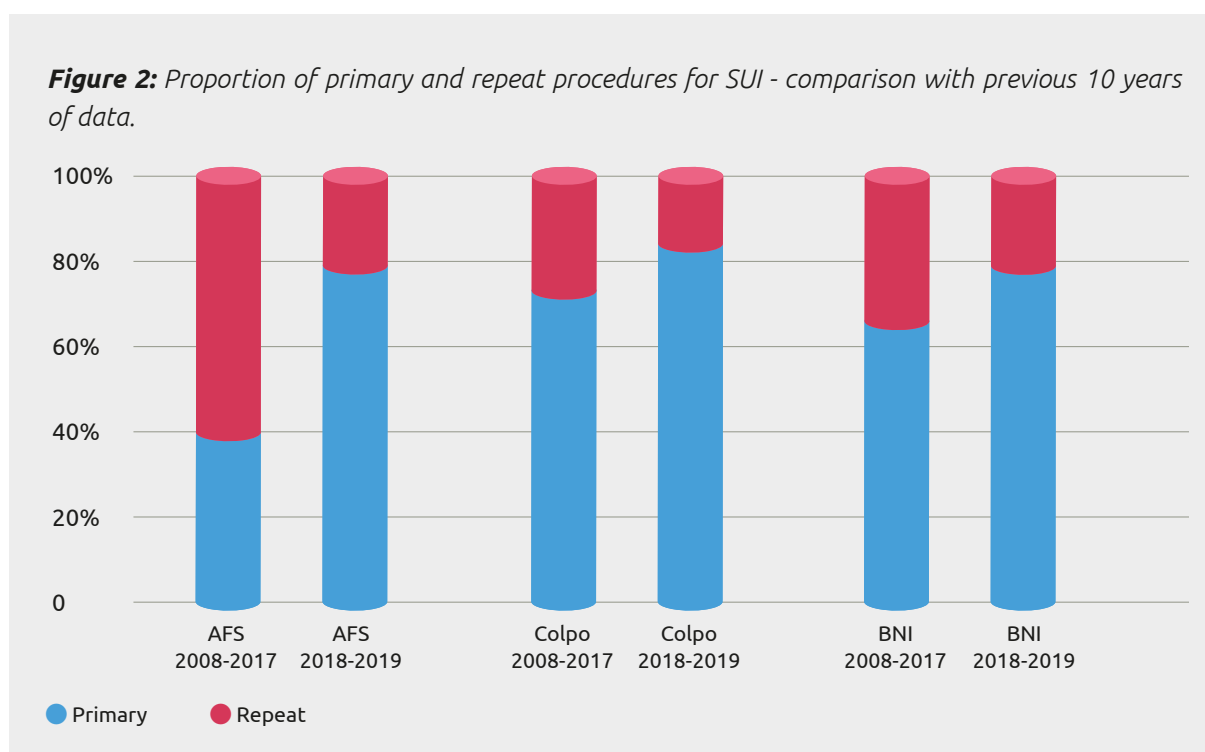
The 1st BSUG National Report (2008-2017) estimated that the BSUG database captured approximately 40% of continence procedures when compared to HES data. Based on the availability of HES data for the period April 2017 to March 2019², data capture had increased to 60%.

CHAPTER 4: Primary and Repeat Non-mesh Procedures for SUI

The number of procedures for primary and recurrent incontinence for 2018-2019 and 2008-2017 is shown in *Table 7* and *Figure 2*.

Table 7: The number (%) of primary and repeat procedures for SUI - comparison with previous 10 years of data.

	Year	n (% excluding unanswered)			
		Unanswered	Primary	Repeat	Total
AFS	2018-2019	44	352 (79%)	93 (21%)	489
	2008-2017	10	98 (40%)	144 (60%)	252
Colposuspension	2018-2019	75	935 (84%)	176 (16%)	1186
	2008-2017	50	628 (73%)	234 (27%)	912
BNI	2018-2019	246	2724 (79%)	720 (21%)	3690
	2008-2017	164	1616 (66%)	841 (34%)	2621



Autologous fascial sling (AFS) was performed for recurrent incontinence in only 21% of cases in the last 2 years compared to 60% of cases in the previous report. Similarly, BNI was undertaken for recurrent incontinence in 21% cases in the last 2 years compared to 34% in the previous report; 16% of colposuspensions undertaken in the last 2 years were for recurrent incontinence compared to 27% in the previous report. This indicates that these operations are now much more likely to be undertaken in patients who have not undergone previous continence surgery.

CHAPTER 5: Pre-procedure Work up for Non-mesh Continenence 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	372	435	400	410
No. of cases	418	444	412	416
%	89	98	97	98.6
Lap colpo				
Yes	373	435	439	439
No. of cases	433	445	444	445
%	86	98	99	98.7
Open colpo				
Yes	583	622	614	604
No. of cases	642	635	622	645
%	91	98	99	93.6
BNI				
Yes	2748	2953	2973	2785
No. of cases	3093	3130	3012	3087
%	74	94	99	90.2

CHAPTER 6: Outcome of Non-mesh Continenence Procedures

The raw data for this report was extracted from the database in January 2020. Follow-up data was available for 58.7% of cases operated on in 2018. As expected, it was lower, at 38.6%, for cases operated on in 2019.

6.1 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 PGH for urinary incontinence for each procedure is shown in *Table 9* and *Figure 3*.

Table 9: PGH for incontinence after surgery.

	AFS		Lap Colpo		Open Colpo		BNI	
	N	% (N=216)	N	% (N=203)	Cases	% (N=352)	N	% (N=1781)
Unanswered	273	-	280	-	351	-	1909	-
Very much better	149	69.0%	128	63.1%	249	70.7%	525	29.5%
Much Better	44	20.4%	35	17.2%	62	17.6%	477	26.8%
Little Better	12	5.6%	20	9.9%	25	7.1%	334	18.8%
No Change	6	2.8%	12	5.9%	11	3.1%	375	21.2%
Little Worse	0	-	4	2.0%	2	0.6%	41	2.3%
Much Worse	1	0.5%	3	1.5%	3	0.9%	22	1.2%
Very Much Worse	4	1.9%	1	0.5%	0	-	7	0.4%
Total	0	100%	483	100%	703	100%	3690	100%
VMB + MB*	193	89.4%	163	80.3%	311	88.4%	1002	56.3%

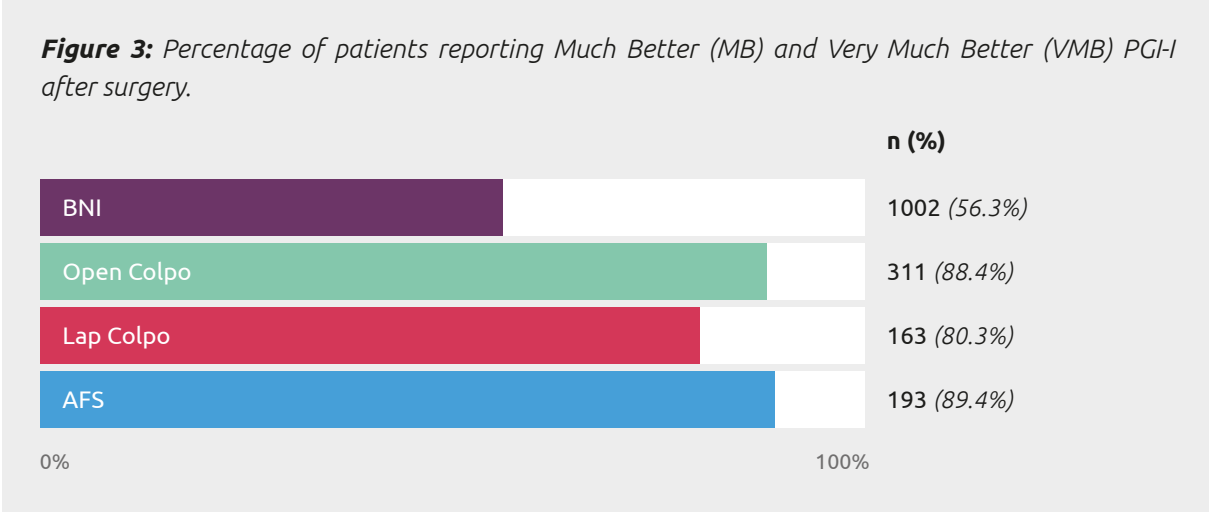
*VMB + MB – Very much better + much better

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 at 89.4% and 88.4% respectively. The cure rate after laparoscopic colposuspension was lower at 80.3%.

The difference in cure rate between laparoscopic colposuspension (80.3%) and AFS (89.4%) was statistically significant (p value 0.01, chi-square).

The difference in success rate between laparoscopic colposuspension (80.3%) and open colposuspension (88.4%) is also statistically significant (p value 0.01, chi-square).

BNI had the lowest cure rate at 56.3%.



6.2 GLOBAL IMPRESSION OF IMPROVEMENT AFTER SOLE PROCEDURES AND THOSE WITH CONCOMITANT OPERATIONS

For each of the procedures, we also looked at the cure rate ('very much better' & 'much better' PGI-I) for sole procedures and those where a concomitant procedure was undertaken (*Table 10*). Total number of cases includes followed up procedures only.

Table 10: PGI-I sole procedures and those with concomitant operations.

	Sole procedure	With concomitant operation	P value (chi square)
AFS			
VMB + MB	148	45	0.39
No. of cases	163	53	
%	90.8	84.9	
Lap colpo			
VMB + MB	118	45	0.02
No. of cases	139	64	
%	84.8	70.3	
Open colpo			
VMB + MB	204	107	0.07
No. of cases	225	127	
%	90.7	84.2	
BNI			
VMB + MB	863	139	0.4
No. of cases	1523	258	
%	56.6	53.9	

VMB + MB – 'Very much better' + 'much better'

CHAPTER 7: Complications of Non-mesh Continence Procedures

7.1 INTRA-OPERATIVE COMPLICATIONS

The intraoperative complications for each procedure are shown in *Table 11*. The 'overall' complication rate is the sum of the complication rate for sole procedures and those with concomitant operations. Total number of cases for each procedure excludes the cases where the information had been left unanswered. Bladder injury was the most common intraoperative injury (3.1 - 5.2%) followed by blood loss >500ml (0.2 – 1.8%).

Table 11: Intraoperative complications for all continence procedures, sole continence procedures and procedures with concomitant operations.

	AFS			Lap Colpo			Open Colpo			BNI		
	Cases	N	%	Cases	N	%	Cases	N	%	Cases	N	%
Ureteric injury												
Overall	0	484	-	1	479	0.2%	0	700	-	0	3634	-
Sole	0	368	0	1	301	0.3%	0	470	-	0	3163	-
Concomitant	0	116	0	0	178	-	0	230	-	0	471	-
Bladder injury												
Overall	21	484	4.3%	25	481	5.2%	22	700	3.1%	0	3634	-
Sole	15	368	4.1%	14	302	4.6%	16	470	3.4%	0	3163	-
Concomitant	6	116	5.2%	11	179	6.1%	6	230	2.6%	0	471	-
Vaginal buttonhole												
Overall	0	484	-	2	479	0.4%	1	700	0.1%	0	3634	-
Sole	0	368	-	1	301	0.3%	0	470	0	0	3163	-
Concomitant	0	116	-	1	178	0.6%	1	230	0.4%	0	471	-
Urethral injury												
Overall	2	484	0.4%	0	479	-	0	700	-	0	3634	-
Sole	1	368	0.3%	0	301	-	0	470	-	0	3163	-
Concomitant	1	116	0.9%	0	178	-	0	230	-	0	471	-
Bowel injury												
Overall	0	484	-	0	479	-	1	700	0.1%	0	3634	-
Sole	0	368	-	0	301	-	0	470	-	0	3163	-
Concomitant	0	116	-	0	178	-	1	230	0.4%	0	471	-
Vascular injury												
Overall	0	484	-	0	479	-	0	700	-	0	3634	-
Sole	0	368	-	0	301	-	0	470	-	0	3163	-
Concomitant	0	116	-	0	178	-	0	230	-	0	471	-
Neurological injury												
Overall	0	484	-	0	479	-	0	700	-	0	3634	-
Sole	0	368	-	0	301	-	0	470	-	0	3163	-
Concomitant	0	116	-	0	178	-	0	230	-	0	471	-
Blood loss >500ml												
Overall	9	485	1.8%	1	479	0.2%	9	700	1.3%	0	3634	-
Sole	2	368	0.5%	1	301	0.3%	6	470	1.3%	0	3163	-
Concomitant	7	117	6.0%	0	178	-	3	230	1.3%	0	471	-

7.2 POSTOPERATIVE COMPLICATIONS

The postoperative complications for each procedure are shown in *Table 12*. The 'overall' complication rate is the sum of the complication rate for sole procedures and those with concomitant operations. Total number of cases for each procedure excludes the cases where the information had been left unanswered.

Catheterisation for >10 days was the most common postoperative complication (0.8 -15.0%) followed by readmission within 30 days (1.8 – 13.0%).

Table 12: Postoperative complications for all continence procedures, sole continence procedures and procedures with concomitant operations.

	AFS			Lap Colpo			Open Colpo			BNI		
	Cases	N	%	Cases	N	%	Cases	N	%	Cases	N	%
Blood Transfusion												
Overall	3	484	0.6%	0	479	-	3	698	0.4%	0	3634	-
Sole	1	368	0.3%	0	301	-	3	469	0.6%	0	3163	-
Concomitant	2	116	1.7%	0	178	-	0	229	-	0	471	-
Thrombo-embolism												
Overall	1	484	0.2%	0	478	-	0	698	-	0	3634	-
Sole	1	368	0.3%	0	300	-	0	469	-	0	3163	-
Concomitant	0	116	-	0	178	-	0	229	-	0	471	-
Return to Theatre <72hrs												
Overall	0	245	-	1	229	0.4%	6	431	1.4%	0	2182	-
Sole	0	181	-	0	156	-	6	286	2%	0	1721	-
Concomitant	0	64	-	1	73	1.3%	0	145	-	0	289	-
Catheterised >10days												
Overall	37	248	15%	11	229	4.8%	25	430	5.8%	17	2008	0.8%
Sole	26	185	14%	7	155	4.5%	18	285	6.3%	13	1720	0.7%
Concomitant	11	63	17%	4	74	5.4%	7	145	4.8%	4	288	1.4%
Readmitted <30days												
Overall	33	244	13%	15	222	6.7%	40	428	9.3%	36	1996	1.8%
Sole	26	182	14%	6	150	4%	26	282	9.2%	24	1710	1.4%
Concomitant	7	62	11%	9	22	12%	14	146	9.6%	12	286	4.2%
Death												
Overall	0	483	-	0	478	-	0	698	-	0	3632	-
Sole	0	367	-	0	300	-	0	469	-	0	3161	-
Concomitant	0	116	-	0	178	-	0	229	-	0	471	-

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