



BRITISH SOCIETY OF
UROGYNAECOLOGY (BSUG)

**BLADDER NECK INJECTIONS IN THE UK
2018-2019**

NATIONAL REPORT

BSUG AUDIT AND DATABASE COMMITTEE 2020

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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 from many consultants and centres have been recorded. 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.

Two National Reports on Stress Urinary Incontinence Surgery have been published using data from the Audit Database from 2008 to 2019. The two reports have highlighted the trends of various continence procedures over the years. In 2018 and 2019, a sharp increase in the number of bladder neck injections (BNIs) was seen after the 'pause' on the use of midurethral tapes (MUT) was announced by the Secretary of State for Health and Social Care and the Chief Medical Officer in July 2018. Due to the large number of BNIs undertaken in this two-year period, we have produced this report which details the types of BNI procedures undertaken, how they were performed and their outcomes.

ABBREVIATIONS

Bladder neck injection (BNI)

British Society of Urogynaecology (BSUG)

Mid-urethral tape (MUT)

National Health Service (NHS)

National Institute for Health and Care Excellence (NICE)

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

Patient-reported outcome measures (PROMs)

Royal College of Obstetricians and Gynaecologists (RCOG)

Stress Urinary Incontinence (SUI)

Summary of Report

This audit analysed bladder neck injection (BNI) procedures for the timeframe 2018-2019. BNIs for SUI increased significantly in 2018 and 2019 compared to the previous years. In 2019, 65.0% of all continence operations recorded in the BSUG database were BNIs. Bulkamid was the most frequently used bulking agent, comprising 92.4% of procedures. 79.0% of BNIs were primary procedures for SUI with 21.0% for recurrent SUI. 13.0% of cases were repeat BNIs. 87.0% of BNI were performed as sole procedures.

General anaesthesia was most used to carry out BNIs and comprised 52.0% of cases. Local anaesthetic alone was used in 34.0% of cases. 15.0% of cases were carried out in an outpatient setting whilst 82.0% were day cases.

As expected, BNIs had a low complication rate. No intraoperative complications were recorded. Only 2 postoperative complications were recorded. For sole BNIs, 0.7% of cases required catheterisation for more than 10 days and 1.4% were readmitted within 30 days of the procedure.

Patient-reported global impression of improvement was recorded in 48.3% of cases. 98.7% of cases were followed-up at 6 months or less with the majority occurring at 3 months. Overall, 56.3% of patients reported that they were 'much better' or 'very much better.'

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 AUDIT TIMEFRAME AND DATABASE USAGE

This report looked at bladder neck injection (BNI) procedures undertaken from the beginning of 2018 to the end of 2019. During this period, 107 NHS and private centres added procedures to the BSUG database.

1.3 AUDIT LIMITATIONS

The BSUG database is a voluntary database used by individual surgeons to record outcomes of their surgical procedures. BNIs are also undertaken by urologists who may not be BSUG members. Therefore, not every BNI performed for the treatment of SUI 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.

1.4 OPERATIONS INCLUDED

Various types of BNIs have been used in UK. The BSUG database allows users to record the following BNI options (12 in total):

- Cystoscopic BNI – Macroplastique / Collagen / Contigen / Tegress / Bulkamid / Other
- Coaptite injectable implant
- Periurethral BNI
- Non-Cystoscopic BNI – Zuidex / Durasphere / MIS / Other

CHAPTER 2: Numbers and trends

2.1 NUMBER OF BNIS

There were 3690 BNIs recorded in the database in 2018-2019. They were the most frequently performed procedures for SUI in 2018 and 2019, making up 54.7% and 65.0% of all operations respectively.

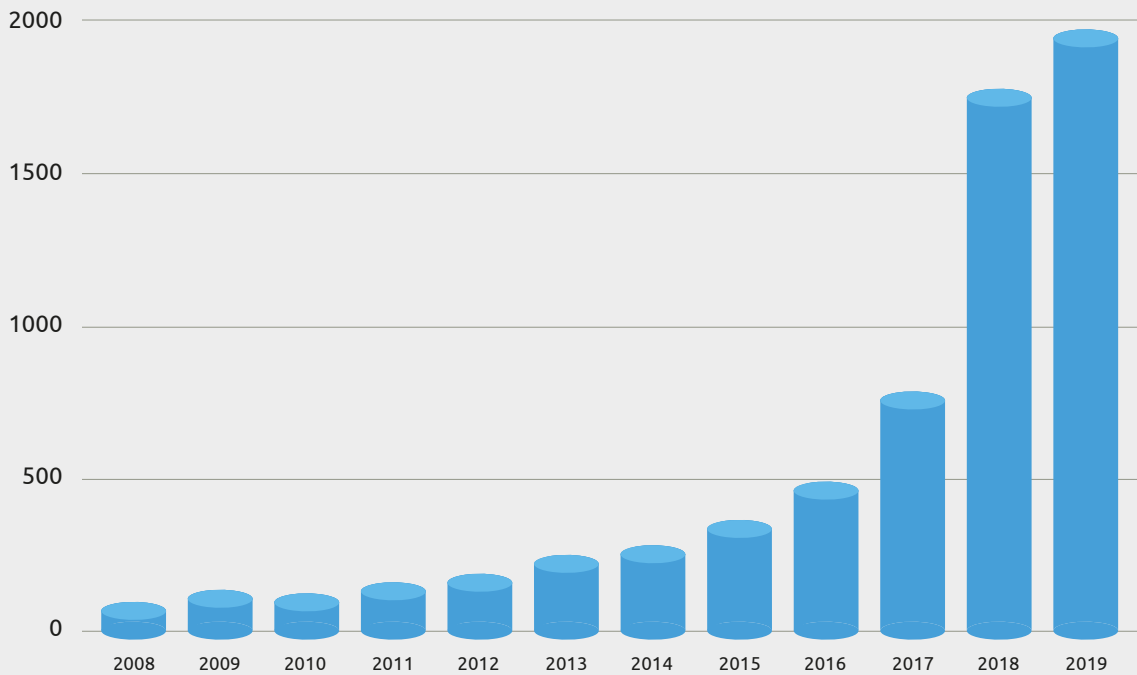
2.2 TRENDS

Table 1 and Figure 1 show the number of BNIs per year from 2008 to 2019. BNIs as a proportion of all procedures for SUI was low up till 2014 (averaging 3.8%). Subsequently, there was a gradual rise in the proportion even before the 'pause' on MUTs' in July 2018. There was an exponential increase in the number of BNI procedures from 2018.

Table 1: The number of BNI procedures per year 2008-2019

Year	BNI n (% of annual continence procedures)	All continence procedures
2008	71 (2.9)	2456
2009	111 (3.6)	3060
2010	99 (3.3)	2968
2011	134 (3.9)	3403
2012	163 (4.5)	3627
2013	226 (3.2)	6977
2014	256 (5.0)	5099
2015	340 (7.4)	4573
2016	463 (11.0)	4163
2017	758 (20.8)	3635
2018	1748 (54.7)	3191
2019	1942 (65.0)	2986
Total	6311	46138

Figure 1: The number of BNI procedures per year 2008-2019



2.3 PRIMARY PROCEDURES AND PROCEDURES FOR RECURRENT SUI

79.0% (2724) of BNIs were primary procedures for SUI. 21.0% (720) were for recurrent SUI. In comparison, the 1st National Report on Stress Incontinence Surgery which evaluated data from the previous 10 years (2008-2017) reported that 66.0% of BNIs were primary procedures and 34.0% were for recurrent incontinence. 13.0% (448) of cases were top-up BNIs.

CHAPTER 3: Surgical data

3.1 TYPE OF BNI

Table 2 shows the different types of BNIs recorded in the database in 2018-2019. Bulkamid was the most frequently used bulking agent, making up 92.4% of the cases.

Table 2: Type of BNI

Type of BNI	n	%
Cystoscopic BNI-Bulkamid	3411	92.4
Cystoscopic BNI-other	112	3.03
Periurethral BNI	63	1.7
Non-cystoscopic BNI-Durasphere	42	1.14
Cystoscopic BNI-Macroplastique	30	0.8
Non-cystoscopic BNI-MIS	26	0.7
Cystoscopic BNI-Tegress	3	0.1
Non-cystoscopic BNI-other	2	0.1
Coaptite Injectable Implant	1	0.03
Total	3690	100

3.2 SOLE PROCEDURES AND THOSE WITH CONCOMITANT OPERATIONS

Overall, 87.0% of BNIs were sole procedures (Table 3). The proportion of sole Bulkamid procedures was 89.4% compared to 58.8% with other types of BNIs.

Table 3: Sole BNIs and those with concomitant operations

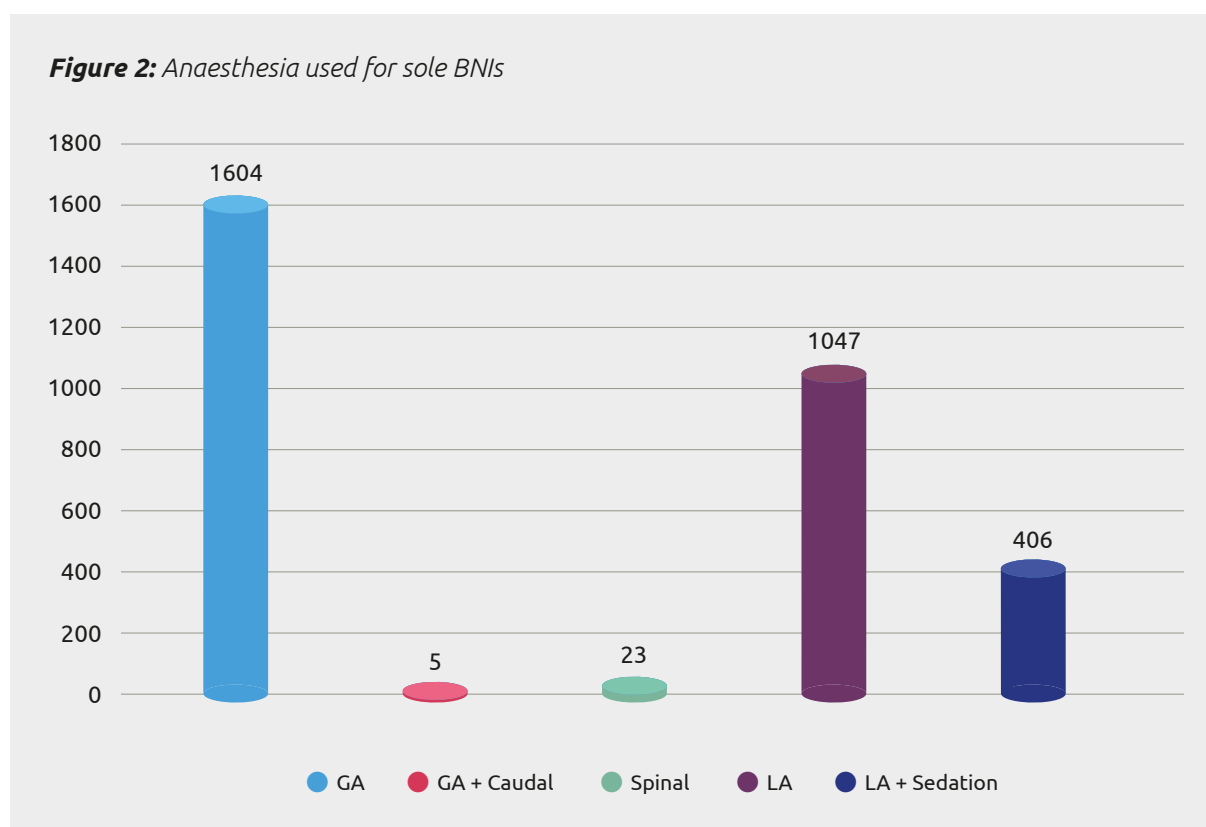
Type of BNI	n (%)		Total
	Sole procedure	With concomitant procedure	
Bulkamid	3048 (89.4)	363 (10.6)	3411
Other BNI	164 (58.8)	115 (41.2)	279
Total	3212 (87.0)	478 (13.0)	3690

3.3 ANAESTHESIA FOR BNIS

BNIs can be undertaken using a variety of different anaesthetic techniques. The type of anaesthesia used is influenced by the presence of concomitant operations. Therefore, only sole BNIs were analysed. The type of anaesthetic used for sole BNIs is shown in *Table 4* and *Figure 2*. 52% of BNIs were carried out under general anaesthesia. Local anaesthesia only was used in 34.0% of cases.

Table 4: Anaesthesia used for sole BNIs

Type of anaesthesia	n (% excluding unanswered)
Unanswered	137
● General anaesthesia	1604 (52.0)
● General anaesthesia + Caudal	5 (0.2)
● Spinal	23 (0.8)
● Local anaesthesia	1047 (34.0)
● LA + sedation	406 (13.0)
Total	3212

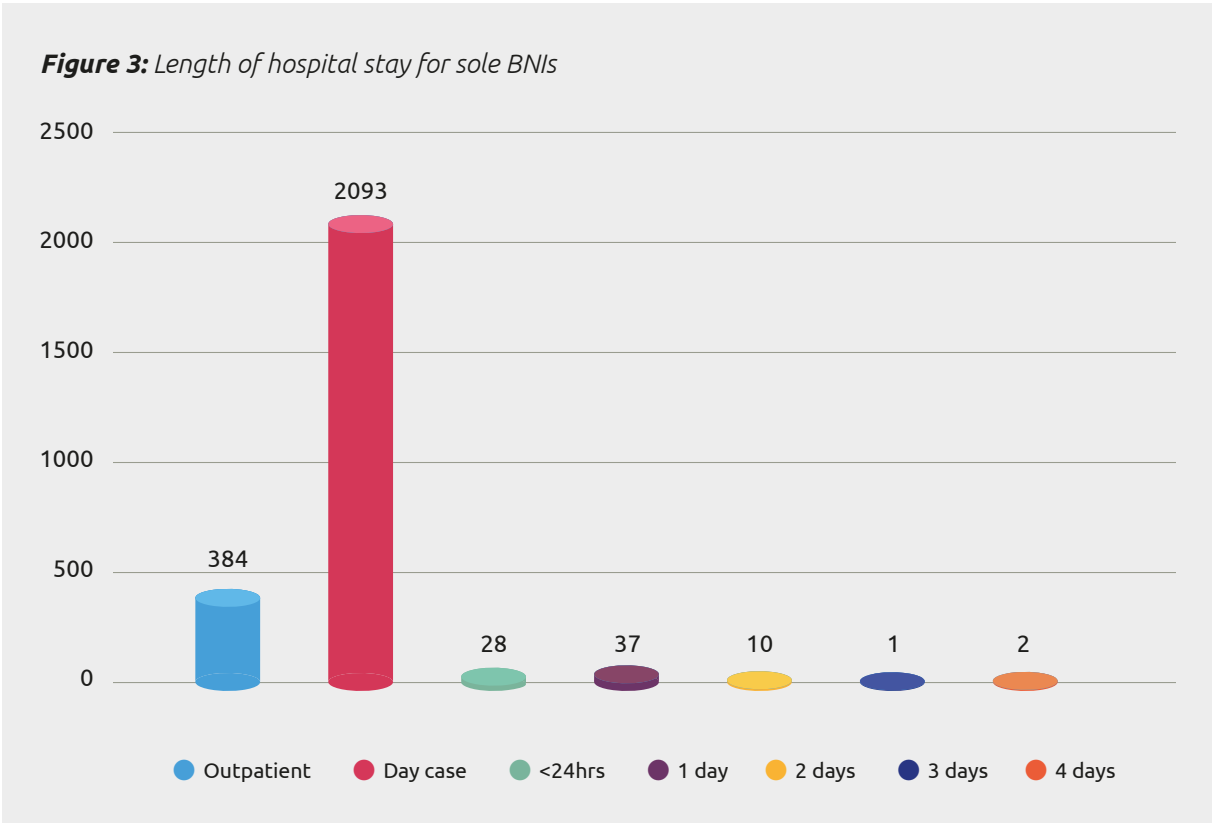


3.4 LENGTH OF POSTOPERATIVE STAY

The length of stay after BNIs is influenced by the presence of concomitant operations. Therefore, only sole BNIs were analysed (Table 5 and Figure 3). 15.0% and 82.0% of cases were outpatient and day case procedures respectively.

Table 5: Length of hospital stay for sole BNIs

Length of stay	n (% excluding unanswered)
Unanswered	657
● Outpatient	384 (15.0)
● Day Case	2093 (82.0)
● <24 hours	28 (1.0)
● 1 day	37 (1.5)
● 2 days	10 (0.4)
● 3 days	1 (0.03)
● 4 days	2 (0.07)
>4 days	0
Total	3212



CHAPTER 4: Complications

4.1 INTRAOPERATIVE AND POSTOPERATIVE COMPLICATIONS RECORDED

The database records pre-specified intraoperative and postoperative complications (*Table 6*).

Table 6: *Intraoperative and postoperative complications*

Intraoperative complications
Ureteric injury
Bladder injury
Bowel injury
Vaginal buttonhole
Urethral injury
Neurological injury
Vascular injury
Blood loss > 500 ml

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

4.2 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 Gynaecologists² (*Table 7*).

Table 7: *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

4.3 INCIDENCE OF COMPLICATIONS

It is important to note that BNI 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 BNI procedures and the complication rate for BNI procedures with concomitant operations are reported separately (*Table 8*).

There were no intra-operative complications reported for BNIs.

The only postoperative complications were catheterisation for >10 days and readmission within 30 days of the procedure. No other postoperative complications were recorded. For sole BNI procedures, the incidence was 0.7% and 1.4% respectively.

Table 8: Postoperative complications for BNIs

	Bulkamid			Other BNIs			All BNIs			Risk
	Cases	n	%	Cases	n	%	Cases	n	%	
Catheterisation for >10 days										
Overall	16	1840	0.9%	1	168	0.6%	17	2008	0.8%	Uncommon
Sole	13	1628	0.8%	0	92	-	13	1720	0.7%	Uncommon
Concomitant	3	212	1.4%	1	76	1.3%	4	288	1.4%	Common
Readmission within 30 days of the procedure										
Overall	35	1828	1.9%	1	168	0.6%	36	1996	1.8%	Common
Sole	23	1618	1.4%	1	92	1.1%	24	1710	1.4%	Common
Concomitant	12	210	5.7%	0	76	-	12	286	4.2%	Common

CHAPTER 5: Patient-reported outcomes

5.1 FOLLOW-UP INTERVAL AFTER SURGERY

The database records pre-specified follow-up intervals after surgery at 6 weeks, 3 months, 6 months and 1 year. It was recorded in 50.9% (1877) of cases (*Table 9*). 52.2% of follow-ups occurred at 3 months (*Table 9*).

Table 9: Follow-up interval after BNIs

Follow up interval	n (% excluding unanswered)
6 weeks	595 (31.7)
3 months	979 (52.2)
6 months	279 (14.8)
12 months	24 (1.3)
Unanswered	1813
Total	3690

5.2 PATIENT-REPORTED GLOBAL IMPRESSION OF IMPROVEMENT

The efficacy of BNIs was assessed using patient-reported global impression of improvement (PGI-I). The scale has 7 outcome categories and is specific to an improvement in SUI (*Table 10*).

Table 10: PGI-I after BNIs

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

5.3 EFFICACY OF BNIS

PGI-I was recorded in 48.3% (1781) of cases. When the years 2018 and 2019 were analysed separately, the follow-up rate was 58.3% and 39.2% respectively. It was lower for 2019 as data extraction for the audit took place in January 2020 when cases might not have had follow-up yet.

Patients were considered cured if a 'much better' or 'very much better' PGI-I was recorded. Overall, 56.3% of patients were cured. The cure rate after Bulkamid compared to other BNIs was 58.1% and 34.9% respectively (p value <0.00001, chi square) (*Table 11*).

Table 11: Patient-reported global impression of improvement - Incontinence (PGI-I) after BNIs

	Bulkamid		Other BNIs		All BNI	
	n	% n=1635	n	% n=146	n	% n=1781
Unanswered	1776	-	133	-	1909	-
Very much better	501	30.6%	24	16.4%	525	29.5%
Much Better	450	27.5%	27	18.5%	477	26.8%
Little Better	304	18.6%	30	20.5%	334	18.8%
No Change	323	19.7%	52	35.6%	375	21.1%
Little Worse	31	2%	10	7%	41	2.3%
Much Worse	19	1.2%	3	2%	22	1.2%
Very Much Worse	7	0.4%	0	-	7	0.4%
Total	3411	100%	279	100%	3690	100%
VMB + MB*	951	58.1%	51	34.9%	1002	56.3%

VMB + MB* – Very much better + much better

5.4 PGI-I FOR SOLE PROCEDURES AND THOSE WITH CONCOMITANT OPERATIONS

BNI procedures may have been carried out with concomitant operations that may have a confounding effect on efficacy. To mitigate this, PGI-I for sole BNI procedures and PGI-I for BNI procedures with concomitant operations are reported separately (*Table 12*). Patients were cured if a ‘very much better’ or ‘much better’ PGI-I was recorded.

For Bulkamid procedures, the cure rate after sole procedures and those with concomitant operations was 57.6% and 62.4% respectively.

For other BNIs, the cure rate after sole procedures and those with concomitant operations was 40.2% and 28.0% respectively.

Table 12: PGI-I sole procedures and those with concomitant operations

		Sole procedure	With concomitant operations	p value (chi square)
Bulkamid	VMB + MB	830	121	P=0.2
	No. of cases	1441	194	
	%	57.6%	62.4%	
Other BNIs	VMB + MB	33	18	P=0.1
	No. of cases	82	64	
	%	40.2%	28.0%	

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