A national UK audit of suprapubic catheter insertion practice and rate of bowel injury with comparison to a systematic review and meta-analysis of available research

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Abstract
Objectives: Limited data exist on the risks of complications associated with a suprapubic catheter (SPC) insertion. Bowel injury (BI) is a well-recognized albeit uncommon complication. Guidelines on the insertion of SPC have been developed by the British Association of Urological Surgeons, but there remains little evidence regarding the incidence of this complication. This study uses contemporary UK data to assess the incidence of SPC insertion and the rate of BI and compares to a meta-analysis of available papers.

Methods: National Hospital Episodes Statistics data were searched on all SPC insertions over an 18-month period for operating procedure codes, Code M38.2 (cystostomy and insertion of a suprapubic tube into bladder). Patients age, 30-day readmission rates, 30-day mortality rate, and catheter specific complication rate were collected. To estimate the BI rate, we searched patients who had undergone any laparotomy or bowel operation within 30 days of SPC insertion. Trusts were contacted directly and directed to ascertain whether there was SPC-related BI. PubMed search to identify papers reporting on SPC related BI was performed for meta-analysis

Results: 11473 SPC insertions took place in the UK in this time period. One hundred forty-one cases had laparotomy within 30 days. Responses from 114 of these cases reported one BI related to SPC insertion. Meta-analysis showed an overall BI rate of 11/1490 (0.7%).

Conclusions: This is the largest dataset reported on SPC insertions showing a lower than previously reported rate of BI. We recommend clinicians use a risk of BI of less than 0.25% when counseling low-risk patients.

Keywords
bowel injury, complications, suprapublic catheter

1 | INTRODUCTION

The suprapubic catheter (SPC) is commonly used for both emergency and long-term bladder drainage with 6706 SPC
insertions recorded in the UK between April 2017 and March 2018. Twenty-five percent of SPC insertions are performed in an emergency setting, usually when urethral catheterization has failed or is contraindicated. Emergency SPC procedures are often performed on the ward or in the emergency department, commonly using a closed (or blind) technique. Elective SPC insertion is more often performed in theatre with cystoscopy (+/- ultrasound) guidance for patients requiring long-term bladder drainage. Some cases are performed using an open cystotomy approach, for example in patients with previous abdominal surgery where there is an increased risk of anterior abdominal wall bowel adhesions.

Limited high-quality data exist on the risks of complications associated with SPC insertion. Bowel injury (BI) is a well-recognized albeit uncommon complication and usually requires emergency surgical treatment. As highlighted in the National Patient Safety Agency (NPSA) rapid response report in 2009, this is a life-threatening complication, a fact that should be taken into consideration during the consent process. Practice guidelines on the insertion of SPC that aim to reduce the risk of BI were developed by the British Association of Urological Surgeons (BAUS), but there remains little contemporary evidence regarding the incidence of this complication or how it may be avoided.

The objectives of this study are to assess the current national incidence of SPC insertion and the rate of BI from a contemporary UK dataset. We also performed a systematic review and meta-analysis of available research on BI rates from SPC insertion.

2 | MATERIALS AND METHODS

A search of the National Hospital Episodes Statistics (HES) data was performed on all SPC insertions between April 2015 and October 2016 for operating procedure codes, Code M38.2 (cystostomy and insertion of a suprapubic tube into bladder). Patient age, 30-day readmission rate, 30-day mortality rate, and catheter specific complication rates were also collected. Cause of death was not collected.

To estimate the BI rate, we searched for patients who had undergone any laparotomy or bowel operation (Table 1) within 30 days of SPC insertion. As HES is unable to determine the reason for these subsequent procedures, individual NHS hospital Trusts were contacted and an anonymized questionnaire completed to ascertain whether the indication for subsequent bowel operation was an SPC-related BI (Appendix 1 and 2). Unless it was related to BI the reason for laparotomy was not collected.

Accuracy of coding for SPC insertion was analyzed by performing a retrospective subset analysis of the last 100 SPC insertions at a single NHS hospital trust site.

Systematic review and meta-analysis were performed with a PubMed search to identify papers reporting on SPC related BI. Search terms used were “suprapubic catheter” and “bowel injury” or “complications.” We excluded any expert opinion, case studies, individual reviews, and included only those that reported BI rate. This left eight papers. Year of publication, location of publication, case number reported, and rate of BI were collected.

3 | RESULTS

A total of 11 473 SPC insertions took place in the UK in the 18-month period between April 2015 and October 2016. Patients were aged from 0 to 100 years, with 64% being over 60% and 6% under 20-year old. Of all HES

| Operation                        | OPCS codes                  | No (%) |
|----------------------------------|-----------------------------|--------|
| Subtotal colectomy               | H06.3H07.1 H07.2 H07.3 H07.4 H07.9H08.4H09.1 H09.2 H09.3 H09.5 H09.8H10.1 H10.2 H10.3 H10.4 H10.5H15.8H29.9 | 47 (33) |
| Loop colostomy                   | H15.1                       | 34 (24) |
| Anterior resection               | H33.3 H33.4 H33.6           | 26 (18) |
| End colostomy (no resection)     | H15.2                       | 14 (10) |
| AP resection                     | H33.1 H33.8                 | 10 (7)  |
| Exteriorisation of bowel          | H15.9                       | 3 (2)   |
| Total colectomy                  | H05.9                       | 1 (1)   |
| Closure of colostomy             | H15.4                       | 4 (3)   |
| Refashioning of colostomy        | H15.3                       | 1(1)    |
| Other op on bowel                | H62.8                       | 1(1)    |
| Total                            |                             | 141     |
database recorded SPC insertions, 7347 (64%) were elective, 3866 (34%) emergency, and 260 (2%) unknown.

The single-site subset analysis showed that 99 of 100 (99%) SPC insertions were coded correctly. The one case that was not coded correctly was a patient who had an SPC change rather than insertion. This suggests the HES coding search parameters used were appropriate and validates the coding and capture process.

The all-cause 30-day readmission rate was 17%, which includes admissions for reasons unrelated to the SPC. There were 618 30-day readmissions coded for catheter specific complications (5%), most commonly a mechanical catheter problem (59%).

The total all-cause mortality rate within 30 days of SPC insertion was 167 (1.5%). The cause of mortality as documented on the patient death certificate was not collected. Of these 22 (13%) were elective insertions, 142 (85%) emergency insertions, and 1 (0.6%) unknown.

One hundred forty-one patients underwent laparotomy surgery within 30 days of an SPC insertion in 80 different NHS trusts, (some at same time as SPC insertion). The operation performed at laparotomy for each of these cases is tabulated below (Table 1). Reason for laparotomy was not collected.

Responses from the BAUS UK hospital survey were received for 114 (81%) of the cases. Of the reported laparotomies, there was one recorded BI associated with SPC insertion. In this case, the SPC was inserted by a subconsultant grade urologist in the operating theatre using a trocar technique. No preceding risk factors for BI were identified (previously reported risk factors include body mass index [BMI] >35, previous lower abdominal surgery, small capacity nondistended bladder). The injury was identified within 24 hours of SPC insertion and was repaired with subtotal colectomy. The patient made a full recovery.

The BI rate in this large, contemporary UK series was, therefore, one in 11 473. Data from previous studies are summarised in Table 2.

4 | META-ANALYSIS

Analysis of data before the 2009 NPSA report revealed two studies with datasets ranging from 185 to 219, which reported an incidence of BI of 2.4% to 2.7% and a mortality rate of 1.8%.6,7 Metanalysis of these data shows a BI rate of 10/404, 2.4%.

Since the NPSA reports more recent studies have reported much lower rates of BI from 0% to 0.2%, based on datasets ranging from 24 to 585 SPC insertions between 2011 to 2014.8-13 Metanalysis of these data shows a BI rate of 1/1086, 0.09%.

An overall metanalysis of the available data shows a BI rate of 11/1490, 0.7% (Table 2).

5 | DISCUSSION

In 2009 the NPSA, a forerunner of NHS Improvement, issued a rapid response report on minimizing risks of catheter insertion. This stated that from September 2005 to June 2009 there were reports of three deaths and seven cases of severe harm relating to the insertion of SPCs. Recommendations from the NPSA report include the use of ultrasound (US) guidance when the bladder cannot be palpated despite adequate filling (>300 mL). They recommend the use of open SPC insertion in cases of previous lower abdominal surgery or patients whom the bladder cannot be adequately distended (<30 mL). They acknowledge that there is no sufficient evidence base to support the use of US during SPC insertion, however, and when utilized that it should only be performed by trained individuals.14

Following the NPSA report, in 2011 BAUS published guidelines for SPC insertion, recommending that the US may be used as an adjunct to SPC insertion but only by a practitioner with appropriate training and experience. BAUS recommend the use of US in patients for whom the bladder cannot be palpated due to obesity. In contrast to the NPSA report, BAUS recommend that in patients with previous lower abdominal surgery or a bladder that will not distend open SPC insertion or US guidance can be used. They also comment that there is a conspicuous lack of research data and a need for further information on this.5

The disparity between BI rates reported before and after the NPSA report in 2009 (2.4% and 0.09%,

| Reference | Year | Location | No. | No. BI (%) |
|-----------|------|----------|-----|------------|
| Sheriff et al6 | 1998 | UK | 185 | 5 (2.7) |
| Ahluwhalia et al7 | 2006 | UK | 219 | 5 (2.4) |
| Cronin et al8 | 2011 | USA | 585 | 1 (0.2) |
| Edokpolo et al9 | 2011 | USA | 44 | 0 |
| Jacob et al10 | 2012 | Not stated | 25 | 0 |
| Goyal et al12 | 2012 | UK | 72 | 0 |
| Zacharia et al10 | 2013 | India | 53 | 0 |
| Johnson et al11 | 2013 | USA | 307 | 0 |

Abbreviation: SPC, suprapubic catheter.
respectively) may be explained in terms of changes in technique, availability of newer Seldinger devices for SPC insertion (such as the Mediplus S-Cath System), or patient selection factors following advice from the NPSA and BAUS.

This contemporary series of 11,473 patients undergoing SPC insertion identified only one BI. This study analysis would suggest that the risk of BI is significantly lower than historical data suggest and is more in line with smaller recent reports.

It is likely that the majority of bowel injuries will have been identified in this study, yet some may have been missed through poor coding. Analysis of coding at a single Trust indicates that coding was correct in 99% of patients, although it is accepted that there would be variation in coding amongst different trusts. Our HES search might also have missed cases where BI was managed nonoperatively, but it is anticipated that successful conservative treatment of BI is rare. The range of post-SPC procedures identified for further investigation was comprehensive and deliberating overinclusive, and it is unlikely that any BI-related operations were missed. We also recognize that some cases of BI may have been missed due to a delayed presentation. A small proportion of patients only present with BI at the time of the first SPC exchange. The majority of bowel injuries would be expected to present within 30 days of insertion, however. It is therefore unlikely that the BI risk is substantially higher than stated.

Our data include 727 patients aged under 20-year old. It is likely that the risk factors for BI are very different in this group. This group did not undergo any postoperative bowel procedures and no bowel injuries were identified.

We acknowledge limitations to this study. Data are missing for 27 of the total 141 laparotomies performed (19%) and the BI rate may, therefore, be underestimated. However, even if it was assumed that all such cases had a BI secondary to SPC insertion (which is unlikely) then the BI rate would still be in line with recent smaller studies at 0.24% (28/11473).

Although we have not been able to investigate possible risk factors for BI, it is accepted that the risk of BI is higher in certain patient populations (eg, high BMI and previous lower abdominal surgery) and US guidance is recommended in such cases to identify the bladder. However, the matter of exactly how US guidance should be used has not been addressed and there is a variation in practice. Many clinicians advocate the use of intraoperative US to identify bowel loops during needle insertion. This is challenging, even for an experienced operator, and must be performed by a clinician with expertise in US-guided interventional procedures.

The thirty-day mortality rate in this series is 1.5%. The mortality rate is not caused specific to SPC insertion and may reflect the age and comorbidities of the groups of patients requiring SPC insertion, some of whom may be receiving an SPC as part of ongoing palliative care. We have no access to cause of death though HES data, and a detailed analysis of the cause of death is beyond the scope of this study.

This study suggests that the risk of BI after SPC insertion is lower than previously reported. To proceed with SPC insertion without US guidance in patients in the absence of risk factors for BI would appear to be safe, and patients can be reassured that the risk of BI is less than 0.25% as in the BAUS patient information leaflet.

6 | CONCLUSION

This is the largest dataset reported on SPC insertions showing a lower than previously reported rate of BI from SPC insertion. We recommend clinicians use a risk of BI of less than 0.25% when counseling low-risk patients about SPC insertion. We would recommend the use of US in experienced hands for cases with palpable bladder despite adequate distension and in cases with open lower abdominal surgery.

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APPENDIX

1. Letter to trusts re. bowel injury

Dear Sir,

I am writing on behalf of BAUS. Following a patient death in 2016, we have been instructed by HM Coroner to ascertain the risks associated with the insertion of SPCs in England. To this end, we have compiled a list of patients at your trust who have had an SPC insertion procedure and may have sustained a BI during the procedure (on the basis of HES data).

To clarify these data, we require further information regarding these patients from your trust. As the HES data are anonymous, it will be necessary for your trust to identify these cases from the procedure codes, procedure dates, and from Secondary User Service data. This will allow you to identify the patients (through coding systems), and I would be grateful if you could arrange for the medical records to be reviewed.

The attached sheets contain the details of each patient and a number of questions that need to be completed. I would be grateful if these sheets could be returned to me at the address above. Any queries can be directed to the email address below.

Yours faithfully,

Richard Parkinson
Consultant Urologist
On behalf of the British Association of Urological Surgeons
richard.parkinson@nuh.nhs.uk

2. Questionnaire to trusts regarding bowel injury

Patient details:
We cannot know whether the bowel procedure was related to the SPC insertion or not. Please use the above data to identify the patient(s) from your coding systems, then review the medical notes to answer the questions below.
Questions:
Did the patient have a BI following SPC insertion?
  Yes
  No
If no, no further questions need to be answered
If yes, please answer all questions below

What grade of doctor performed the SPC insertion procedure?
  CT trainee
  ST trainee
  Trust grade
  Consultant
Which specialty?
  Urology
  Gynaecology
  General surgery
  Emergency department (A&E)
  Other
Where was the SPC inserted?
  On the ward or ED (A&E)
  In the operating theatre
  In the radiology department
What type of procedure was performed?
  Blind trocar insertion (with or without cystoscopy)
  USS-guided trocar insertion (with or without cystoscopy)
  Insertion using Hargrove's (or similar) urethral sound
  Open insertion
Which of the following risk factors for BI were present?
  BMI >35
  Previous lower abdominal open surgery
  Small capacity or nondistended bladder
When was the BI identified?
  During the SPC insertion procedure
  Within 24 hours of the SPC insertion procedure
  During the same admission
  After discharge from hospital
What was the outcome of the BI?
  Repair of damage with full recovery
  Repair with permanent adverse effects
  Death
  What were the outcomes of the trusts safety incident investigation?