Project title		A Danish Audit of Small Bowel Obstruction
Participating Centres		Bispebjerg Hospital; Herlev Hospital; Hillerod Hospital; Hvidovre Hospital; Slagelse Hospital; Zealand University Hospital, Køge;
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1. Background

Small bowel obstruction (SBO) is a common and potentially life-threatening acute surgical condition. A minority of patients present with a clear indication for urgent surgical intervention, either on the basis of clinical or radiological assessment (clinical signs of peritonitis/sepsis; suspicion of bowel ischaemia; closed loop obstructions; irreducible herniae etc.). However, the optimal management of the remaining patients, the majority of whom present with SBO caused by abdominal adhesions, remains a topic of international debate.

In the United Kingdom, the majority of patients with adhesional SBO are managed non-operatively unless a clear indication for acute surgery is found. This approach is based on both the rationale that the acute presentation may resolve with non-operative management and that surgical intervention may lead to the development of further adhesions, leading to further episodes of SBO in the future [1]. The management of adhesional SBO in Denmark is more surgically aggressive, where the majority of patients tend to undergo an acute or urgent operation unless there is a clear contraindication to surgery. The rationale for this approach is that the patient has been admitted with clinically significant adhesions, which will continue to cause intermittent obstruction unless divided. Although there is some evidence to support a more aggressive approach, with a recent retrospective study from Canada demonstrating fewer future episodes of SBO in patients undergoing operative management, the benefit of the acute surgical intervention must be balanced with the risks of peri-operative morbidity [2].

In 2017, a snapshot audit of the outcomes of patients admitted with SBO in the UK was performed, including over 2,400 patients (https://www.acpgbi.org.uk/content/uploads/2017/12/NASBO-REPORT-2017.pdf) [3]. This audit not only identified variations in the management of patients with SBO but also identified several key recommendations to improve the outcomes of this patient group including earlier use of CT scanning, a more standardised approach to non-operative management, a greater focus on nutritional status and optimisation of peri- and post-operative care.

Standardised acute care bundles are now commonplace in Denmark. With a focus on early identification of high-risk surgical patients, these pathways facilitate early radiological diagnoses, pre/peri-operative patient optimisation and early, appropriate surgical intervention. Although one of the key patient groups identified by these pathways, the outcomes of patients admitted with SBO are not routinely audited, which limits further optimisation of patient care.

This quality assessment study aims to provide robust data on the outcomes of patients admitted with SBO in Region Øst in order to identify areas in need of improvement and further research.

2. Objectives

To perform a prospective quality assessment study of the outcomes of management of patients admitted with SBO in Region Øst.

Primary objective

- 30-day morbidity and mortality rates of patients admitted with SBO

Secondary objectives

- 90-day mortality rates of patients admitted with SBO
- To identify the most common causes of SBO in this patient cohort
- To investigate potential variability in the diagnosis and peri-operative management of these patients
- To determine what proportion of patients undergo non-operative vs operative management of SBO
- To determine the success rate of non-operative management in patients with SBO and identify predictors of success/failure
- To determine the incidence and consequence of acute kidney injury in patients with SBO
- To determine the incidence and consequence of malnourishment in patients with SBO

Tertiary objectives

- To identify areas of management of patients with SBO requiring optimisation

- To determine the incidence of recurrent SBO at 1-year, 3-year and 5-year follow-up.

3. Methods

This is a prospective quality assessment study that will be performed across 6 acute general surgical hospitals in Region Øst (Bispebjerg, Herlev, Hillerød, Hvidovre, Køge, Slagelse). Consecutive consenting patients admitted with a diagnosis with SBO will be included from each site over a 3-month period.

Eligible patients will be identified using the following methods during the study period:

- Screening of acute theatre lists
- A data extraction of all diagnoses of ileus (DK567) or subileus (DK566C) from the emergency department and inpatient wards
- A data extraction of from the radiology department of all patients undergoing a small bowel follow-through with water soluble contrast

In the initial study phase, each patient will be followed for 90 days after diagnosis. Relevant clinicopathological variables will be extracted from electronic patient records, which will be entered in a pseudo-anonymised form into a purpose-built REDCap database using a site-specific study number that is individual for each patient. Patient CPR numbers will be stored on secure folders at each site to allow data validation as necessary. The first analysis of the dataset will be performed

once all included patients have reached 90 days follow-up. Patient journals will be accessed again at 1, 3 and 5 years after diagnosis to investigate the tertiary objectives outlined above.

As this study is purely observational, no alterations to standard patient care will be made. The study will be run by a steering committee including senior surgeons acting as local principal investigators from each of the participating centres. An additional collaborator from each centre will be responsible for patient identification and data collection. It is estimated that each centre will identify between 20-30 eligible patients each month, giving a final cohort size of 360-540 patients.

4. Patients

Inclusion criteria

- Age ≥ 18 years old
- Radiological or clinical diagnosis of mechanical SBO made from 00:00 on 22/02/2021 until 23:59 on 21/05/2021
- Admitted to one of the 6 participating centres

Exclusion criteria

- SBO presenting within 30 days of a previous abdominal operation

5. Risks and side effects of study

This is a prospective observational study of patient outcomes. As such, there are no risks or potential side effects for the patients that will be included.

6. Access to patient journals

Patient journals will be accessed in order to extract relevant clinicopathological data. The local principal investigators are responsible for the relevant study approvals, which should be made as a quality assessment project. As described above, patient journals will be accessed at 4 timepoints during this study:

- Period 1 – from diagnosis until 90 days follow-up
- Period 2 – 1 year after diagnosis
- Period 3 – 3 years after diagnosis
- Period 4 – 5 years after diagnosis

7. Data storage and security

Patient identifiable data will be stored in a secure folder at each specific site. The local principal investigators will be responsible for establishing and maintaining these folders. Only those directly involved with the study will have access to these files. Relevant clinicopathological variables will be entered into a purpose-built REDCap database in an anonymised form. Each site will have a specific REDCap login with site-specific patient study numbers.

Any patient identifiable data will be permanently deleted within 5 years of the study start (i.e. 31/12/2026).

8. Publication of results

This study is registered on www.clinicaltrials.gov – NCT04750811. The results of the study will be published in scientific journals and presented at international conferences.

9. References

[1] Lee MJ, Sayers AE, Wilson TR, Acheson AG, Anderson ID, Fearnhead NS, et al. Current management of small bowel obstruction in the UK: results from the National Audit of Small Bowel Obstruction clinical practice survey. Colorectal Dis. 2018;20:623-30.

[2] Behman R, Nathens AB, Mason S, Byrne JP, Hong NL, Pechlivanoglou P, et al. Association of Surgical Intervention for Adhesive Small-Bowel Obstruction With the Risk of Recurrence. JAMA Surg. 2019;154:413-20.

[3] Lee MJ, Sayers AE, Drake TM, Marriott PJ, Anderson ID, Bach SP, et al. National prospective cohort study of the burden of acute small bowel obstruction. BJS Open. 2019;3:354-66.