National Audit of Small Bowel Obstruction

(NASBO)

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Lay Summary

Bowel obstruction is a common problem. People with a blockage in their bowel have symptoms including vomiting, abdominal bloating and inability to open their bowels. For the time that they have this problem, they are unable to eat or drink and require a drip to support them. Patients are sometimes treated by putting a tube through the nose into the stomach to drain fluid and sometimes with an operation. This national audit will look at how we manage these patients and how we address nutrition, to see if we can improve this.

Background:

Bowel obstruction is a common condition presenting to the emergency surgery take. Symptoms include abdominal pain, distension, vomiting and obstipation. This interruption of bowel function causes a state of starvation that may be prolonged for treatment considerations. The most frequent site of this blockage is the small intestine. Emergency surgery for small bowel obstruction accounted for half of all emergency laparotomies in England and Wales during 2014-2015 (1). Surgery for intestinal obstruction is associated with high rates of morbidity and mortality, making this a significant burden of disease (2).

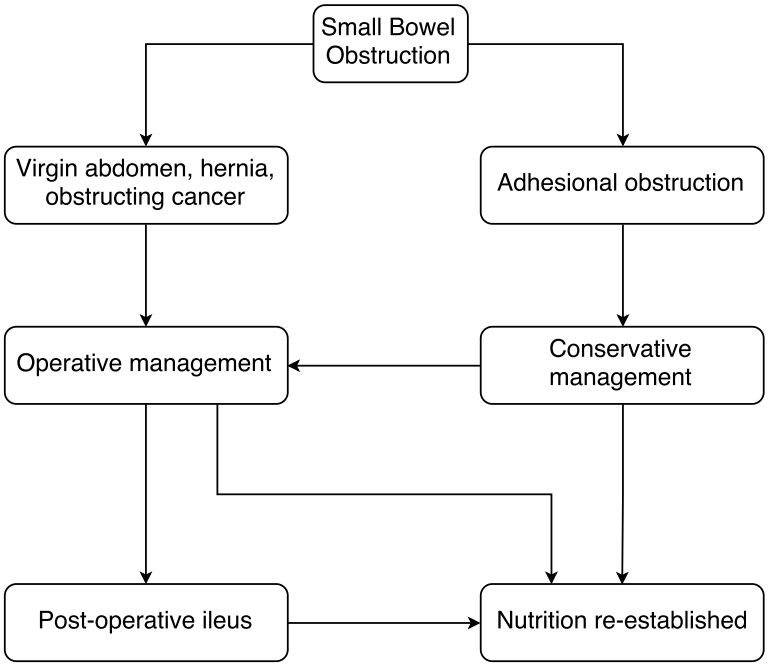

Figure 1: Flow-chart of pathways through small bowel obstruction management.

Small bowel obstruction can be caused by adhesions, hernia, malignancy and volvulus. Adhesions may be managed conservatively in the first instance, with return to normal diet after a period of starvation lasting a few days. Some patients managed with an operation in the first instance. These patients are likely to have a period of ileus post-operatively and so have a period of post-operative starvation. The third group of patients are managed conservatively to start with, but fail to resolve their obstruction or become unwell. They then undergo surgical management, with the resulting ileus and prolonged period of starvation. This is summarised in figure 1. There is evidence that delays in surgery and prolonged conservative management are associated with poor outcomes (3). Complications of operative management have been reported in up to 41% of elderly patients (4).

Hospital patients are frequently found to be malnourished at admission, and this has been associated with increased rates of mortality, morbidity and length of stay (5, 6). This is relevant

to the cohort of patients with intesinal obstruction as some may have an underlying diagnosis of local or disseminated malignancy causing a chronic malnourished state.

Recommendations for the management of malnutrition in patients have been set out in NICE clinical guideline 32 (CG32) and the British Association for Parenteral and Enteral Nutrition (BAPEN) document 'Perioperative Nutrition' (7, 8). The BAPEN document is intended for elective surgery, but has aspects which could be applied to emergency surgery. This includes recommendations around nutritional screening of those likely to undergo major surgery. These patients should be deferred and nutritionally optimised in the elective setting. The guidelines specifically recommend that those with intestinal failure should receive parenteral nutrition. NICE guidance advocates the use of parenteral nutrition in those with more than five days of starvation or with high nutrient losses. Patients with bowel obstruction may not be managed in line with these recommendations.

Aim:

To assess outcomes and impact of guidelines for malnourished patients in small bowel obstruction

Objectives

1. To examine use of malnutrition tools in patients with bowel obstruction

2. To examine outcomes in patients with small bowel obstruction and feed-back findings at unit level.

3. To assess whether patients identified as malnourished receive appropriate management in line with national guidelines.

4. To examine outcomes of patients with bowel obstruction and identify outcomes in patients who are malnourished.

Primary outcomes

1. In-hospital mortality
2. In-hospital morbidity
3. Length of stay
4. Unplanned readmissions at 30-days post discharge

Audit standards and expectation:

Source	Measure	Evidence	Expectation
NICE guidance CG 32	Use of nutritional risk tool to assess for malnutrition	MUST, NRI or other nutrition score in nursing documentation or clinical notes	100%
	Dietitian/nutrition team assessment following identification of malnutrition	Documentation in patient notes	100%
	Institution of nutritional intervention following identification of malnutrition	Documentation in patient notes	100%

Ethics:

This is a combined audit and service evaluation. As such it does not require ethical approval. All participating units must provide evidence of registration with local audit/clinical governance structures and, permission from the Caldicott Guardian for entry of pseudoanonymised data into REDCap.

Project team structure

NASBO Steering Group

This comprises of a core group of surgical trainees and consultant general surgeons representing SYSuRG, WMRC, ACPGBI and NELA. The steering group is responsible for protocol design, data handling, analysis, dissemination of results and the preparation of manuscripts. The NASBO Steering Group are responsible for the use of data resulting from this project.

Local leads

The local leads are responsible for the co-ordinating and organisation of local NASBO teams. This role should normally be filled by a Consultant Surgeon who participates in the provision of emergency general surgery. The local lead will sponsor the registration of the audit and ensure that collaborators act in accordance with local clinical governance and guidelines. The local leads act as a link between the local NASBO team and the NASBO Steering Group. They are the first point of contact for local collaborators and are responsible for the dissemination of information to local collaborators from the NASBO Steering Group.

Local NASBO Team

This comprises of a local lead, up to three other collaborators and one independent validator – who may be doctors, medical students, nurses or allied healthcare professionals. There is a maximum of four collaborators per local NASBO team and one validator. The local NASBO team is responsible for putting in place means of identifying all eligible patients and capturing the required data. They should also identify an independent member of the team to validate data.

Trainee Research Collaborative Leads

We are working with trainee research collaborative groups to support delivery of this project. We are liaising with leads of these groups to support recruitment of sites and trainees to for data collection.

Local Project Registration & Data governance

NASBO should be registered as a clinical audit. It is the responsibility of the local NASBO team at each site to identify a local consultant surgeon to supervise them and ensure that NASBO is registered appropriately with their trusts' clinical governance department.

The local NASBO team should seek the permission of their Trust's Caldicott Guardian in order to submit data to the REDCap system. No data should be uploaded to REDCap prior to approval from the Caldicott Guardian.

If there are any difficulties encountered with clinical audit registration then seek advice from the local supervising consultant or contact the NASBO steering group (contact@nasbo.org.uk) as required.

Method:

Prior to undertaking the prospective assessment of practice, it is important to describe the settings and processes that underpin the care of patients with SBO.

Establishing Practice

As there are no formal guidelines for the management of SBO in the UK, there is likely to be variation in the pathway of care for these patients. A questionnaire has been designed to assess areas of perceived variation in care, including use of gastrograffin, timing of and indicators for surgery, and surgical approaches. Each centre lead will be asked to obtain responses from their consultant colleagues and return the questionnaire to contact@nasbo.org.uk . Any paper published on this survey data alone will be outside the collaborative authorship model.

Profile of Centre

In order to describe local processes and resources, each site will be asked to complete a site profile questionnaire (Appendix B) when they register. This assesses availability of imaging, theatres, emergency rota set-up, care for increased dependency patients and access to nutritional support services.

Identification of patients

Patients referred to emergency surgical take with a working diagnosis made by the admitting surgical team of small bowel obstruction will be screened for inclusion at the point of clinical handover (typically 0800).

For the purpose of this study, small bowel obstruction will be defined as a clinical diagnosis of small bowel obstruction as determined by specialist trainee (ST3+) or consultant surgeon during that admission.

Inclusion and exclusion criteria

Inclusion criteria:

- Patients who are admitted direct to the emergency surgery service (via A&E or GP)

  OR

- Patients who are referred to the emergency surgical team from another inpatient team (e.g. medicine)

  AND

- With a diagnosis of small bowel obstruction by ST3 or above

Exclusion criteria:

- Patients who have had abdominal surgery within the same hospital admission prior to first symptoms of small bowel obstruction
- Pregnant women
- <16 years old
- Patients with large bowel obstruction (even when signs of small bowel obstruction are present)
- Patients with total length of stay <24 hours

Patients who are initially included but later excluded should be recorded on the REDCap system, with reason for exclusion documented.

Data collection period

Prospective patient identification will be undertaken over a two-month period.

Snapshot data will be collected at days 1, 3, 5 and 7 of hospital stay.

Identification of outcomes of management whilst an inpatient will be recorded

For patients discharged before the end of the study, 30-day readmissions post-discharge will be identified.

Data collection procedure

At registration, the Centre lead will complete a site profile form and return this to the steering committee, along with audit and Caldicott approvals. This form is presented in Appendix B.

Data collection will be using the form presented in Appendix C. Hospital or NHS number will not be entered onto this form, but will be kept separately with a key sheet. Data should be collected prospectively for maximum accuracy. As there is variation in use of nutritional assessment tools across hospitals, the tool asks only if the patient is defined as malnourished by the local definition.

Patients will be screened for inclusion, and data collected where appropriate. Basic demographics and comorbidities (in the form of Charlson Comorbidity Index) will be recorded. This allows standardisation of comparisons between any groups. Documentation will be assessed for time period since they last tolerated food, as well as recording of local malnutrition scoring tool and any resulting actions. Data on aetiology will be recorded as will initial management strategy (i.e. first 24 hours). This is split into operative e.g. early operation for congenital band in virgin abdomen, conservative management, or e.g. trial of nasogastric tube

and catheter. Treatment intent is also captured. This includes curative i.e. treatment intended to resolve obstruction such as adhesiolysis, temporising i.e. procedure offering temporary relief prior to definitive procedure e.g. stoma, or palliative management which may be conservative only. Timing and nature of any intervention will be recorded.

Recognition and intervention in malnutrition will be assessed. Interventions have been simplified to oral supplements, enteral feeding and parenteral feeding.

At 30-days following discharge, hospital systems should be interrogated for evidence of unplanned readmission.

Completed datasheets will be entered onto the secure REDcap system, hosted by the University of Sheffield (https://redfox.shef.ac.uk/). Access to data-entry will be via issued accounts. The REDcap data form matches the pro forma, but has an additional field capturing the collaborator ID number to allow attribution.

Data Collation

All data will be handled in accordance with the Data Protection Act 1998.

Data will be collected and stored online through a secure server running the Research Electronic Data Capture (REDCap) web application (ref). REDCap allows collaborators to enter and store data in a secure system. Collaborators will be given secure REDCap project server login details, allowing secure data storage on the REDCap system. All transmission and storage of web by this system is encrypted and compliant with HIPAA-Security Guidelines the United States. Data from this study will be retained on University of Sheffield servers and will not be removed from the UK.

No patient identifiable information will be uploaded or stored on the REDCap database. Collaborators will anonymise patients by recording patient hospital numbers alongside REDCap numbers in a separate spreadsheet in order to aid the collection of data locally. This should be held on secure, password computer systems. Any files should be encrypted for added security. Collaborators may also wish to initially use a paper version of the data collection pro-forma. Paper copies of any data should be destroyed as confidential waste within the centre once uploaded to REDCap.

REDCap accounts will not be issued until evidence is provide via your hospital's local lead that the following approvals are in place at your centre:

(i) Successful registration of NASBO with the audit department.

(ii) Caldicott Guardian permission for data to be submitted to REDCap.

Training Materials

As with previous multicentre studies, we will deliver online training to ensure standardisation. This will be delivered through online presentation of project rationale, how to complete the pro forma, and how to use the REDCap system for return of forms.

Pilot Study Period

There will be an initial two-week study period from October 24th-November 6th 2016. This will permit a trial of the data-collection pro forma and IT systems supporting the project.

Process results from the pilot will be reviewed at a steering group meeting in November 2016. If no or minor modifications only are required, these will be made and the project will proceed as planned. Updated documents will be available from the study website. If a major issue is identified, which requires significant modification of the project, the main data collection window will be delayed to allow this to be addressed.

Local pilot

In order to overcome a learning curve in identifying patients for inclusion, data collection and using REDCap, participating centres are strongly advised to pilot patient identification and data collection prior to their formal data collection start date. Any problems encountered can then be resolved prior to formal data collection either locally or with support from the steering committee.

Full Study Period

The steering group will provide documents to facilitate local audit registration at least three months prior to commencement of data collection.

The study period is:

Period	Date
Case Identification period	16/01/2017-13/03/17
Data collection period (readmissions) ends	30/04/2017
Validation completion date	30/05/2017

Validation

Validation will be performed on 25% of data fields for 10% of cases. The validated fields will include key demographic and outcome data. These fields are outlined in a separate document.

Analysis plan

Statistical support will be obtained from Sheffield Clinical Trials Unit. A formal statistical analysis plan will be developed with this group following the pilot study.

Descriptive analysis:

Description of demographics of captured patients including gender, median age, aetiology of SBO and management pathway will be performed. Data on complications of management will be described.

Specific results to be reported are described as in the table below

Description	Units of analysis	Reported
Proportion of cases where period of NBM pre-admission clearly documented		As percentage of all patients
Screening for malnutrition with MUST/NRI or other score	Day 1 Day 3 Day 5 Day 7	As percentage of all patients
Assessment by dietitian following identification of malnutrition	Day 1 Day 3 Day 5 Day 7	As percentage of patients identified as malnourished
Nutritional intervention following identification of malnutrition	Day 1 Day 3 Day 5 Day 7	As percentage of patients identified as malnourished
30-day mortality		As comparison of malnourished vs non-malnourished as whole, operated and non-operated groups. Further

		analysis of malnourished with nutritional intervention vs no intervention
In-patient morbidity		As comparison of malnourished vs non-malnourished as whole, operated and non-operated groups. Further analysis of malnourished with nutritional intervention vs no intervention. To describe morbidity in palliative management patients

Authorship

Local NASBO team collaborators and data validators will be eligible for PubMed-citable co-authorship as collaborators, provided a validated dataset is returned by the closing data of the project (30th May 2017). There is a maximum of four collaborators per local team and one independent validator, unless an increase in the local team is agreed in advance by the Steering Group. Centres with >5% missing data will be excluded from the analysis and the contributing local team removed from the authorship list.

Sponsorship through the audit approval process by a consultant/senior does not constitute authorship. Similarly, inclusion of a consultants' patients in the audit is not sufficient reason for authorship. All members of the local team should participate in the process of registering the audit, identifying patients, collecting data and ensuring >95% completeness and >98% accuracy targets are met.

Data ownership

Following analysis, each unit will receive their own raw data, and a summary of national data. This will allow comparision to local performance and enable local quality improvement work. Data will be held on the University of Sheffield REDCap server. The Steering Group anticipate the data will be made available as open access for all NASBO collaborators.

Quality assurance

This protocol was written with guidance and support through the Association of Coloproctology of Great Britain and Ireland (ACPGBI) Small Bowel Obstruction Delphi Group. The protocol was interactively presented at steering group meetings on 26th May 2016 and 29th October 2016 either side of a pilot study, run in 8 centres in October 2016. The study protocol was refined following feedback from these meetings.

Expected Outputs:

All data will be reported as a whole cohort. Unit level data for comparison will be fedback to collaborators to support local service improvement.

This project will be submitted for presentation at a national or international surgical conference.

Manuscript(s) will be prepared following close of the project.

Further steps

With results from the audit, we will identify an intervention and repeat the audit post-intervention.

Examples of intervention may include:

- Dietitian assessment upon admission
- Accelerated management pathway

Appendix A: See Separate Document

Appendix B: See Separate Document

Appendix C: See Separate Document

Appendix D: See Separate Document

Appendix E: See Separate Document

Appendix F: Abbreviations

ACS - Acute Coronary Syndrome

AIDS - Acquired Immuno-Deficiency Disorder

BAPEN - British Association for Parenteral and Enteral Nutrition

CCF - Congestive Cardiac Failure

CKD - Chronic Kidney Disease

COPD - Chronic Obstructive Pulmonary Disease

CT – Computer Tomography

CVA - Cerebrovascular Accident

CVC - Central Venous Catheter

DM - Diabetes Mellitus

DVT – Deep Vein Thrombosis

GA – General Anaesthetic

GP – General Practitioner

HDU – High Dependency Unit

IHD - Ischaemic Heart Disease

ITU – Intensive Therapy Unit

LBO - Large Bowel Obstruction

LRTI - Lower Respiratory Tract Infection

MI - Myocardial Infarction

MUST - Malnutrition Universal Screening Tool

N – No

NA – Not Applicable

NBM – Nil By Mouth

NELA – National Emergency Laparotomy Audit

NG - Nasogastric

NICE – National Institute of Clinical Excellence

NJ – Nasojejunal

NRI – Nutritional Risk Index

PE – Pulmonary Embolism

PICC - Peripherally Inserted Central Catheter

PN – Parenteral Nutrition

PVD - Peripheral Vascular Disease

REDCap – Research Electronic Data Capture (http://projectredcap.org)

SBO - Small Bowel Obstruction

SLE - Systemic lupus erythematosus

SSI – Surgical Site Infection

TIA – Transient Ischaemic Attack

US – Ultrasound Scan

UTI – Urinary Tract Infection

Y - Yes

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