Prospective nationwide audit of the management of adhesive small bowel obstruction: a snapshot study

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Study protocol

Background

Adhesion formation after surgical operations in abdomen and pelvis is the most common cause for long-term postoperative complications. These adhesions can have various consequences like adhesive small bowel obstruction, need for adhesiolysis in future operations, chronic abdominal pain, secondary infertility (1). Adhesive small bowel obstruction (ASBO) is the most common pathology of the small bowel and frequently results in surgical emergencies (2). Formation of adhesions can begin within a few hours after an operation (3). Characteristics of ASBO is the presence of abdominal pain, vomiting, distention, and obstipation in conjunction of confirmatory imaging (4). In the UK small bowel obstruction accounted for 51% of all emergency laparotomies (5). Scott el al. recently published on 7 emergency surgery procedures counting for 80% of morbidity and death related to emergency surgery (6). ASBO was the most common diagnosis for both the top-2 and top-5 procedure in this list.

The incidence of small bowel obstruction following peritoneal surgery is estimated between 9% to 15%, with adhesions being the most common cause of SBO, accounting for almost 60% of all cases of bowel obstruction (7). Approximately 20-30% of cases requires a reoperation to resolve ASBO.

Remarkably, little is known about the optimal management of ASBO, despite the huge morbidity and economic burden of ASBO (8). The World Society for Emergency Surgery published a consensus guideline for Diagnosis and Management of adhesive small bowel syndrome. These guidelines are not universally implemented and their recommendations are based on low quality evidence and sometimes conflicting literature (9). Diagnosis and treatment of ASBO therefore often depend on surgeon's preferences rather than evidence based medicine.

In this nationwide audit we will study differences in the management and outcomes of patients admitted with ASBO to surgical emergencies units in the Netherlands. By analysing these differences we hope to learn from best practices, and define new research questions to improve the diagnosis and treatment of ASBO.

Purpose and Research Question

In this research the differences in the management and outcomes will be studied from patients admitted with ASBO to surgical emergencies units in the Netherlands. The research question is:

''What is the impact of different variations in management and treatment of adhesive small bowel obstruction in the Netherlands on patient outcomes?''

A nationwide cohort is being observed over a short period of time, to answer the following four defined questions.

1. How many patients in the Netherlands presenting with adhesive small bowel obstruction have a CT-scan in their diagnostic work-up? And in how many patients does CT-scan impact initial management of ASBO (i.e. different cause of SBO found, or conservative trial vs. direct surgery)?
2. How long do Dutch surgeons continue a conservative trial in patients with persistent obstruction who are not clinically deteriorating?

3. Does continuing a conservative trial for more than 72 hours adverse impact final outcomes?
4. How many patients that are surgically treated for ASBO in the Netherlands have laparoscopic surgery and what are the outcomes of laparoscopic surgery?

The analysis of these defined questions will offer insights in how differences in management can impact outcome. Further, the data will also be used to generate new hypotheses on best practice in management of ASBO.

Plan of investigation

The study design of this study is a prospective observational cohort study. We will use a snapshot study design, to include a large cohort of patients with a clinical suspicion of ASBO over a period of 6 months. This design has previously been used in the Dutch surgical society to gather data of a large group of patiënts over a short period of time (10). We will include as many patients as possible with a clinical suspicion of ASBO over a period of 6 months. We will contact every hospital in our country with an informative letter about our research. When the hospital accepts to participate in the collaborative study group, a digital snapshot questionnaire will be send to provide hospital characteristics and patient data about symptoms, diagnosis, imaging, risk factors and treatment. The questionnaires will be filled by local collaborating research partners, for each patient with a suspicion of ASBO. The questions will be clear and easy to fill in. Therefore it is not a big threshold for the hospitals to participate and a lot of information can be received.
The database will be finished in Castor, in which the questionnaires will be filled in. We aim to include 500 patients with ASBO over 6 months of time. Our analysis will include regression analysis for variation in clinical management and outcome of ASBO treatment. The results will be used to form new hypotheses and update guidelines on management of ASBO.
The METC of the Radboudumc has given approval for this study. This study is not WMO- compulsory.

Data and statistical analysis

Baseline data consisted of patients age, sex, Charlson comorbidty index, ASA classification and the number of previous abdominal operations. Categorical data will be analysed using a Chi-square or Fisher's exact test, as appropriate. Continues data will be analysed using independent t-test or Mann-Whitney U test if not normal distributed. Continuous variables are presented as means with standard deviation, or medians with interquartile range (25–75) if non-normal distribution. Dichotomous or categorical variables are presented as absolute numbers and percentages. $P < 0.05$ was considered significant. All analyses will be performed using SPSS version 23°0 (Armonk, NY: IBM Corp).

Data handling

For our data handling we will use the Castor software, made by Ciwit located in Amsterdam, which has been optimized for medical research according to good clinical practice standards. The questions are predefined by the project steering group. Questions will be tested for clarity and will be relatively easy to fill to ensure a high data density, and lowering the threshold for hospitals to participate. The data can be managed in the Castor program, and exported to statistical software packages for analysis. The patient information will be anonymous and coded with numbers in our database. The decoding key of a patient is only available to the hospitals which put their patient into the system.

Societal and ethical justification

This is an observational research project, patients included in this research will not undergo any intervention or treatment as part of the research project. Therefore this study is not WMO-compulsory. The patient cannot be identified from the questionnaire, because the patient data does not contain personal information. Within this study, patients will be used as numbers, without using personal relatable information. This is in line with Good clinical practice.
Assuming that this snapshot study will provide information for an improved guideline for management and treatment of ASBO, the relevance for science of society will be noticeable for different kind of stakeholders. Potential stakeholders are clinicians, patients, health insurance companies and patient societies.

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