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OBSERVATIONAL STUDY

PROTOCOL

Study Title: *Pragmatic Investigation of Surgical versus Medical management in non-emergent Adhesive Small Bowel Obstruction: a prospective multicenter observational cohort study (SBO-CHOICE).*

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Background

Adhesive small bowel obstruction (ASBO) is one of the most frequent causes of emergency surgical admission and a major contributor to morbidity, hospital readmissions, and healthcare costs. It accounts for approximately 20% of emergency surgical presentations, with postoperative adhesions responsible for up to 75% of cases, representing a paradigmatic long-term complication of abdominal surgery [1,2]. The incidence of ASBO is estimated at around 9% among patients with previous abdominal surgery, with higher risk following colorectal resections, oncologic gynecological procedures, and multiple abdominal operations [3,4]. Surgical approach influences

long-term risk, with laparoscopic procedures associated with a lower incidence of ASBO requiring surgery compared with open surgery [5].

In the absence of absolute indications for emergency surgery—such as peritonitis, bowel ischemia, strangulation, or hemodynamic instability—current guidelines recommend an initial non-operative approach. Conservative management, including gastrointestinal decompression, fluid and electrolyte resuscitation, and close clinical and radiological monitoring, is successful in approximately 70–80% of patients with uncomplicated ASBO [6,7]. Water-soluble contrast media have become an integral component of conservative treatment, providing both diagnostic and therapeutic benefits by predicting resolution and identifying patients unlikely to benefit from prolonged non-operative management [8]. Advances in computed tomography have further improved diagnostic accuracy and risk stratification, allowing reliable identification of complete obstruction, transition points, and radiological signs of ischemia or strangulation [9–11].

Despite the high success rate of non-operative management, ASBO is associated with significant short- and long-term morbidity and mortality, with reported 1-year mortality rates ranging from 3% to 35%, particularly within the first 90 days after admission [4]. Recurrent ASBO is common, with each episode increasing the risk of further recurrence and shortening the interval between events. Long-term outcomes appear to differ according to treatment strategy, as surgical management has been associated with a lower risk of subsequent ASBO compared with conservative treatment (13% vs. 21%; hazard ratio 0.62) [11].

Recent observational studies and systematic reviews suggest that surgical treatment during the index admission may reduce the risk of future adhesive obstruction compared with repeated non-operative management in selected patients, with reported reductions in long-term recurrence rates of up to 40–60%



[12–14]. Operative management of the initial ASBO episode has been associated with a significantly lower risk of recurrence, whereas delayed surgery beyond 72 hours is linked to increased perioperative risk [3,14,15]. Nevertheless, surgery carries inherent risks and may promote new adhesion formation, making the indication for operative intervention discretionary in the absence of absolute criteria.

Overall, high-quality evidence defining optimal patient selection and timing of surgery remains limited, with substantial heterogeneity across institutions [13,15]. Consequently, in patients with ASBO not requiring immediate surgery, treatment decisions continue to rely largely on surgeon judgment and institutional practice rather than robust comparative data, representing a persistent vexata quaestio in the literature [15].



Study Aim

To determine whether patients admitted with non-emergent adhesive small bowel obstruction, in whom surgical intervention is considered clinically acceptable but not mandatory, experience better outcomes if they undergo surgery during the index hospitalization or if they are managed exclusively with medical therapy and discharged without surgery.

Specifically, the study aims to evaluate whether surgical or non-surgical management during the index admission influences the risk of subsequent hospital readmission for adhesive small bowel obstruction.

Additional analyses will evaluate predefined post-discharge complication patterns associated with each management strategy.

Study Design

The present study is designed to prospectively compare real-world outcomes of patients with non-emergent ASBO managed either surgically or non-operatively during the index hospitalization, aiming to provide robust short-, mid-, and long-term outcome data within a rigorously defined clinical framework.

This is a multicenter, prospective, observational cohort study. The study does not impose any diagnostic or therapeutic algorithm. All clinical decisions are made according to routine practice and the independent judgment of the attending surgeon and not modified the common clinical practice.

Patients will be prospectively enrolled and followed over time and outcomes will be compared between two management strategies adopted during the index hospitalization.

Setting and follow up

Recruitment will be performed by surgeons participating in the study during patient access from the emergency department to the general surgery unit according to the inclusion criteria. the enrollment period will last 1 year which will be followed by five years for follow-up. The follow-up will take place according to the following methods as summarized in figure 1:

BASELINE VISIT (Visit 1)

Record personal data (age, sex)



Verify inclusion/exclusion criteria

Perform physical examinations needed to determine eligibility

Collect medical and medication history

Assess functional status

A contrast-enhanced abdominal CT-scan will be performed to confirm the diagnosis

Obtain and document consent from the participant on study consent form

INTERMEDIATE VISIT

Day of discharge (Visit 2)

Record operative data (Type of operative approach, intraoperative complication,)

Record major complications occurred in the post-operative period and classify them according to Clavien-Dindo classification (Table 1)

Record length of postoperative hospital stay

FOLLOW UP VISIT

First Follow up visit (Day 30 after discharge, Visit 3, follow up by phone)

Record complications that occurred in the post-discharge period and classify them according to Clavien-Dindo classification (Table 1).

Record re-admission and reasons for re-admission

Record histopathological tumor information

Second Follow up visit (Day 90 after discharge, Visit 4, follow up by phone)

Record major complications that occurred in the post-discharge period and classify them according to Clavien-Dindo classification (Table 1).

Record re-admission and reasons for re-admission

Third Follow up visit (6 Months after discharge, Visit 5, follow up by phone)

Record major complications that occurred in the post-discharge period and classify them according to Clavien-Dindo classification (Table 1).

Record re-admission and reasons for re-admission



Fourth Follow up visit (1 year after discharge, Visit 6, follow up by phone)

Record major complications that occurred in the post-discharge period and classify them according to Clavien-Dindo classification (Table 1).

Record re-admission and reasons for re-admission

Fifth Follow up visit (2 year after discharge, Visit 7, follow up by phone)

Record major complications that occurred in the post-discharge period and classify them according to Clavien-Dindo classification (Table 1).

Record re-admission and reasons for re-admission

Sixth Follow up visit (3 year after discharge, Visit 8, follow up by phone)

Record major complications that occurred in the post-discharge period and classify them according to Clavien-Dindo classification (Table 1).

Record re-admission and reasons for re-admission

Seventh Follow up visit (4 year after discharge, Visit 8, follow up by phone)

Record major complications that occurred in the post-discharge period and classify them according to Clavien-Dindo classification (Table 1).

Record re-admission and reasons for re-admission

FINAL VISIT

Eighth Follow up visit (5 year after discharge, Visit 9, follow up by phone)

Record major complications that occurred in the post-discharge period and classify them according to Clavien-Dindo classification (Table 1).

Record re-admission and reasons for re-admission

Study Population

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The study population includes all consecutive adult patients (≥ 18 years of age) presenting acutely (unplanned) and non-elective presentation to hospital for urgent or emergency reasons) at the participating centers with a clinical and radiological diagnosis of Adhesive small bowel obstruction.

All enrolled patients will be managed according to routine clinical practice.

Based on the treatment received during the index hospitalization, patients will be categorized into two groups:

Surgical Group

Patients who undergo operative management for ASBO during the index hospitalization.

Non-Surgical Group

Patients who are discharged without surgery, having achieved resolution of obstruction through medical management alone.

The decision to operate or not is entirely at the discretion of the attending surgeon. No predefined criteria, timing thresholds, or algorithms are imposed.

Medical management is not standardized, and may include:

- Nasogastric decompression or no decompression
- Duration of fasting
- Intravenous fluid and electrolyte therapy
- Use or non-use of water-soluble contrast agents
- Duration of conservative treatment

This pragmatic approach is intentional and reflects real-world clinical practice.

Although treatment is not protocolized, participating centers are encouraged to observe.

Patients for up to 72 hours before defining conservative treatment failure, unless clinical deterioration occurs.

Suggested criteria for failure of conservative management include: Persistent obstruction after 72 hours; Clinical deterioration; Development of exclusion criteria.

Patients Selection



Inclusion Criteria

Patients are eligible for enrollment if all the following criteria are met:

- Age ≥ 18 years
- Admission for suspected small bowel obstruction
- Diagnosis of adhesive small bowel obstruction supported by:
- Clinical criteria, including at least two of the following: Objectively abdominal pain consistent with bowel obstruction, persistent vomiting or nasogastric aspirate, Abdominal distension, failure to pass flatus or stool.
- CT findings consistent with small bowel obstruction, including: Dilated small bowel loops with air-fluid levels, Identification of one or more transition points, Absence of alternative causes of obstruction.
- CT features compatible with adhesions, such as: Abrupt transition without mass lesion, Beak sign or angulation of bowel loops, Adhesive bands or clustering of loop

Exclusion Criteria

Patients will be excluded if any of the following conditions are present at admission or develop during initial assessment:

- Clinical or radiological signs of bowel ischemia or strangulation, including:
- Peritonitis
- Pneumatosis intestinalis
- Portal venous gas
- Free intraperitoneal air
- Reduced or absent bowel wall enhancement on CT
- Closed-loop obstruction
- Hemodynamic instability or acute abdomen with systemic compromise
- Obstruction due to causes other than adhesions
- Recurrent adhesive small bowel obstruction (defined as any previous episode of clinically suspected or radiologically confirmed adhesive small bowel obstruction occurring before the index admission, regardless of whether the episode required hospital admission or was managed in an outpatient setting). During enrollment,
- investigators will record the number and approximate timing of previous obstructive episodes,



including those not requiring hospital admission.

- Immediate need for emergency surgery
- Inability to provide informed consent
- Pregnancy

Outcome Measures

Primary Endpoint

Hospital readmission for adhesive small bowel obstruction within 12 months after the index admission, defined using the same clinical and CT criteria applied for study inclusion.

Secondary Endpoints

- Emergency surgical intervention incidence during follow-up due to the development of absolute surgical indications including bowel ischemia, strangulation, peritonitis, or hemodynamic instability.
- All-cause of mortality.
- Length of hospital stay during index admission.
- Post-discharge complications, specifically including:
 - Recurrent adhesive small bowel obstruction requiring hospital readmission;
 - Adhesion-related reoperation (elective or emergency);
 - Obstruction-related complications requiring invasive procedures (e.g., nasogastric decompression requiring hospital admission, percutaneous decompression, or prolonged parenteral nutritional support).

Quality of life assessment, evaluated using:

- SF-36 (general health-related quality of life)
- GIQLI (Gastrointestinal Quality of Life Index) for bowel-related function.
- Missing data in quality-of-life questionnaires will be handled using appropriate statistical methods, including multiple imputation when applicable.



- Elective or discretionary reoperations for recurrent obstruction without objective emergency
- criteria are not considered secondary endpoints, as they reflect the same arbitrariness underlying the index decision.

Sample size

Assuming a two-sided significance level (alpha) of 0.05 and a statistical power of 80%, a total sample of 690 patients (345 per group) is needed.

Definition of study conclusion

The study involves one year of participant enrollment followed by five years of follow-up, to be carried out on all patients, including those enrolled in the final stages of the recruitment period, and subsequent data analysis. The study can be considered concluded for each individual patient at the end of the follow-up period. .

Data management

All epidemiological, clinical, and surgical data will be collected on a Case Report Form (CRF) that will be completed by accessing to a protected data system. Data will be collected and stored online on a dedicated, secure server that allows collaborators to enter and store data in a secure system, via the Research Electronic Data Capture (REDCap) web application. The link for accessing the completion of the CRF will be sent via email to only one contact person (Local Lead) of each participating center. All participating centers will be required to register the study according to local regulations, evidence of which must be uploaded onto REDCap prior to the commencement of data collection from each respective site. As this is an observational study, no changes to normal patient management are required.

No patient-identifiable data (name, date of birth, address, telephone number, etc.) will be recorded.

Every local investigator will be responsible for entering data on the online case report form for every patient included in the study.

The data collected will be stored for 25 years. The data collected will be processed using pseudonymization methods. In particular, all personal data are associated with an alphanumeric code that replaces the identification data of the interested party. The personal data are processed in association with this non-



directly identifying information and the correlation between this and the identification data of the interested party is maintained separately, ensuring confidentiality with appropriate technical and organizational security measures.

Statistical plan

Statistical expertise will be available to the authors. Descriptive statistics of the groups of interest will be evaluated using classical statistical tests. For nominal and ordinal variables expressed as absolute frequencies and percentages, the chi-square test or Fisher's exact test will be used. For quantitative variables with a normal Gaussian distribution reported as mean $\pm$ standard deviation, the ANOVA test will be calculated. For non-normal quantitative variables reported as median and range, the non-parametric Mann-Whitney U test will be used. Furthermore, since p-values ≤ 0.05 for the above tests are highly sensitive in large sample sizes, standardized differences in means/proportion between groups will also be calculated to assess clinical relevance. Statistical analysis will be performed with SPSS VR Statistics version 24.0 (IBM, Armonk, NY, USA).

Administrative Aspects

Study Funding

This research has not received any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

Ethical considerations

This is a national observational study, it will not attempt to change or modify the clinical practice of the participating physicians. The study will meet and conform to the standards outlined in the Declaration of Helsinki and Good Epidemiological Practices. Every clinical center attending the study is responsible for Ethics Committee approval depending on the local policy for observational and noninterventional studies. All surgeons involved in the patients' recruitment will be included in the research authorship.

Acquisition of informed consent and data processing

This observational study will not attempt to change or modify the laboratory or clinical practices of the participating physicians. Informed consent is a process that is initiated prior to the individual agreeing to participate in the study and continues throughout study participation. Extensive discussion of risks and



possible benefits of study participation will be provided to participants and their families, if applicable. A consent form describing in detail the study procedures and risks will be given to the participant. Consent forms will be EB approved, and the participant is required to read and review the document or have the document read to him or her. The investigator or designee will explain the research study to the participant and answer any questions that may arise. The participant will sign the informed consent document prior to any study-related assessments or procedures. Participants will be given the opportunity to discuss the study with their surrogates or think about it prior to agreeing to participate. They may withdraw consent at any time throughout the course of the study. A copy of the signed informed consent document will be given to participants for their records. The rights and welfare of the participants will be protected by emphasizing to them that the quality of their clinical care will not be adversely affected if they decline to participate in this study. The consent process will be documented in the clinical or research record.

Conflict of Interest

No conflict of interest by the principal investigator.

Data Ownership and Publication Policies

The transmission or dissemination of data, through scientific publications and/or presentations at congresses, conferences and seminars, participation in multicenter studies, will be exclusively following a purely statistical processing of the same, or in any other way in an absolutely anonymous form. Responsible for the entire research and therefore the data processing and data owner is the Promoter of the study. (Italian State Decree 30 November 2021 (<https://www.gazzetta.ufficio.it/eli/id/2022/02/19/22A01189/sg>))

The promoter as well as the main experimenter conceived the study, is responsible for it and will coordinate the collection and analysis of the data through a steering committee.

Being a multicenter study, each center will indicate a local lead and two collaborators who will be responsible for their collected data and their transmission.

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