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IMPEL

International Multi-center Profile of Emergency Large-Bowel Obstruction Management and Outcomes

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Partner Societies

ESTES EUROPEAN SOCIETY FOR TRAUMA AND EMERGENCY SURGERY

ESCP

ASCRS American Society of Colon & Rectal Surgeons

STUDY PROTOCOL

IMPEL: An international, time-bound, prospective observational clinical snapshot audit of the epidemiology and management of large-bowel obstruction

ClinicalTrials.gov Study Registration ID* NCT07458867

***Registration is undertaken for transparency and international coordination and does not imply classification as human-subjects research. Local regulatory classification (audit, service evaluation, or research exemption) is determined by each participating center in accordance with applicable national and institutional requirements.**

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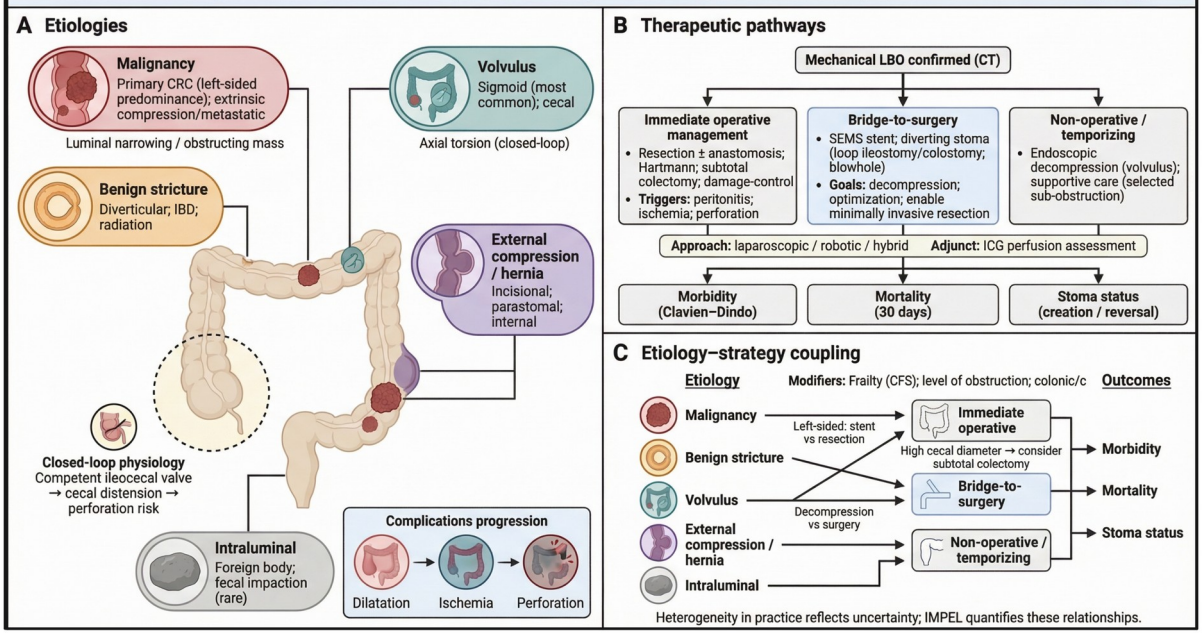
IMPEL

International Multi-center Profile of Emergency Large-Bowel Obstruction Management and Outcomes

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ESTES EUROPEAN SOCIETY FOR TRAUMA AND EMERGENCY SURGERY · ESCP · ASGBI Association of Surgeons of Great Britain and Ireland · ASCRS American Society of Colon & Rectal Surgeons

Mechanical Large-Bowel Obstruction (LBO): Etiologies, Management Pathways, and Outcomes Coupling



Background and Rationale

Mechanical large-bowel obstruction (LBO) is a common and high-acuity emergency surgical presentation associated with substantial morbidity, mortality, and health-care resource utilization. Patients frequently present with evolving physiologic derangement, including dehydration, electrolyte imbalance, sepsis, and risk of bowel compromise or perforation. Despite the clinical importance of this condition, contemporary evidence describing real-world management of LBO remains limited. Existing literature is dominated by retrospective analyses, cancer-specific cohorts, and single-center series, with guideline recommendations frequently extrapolated from heterogeneous datasets.

In routine practice, marked variation exists in diagnostic pathways, timing of operative intervention, selection of operative strategy, and postoperative care. Differences in the use of computed tomography, endoscopic decompression, thresholds for urgent surgery, choice between single-stage and staged procedures, and postoperative monitoring reflect local practice patterns rather than a robust prospective evidence base. These variations are likely to influence outcomes including postoperative complications, mortality, stoma formation, and the probability of subsequent restoration of bowel continuity.

The International Multicenter Profile and Evaluation of Large-Bowel Obstruction (IMPEL) study applies a time-bound, prospective snapshot audit methodology to address these gaps. By capturing consecutive patients across diverse acute-care hospitals within a defined inclusion window, IMPEL provides a structured description of contemporary diagnostic and therapeutic pathways and their associated outcomes. The prospective design minimizes misclassification and temporal ambiguity inherent in retrospective studies and enables consistent capture of operative findings, postoperative complications, and follow-up outcomes. The resulting dataset is intended to support service evaluation, benchmarking, and identification of potentially modifiable processes of care, while providing a foundation for future guideline development and formally approved interventional studies.

Study Objectives

IMPEL intends to audit routinely collected clinical data in adult patients presenting with mechanical large-bowel obstruction. The primary objective is to **characterize contemporary management strategies and short-term outcomes across participating centers, with particular attention to diagnostic pathways, operative timing, surgical strategy, and stoma-related outcomes**. A further objective is to enable participating centers to **benchmark local practice and outcomes against aggregated international data** derived from comparable health-care settings.

Secondary objectives include **description of postoperative morbidity and mortality, patterns of non-operative management, utilization of critical-care resources, and six-month stoma status**. Associations between routinely collected clinical variables and observed outcomes will be explored to inform **quality-improvement initiatives and future hypothesis-driven work**.

Study Design

IMPEL is a multicenter, non-randomized, time-bound prospective clinical audit and service evaluation initiative conducted using a standardized snapshot methodology and based exclusively on routinely collected clinical data. [3] Each participating center will include all eligible adult patients over a consecutive ninety-day inclusion period selected within a predefined six-month global study window. Data collection will occur contemporaneously using electronic case report forms, with follow-up extending to six months after index admission. For regulatory purposes, IMPEL is designed to meet criteria for audit, quality improvement, or observational research exemption in many jurisdictions; final classification is determined locally.

No experimental interventions are introduced, and no additional investigations or procedures beyond standard clinical care are required. The audit does not mandate, recommend, modify, or discourage any diagnostic or therapeutic decisions and does not influence local clinical pathways. All patients will be managed entirely according to local standards of care. Any later comparative analyses, including analyses framed using target trial emulation principles, will be conducted only after completion of routine clinical care and will use de-identified observational data. These analyses will not alter eligibility, treatment selection, timing of intervention, follow-up, or clinician decision-making.

Study Participants

Eligible participants include adults aged eighteen years or older admitted with mechanical large-bowel obstruction, defined radiologically, clinically, or intraoperatively. This includes obstruction due to malignancy, volvulus, diverticular or inflammatory stricture, radiation-induced stricture, extrinsic compression, hernia involving the colon, or large-bowel perforation attributable to mechanical obstruction. Both operative and non-operative cases are eligible for inclusion.

Patients with functional obstruction without a structural cause, isolated diverticular perforation without obstruction, elective admissions for chronic or subacute narrowing, and patients younger than eighteen years will be excluded. Pregnant persons will be included or excluded in accordance with local clinical governance policy and consultant-level decision-making.

Case Identification and Enrollment

Designated site investigators will identify eligible cases through daily review of emergency department admissions, radiology reports, surgical admission and handover lists, and emergency operating theatre logs. All eligible cases during the inclusion window should be captured consecutively to minimize selection bias.

Each included case will be assigned a unique audit identifier. Local governance requirements for clinical audit or service evaluation approval will be followed. Retrospective inclusion of cases inadvertently missed during the inclusion window is permissible only where reliable contemporaneous clinical data are available.

Data Collection

No study-specific clinical assessments, imaging, procedures, treatments, or mandated patient contact are required. Anonymized data will be entered into a secure, firewalled REDCap® database hosted by the Center for Emergency Surgery Outcomes Research (CESOR). Data collection instruments capture patient demographics, comorbidities, presenting physiology, diagnostic imaging and timing, operative and non-operative management strategies, postoperative complications, and in-hospital outcomes. To ensure full de-identification, the database does not capture absolute dates or times of admission, imaging, operative intervention, discharge, or follow-up. All temporal variables are recorded exclusively as relative intervals (e.g., hours from presentation to imaging, days from admission to surgery, days from discharge to follow-up). No calendar dates, clock times, or direct temporal identifiers are collected or transferred. Thirty-day morbidity and mortality will be recorded, and six-month follow-up will ascertain stoma status and late complications. Patient-reported gastrointestinal recovery will be assessed using the PRO-diGI instrument where available through routine clinical follow-up pathways. No additional patient contact is mandated beyond usual care.

Data Management and Confidentiality

All data uploaded to the central database will be fully de-identified prior to transfer. Direct patient identifiers will not be transmitted. Where required, a local linkage log, mapping patient identifier to audit identifiers, will be retained securely at each participating site and will not be shared externally. All data uploaded to the central database are fully de-identified prior to transfer. Direct patient identifiers are not transmitted, and no absolute dates or times of clinical events are collected. Temporal information is recorded solely as relative time intervals, consistent with HIPAA Safe Harbor standards and equivalent international de-identification frameworks, including NHS small-number suppression principles. Where required, a local linkage log mapping institutional identifiers to audit identifiers is retained securely at each participating site and is not shared externally. Data storage and transfer comply with applicable data-protection regulations, including the UK and EU General Data Protection Regulation (GDPR) and, where applicable, the United States Health Insurance Portability and Accountability Act (HIPAA). Institutional information-governance policies and data-processing agreements will be followed at each participating center. Only fully de-identified data are transferred to the coordinating center. No direct identifiers, limited datasets, or re-identifiable information are shared. Local sites retain any linkage files securely and do not transmit them. The coordinating center does not receive protected health information (PHI) as defined under HIPAA and does not have the ability to re-identify individuals. As such, data transfer does not constitute disclosure of PHI and does not require a Data Use Agreement under HIPAA or GDPR. Each participating center remains the data

controller for its own patients' data in accordance with applicable law; the coordinating center acts as a data recipient for de-identified information only.

Risk-Benefit Assessment

This clinical audit and service evaluation is considered minimal risk, as it involves analysis of routinely collected clinical data and does not alter patient management. Participants will not be exposed to additional investigations, procedures, or costs because of inclusion in the audit. Potential benefits include improved understanding of contemporary practice, support for local quality-improvement initiatives, and benchmarking against international standards in the management of mechanical large-bowel obstruction.

Statistical Analysis

Analyses will be primarily descriptive, summarizing patient characteristics, diagnostic and management pathways, and outcomes across participating centers. Associations between routinely collected clinical variables and observed outcomes will be explored using appropriate multivariable and observational analytic techniques, accounting for clustering by center and potential confounding. Missing data will be handled using prespecified strategies consistent with best practice for observational studies. All analyses will follow the STROBE framework for transparent reporting of observational cohort data. A detailed Statistical Analysis Plan will be finalized prior to database lock. Where comparative questions are examined, analytic frameworks may use target trial emulation principles to define eligibility, time zero, treatment strategies, and estimands. These methods are analytic only and do not imply treatment assignment, randomization, protocolized care, or deviation from local standard practice.

Governance

The audit is overseen by an international Steering Committee coordinated by CESOR, with representation from the European Society for Trauma and Emergency Surgery, the European Society of Coloproctology, the American Society of Colon and Rectal Surgeons, and the Association of Surgeons of Great Britain and Ireland. ClinicalTrials.gov registration is undertaken for transparency and international coordination. Registration does not alter the study's non-interventional audit/service-evaluation design and does not supersede local determinations regarding audit, service evaluation, exemption, or research ethics classification.

The IMPEL Steering Committee will consider proposals for secondary analyses that are scientifically and ethically appropriate. Any secondary use is subject to Steering Committee

approval and the applicable local regulatory and governance requirements. Only de-identified data will be used for any approved secondary analyses.

IMPEL is an international, minimal-risk observational initiative based on routinely collected clinical data. In many jurisdictions, including the United Kingdom, it is expected to qualify as a clinical audit or service evaluation. In the United States, participating centers may determine that the study meets criteria for exemption under 45 CFR 46.104(d), including categories relating to secondary research use of identifiable information or quality-improvement activities. Within the European Union and other regions, local ethics committees may classify the study as audit, service evaluation, or exempt observational research in accordance with national regulations. Each participating center is responsible for securing the appropriate local determination prior to case inclusion.

Unanticipated issues, protocol deviations, or data-governance concerns will be managed in accordance with local clinical governance, audit, or ethics-oversight policies, as applicable. Substantive protocol amendments will be reviewed by the Steering Committee and communicated to participating centers, with local approval sought where required. No site is required to seek central ethics approval; all regulatory determinations are made locally. Data access is limited to authorized study personnel through role-based permissions, and all access and modifications are logged. No secondary data sharing outside the IMPEL Steering Committee–approved analyses will occur without separate local and central approvals. Where required by institutional policy, sites may execute a brief data-transfer acknowledgement; however, the study design does not mandate bilateral data sharing agreements for participation.

Study Timeline

Center registration and local approvals will occur prior to initiation of data collection. Each center will undertake a consecutive ninety-day inclusion period within the global six-month study window. Six-month follow-up will be completed for all included patients, after which the database will be locked and analyses undertaken.

Appendices

Appendix A: Data Collection Instruments and Data Dictionary Overview (IMPEL)

Module (DCI)	Title	Key Data Elements Captured
DCI 1	Screening and Case Ascertainment Log	Records all patients screened during the local audit window, including eligibility status, inclusion or exclusion outcome, and reason for non-inclusion. Supports verification of consecutive case capture and assessment of ascertainment completeness at each participating center.
DCI 2	Patient Demographics and Presentation	Baseline characteristics at admission, including age, sex, relevant comorbidities, prior abdominal surgery, and baseline functional status. Presenting features such as abdominal pain, distension, vomiting, obstipation, symptom duration, initial vital signs, and suspected anatomic level and etiology of obstruction are recorded.
DCI 3–5	Past Medical History, Functional Status, and Pre-Admission Care	Medical and surgical history including comorbidity burden, malignancy history, prior colorectal disease, and chronic medication use. Records pre-admission management such as antibiotics, bowel decompression, inter-hospital transfer, and baseline mobility or dependency to support risk adjustment.
DCI 6	Emergency Department Assessment and Initial Management	Diagnostic and management data from arrival to definitive decision-making, including timing and modality of imaging, key laboratory results, resuscitative measures, nasogastric or rectal decompression, endoscopic evaluation where performed, and time intervals to operative or non-operative management decisions.
DCI 7	Operative and Procedural Details	For patients undergoing intervention, captures timing and urgency of procedure, operative approach, intraoperative findings, extent of resection, anastomosis or stoma creation, use of staged or damage-control strategies, and relevant intraoperative adjuncts, based on routine operative documentation.
DCI 8	In-Hospital Course and Outcomes	Post-intervention and inpatient course, including admission to critical care, organ support requirements, re-interventions, and postoperative complications graded using standardized systems such as Clavien–Dindo. Records length of stay, discharge destination, and in-hospital mortality.
DCI 9	Follow-Up and Stoma Outcomes	Post-discharge outcomes including thirty-day vital status, readmissions, and return to theatre. Six-month follow-up documents stoma status, including persistence or reversal, and late complications identified through routine clinical follow-up pathways. Patient-reported gastrointestinal recovery is recorded using PRO-diGI where available.

Fields describing clinical feasibility, treatment intent, or reason for pathway selection are abstracted retrospectively from routine documentation and are collected solely to describe real-world decision-making. They do not guide or constrain care.

