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A systematic review of outcomes reported in small bowel obstruction research

Short title: Outcomes reported in SBO Research

Katie Mellor MSc[1], Daniel Hind PhD[1], Matthew J Lee MBChB BMedSc MRCS[2,3]

1. Clinical Trials Research Unit, School of Health and Related Research, Sheffield S1 4DA

2. Medical School, University of Sheffield, S10 2RX

3. Sheffield Teaching Hospitals NHS Foundation Trust, Sheffield, UK, S5 7AU

Corresponding author

Matthew Lee

Department of General Surgery, Northern General Hospital, Herries Road, Sheffield S5 7AU

Telephone: +44 0114 243 4343

Fax: +44 0114 256 0472

Email: m.j.lee@sheffield.ac.uk

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Abstract

Background

Small bowel obstruction (SBO) is a condition which is commonly treated by general surgeons. The evidence base for treatment of this condition is limited in part by variable reporting of outcomes in the literature. The aim of this study was to identify commonly used outcomes in research on SBO.

Methods

This review was reported in line with PRISMA guidelines and registered with PROSPERO (CRD42017065538). Searches were performed of MEDLINE, EMBASE and CENTRAL databases to identify prospective cohort or randomised trials reporting outcomes of interventions in SBO. Studies addressing diagnostics, paediatric populations, and SBO due to malignancy were excluded. Studies were screened for inclusion. Study and outcome characteristics were extracted into a predesigned proforma and mapped onto the OMERACT framework.

Results

A total of 1,222 studies were screened for eligibility, 74 full text articles retrieved and 51 studies included for synthesis. A total of 50 different outcomes were used. Duration of hospital stay was the most frequently reported outcome (n=21 studies). Resolution of SBO was reported in 12 studies, but only defined in 8 studies which used 6 different definitions. Patient reported outcomes were reported in only four studies.

Discussion

There is a high degree of variation in the outcomes reported in SBO research. There is a clear need for a core outcome set. Development of a patient reported outcome measure for this condition should also be explored.

Background

Small bowel obstruction is a common condition, accounting for around half of all emergency laparotomies each year[1]. Outcomes for this condition are poor, with high rates of morbidity and mortality reported[1 2]. As this is a high volume condition with poor outcomes, it is important to improve the care of patients with small bowel obstruction, through quality improvement and research[3 4].

It is well recognised that surgery lacks the high-quality evidence in the form of randomised controlled trials seen in other clinical fields[5]. One of the challenges to research both in trials and cohort studies is selective reporting bias, which limits comparison of studies and has potential to skew reporting of key benefits and harms of treatments[6 7]. In order to address this, it is important to have a common set of outcomes with matching definitions. This could be achieved through the development 'Core Outcome Set' (COS), defined as 'an agreed, standardised set of optimal outcome measures that should be reported, as a minimum, in all studies investigating a specific clinical population'[8]. In 2010, the Core Outcome Measures in Effectiveness Trials (COMET) initiative (http://www.comet-initiative.org/) was launched with the aim of addressing the problem of a lack of outcome measurement standardisation in clinical trials[9]. Core outcome sets have already been produced in other surgical conditions[10 11]. The first step in the production of a COS is to identify commonly used outcomes in the literature. Qualitative work is undertaken with patients to identify additional outcomes of importance. The long list is then presented to stakeholders including clinicians and patients and a consensus process (e.g. Delphi) is followed to reach a consensus on which are most important[12].

The aim of this study was to identify and categorise outcomes used in research on small bowel obstruction.

Method

A protocol for this systematic review is available on PROSPERO (registration: CRD42017065538). The review is reported according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines[13].

Search strategy

A search strategy was devised with input from a librarian at the School of Health and Related Research, University of Sheffield. Electronic databases searched included: MEDLINE (accessed through the PubMed interface), EMBASE (accessed through the OVID interface), and the Cochrane Central Register of Controlled Trials (CENTRAL). Validated filters were used to search for RCTs in EMBASE, and MEDLINE[14 15]. The search strategy is presented in appendix 1. Backwards citation tracking of reference lists of relevant reviews, and forwards citation tracking of relevant articles, were also used, as per COMET guidance[16]. Further hand searching of all titles and relevant abstracts of studies published in the 'British Journal of Surgery', and 'Annals of Surgery' were used to identify relevant publications within the last 20 years.

Eligibility criteria

All randomised controlled trials (RCTs) and prospective cohort studies were included. No restriction was placed on publication date. Only English language articles were included due to time and resource constraints. The target population was adults with SBO, irrespective of duration of disease. Studies evaluating the clinical effectiveness of any therapeutic intervention for SBO were eligible. No restriction was placed on comparator interventions. Any construct used to evaluate the clinical effectiveness of therapeutic interventions for SBO were eligible.

Manuscripts which were retrospective, conference abstracts of study protocols were excluded. Studies addressing diagnosis of SBO or treatment in paediatric populations were excluded. Reports

of SBO due to peritoneal carcinomatosis, left sided colonic tumour, or immediately following other procedures, were also excluded as cancer related outcomes are less applicable to the general SBO population.

Study selection

Literature search results were exported and de-duplicated manually by comparing multiple data from each publication. One researcher considered the title and abstract of each study identified, and obtained the full texts of studies included at this stage. When full texts could not be accessed through the University of Sheffield resources, or by request to the author, they were requested through the British library. One researcher analysed the full texts of each study to identify those for inclusion. Guidance from the research team was sought regarding eligibility queries.

Data extraction and analysis

Data on publication details, study design and characteristics, intervention/comparator details, outcome measures and definitions were extracted into a pre-designed pro forma.

Outcome data were extracted as reported, and tables were constructed to indicate reported or omitted outcomes. Composite outcomes, or umbrella terms, such as 'complications', were decomposed into their component constructs. Outcomes were subsequently categorised into domains based on the OMERACT Filter 2.0 framework[17]. OMERACT is a framework for selecting and measuring outcomes when deciding which outcomes to include in a COS. OMERACT specifies four core areas (death, life/impact, resource use/economic impact, and pathophysiological manifestations) which are recommended to be considered and measured to assess the overall effect of an intervention on a specific health condition.

In keeping with similar reviews where list of outcomes reported are collated and not synthesised[18 19], neither bias or quality assessment or meta-analysis of included studies was planned.

Results

Search

Electronic database searches retrieved 1,467 results. 31 additional results were obtained through other sources: 5 through citation tracking, 14 through screening reference lists, and 12 through hand searching of key journals (5 from the British Journal of Surgery, and 7 from the Annals of Surgery). After de-duplication 1,222 results remained to be screened; 74 full texts were retrieved and 23 were excluded, leaving 51 studies were included in the final review (Figure 1).

Included studies were published between the years of 1988 – 2015. Twenty studies focussed on operative management of SBO (3 RCTs[20 21 22], and 17 prospective cohort studies[2 23-38]) 31 focussed on conservative management (21 RCTs[39-59], and 10 prospective cohort studies[60-68]). Study characteristics presented in supplementary file 1.

A range of 50 different outcome measures were reported within the 51 included studies. These outcomes were then categorised into 9 separate domains and mapped to core areas based on the OMERACT Filter 2.0, displayed in Table 1.

Synthesis of results

Application of the OMERACT Filter to outcomes found areas of overlap where outcomes could be categorised in multiple domains. For example, outcomes associated with pain, specifically pain scores as assessed using a scale, could be interpreted either as a patient reported outcome (PRO; core area 'life impact'), or as an analgesic measure (core area of 'pathophysiological manifestations'), see Figure 2.

Pathophysiological manifestations

The pathophysiological manifestation core area encompassed three sub-domains: 'General procedural measures', 'procedure specific measures' and 'analgesic measures', to which 17 outcomes were assigned. General procedural measures included outcomes applicable to most therapeutic interventions including the 'duration of hospital stay' and 'time to resolution'. The term 'resolution' was reported in 12 studies, and defined in 8 (Table 2). There was significant heterogeneity surrounding the definition, and the outcome can be described as a 'compound outcome', for which different authors select different components to encompass the same concept, with no standardised description. The most frequently used definition of 'resolution' involved both the absence of associated symptoms, and radiographic improvement. One study that used this definition recognised the absence of certain components, suggesting additional concepts such as the reduction in abdominal pain would improve the definition[65]. The sub-domain 'procedure specific measures' included outcome measures reported that were largely dependent on the study intervention. For example, studies of operative management commonly reported the 'conversion rate' from laparoscopy to laparotomy when laparoscopy was used, and the 'rate of bowel resections', however only one study specified the median resection length[67]. Studies looking at conservative management, namely water soluble contrast agents, reported outcomes such as 'detection of contrast in the colon' and the 'suitability and tolerability of contrast media'. Other outcome measures were intervention specific and only reported in a few studies. The final sub-domain 'analgesic measures' contained outcomes reported across only two studies.

Resource use

The resource use core area contains the domain 'process measures' only, to which 13 outcomes were assigned. The majority of these outcomes were based on the rates and successes of different interventions, such as 'operative rate', 'time from admission to intervention' and 'intervention success rate' (defined in two studies as whether patients remained 'asymptomatic after the last follow-up')[24 38].

Life impact

The life impact core area was the most diverse, containing 20 different outcomes. This core area was categorised into 5 sub-domains. The sub-domain 'GI recovery' includes outcomes associated with dietary resumption and return of bowel function (defined in 7 studies as the first bowel movement, and appearance of flatus and/or defecation)[20 36 37 44 54 57 68]. Four studies reported PROs', but no studies reported on patient overall quality of life.

Complications of management

Clinician reported outcomes (CRO's) were frequently assessed within the studies with 37 studies (73%) reporting at least one of the outcomes 'mortality', 'morbidity' or 'complications of management'. The range of complications reported within studies varied, and some studies categorised complications into 'intraoperative' and 'postoperative'[20 26 30 38 59]; 'early' and 'late'[22]; 'medical' and 'surgical'[27 67]; or 'all' and 'major',[36] however, most did not offer such categorical reporting. Most studies reported a breakdown of the varied health states that contributed to the complication composite outcome, seven studies did not. In total, 43 unique outcome terms associated with complications were identified. The most frequently reported complications were mapped to domains of 'direct procedural', 'systemic post-operative', 'local post-operative' and 'Gastrointestinal (GI) recovery' (Figure 3 & Table 3). There was inconsistency within the reporting of the outcomes 'anastomotic breakdown', and 'small bowel leakage', and 'small bowel recurrence' either as individual outcomes or as a component of the compound outcome 'complications'[20 30 31 37 45 54].

Long-term outcomes and others

Other study specific CRO's were also reported[21 44]. The final sub-domain 'long term outcomes' includes 'hospital readmission rate'[27 36 40], and outcomes associated with SBO recurrence.

Discussion

This study reports the results of a systematic review and categorisation of outcomes reported in studies on small bowel obstruction. It is the first to attempt to classify outcomes for this condition using the OMERACT tool.

In keeping with other surgical conditions, there was a high degree of variation in the outcomes reported across studies[69,70], especially around 'resolution'. 'Resolution' was often a composite outcome[71] requiring several criteria to be met. These component criteria can be vague (e.g. tolerance of food) and therefore open to gaming and bias[72]. Variation was also noted in the reporting of complications of management, where complications were groups and reported in different manners across studies. It is recognised that the variable reporting of outcomes is often linked to publication bias[73].

In the 51 included studies, only four included a patient reported outcome measure. The patient reported measures were pain, distress and satisfaction, measured on visual analogue scales or unvalidated self-rating measures. Whilst these measures should be easy to reproduce, they address only one aspect of patient experience and outcome. For example, a patient undergoing an operation may have temporarily increased pain but earlier resolution of distention and return of gut function than a patient managed conservatively, and these factors may affect their reported outcome in different ways[28]. The fact that an outcome measure is often used does not mean that its measurement properties are robust[16], assessment of which requires further work, using the COnsensus-based Standards for the selection of health status Measurement Instruments (COSMIN) assessment tool[74]. One patient reported outcome measure (PROM) has been developed for patients with small bowel obstruction. The population from which it was derived was predominantly one with recurrent SBO, and relates to longer term outcomes associated with this. This may limit applicability to the general SBO population, despite other positive aspects of this PROM[75]. This is an area which requires further attention, either with the development of a patient reported outcome

measure for SBO, or through routine use of generic patient outcome measures across multiple domains.

The main limitation of this study is study selection by a single author. Despite this, we believe this work is robust; we have followed a predefined protocol, used validated techniques to ensure reliability of the search strategy, and manually searched key sources for additional studies. Second reviewers were involved in extraction, checking and synthesis of data.

There are a number of further steps required to generate a core outcome set. These include qualitative work with patients to elucidate patient centred outcomes which might not occur to a clinician. These outcomes should be added to the long-list identified here, and prioritised by stakeholders, using a consensus method such as Delphi. Appropriate measures for the outcomes should also be selected, and these measures should be selected for their demonstrated properties of reliability and validity. Whilst we cannot propose a definitive core outcome set here, it is likely to include: time to resolution/gastrointestinal recovery using a composite measure such as GI-2[76], whether surgical intervention is performed and the time to this event, small bowel resection rates, use of critical care facility, duration of hospital stay, and mortality. Specific complications of management should be reported including surgical site infection, cardiac complications, respiratory complications, renal complications, delirium, and surgical complications including abdominal wall dehiscence, enterotomy, and unplanned return to theatre.

Until a core outcome set is finalised, we would encourage researchers in this field to carefully consider the outcomes they report in prospective and trial based research, and ensure that clearly defined, reproducible measures are used to facilitate comparison between trials.

Conclusion

There is a high degree of heterogeneity in selection and definition of outcomes in small bowel obstruction research. This shows a clear need for consensus between researchers, and the need for a core outcome set. Development of a patient reported outcome measure for this condition should also be explored.

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Table Legends

Pathophysiological manifestations	General procedural measures	1. Duration of hospital stay;[17,18,20–25,28,30,33–40,42–48,50–52,55–59,63,66,67] 2. Time to resolution;[37,40,44–46,48,56–60,63] 3. Time from admission to relief of obstruction[50]	36 (71) 12 (24) 1 (2)
	Procedure specific measures	4. Detection of contrast the colon;[38,44,57,59,60,62,63,66,67] 5. Conversion rate from laparoscopic surgery to laparotomy (if laparoscopic surgery used);[21–23,27,28,33,35,36] 6. Rate of bowel resections;[17,25,34,39,45,46,66] 7. NG tube placement duration;[18,47,48,55,66] 8. Daily NG tube output;[48,55,60,63] 9. Time until abdominal radiographic improvement;[42,63] 10. Microbiological measurement of bacterial translocation;[18] 11. Mean time for gas canalisation;[36] 12. Clinical evidence of systemic inflammatory response' as measured by recovery of WBC counts, CRP level and ESR;[42] 13. Suitability and tolerability of contrast media (based on taste, radiologic efficacy and patient reactions);[64] 14. Presence of other sutures[17]	9 (18) 8 (16) 7 (14) 5 (10) 4 (8) 2 (4) 1 (2) 1 (2) 1 (2) 1 (2)
	Analgesic measures	15. Time until resolution of pain;[36] 16. Time until relief of abdominal pain/distention;[42] 17. Abdominal pain since laparoscopic lysis[36]	1 (2) 1 (2) 1 (2)
Resource use	Process measures	18. Operative rate;[25,30,37,39–45,50,51,55,57,63,65–67] 19. Non-operative management success rate;[25,37–41,43,47,51,58–60,63,66,67] 20. Rate of surgery after failed non-operative management;[30,37–42,45,47,58,60,61,66,67] 21. Procedure duration;[17,18,21,22,27,28,33,36,45,49,51,53] 22. Time from admission to intervention;[30,38,39,45–47,56,58,59,66,67] 23. Operative findings;[33,47,51,60,66] 24. Intervention success rate;[21,22,36,49] 25. Incidence of bowel strangulation;[25,45,46] 26. Duration of radiation exposure;[49,53] 27. Total number of treatments;[58] 28. Admission to the Intensive Care Unit (ICU);[30] 29. ICU length of stay;[30] 30. Duration of IV therapy[45]	18 (35) 15 (29) 14 (27) 12 (24) 11 (22) 5 (10) 4 (8) 3 (6) 2 (4) 1 (2) 1 (2) 1 (2) 1 (2)
Life impact	GI recovery	31. Time until return of bowel function;[17,34,35,37,42,52,55,66,67] 32. Time until resumption of a liquid diet;[18,33,35,55,60,62,66] 33. Time until resumption of a solid diet;[18,35,60] 34. Gastric upset[52]	9 (18) 7 (14) 3 (6) 1 (2)
	PRO	35. Pain scores (visual analogue scale and verbal rating scale);[55,66] 36. Patient distress (visual analogue scale);[49] 37. Patient satisfaction[48]	2 (4) 1 (2) 1 (2)

	CRO	38. Complications of management;[17–19,23–25,27–30,33–37,40,41,43,45–49,52,53,56,57,59,63,65,66] 39. Mortality;[17,19,21–25,27–30,32–36,45–47,51,56,59,63,65] 40. Morbidity;[17,19,21–23,25,28,29,31,34,47,51,55] 41. Small bowel transit time;[18,64] 42. Drainage volume on first day;[42] 43. Intra-abdominal pressure gradient before and after intervention;[18] 44. Forced expiratory volume (1 second/forced vital capacity);[18] 45. Blood loss[17]	31 (61) 24 (47) 13 (25) 2 (4) 1 (2) 1 (2) 1 (2) 1 (2)
	Long term outcomes	46. SBO recurrence rate;[17,19,24,26–28,31,32,35,36,41–44,48,51,54,57,60,65,67] 47. Recurrences submitted to surgery/reoperation;[17,19,22,29,32,35,36,44,57] 48. Hospital readmission rate;[24,34,38] 49. Time to recurrence;[24,44,57] 50. Recurrence free survival[44,54,57]	21 (41) 9 (18) 3 (6) 3 (6) 3 (6)

NG = nasogastric, WBC = White Blood Count, CRP = C-reactive protein, ESR = Erythocyte sedimentation rate, ICU = Intensive care unit, IV = intravenous, SBO = Small bowel obstruction

Table 1: Summary of outcomes reported in OMERACT Framework

Study	Term used	Definition
Ambiru. 2008[54]	Resolution rate	'The number of admissions after which the patient left the hospital without undergoing surgery to resolve the disease / total number of admissions'
Burge. 2005[36]	Resolution	'Flatus and bowel motion'
Choi. 2002[52] **Choi. 2005**[55] **Rajkumar. 2014**[59]	Complete resolution	'Established when the symptoms and signs of obstruction subsided, and abdominal radiographs did not show the small bowel dilated'
Di Saverio. 2008[53]	Resolution	'Complete resolution of clinical and radiological signs and symptoms, with tolerance to a solid food diet'
Fevang. 2000[42]	Obstruction resolved	'Judged by the passage of contrast into the colon or the anal passage of flatus and stools'
Gong. 2013[44]	Complete resolution	'Established when symptoms and signs of obstruction subsided, normal flatus and defecation returned, and there was no relapse of obstructive symptoms after withdrawal of somatostatin'

Table 2: 'Resolution' of Small Bowel Obstruction and reported definitions.

Complication	Frequency (%)
Wound infection [18,21,23–25,27–29,33,35,46,48,52]	13 (25.4)
Cardiac [23–25,29,30,32,34,35,46]	9 (17.6)
Pneumonia [23,25,28–30,41,43,46,48]	9 (17.6)
Urinary [24,29,30,33–35,43]	7 (13.7)
Bleeding [23,25,28,29,35,65]	6 (11.7)
Respiratory [25,30,32–34,52]	6 (11.7)
Sepsis [19,24,27,29,30,34]	6 (11.7)
Prolonged/postoperative ileus [24,27,29,41,47]	5 (9.8)
Pulmonary [18,23,24,29,35]	5 (9.8)
Thrombosis or embolism [19,24,25,29,46]	5 (9.8)
Anastomotic breakdown [17,30,35,52]	4 (7.8)
Recurrent obstruction [27,28,35,43]	4 (7.8)
Renal [29,30,33,34]	4 (7.8)
Abdominal infection [25,35,46]	3 (5.8)
Enterotomy [27,28]	2 (3.9)
Organ injury/failure [23,32]	2 (3.9)
Peritonitis (unrecognized or secondary perforation) [35,41]	2 (3.9)
Vomiting [19,57]	2 (3.9)
Access injury [28]	1 (1.9)
Bowel resections [57]	1 (1.9)
Bowel strangulation [57]	1 (1.9)
Catheter related infections [48]	1 (1.9)
Cholestasis [48]	1 (1.9)
Coma [29]	1 (1.9)
Dehiscence [29]	1 (1.9)
Delirium [34]	1 (1.9)
Diabetic [24]	1 (1.9)
Failure to wean from ventilator >48 hr [29]	1 (1.9)
Incisional hernia [28]	1 (1.9)
Intestinal necrosis [24]	1 (1.9)
Intraperitoneal abscess [24]	1 (1.9)
Mental disorders [19]	1 (1.9)
Nerve injury [29]	1 (1.9)
Nostril erosion [43]	1 (1.9)
Paralytic Ileus [33]	1 (1.9)
Patients requiring Percutaneous Transhepatic Cholecystostomy (PTC) [48]	1 (1.9)
Perforation [23]	1 (1.9)
Persistent obstruction [41]	1 (1.9)
Pneumothorax [48]	1 (1.9)
Small bowel leakage [17]	1 (1.9)
Small bowel paralysis [23]	1 (1.9)

Unplanned intubation [29]	1 (1.9)

Table 3: Complications reported

Figure Legends:

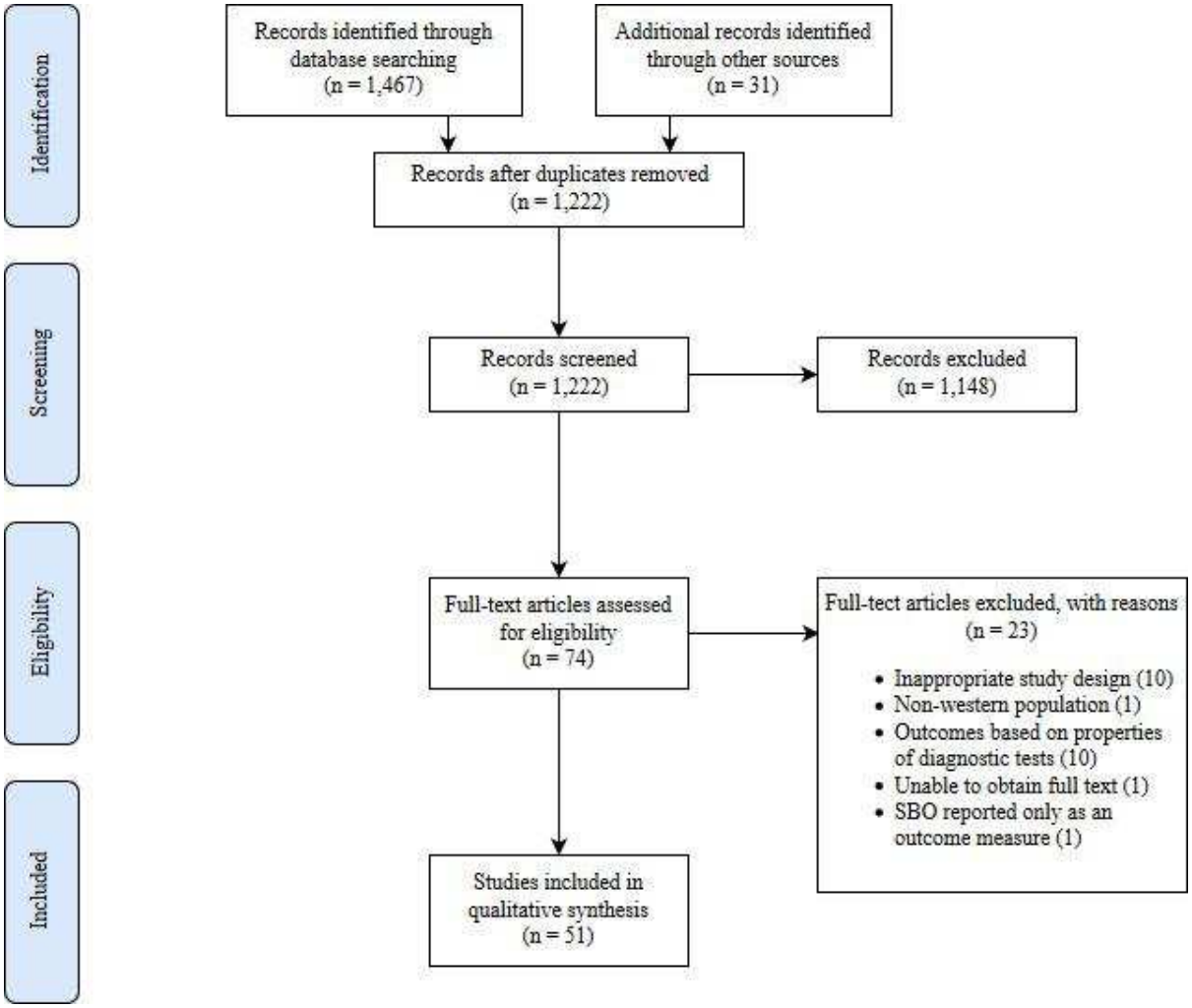

Figure 1: PRISMA Flowchart

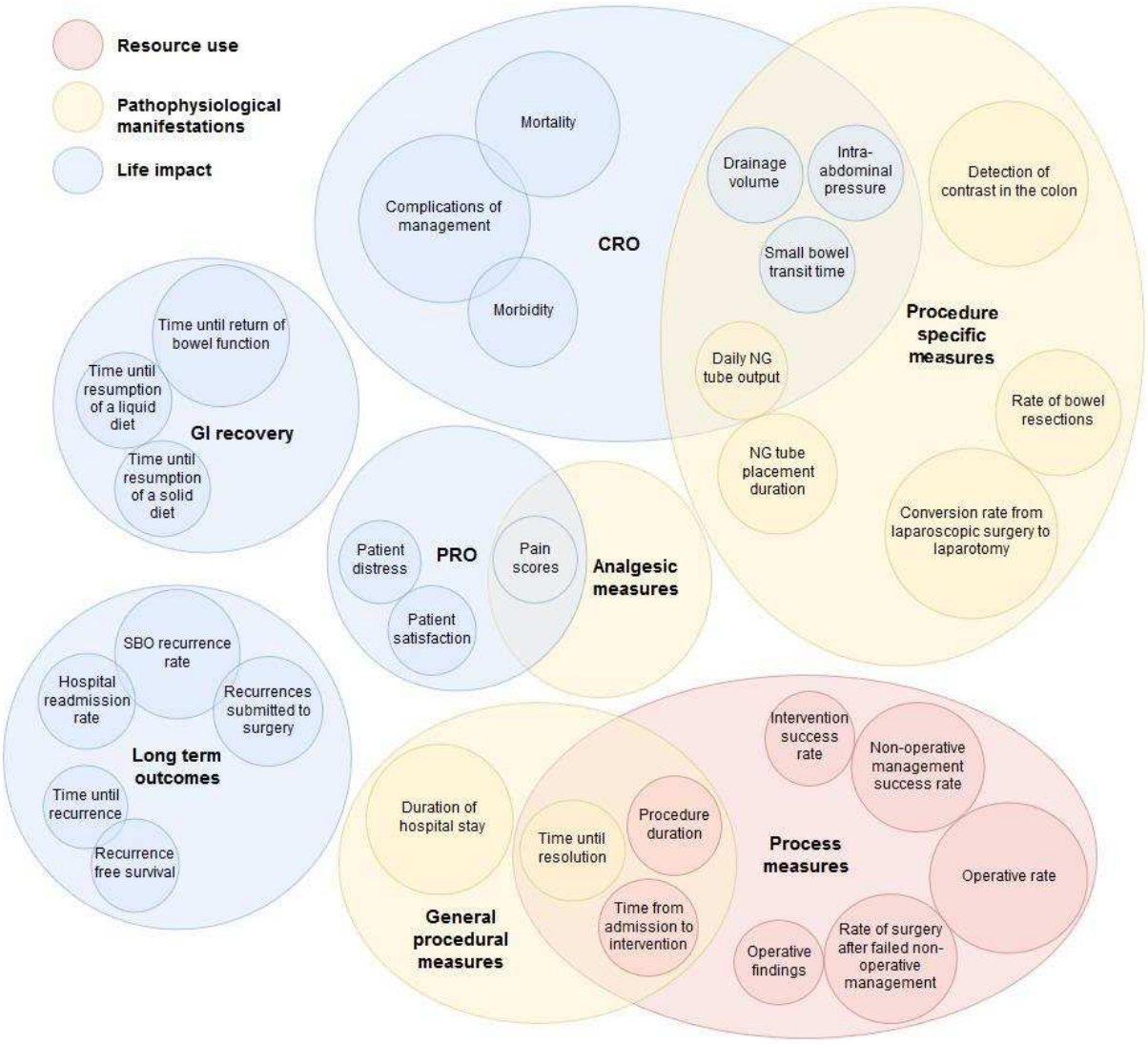

Figure 2: Outcomes reported arranged according to the OMERACT frameworks. Circles proportionate to frequency of reporting.

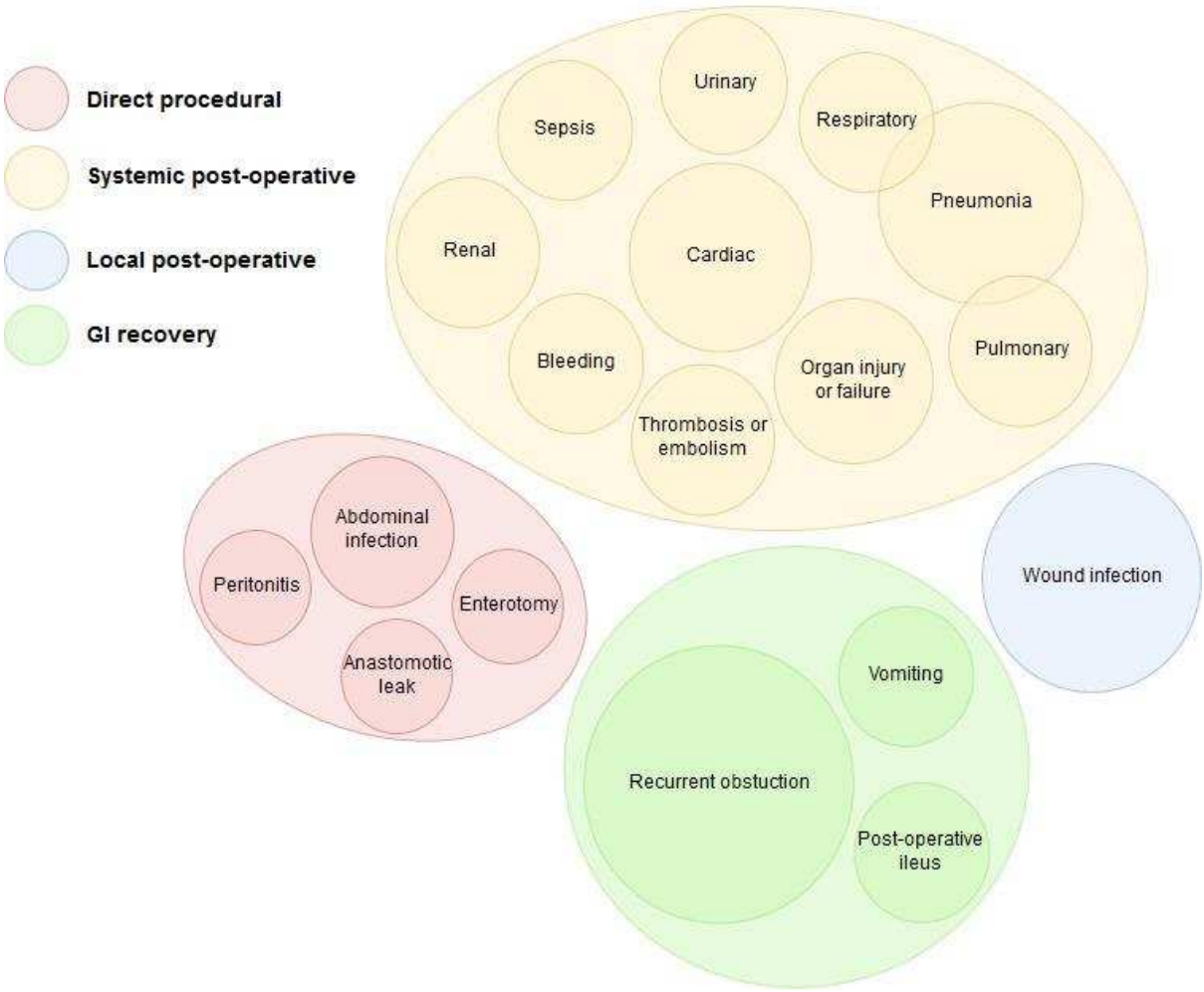

Figure 3: Complications reported grouped by type. Circles proportionate to frequency of reporting.