Laparoscopic versus open approach for adhesive small bowel obstruction, a systematic review and meta-analysis of short term outcomes

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BACKGROUND: Adhesive small bowel obstruction (ASBO) is one of the most frequent causes of emergency hospital admissions and surgical treatment. Current surgical treatment of ASBO consists of open adhesiolysis. With laparoscopic procedures rising, the question arises if laparoscopy for ASBO is safe and results in better patient outcomes. Although adhesiolysis was among the first surgical procedures to be approached laparoscopically, uncertainty remains about its potential advantages over open surgery. Therefore, we performed a systematic review and meta-analysis on the benefits and harms of laparoscopic surgery for ASBO.

METHODS: A systematic literature review was conducted for articles published up to May 2019. Two reviewers screened all articles and did the quality assessment. Consecutively a meta-analysis was performed. To reduce selection bias, only matched studies were used in our primary analyses. All other studies were used in a sensitivity analyses. All the outcomes were measured within the 30th postoperative day. Core outcome parameters were postoperative mortality, iatrogenic bowel perforations, length of postoperative stay [days], severe postoperative complications, and early readmissions. Secondary outcomes were operative time [min], missed iatrogenic bowel perforations, time to flatus [days], and early unplanned reoperations.

RESULTS: In our meta-analysis, 14 studies (participants = 37.007) were included: 1 randomized controlled trial, 2 matched studies, and 11 unmatched studies. Results of our primary analyses show no significant differences in core outcome parameters (postoperative mortality, iatrogenic bowel perforations, length of postoperative stay, severe postoperative complications, early readmissions). In sensitivity analyses, laparoscopic surgery favored open adhesiolysis in postoperative mortality (relative risk [RR], 0.36; 95% CI, 0.29–0.45), length of postoperative hospital stay (mean difference [MD], −4.19; 95% CI, −4.43 to −3.95), operative time (MD, −18.19; 95% CI, −20.98 to −15.40), time to flatus (MD, −0.98; 95% CI, −1.28 to −0.68), severe postoperative complications (RR, 0.51; 95% CI, 0.46–0.56) and early unplanned reoperations (RR, 0.82; 95% CI, 0.70–0.96).

CONCLUSION: Results of this systematic review indicate that laparoscopic surgery for ASBO is safe and feasible. Laparoscopic surgery is not associated with better or worse postoperative outcomes compared with open adhesiolysis. Future research should focus on the correct selection of those patients who are suitable for laparoscopic approach and may benefit from this approach. (*J Trauma Acute Care Surg.* 2020;88: 866–874. Copyright © 2020 Wolters Kluwer Health, Inc. All rights reserved.)

LEVEL OF EVIDENCE: Systematic Review/Meta-analysis, Level III.

KEY WORDS: Adhesive small bowel obstruction; ASBO; laparoscopic surgery; acute surgery.

Small bowel obstruction (SBO) is one of the leading causes of an emergency admission to a general surgical ward and one of the most frequent indications for emergent abdominal operations worldwide.[1,2] Adhesions are the most common etiology for SBO in developed world countries and account for approximately 60% of all episodes.[3–5] The incidence of adhesive SBO (ASBO) is related to the extent of peritoneal injury in patients who underwent surgery, or with a history of inflammatory bowel disease.[6] Hospital stay for an episode of ASBO can easily be prolonged for over 1 week, regardless from nonoperative or operative management.[7,8] Recurrence rates for an episode of ASBO are high,[9] operative management of a first episode of ASBO might reduce the risk of readmission for ASBO.[10] Operative management of ASBO usually consists of an exploratory laparotomy with adhesiolysis. With the rise of laparoscopic surgery, and its many benefits, laparoscopic adhesiolysis has been suggested as a new surgical approach to ASBO. Potential benefits of laparoscopic adhesiolysis include faster recovery, less pain, and fewer recurrences of adhesions.[11] The first laparoscopic adhesiolysis for ASBO was performed in 1972 by Mouret.[12] Since several papers have published favorable results of the laparoscopic approach. Implementation of laparoscopic surgery for ASBO, however, is slow, and there is concern for an increased risk of iatrogenic bowel injury.[13] Unfortunately, evidence supporting laparoscopy over open surgery in reducing the risk for ASBO recurrence is not strong.[14]

With the aim to assess feasibility, safety, and efficacy of laparoscopic adhesiolysis, we conducted a systematic review in 2009, according to the recommendations of The Cochrane Collaboration and the Cochrane Colorectal Group.[15] Search results included no randomized controlled trials (RCTs) or prospective observational studies which compared laparoscopy with open surgery for patients with ASBO.[16]

Nowadays, we have performed an updated systematic review and meta-analysis, analyzing the available evidence from the literature on the benefits and harms of laparoscopic surgery for ASBO.

MATERIALS AND METHODS

We performed a systematic review of literature up to 20 May 2019 according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses guidelines.[17] The protocol of this systematic review and meta-analysis has been registered on PROSPERO CRD42018107087 (http://www.crd.york.ac.uk/prospero). This systematic review included RCTs, matched studies, and unmatched studies, irrespective of their publication status or language. General population (children and adults), irrespective of race, sex, health status, or geographical location, who have undergone full laparoscopic or laparoscopy-assisted versus open adhesiolysis for ASBO were included in this review.

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Types of Outcome Measures

All the outcomes were measured within the 30th postoperative day. Primary outcome were the results of comparison of laparoscopic and open surgery for ASBO in RCTs and matched cohort studies on core clinical outcomes. Five core clinical outcome parameters were defined: postoperative mortality, iatrogenic bowel perforation, severe postoperative complications, length of postoperative hospital stay (LOS) [days] and early unplanned readmissions (within 30 days of discharge). Severe postoperative complications were classified as Clavien-Dindo III–IV. [18] Secondary outcome measures were operative time [minutes], missed iatrogenic bowel injuries, unplanned reoperations (within 30 days of discharge), and time to flatus [days]. A radar chart was constructed to visualize differences in core clinical outcome parameters.

Literature Search Strategy

A systematic literature search was performed in PubMed, Scopus and Web of Science, for studies reporting data on laparoscopic management of ASBO, published between 1980 and 2019. The search was performed by entering the following keywords: ("laparoscopic adhesiolysis" OR "laparoscopic lysis" OR "laparoscopic management") "AND ("small bowel obstruction" OR "adhesive bowel obstruction"). Two independent reviewers (RC, NV) individually assessed all titles and abstracts focusing on laparoscopic adhesiolysis for ASBO. Disagreement was solved through discussion. In case of persistent disagreement, the study was discussed with a third reviewer. Successively the full-text of relevant studies were obtained and evaluated. After inclusion, data from each study were independently extracted by two reviewers. If necessary, we contacted the corresponding author of the study to obtain additional research data.

Assessment of Risk of Bias in Included Studies

The risk of bias of the included studies was independently assessed by two independent reviewers (R.C., N.V.). To evaluate the methodological quality of the included studies the Cochrane "risk of bias" assessment tool for RCTs[19,20] and the methodological index for nonrandomized studies (MINORS) were used.[21] In RCTs, the risk of bias was considered high if a high risk was scored in one or more of the five key domains. In nonrandomized studies, the risk of bias was considered high if the MINORS score resulted in greater than 20 points, or groups were not adequately matched (see below). Analysis of publication bias was performed using a funnel plot.

Matching methods were assessed in all included studies. For a study to be included in the matched study group, matching should have been based on relevant surgical items. The

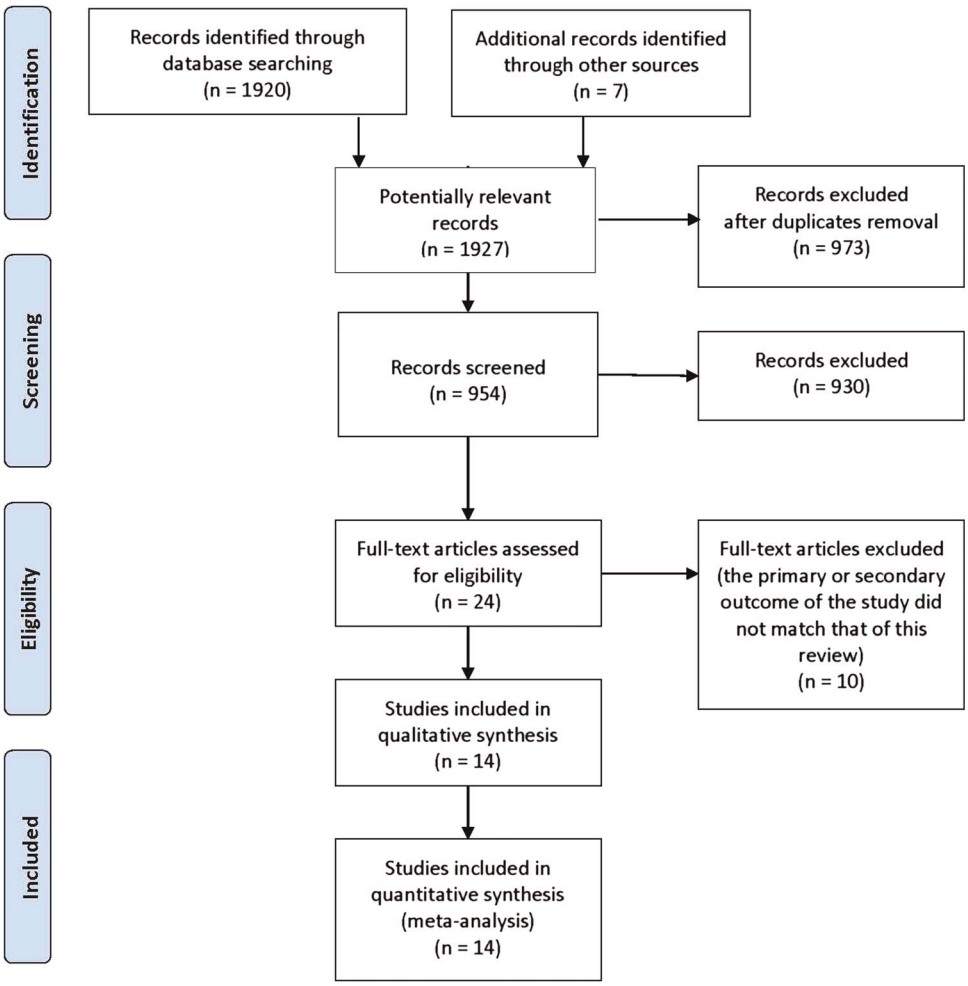

Figure 1. PRISMA flow diagram. PRISMA, Preferred Reporting Items for Systematic Reviews and Meta-Analyses.

definition of relevant surgical items for matching results from discussion between the authors and reflect selection criteria for patients in RCTs. Consensus was reached that we considered matching of sufficient quality to consider a study as low risk of bias, if matching factors comprised at least the following three domains: (1) expected or observed extend and type of adhesions (e.g., number of previous abdominal operations performed laparoscopic or open, type of adhesions observed [single band/dense adhesions]); (2) descriptors indicating critical illness (e.g. suspected perforation before surgery, sepsis, suspected strangulation); (3) medical history (e.g., American Society of Anesthesiologists [ASA] status, comorbidity). If studies were not matched on all three domains, we considered them high risk of bias, and the study was not used in the primary analyses of the primary and secondary outcome measures for this review. Thus, these studies were used in the unmatched analysis.

Analysis

Core clinical outcome parameters and secondary outcome parameters were separately analyzed for RCTs and matched studies and for unmatched studies. All matched studies were included in the analysis of primary and secondary outcome measures. Unmatched studies were included only in sensitivity analyses. We used the Mantel-Haenszel method for dichotomous data, presented as relative risks (RR) with 95% confidence intervals (CIs). We used the inverse variance method to pool continuous data; results are presented as mean difference with 95% CIs. Analyses were based on "intention-to-treat," that is, all patients in whom laparoscopic surgery was converted to open surgery were analyzed in the laparoscopic group. The I2 test was used for heterogeneity assessment. A value exceeding 50% was significant of heterogeneity. In the absence of statistical heterogeneity, we used a fixed-effect model; otherwise, we used a random-effects model. The data analysis was performed using the meta-analysis software Review Manager (RevMan) v 5.3.5 (Copenhagen: The Nordic Cochrane Centre, The Cochrane Collaboration, 2018).

Sensitivity Analysis

As a sensitivity analysis, we performed analysis of all studies, including the unmatched cohorts. Outcome measures were compared between the matched studies and all studies (including the unmatched studies).

RESULTS

We retrieved 1.927 records with our search strategy, 973 records were excluded because they were duplicated. Subsequently, 954 titles and abstracts were evaluated, 930 abstracts were excluded because they did not meet inclusion criteria. Full text was evaluated in 24 studies: 14 studies included[22–35] and 10 excluded[36–45] (Fig. 1). The characteristics of excluded studies and the reasons for the exclusion are reported in Supplemental Digital Content 1, Table 1, http://links.lww.com/TA/B615.

Characteristics of the Studies Included

In 14 studies[22–35] 37,007 patients were enrolled, including 1 RCT (n = 100). After assessment of matching methods, 2 studies (n = 154) were classified as matched studies, and 11 studies were classified as unmatched studies (n = 36,753) (Supplemental Digital Content 2, Table 2, http://links.lww.com/TA/B616). The RCT, laparoscopic versus open adhesiolysis for adhesive small bowel obstruction (LASSO) trial, was performed in two countries (Finland and Italy) and enrolled 100 patients between 2013 and 2018.[22] The duration of the enrolment of the participants reported, ranged between 1 and 11 years.

Methods of Matching

Matching in the study of Hackenberg et al. was performed using propensity score-matching based on items in all three matching categories. Surgical aspects included: ASA classification, number of previous abdominal operations, number of previous conservatively managed ASBO episodes, duration of symptoms, suspected bowel strangulation, hemodynamically unstable. Based on these items, there was a low risk of selection bias.

Yao et al. matched on items in all three categories using propensity score matching, including: Systemic Inflammatory Response Syndrome (SIRS) (at presentation), ASA classification, comorbidities, type of adhesions (isolated band, simple, dense), time to operation, number of previous abdominal operations, comorbidities, and maximum bowel diameter on CT. This study was marked as a low risk of selection bias.

Some other studies attempted matching but did not match on all three predetermined domains.

Quality Assessment of the Studies Included

Intention to treat design was applied in 10 studies (Supplemental Digital Content 2, Table 2, http://links.lww.com/TA/B616). According to the author's judgment, the assessment of the RCT showed a "low risk of bias" in the greatest number of analyzed items (random sequence generation, selection bias, allocation concealment, selection bias), whereas a high risk of bias was reported for blinding of participants and personnel (performance bias). The mean score of the methodological assessment of the matched studies was 20 (moderate risk) (Supplemental Digital Content 3, Table 3, http://links.lww.com/TA/B617). Mean score for unmatched studies was 18 (high risk) Supplemental Digital Content 3, Table 3, http://links.lww.com/TA/B617. A summary of the main findings per study is provided in Supplemental Digital Content 4, Table 4, http://links.lww.com/TA/B618.

Core Clinical Outcomes

Postoperative 30-day Mortality

Mortality was reported in the RCT, and all two matched studies. There was no significant difference in mortality between the laparoscopic (1.6%, 2/128) and open adhesiolysis cohort (2.4%, 3/126) (RR, 0.70; 95% CI, 0.14–3.51; $I^2 = 0\%$; Fig. 2*A*).

Iatrogenic Bowel Perforation

This parameter was reported in the RCT and one matched study. There was no significant difference in iatrogenic bowel perforations between the laparoscopic (10.5%, 8/76) and open adhesiolysis cohort (4.1%, 3/74) (RR, 2.61; 95% CI, 0.72–9.42; $I^2 = 0\%$; Fig. 2*B*).

Length of Postoperative Hospital Stay (Days)

The LOS was only reported in the RCT. There was no significant difference in LOS between the laparoscopic and open

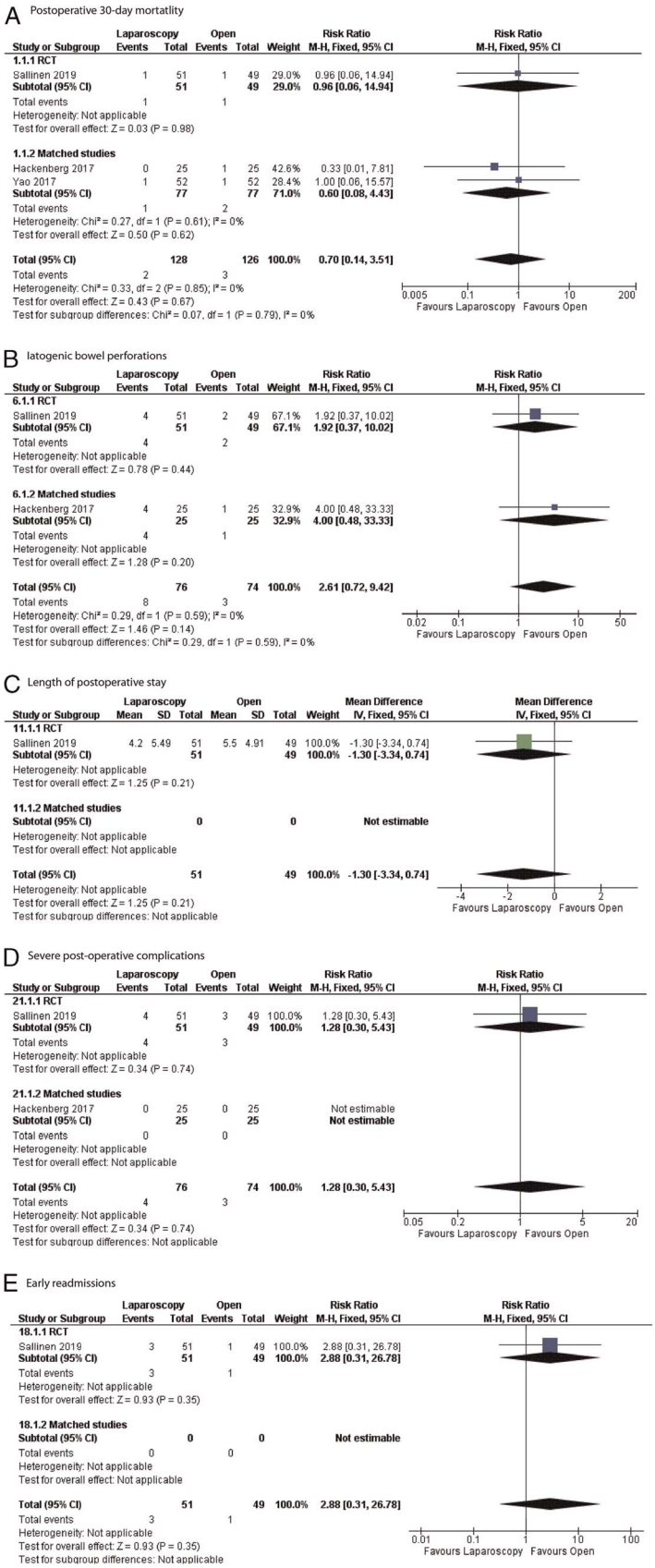

Figure 2. Forest plot core clinical outcomes.

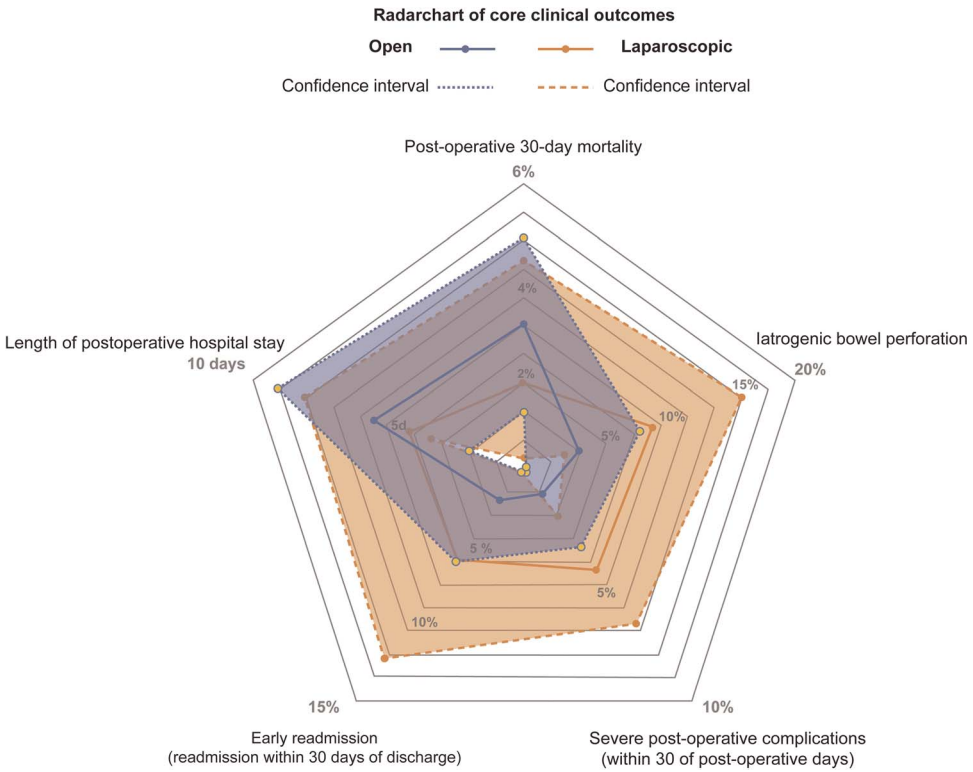

Figure 3. Radar chart core clinical outcome.

adhesiolysis cohort (MD, −1.30; 95% CI, −1.30 to 0.74, I^2 = not applicable [NA]; Fig. 2*C*).

Severe Postoperative Complications

The RCT and one matched study reported this outcome parameter. There was no significant difference in the incidence of severe postoperative complications between the laparoscopic (5.3%, 4/76) and open adhesiolysis cohort (4.1%, 3/74) (RR, 1.28; 95% CI, 0.30–5.43; I^2 = NA; Fig. 2*D*).

Early Readmissions (Within 30 Days of Discharge)

Only the RCT reported this outcome. There was no significant difference in the incidence of early unplanned readmissions between the laparoscopic (5.9%, 3/51) and open adhesiolysis cohort (2.0%, 1/49) (RR, 2.88; 95% CI, 0.31–26.78; I^2 = NA; Fig. 2*E*).

A summary of core clinical outcome parameters is visualized in Figure 3.

Secondary Outcomes

Operative Time [Min]

Operative time was not reported in the RCT of any of the matched studies.

Missed Iatrogenic Bowel Perforation

The RCT and one matched study presented this outcome. There was no significant difference in the incidence of missed iatrogenic bowel perforations between the laparoscopic (1.3%, 1/76) and open adhesiolysis cohort (0%, 0/74) (RR, 2.88; 95% CI, 0.12–69.16; I^2 = NA) (Supplemental Digital Content 5, Figure 1, http://links.lww.com/TA/B619).

Time to Flatus (Days)

Time to flatus was only reported by Yao et al. Patients in the laparoscopic cohort had a decrease in time to flatus compared with the open adhesiolysis cohort (MD, −1.00; 95% CI, −1.58 to −0.42; I^2 = NA) (Supplemental Digital Content 6, Figure 2, http://links.lww.com/TA/B620).

Early Unplanned Reoperation (30 Postoperative Days)

The incidence of unplanned reoperations was only reported by the RCT. There was no significant difference in the incidence of early unplanned reoperations between the laparoscopic (2.0%, 1/51) and open adhesiolysis cohort (0%, 0/49) (RR, 2.88; 95% CI, 0.12–69.16; I^2 = NA) (Supplemental Digital Content 7, Figure 3, http://links.lww.com/TA/B621).

Sensitivity Analyses

All Studies Included (Including Unmatched Studies)

In sensitivity analyses (Supplemental Digital Content 8, Figs. 4–12, http://links.lww.com/TA/B622), laparoscopic surgery favored open adhesiolysis in postoperative mortality (RR, 0.36; 95% CI, 0.29–0.45; I^2 = 0%), LOS (MD, −4.19; 95% CI, −4.43 to −3.95; I^2 = 97%), operative time (MD, −18.19; 95% CI, −20.98 to −15.40; I^2 = 65%), time to flatus (MD, −0.98; 95% CI, −1.28 to −0.68; I^2 = 0%), severe postoperative complications (RR, 0.51; 95% CI, 0.46–0.56; I^2 = 55%), and early unplanned reoperations (RR, 0.82; 95% CI, 0.70–0.96; I^2 = 0%). There were no differences in other parameters.

DISCUSSION

Fourteen studies were identified that met the criteria to answer our primary or secondary research questions. Results of this systematic review and meta-analysis showed no evidence of superiority for one technique over the other on core clinical outcomes. In sensitivity analysis laparoscopic adhesiolysis for ASBO was associated with a decrease in 30-day mortality, LOS, operative time, time to flatus, risk of severe postoperative complications, and early unplanned reoperations. However, given the methodological limitations of the unmatched studies, these results might be attributable to patient selection.

Laparoscopic surgery for ASBO theoretically offers a number of potential benefits over open surgery (e.g., shorter length of stay, reduction in adhesion reformation), the choice of the best surgical approach in a clinical setting should be made according to many factors. Situations with contraindications for pneumoperitoneum, such as hemodynamic instability, sever bowel distention, or cardiopulmonary impairment, will require an open approach.[36,46] Other factors possibly influencing the selection of surgical approach are: laparoscopic skills of the surgeon and availability of laparoscopic equipment and instruments. Eligibility criteria for a laparoscopic approach to ASBO are: the absence of peritonitis or severe intra-abdominal sepsis, less than severe distension of the bowel on radiological imaging, anticipated single band or limited extent of adhesions, and surgical skills.[37] As reported in most recent guidelines on the management of ASBO, open surgery is indicated for strangulating ASBO or in case of ischemic bowel loops, while laparoscopic approach is most suitable for selected patients presenting at their first episode and with an anticipated single band detected at preoperative radiological imaging.[5,9]

Strengths and Limitations

The major strengths of this review are the systematic approach and the inclusion of data from the first randomized trial comparing laparoscopic with open adhesiolysis for ASBO. We thoroughly screened all included articles for matching methods. Only studies that were matched on relevant surgical items were included in the primary analysis, all other studies were used in the sensitivity analysis. Unmatched studies were not used in the primary analysis to reduce the risk of selection bias. Critically ill patients presenting with ASBO are less likely to undergo laparoscopic procedures for many reasons, including the inability to tolerate pneumoperitoneum and are more prone to postoperative complications. For this reason, outcome parameters are likely to favor the laparoscopic surgery group by selection. Sensitivity analyses indeed showed a favorable effect of laparoscopic surgery for ASBO on some of the outcome parameters when unmatched studies were considered.

Potential limitations of this study should be also discussed. Data on severity of adhesions and preoperative findings were not available in all the included studies, making it more difficult to define criteria for selection of patients for laparoscopy. We included only studies in the matched group if an attempt was made to match for the expected or observed extend and type of adhesions (e.g., number of previous abdominal operations performed laparoscopic or open, type of adhesions observed [single band/dense adhesions]). We included only studies in the matched group if an attempt was made to match for the expected or observed extend and type of adhesions (e.g., number of previous abdominal operations performed laparoscopic or open, type of adhesions observed [single band/dense adhesions]). Due to strict selection criteria meta-analysis of some outcomes was based only on one study. These results of the meta-analysis are, therefore, somewhat less reliable. Core clinical outcomes that were only based on only one study were LOS and early readmissions. These parameters were only reported in the LASSO trial.[22] The LASSO trial was powered on length of hospital stay. In their analysis of the geometric means a significant difference was found, although this was not confirmed in our analysis using inverse variance for continues outcomes. The difference was also smaller than accounted for in the sample size calculation of the LASSO trial (1.3 days vs, 2.5 shorter hospital stay). A potential beneficial effect of laparoscopy on LOS therefore still needs to be confirmed in future studies that are well matched and powered. Timing of surgery for ASBO also remains a controversial issue; within the included studies there was heterogeneity regarding the timing of surgery. In a recent update of the Bologna guidelines and a Delphi consensus study, for patients not requiring emergent surgical exploration, a trial of nonoperative management can be continued safely as far as for 72 hours.[9,38] When surgery is performed after more than 72 hours of conservative trial, an increase in mortality is observed.[9,39]

A potential limitation of our study is the intention to treat design, therefore, not considering laparoscopic conversions to open surgery. Several studies did not report the causes and outcomes for conversion,[22,26,28–30,32,34,35] or they did not report conversion rates at all. The matched studies had an accurate description of standardized surgical techniques used in the laparoscopic group. Nevertheless, technical biases might occur because laparoscopic surgery for ASBO is a highly complex procedure and results depend on the experience of the surgeon and also the characteristics and localization of the adhesions which requires a tailored surgical approach and a standardized technique. The choice of the surgical approach for ASBO depends on many factors, some of which could be controlled for by matching in nonrandomized studies. Examples, however, of factors that are difficult to control for in nonrandomized studies include the laparoscopic skills of the surgeon, experience of the full operative team, and the impact of performing surgery at night hours.

There is no broad accepted outcome for restore of bowel function. Many of the included studies use a wide variety of outcome parameters to predict restore of bowel function. Recently, a study was started to develop a core outcome set for gastrointestinal recovery in the context of postoperative ileus and small bowel obstruction.[40] Since, to date, there is no consensus on a single parameter for restore of bowel function, we designed a set of key clinical outcome parameters as primary endpoint for this study. Radar charts are increasingly used in recent years to compare the total value (and sometimes costs) of different interventions, as opposed to comparison on a single outcome parameter.[41]

Comparison to Other Literature

Over the past decades, laparoscopic surgery became the standard of care in several fields of elective surgery. A retrospective study which included over 13,000 patients from the American College of Surgeons prospective National Surgical

Quality Improvement Program data set reported a significant increase of application of laparoscopy from 17% in 2006 to 29% in 2013.[42] Grafen et al.[43] found that patients who underwent successful laparoscopic adhesiolysis for ASBO had fewer prior operations and were younger with a lower ASA score, had shorter operative time and postoperative length of stay compared with patients who underwent open or converted adhesiolysis for ASBO. A recent systematic review which included 18 comparative non randomized studies ranging from 1990 to 2017 reported that the ASA score of patients who underwent laparoscopic adhesiolysis was significantly lower compared with the open group.[44]

Unlike the results of a recent review, where iatrogenic bowel injury is less frequent in laparoscopic surgery,[44] our review showed no significant difference in the risk of iatrogenic bowel injury in open or laparoscopic adhesiolysis. Moreover, there was no significant difference in missed bowel injuries. Previous studies showed a higher risk of missed bowel injures in the presence of distended bowel and multiple complex adhesions[45,47] and during emergency surgical exploration.[48]

A review published in 2012 concluded that laparoscopy can significantly reduce the duration of postoperative ileus, as well as the incidence of pulmonary complications with no statistically significant reduction of intraoperative bowel injuries rates and overall mortality.[49] In our review, laparoscopic surgery was not associated with a reduction of time to flatus. More recently, another review of 14 nonrandomized studies showed that laparoscopic adhesiolysis can reduce risk of morbidity, in-hospital mortality, and surgical infections.[50] In our primary analyses, we found no difference in postoperative mortality or postoperative complications; however, in sensitivity analysis, laparoscopic surgery might be associated with a decrease in postoperative mortality (RR, 0.36; 95% CI, 0.29–0.45), and severe postoperative complications (RR, 0.51; 95% CI, 0.46–0.56).

CONCLUSION

The present systematic review showed that laparoscopic surgery for ASBO is feasible, as it is associated with similar adverse events rates compared with open surgery. Nevertheless, we found no evidence for superiority of one technique over the other. Future research should focus on the correct selection criteria to identify which patients are suitable for a laparoscopic approach and may benefit from this approach.

AUTHORSHIP

R.C. made substantial contributions to the analysis and interpretation of data; drafting the work and revising it critically for important intellectual content; final approval of the version to be published; agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. P.K. made substantial contributions to the conception, design of the work, the analysis and interpretation of data; revising the work critically for important intellectual content; final approval of the version to be published; agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. C.R. made substantial contributions to the conception, design of the work; revising the work critically for important intellectual content; final approval of the version to be published; agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. Rt.B. made substantial contributions to the conception, design of the work; revising the work critically for important intellectual content; final approval of the version to be published; agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. M.Z. made substantial contributions to the conception, design of the work; revising the work critically for important intellectual content; final approval of the version to be published; agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. G.P. made substantial contributions to the conception, design of the work; revising the work critically for important intellectual content; final approval of the version to be published; agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. P.R. made substantial contributions to the conception, design of the work; revising the work critically for important intellectual content; final approval of the version to be published; agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. R.M. made substantial contributions to the conception, design of the work; revising the work critically for important intellectual content; final approval of the version to be published; agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. M.C. made substantial contributions to the conception, design of the work, the analysis and interpretation of data; revising the work critically for important intellectual content; final approval of the version to be published; agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. Sd.S. made substantial contributions to the conception, design of the work, the analysis and interpretation of data; drafting the work and revising it critically for important intellectual content; final approval of the version to be published; agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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