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REVIEW

Wound protectors in reducing surgical site infections in lower gastrointestinal surgery: an updated meta-analysis

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Abstract

Background Surgical site infection (SSI) is a common complication in gastrointestinal surgery. Wound protection devices are being increasingly used in the attempt to reduce infection rates. We performed a meta-analysis to determine if wound protectors reduce the incidence of SSIs in lower gastrointestinal surgery.

Methods MEDLINE and EMBASE databases were searched between 1946 and 2016. Randomized controlled trials comparing wound protector versus no wound protector in lower gastrointestinal surgery were included. Our primary outcome was surgical site infection. Subgroup analysis was conducted comparing single-ring versus dual-ring wound protectors.

Results Twelve RCTs with 3029 participants were included. There was a significant decrease in the odds of developing SSI in the wound protector group (OR 0.64, 95% CI 0.45–0.90, $P<0.01$, $I^2=55\%$). There was evidence of a subgroup effect ($P=0.01$) with dual-ring wound protectors associated with significantly lower incidence of SSIs (OR 0.31, 95% CI 0.18–0.52, $P<0.0001$, $I^2=12\%$), which was not appreciated in the single-ring group (OR 0.84, 95% CI 0.67–1.04, $P=0.11$, $I^2=0\%$).

Conclusions Wound protector use is associated with decreased odds of developing SSI in patients undergoing lower gastrointestinal surgery. There was a subgroup effect when comparing dual-ring to single-ring devices.

Keywords Surgical site infection · Wound infection · Colorectal surgery · Appendix · Gastrointestinal surgery

Surgical site infection (SSI) is a common complication in the setting of gastrointestinal surgery, with reported infection rates between 4.0 and 25.2% [1–5]. Procedures involving the rectum have higher reported rates of SSI, around 18%, compared to procedures of the colon, which report an SSI rate of around 8–9% [4, 6]. The use of laparoscopy appears to have a protective effect, lowering the SSI rate in colorectal surgery by nearly 50% or more depending on the study [1, 7, 8].

SSIs can increase hospital length of stay, incur increased costs, and contribute to postoperative mortality [9, 10]. A CDC report from 2009 calculated the attributable cost of SSIs to fall in the range of $10,443–$25,546 per infection [11]. In addition to aseptic technique and antibiotic prophylaxis, wound protection devices (alternatively called "wound guards" or "wound retractors") have been increasingly used in the effort to reduce SSI rates. These devices form a physical barrier between the wound edges and the contaminated surgical field. There are two widely available forms: a single ring that lies within the abdominal cavity connected to a protective drape that extends outward, or two rings that are connected cylindrically by impenetrable plastic with one ring inside the wound and the other secured on the outside. The barrier to routine use of these types of devices is cost [12].

In recent years, several meta-analyses have been published looking at the effectiveness of wound protectors in preventing SSIs in abdominal surgeries [13–16]. These

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reviews found that SSIs were reduced when using wound protectors, but included a heterogeneous patient population (including all types of abdominal surgeries), and have not assessed a number of recently published higher quality RCTs.

There is no published meta-analysis that focuses primarily on wound protectors in lower gastrointestinal surgery. These procedures are clean-contaminated or contaminated procedures, which are associated with higher rates of SSIs compared to most other surgeries [9, 17, 18]. Therefore, the potential benefit of wound protectors in reducing SSI would be particularly relevant to this subset of patients.

The objective of our meta-analysis was to perform an updated review of the literature to determine if wound protector placement reduces the incidence of SSIs in lower gastrointestinal surgery. We also included subgroup analyses that compared single-ring versus double-ring devices, as well as target organs (colorectal, appendix, and other organs).

Materials and methods

Inclusion criteria

All randomized controlled trials that compared wound protector with no wound protector in surgical procedures involving the large or small bowel were included in this meta-analysis. RCTs that primarily focused on non-lower gastrointestinal surgery (e.g., biliary, gynecological, urological, or vascular procedures) were not included. Both single- and dual-ring wound protectors were included. Studies were included regardless of laparoscopic or open technique, stoma creation or none, malignant or benign disease, and CDC wound classification. We decided to include all wound classes to represent the scope of all bowel surgery, which predominantly involves clean-contaminated and contaminated wounds, but also occasionally involves dirty wounds. Studies were eligible regardless of date of publication or language of publication. Studies were included if length of follow-up was at minimum the length of the hospital stay. All included trials assessed our a priori outcomes.

Outcomes

SSI within 30 days of surgery was the primary outcome for this study. We included SSI as defined by the study authors. We did not limit the definition of this outcome to any particular classification (i.e., CDC classification), and all CDC classes for SSI (superficial incisional, deep incisional, and organ space) were included. Secondary outcomes included fascial dehiscence, hernia, and perioperative complications as defined by study authors.

Search strategy

The EMBASE (1947–2016) and MEDLINE (1946–2016) databases were searched on August 4, 2016. Furthermore, references cited in related reviews and included trials were examined for additional studies that may fit the inclusion criteria.

The EMBASE search strategy was performed using the following headings: (exp surgical drape or wound edge protector.mp./ OR exp incision protector.mp./ OR exp wound protect*.mp./ OR exp wound guard.mp./ OR exp alexis.mp./) AND (exp wound infection/ OR exp postoperative complication/).

The MEDLINE search strategy was conducted with the following terms: (exp wound edge protector.mp./ OR exp wound retractor.mp./ OR exp surgical drapes or plastic wound drape.mp./ OR exp incision protector.mp./ OR exp wound protection devices.mp./ OR exp wound guard.mp./ OR exp Alexis.mp./) AND (exp postoperative complications/ OR exp surgical wound infection/).

Study selection

Titles and abstracts identified by our search strategy were reviewed independently and in duplicate (BE and LZ). Duplicate articles were excluded. After title and abstract screening, articles underwent full text review in duplicate to determine if they met the above inclusion criteria. If disagreements were found in study selection, consensus was obtained from the third author (SVP).

Data collection

Data collection was performed independently and in duplicate. A standardized form was used to collect data from the eligible studies, including the following information: patient characteristics (BMI, age, gender), surgical technique (open, laparoscopic), type of procedure (exploration, resection, anastomosis), indication for surgery (malignant disease, benign disease), target organ (colon, rectum, small bowel, appendix), type of wound protector (single ring, dual ring), wound classification (clean, clean-contaminated, contaminated, dirty), and follow-up period. Data collection sheets were compared for consistency; differences were resolved through discussion and consultation with the third author.

Risk of bias

The risk of bias for each study was determined using the Cochrane Collaboration's tool for assessing bias [19]. Assessment criteria included random sequence generation,

allocation concealment, blinding of participants and assessors, completeness of outcome data, selective outcome reporting, and other biases. For each study, the risk of bias was categorized for each variable as "low risk of bias", "high risk of bias", or "unclear risk of bias".

Data analysis

REVMAN 3.5 (Copenhagen: The Nordic Cochrane Centre, The Cochrane Collaboration, 2014) was used to perform the data analysis of our pooled data [20]. The odds ratio was calculated for the primary outcome. We used random effects modeling to account for the expected clinical heterogeneity. Reasons for heterogeneity included variation in the surgical procedure (resection and/or anastomosis and/or stoma creation vs. other), target organ (colorectal vs. small bowel vs. appendix), and classification of wound (clean, clean-contaminated, contaminated, dirty). To further account for the expected heterogeneity, we planned subgroup analyses. We planned subgroup analyses of wound protector type (single ring vs. dual ring), surgical approach (laparoscopic vs. open surgery), and target organ (colorectal vs. appendix vs. other) to explain the heterogeneity.

Quality of evidence

Quality of evidence was assessed using GRADE working group's framework [21], which defines quality as follows: high ("further research is very unlikely to change our confidence in the estimate of effect"), moderate ("further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate"), low ("further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate"), or very low ("any estimate of effect is very uncertain").

This meta-analysis is compliant with the PRIMSA guidelines [22].

Results

The literature search identified a total of 355 eligible studies. After title, abstract, and full text screening, 12 RCTs met the inclusion criteria and were included in this meta-analysis (Fig. 1).

Study characteristics

Table 1 describes the study characteristics of the 12 included studies. Out of these 12 studies, 5 studies looked exclusively at colorectal surgery [23–27], 5 studies included both colorectal surgery and other GI surgery [28–32], and 2 studies looked at appendectomies [33, 34]. Most studies included a follow-up period of at least 30 days [23–30, 33], 2 studies included a shorter follow-up period [32, 34], and 1 study did not clearly state their follow-up period [31]. Single-ring wound protectors were utilized by 7 studies [23, 25, 26, 29–32], while dual-ring wound protectors were used by the remaining 5 studies [24, 27, 28, 33, 34]. Only one study included laparoscopic surgery [25]. Most RCTs included class II and III wounds [23–28, 31–34], while two also included class IV wounds [29, 30].

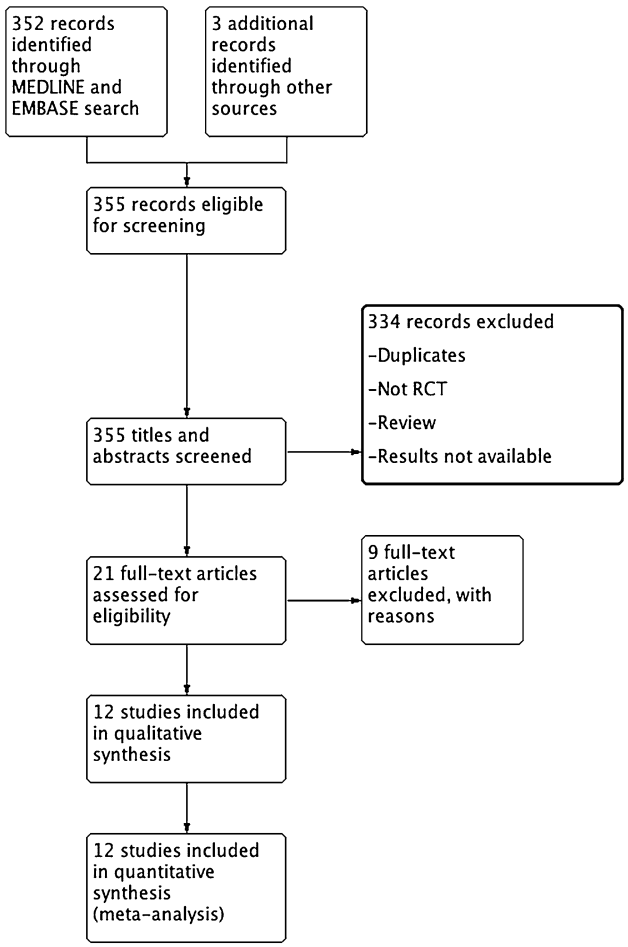

Fig. 1 Study flow diagram

Risk of bias

The risk of bias for the included studies is outlined in Fig. 2. Three of the included RCTs had high risk of bias in at least one assessed category [23, 32, 33]. In the study by Baier et al. [23], participants and outcome assessors were not blinded. In the trial by Silva et al. [33], high risk of bias was introduced by inadequate randomization. In Williams et al. [32], the study protocol changed halfway through the study; instead of wounds being assessed on days 3 and 7,

Table 1 Study characteristics

Study	Type of surgery	Number of participants	Length of follow-up	Inclusion criteria	Exclusion criteria	Wound protector type	Intervention	Control	Outcomes
[23]	Colorectal	• Total: 199 • WEPD: 98 • Control: 101	30 days	• All patients undergoing laparotomy for any reason	• Appendectomy • Ostomy reduction • Reoperation within 30 days for any reason other than SSI	Single ring	3M™ Steri-Drape™ ring drape in S, M, or L according to the incision's length	Wound edges were protected during surgery with wet cloth towels	• SSI • Risk factors for SSI
[24]	Colorectal	• Total: 64 • WEPD: 34 • Control: 30	30 days	• Adult patients undergoing elective colorectal resections via standardized midline incision	• Laparoscopy • Emergency relaparotomy • Contraindication to patient-controlled analgesia (PCA) with morphine	Dual ring	ALEXIS O-Ring retractor	Four abdominal packs and Balfour retraction	• SSI • Postoperative pain
[28]	Colorectal Gastric HPB	• Total: 221 • WEPD: 111 • Control: 110	> 30 days	• Non-traumatic gastrointestinal surgery	• Severe adhesion with a history of laparotomy • Long-term use of steroids • Laparoscopy • Minor surgery such as appendectomy • Probable colon perforation	Dual ring	ALEXIS O-Ring retractor	Wound margin was left untreated	• SSI • Leakage • Abscess
[25]	Colorectal	• Total: 93 • WEPD: 46 • Control: 47	6 months	• > 18 years old capable of giving informed consent • Elective laparoscopic colorectal resection	• Emergency operation • Open colorectal resection • Conversion to open • No chance to place WEPD	Single ring	Vi-Drape	Wet cloth towels were used to cover abdominal wall	• SSI • Reoperations • Readmissions • Postoperative complications • Inpatient costs
[34]	Appendix	• Total: 109 • WEPD: 61 • Control: 48	21 days	• Clinical diagnosis of appendicitis • Planned open appendectomy	• History of insulin-dependent diabetes • Inability to follow-up owing to geographic location	Dual ring	ALEXIS O-Ring retractor	Standard retractors	• SSI

Table 1 (continued)

Study	Type of surgery	Number of participants	Length of follow-up	Inclusion criteria	Exclusion criteria	Wound protector type	Intervention	Control	Outcomes
[29]	Colorectal Small Bowel Gastric HPB Other	• Total: 594 • WEPD: 300 • Control: 294	30–45 days	• Elective open abdominal surgery requiring median or transverse laparotomy • > 18 years • Clean or clean-contaminated procedure	• ASA > 3 • Pregnancy or breastfeeding • Previous laparotomy within 60 days • Planned relaparotomy within 30 days • Planned contaminated operation • Concurrent abdominal wall infections • Severe preoperative neutropenia or immune-suppression • Liver cirrhosis, Child–Pugh B or C	Single ring	Steri-Drape wound edge protector, 3M	Wound edges covered with surgical towels	• SSI • Intraoperative core body temperature
[26]	Colorectal	• Total: 140 • WEPD: 70 • Control: 70	30 days	Adults admitted for elective colorectal surgery involving opening the bowel	• Deferred surgery • Change of operative plans • Unforeseen therapeutic situation	Single ring	Op-drape, Triplus, Sweden	No WEPD	• SSI • Wound culture
[30]	Colorectal Small Bowel Gastric HPB Other	• Total: 749 • WEPD: 376 • Control: 373	30–33 days	• > 18 years • Laparotomy for any surgical indication • Elective and emergency	• Laparoscopic or laparoscopic assisted procedures • Previous laparotomy within 3 months	Single ring	3M Steri-Drape wound edge protector	No WEPD	• SSI • Quality of life • Length of stay Cost effectiveness Patient comorbidities
[31]	Colorectal Other	• Total: 144 • WEPD: 46 • Control: 98	> 3 days	• Abdominal surgery	• Not described	Single ring	Vi-Drape	Standard linen towels or adhesive plastic drape	• SSI • Wound culture

Table 1 (continued)

Study	Type of surgery	Number of participants	Length of follow-up	Inclusion criteria	Exclusion criteria	Wound protector type	Intervention	Control	Outcomes
[27]	Colorectal	• Total: 130 • WEPD: 64 • Control: 66	30 days	• > 18 years • Elective colorectal resection	• Cognitively impaired or otherwise unable to give informed consent • Laparoscopic colorectal resection	Dual ring	ALEXIS O-Ring retractor	Routine retractors	• SSI • Antibiotic usage
[33]	Appendix	• Total: 433 • WEPD: 221 • Control: 212	30 days	• > 15 years • Acute appendicitis • Open surgery	• Other pathology • Lack of prophylactic antibiotics • Histopathology negative for appendicitis • Diffuse peritonitis requiring laparotomy or incision > 11 cm • Laparoscopy • Open or delayed wound closure	Dual ring	Pelosi ring	No WEPD	• SSI
[32]	Colorectal Small Bowel Gastric Biliary	• Total: 167 • WEPD: 84 • Control: 83	7–10 days	• Midline or paramedian laparotomy • Opening of some part of the bowel or biliary tract	• Death within 24 h of operation	Single ring	Vi-Drape	No WEPD	• SSI

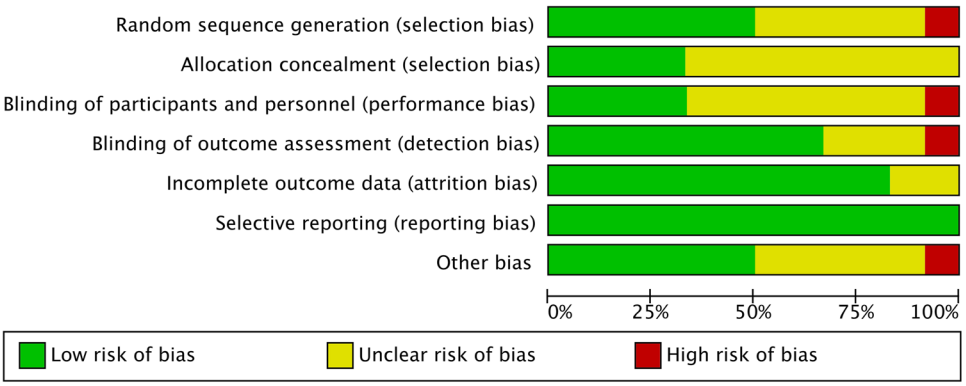

Fig. 2 Risk of bias

patients were assessed on days 7 and 10 in the second half of the study. The study by Psaila et al. did not clearly state their follow-up period, which was classified as an unclear risk of bias.

Surgical site infection

SSI was diagnosed by clinical exam in all studies. Two studies also included wound cultures to supplement their clinical diagnosis [26, 31]. Most studies defined SSI based on the CDC's guidelines on SSI classification [23–25, 27–30, 33]. Four studies used their own definitions of SSI, all of which were similar to the CDC's definition of superficial incisional SSI (e.g., erythema, purulent drainage, or requiring opening of the wound) [26, 31, 32, 34]. Overall, six trials reported superficial SSIs only (including the four studies that used their own definition of SSI) [24, 26, 30–32, 34], two trials reported both superficial and deep incisional SSIs [23, 33], and four trials reported superficial and deep incisional as well as organ space SSIs [25, 27–29]. The pooled data from all 12 studies demonstrated decreased odds of SSI in the wound protector group compared to the control group (OR 0.64, 95% CI 0.45–0.90, $P < 0.01$, $I^2 = 55\%$) (Fig. 3).

Only one study reported other perioperative complications [25], and there were no studies that reported fascial dehiscence or hernia; therefore, there were insufficient data to analyze our secondary outcomes.

Subgroup analysis

Seven out of 12 studies used single-ring wound protectors [23, 25, 26, 29–32], while 5 studies used dual-ring wound protectors (e.g., Alexis O-Ring) [24, 27, 28, 33, 34]. There was evidence of a subgroup difference ($P = 0.01$) between these two groups. The use of dual-ring wound protectors was associated with lower odds of developing SSI compared to the control group (OR 0.31, 95% CI 0.18–0.52, $P < 0.0001$, $I^2 = 12\%$) (Fig. 4). We did not appreciate this effect in the single-ring wound protector subgroup (OR 0.84, 95% CI 0.67–1.04, $P = 0.11$, $I^2 = 0\%$).

There was no evidence of a subgroup difference based on target organ ($P = 0.12$) (Fig. 5).

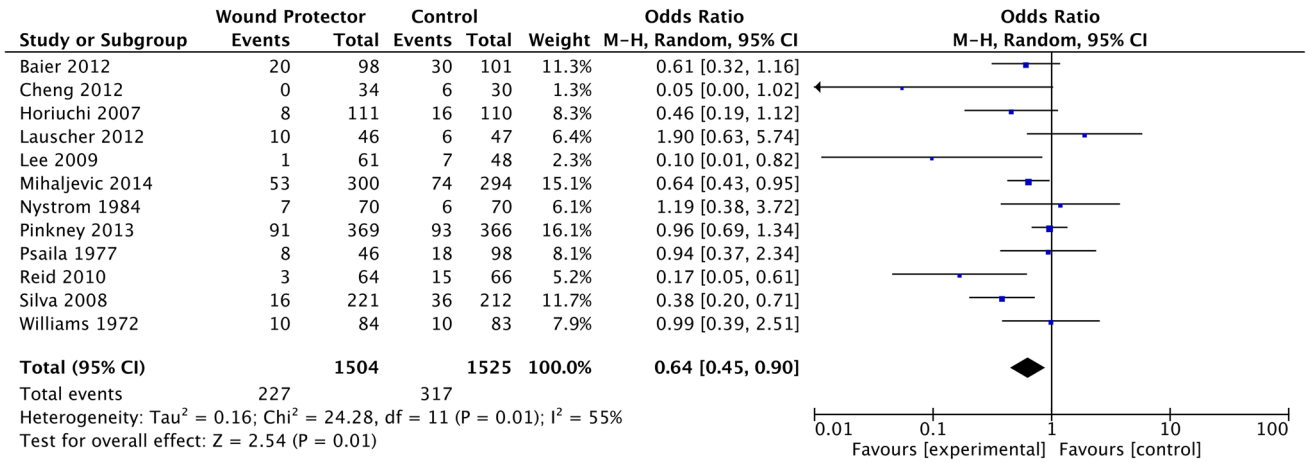

Fig. 3 Forest plot, surgical site infection in wound protector versus no wound protector

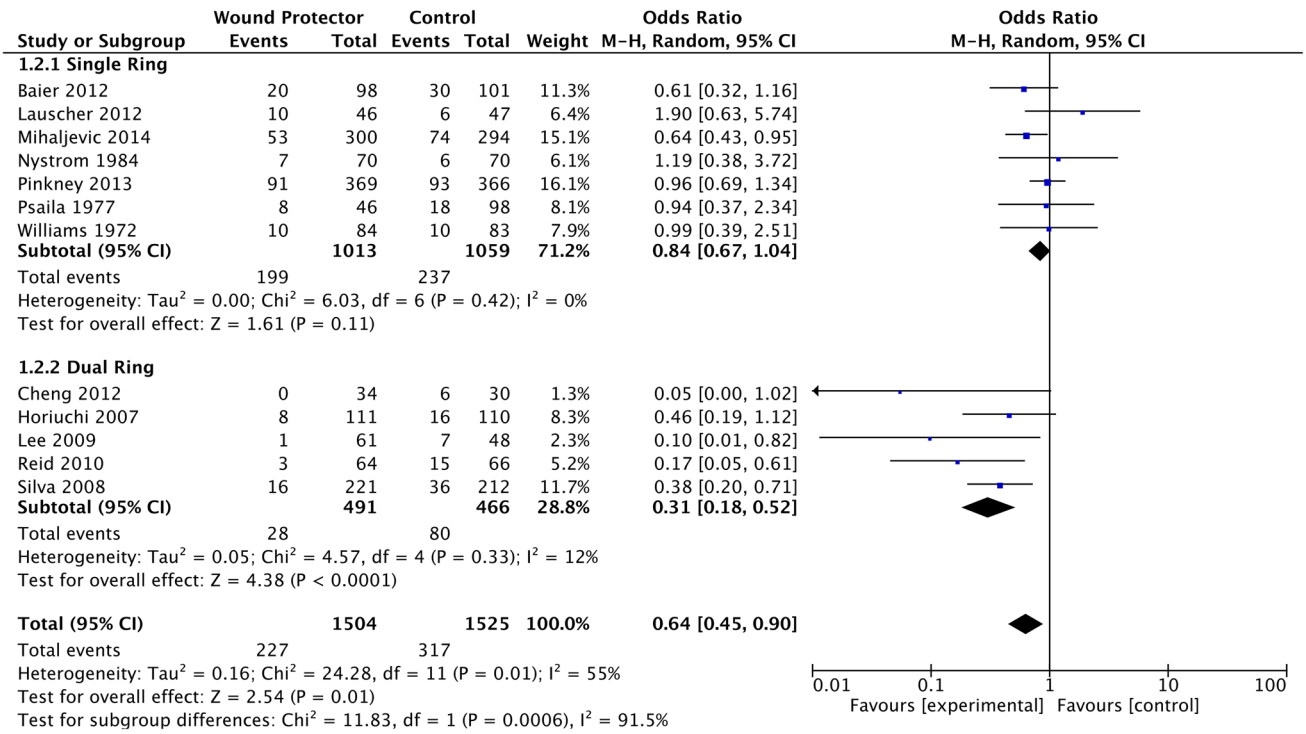

Fig. 4 Forest plot, subgroup analysis of single-ring versus dual-ring wound protectors

GRADE level of evidence

The overall quality of evidence for this meta-analysis was found to be moderate: Table 2 provides a summary of findings. Quality of evidence was downgraded because of concerns in study design (several studies had high risk of bias).

Discussion

Our meta-analysis found that dual-ring wound protectors reduce the odds of SSI in patients undergoing lower gastrointestinal surgery. The quality of evidence was found to be moderate, indicating that further research may have an important impact on our confidence in the estimate of effect and may change the estimate. Our meta-analysis is the most comprehensive and up to date on this topic in this patient population.

Strengths and limitations

The strength of our meta-analysis is the thorough inclusion of all applicable RCTs, including several new trials that have been published in the last 5 years. This allowed us to analyze a larger pooled sample size than previous studies. Our conclusion is congruent with existing meta-analyses on the use of wound protectors, which have all looked at open abdominal surgeries in general [13, 15, 16]. Our study is more specific in the interventions included in that we included lower gastrointestinal surgery only, which is a population that would likely benefit the most from the intervention due to the high incidence of SSIs in bowel surgery compared to other abdominal surgeries [9, 17, 18]. Through the subgroup analyses, we were able to explain the statistical heterogeneity. We demonstrated evidence of a subgroup difference where dual-ring wound protectors reduced SSIs while single-ring retractors did not, which provides greater insight into the choice of wound protection devices.

With the inclusion of two appendectomy trials [33, 34], there was concern that the results may be skewed due to the high number of patients in one of the trials [33]. However, we found no subgroup difference based on target organ (Fig. 5). Three of the included trials were older by several decades [26, 31, 32]. Post hoc analysis found no subgroup difference when comparing the more recent trials to the three older trials ($P = 0.09$) (Supplemental Fig. 1).

There are several limitations to our study. There were insufficient data available to analyze our secondary outcomes of fascial dehiscence, hernia, and perioperative complications. All of the included studies except one [25] looked exclusively at open surgery. Therefore, we have minimal data on the use of wound protectors in laparoscopic procedures. The optimal follow-up period for detection of SSIs is 30 days, which was met by all of the

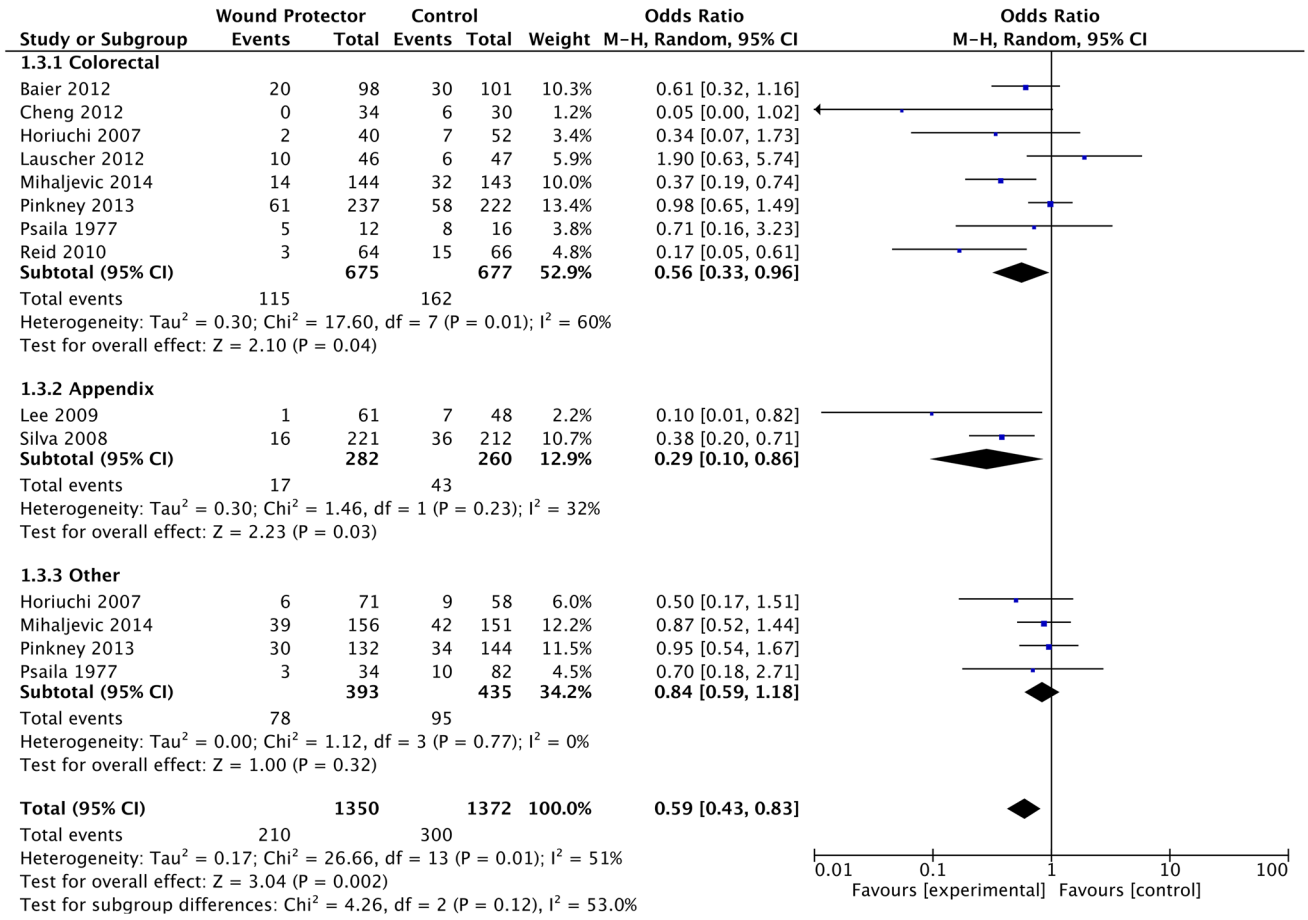

Fig. 5 Forest plot, subgroup analysis of colorectal versus appendix versus other lower gastrointestinal procedures

included RCTs except for three; one followed patients for 21 days [25], another followed for 7–10 days [32], and one trial did not specify the follow-up period (“> 3 days”) [31]. However, even after excluding the two latter studies [31, 32], wound protector use continued to be associated with significantly reduced odds of developing SSI (data not shown).

There was also significant clinical heterogeneity between the RCTs. They varied in terms of overall perioperative care (e.g., skin cleaning, antibiotic choice, mechanical bowel preparation), surgical technique, elective versus emergency cases, and classification of wound contamination. Four studies did not use the standardized CDC definitions of SSI [26, 31, 32, 34]. Despite the possibility of clinical heterogeneity, we were able to explain the statistical heterogeneity through the use of subgroup analyses. Another limitation is that not all studies used the same control group. Some used surgical towels [25, 29–33], while others used standard retractors with no wound coverage [32, 34], adhesive drapes [30, 31], some combination of the previous options [30–32], or did not clearly state what they used [26–28].

Implications

SSIs account for 20% of hospital-acquired infections [35]. SSIs are believed to account for $3.5–$10 billion USD annually in healthcare expenditures [35]. Our data analysis suggests that the use of dual-ring wound edge protectors should be considered in open lower gastrointestinal surgery, including open appendectomies.

Unanswered questions and future research

Further research is required to examine whether wound protectors reduce SSI rates in laparoscopic surgery. Other areas to delineate include the role of wound protectors in elective versus emergency cases, and whether wound protectors are associated with any postoperative or long-term complications.

Table 2 Summary of findings

Wound protector compared to no wound protector for reducing surgical site infection in patients undergoing lower gastrointestinal surgery						
Patient or population: reducing SSI rate in patients undergoing lower GI surgery Setting: patients undergoing any lower GI surgery Intervention: wound protector Comparison: no wound protector						
Outcomes	Anticipated absolute effects[a] (95% CI)		Relative effect (95% CI)	No. of participants (studies)	Quality of the evidence (GRADE)	Comments
	Risk with No Wound Protector	Risk with Wound Protector				
Surgical site infection assessed with clinical diagnosis follow-up: range 3 days to 1 month	Study population 208 per 1000	144 per 1000 (107–192)	RR 0.70 (0.52–0.93)[c]	3029 (12 RCTs)	⨁⨁⨁◯ MODERATE[b]	1 Quality downgraded for serious concerns regarding risk of bias (3 of 12 studies with high risk of bias)

CI Confidence interval, *RR* relative risk

[a]The risk in the intervention group (and its 95% CI) is based on the assumed risk in the comparison group and the relative effect of the intervention (and its 95% CI).

[b]GRADE Working Group grades of evidence

[c]This is related to the odds ratio

High quality: we are very confident that the true effect lies close to that of the estimate of the effect. Moderate quality: we are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.

Low quality: our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect

Very low quality: we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect

Conclusion

Our meta-analysis showed moderate quality of evidence supporting the use of dual-ring wound protectors to reduce the risk of SSI in patients undergoing lower gastrointestinal surgery.

Author contributions LZ: acquisition, analysis, and interpretation of data, drafting of the article, revision of the article. BE: acquisition of data, drafting of the article, revision of the article. SVP: conception and design, analysis and interpretation of data, revision of the article. All authors had final approval of the article.

Compliance with ethical standards

Disclosures Drs. Lisa Zhang, Basheer Elsolh, and Sunil Patel have no conflict of interest or financial ties to disclose.

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