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Role of wound protectors in preventing surgical site infection in patients undergoing abdominal surgery: a meta-analysis of randomized controlled trials

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Abstract

Objective To investigate the role of wound protectors (WPs) in surgical site infection (SSI) prevention in patients undergoing abdominal surgery.

Background Despite practitioners having pursued the ultimate aim of "getting to zero" for centuries, SSI is still a global healthcare burden. WPs are thought to be able to prevent the incision from bacterial contamination, however, contradictory results have been reported.

Method A meta-analysis was performed to compare the SSI rate in patients with and without WPs after abdominal surgery. It includes subgroup analysis of the SSI rate in different surgical sites and different degrees of wound contamination. A systematic literature search was conducted in the PubMed, Embase, Cochrane Library databases, and Web of Science from their respective inceptions until July 6, 2024. All randomized controlled trials with consistent definitions of SSI were included. The bias of each included RCT was assessed by using the Cochrane Risk of Bias 2. To evaluate the risks of random errors resulting from repeated significant testing, a trial sequential analysis was performed. The quality of evidence was assessed by using GRADEpro Guideline Development Tool.

Results A total of 4779 participants were involved in the 19 RCTs. The results showed that the application of WPs during abdominal surgery could significantly reduce the SSI rate (RR = 0.63, 95% CI: 0.50–0.80, $P = 0.0001$, very low certainty evidence). Subgroup analysis showed that the implementation of WPs significantly reduced the SSI rate after colorectal and gastrointestinal surgery (RR = 0.58, 95% CI: 0.38–0.91, $P = 0.02$, very low certainty evidence; RR = 0.49, 95% CI: 0.36–0.67, $P < 0.00001$, moderate certainty evidence, respectively), while had no clear protect role in other types of abdominal surgery. The WPs significantly reduced the SSI rate in patients with a clean-contaminated wound (RR = 0.64, 95% CI: 0.46–0.89, $P = 0.008$, very low certainty evidence) and contaminated or dirty wound (RR = 0.61, 95% CI: 0.41–0.92, $P = 0.02$, moderate certainty evidence), respectively.

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Conclusions The results indicated that the WPs should not be used indiscriminately in all abdominal but gastrointestinal surgery. For patients with contaminated or dirty incisions, WPs should be considered. More studies are needed to determine the effect of WPs in laparoscopic surgery.

Clinical trial number Not applicable.

Keywords Surgical site infection (SSI), Wound protector (WP), Abdominal surgery, Meta-analysis, Colorectal surgery

Introduction

Surgical site infection (SSI) is an infection that occurs at or adjacent to an incision site after an operation. The history of fighting against surgical wound infections by surgeons could date back to the mid-19th century. However, the interpretation of SSI was not once always consistent, especially between the clinical and laboratory outcomes. It was not until 1999, that the United States Centers for Disease Control and Prevention (CDC) presented the "Guideline for Prevention of Surgical Site Infection, 1999". That publication advocated for a definition of SSI and has since emphasized the importance of consistency and standardization in the definition of SSI from that on [1].

It is reported that the SSI rate is about 0.5- 5% in all patients undergoing surgery with an even higher incidence in patients after abdominal surgery. Especially in colorectal surgeries, with the highest rates of SSI is about 15% to over 30%. The incidence of SSI in developing countries is at least three times that of in developed countries [2–6]. The presentation of the "Guidelines for the Prevention of Surgical Site Infection" in 2016 by the World Health Organization indicated the urgency of settling this global issue as SSI was a heavy economic burden and a waste of healthcare resources.

A bundle of care, which includes but is not limited to preoperative bathing and showering, intravenous prophylactic antibiotics, mechanical bowel preparation plus oral antibiotics (MBP + OAB) for patients undergoing colorectal surgery, skin preparation, intraoperative normothermia management and glycemic control, intraoperative wound Irrigation, and so on, has gradually been proposed in decades of practice and study to decrease the SSI rate [6–12].

It is believed that the reduction in exposure to bacteria would decrease the SSI rate after surgery [13, 14]. Thus, the wound protector (WP) device was designed to form a barrier between the wound edge and the operative site to isolate the wound edges from potential bacterial exposure. However, the results of relative studies were inconsistent despite nearly all the meta-analyses confirming the role of WPs in SSI protection [8, 15–18]. The major reason for this controversy is the mixed study designs which included the non-uniform definition of SSI, the various implementations of bundled cares in different studies in different era, and the heterogeneity of different surgical sites and approaches. For example, the definition of SSI in studies conducted by pioneers was not always consistent with that nowadays [19, 20]. Meanwhile, some studies implemented additional well-established care perioperatively while it was not disclosed in some other studies [21–23].

We hypothesized that the WPs have a protective role in SSI after some kinds of abdominal surgeries while having no role in others. To achieve the stability and consistency of the results in terms of utilizing WPs in SSI decreasing, we plan to conduct a meta-analysis of randomized controlled trials (RCTs) regarding the potential role of WPs in SSI protection with some specific restrictions.

Materials and methods

The current meta-analysis was performed according to Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) reporting guidelines. The study protocol was prospectively registered in PROSPERO (CRD42024576426).

Data sources

A systematic literature search for relevant studies was conducted in PubMed(1996), Embase(1974), Cochrane Library databases(1996), and Web of Science (1997)from their respective inceptions until July 6, 2024. The search string initially set in the protocol was " (Surgical Wound Infection OR Surgical Wound Infections OR Surgical Site Infections) AND (wound protector OR wound protection device OR wound infection protector)", which aimed to retrieve literature directly related to the research topic. However, during the actual literature search process, we found that only a limited number of literature resources with relatively narrow content could be retrieved using this search string, failing to meet the need for a comprehensive and in-depth understanding of the research topic. Therefore, we adjusted the search string. The new search string expands the search scope by using the Boolean logic operator "OR" to connect synonyms, near-synonyms, and extended concepts. As a result, we successfully retrieved more abundant and in-depth literature resources. These literatures have provided a more comprehensive theoretical basis and empirical support for our research, effectively promoting the smooth progress of the research and ensuring the reliability and validity of the research results. The same Medical Subject Headings

terms were used in all databases: Surgical Wound Infection, infections, surgical wound, surgical wound infections, wound infections, surgical, infection, postoperative wound, postoperative wound infections, wound infections, postoperative, infection, surgical wound, postoperative wound infection, wound infection, postoperative, wound infection, surgical, surgical site infection, infections, surgical site, infection, surgical site, surgical site infections, wound protector, wound protection device, wound-protection, wound retractor, wound edge protector, wound-edge protector, wound edge protection, alexis, wound isolator, wound infection protector, surgical wound isolator, wound guard, wound ring, ring drape, ring protector, plastic ring.

The titles and abstracts of all the retrieved studies were reviewed by two independent authors (BL and WS). Studies not meeting the inclusion criteria were excluded. The available full texts of the remaining articles were reviewed to further identify eligible studies by two independent authors (BL and WS).

Inclusion and exclusion criteria

The inclusion criteria were as follows: RCTs that investigated the effect of WPs in SSI prevention, patients who underwent abdominal surgery, and the primary endpoint was the SSI rate within 30 days between patients with and without WPs. The WP was defined as a disposable plastic wound edge barrier with either one plastic ring or two plastic rings, no additional function was designed.

The exclusion criteria included: studies that were inconsistent with the CDC definition of SSI.

Analysis of subgroups or subsets

It includes subgroup analysis of the SSI rate in different surgical sites and different degrees of wound contamination. The plan for subgroup analysis based on different degrees of wound contamination was an adjustment made after the protocol was registered.

Data extraction

Data were extracted by two authors independently (BL and JY). In case of any dispute, a third author (SZ) was consulted to reach a consensus. The information extracted included the first-author names, year of publication, study design, study setting, types of surgery, surgical approach, randomization, blinding, information on the WPs, number of cases of SSI, number of cases of superficial SSI, and degree of wound contamination.

Statistical analysis and assessments of Methodological Quality

The Review Manager 5.4 software program was used to perform data analysis. Dichotomous variables were evaluated utilizing risk ratios (RRs) with 95% confidence intervals (CIs). Heterogeneity was described using the I [2] value and categorized into 4 levels: might not be important ($0\% < I^2 < 40\%$), may represent moderate heterogeneity ($30\% < I^2 < 60\%$), may represent substantial heterogeneity ($50\% < I^2 < 90\%$), considerable heterogeneity ($75\% < I^2 < 100\%$). Random-effect models were implemented in the whole process. Subgroup analysis was planned according to the surgical sites which included the colorectal, hepatic-biliary-pancreatic, gastrointestinal, and cesarean section surgery.

The bias of selection of the reported result, measurement of the outcome, missing outcome data, deviations from intended interventions, and randomization process of each included RCT was assessed by two independent authors (BL and SZ) using the Cochrane Risk of Bias 2 (RoB 2) tool.

To evaluate the risks of random errors resulting from repeated significant testing, we conducted a trial sequential analysis (TSA) using TSA 0.9 software. The required information size (RIS) was calculated using a type I error of 5%, a type II error of 20%, and an incidence of 19.1% in the control arm.

The quality of evidence was assessed according to the Grade of Recommendations Assessment, Development, and Evaluation (GRADE) guidelines using The GRADEpro Guideline Development Tool (GDT).

Results

Selected studies

Initially, a total of 3033 potentially relevant records were identified from the abovementioned four databases. After checking according to the inclusion and exclusion criteria, only 19 RCTs were found to be eligible and were included for analysis (Fig. 1). The characteristics of all the included studies are shown in Table 1.

Quality assessment

The results of the Cochrane ROB 2 are shown in Fig. 2. In the total of 19 studies, the overall risk of bias shows that the proportion of low risk is 10.5%, that of some concerns is 52.6%, and that of high risk is 36.8%. Only 6 studies had a low risk of bias while the rest had some concern of bias, no high risk of bias was detected. The details are shown in Fig. 2.

Trial sequential analysis (TSA)

As the trial sequential analysis results showed (Figure S1), the cumulative z-curve crossed the conventional boundary and the required information size (2432) was reached, indicating a sufficient sample size and reliable result.

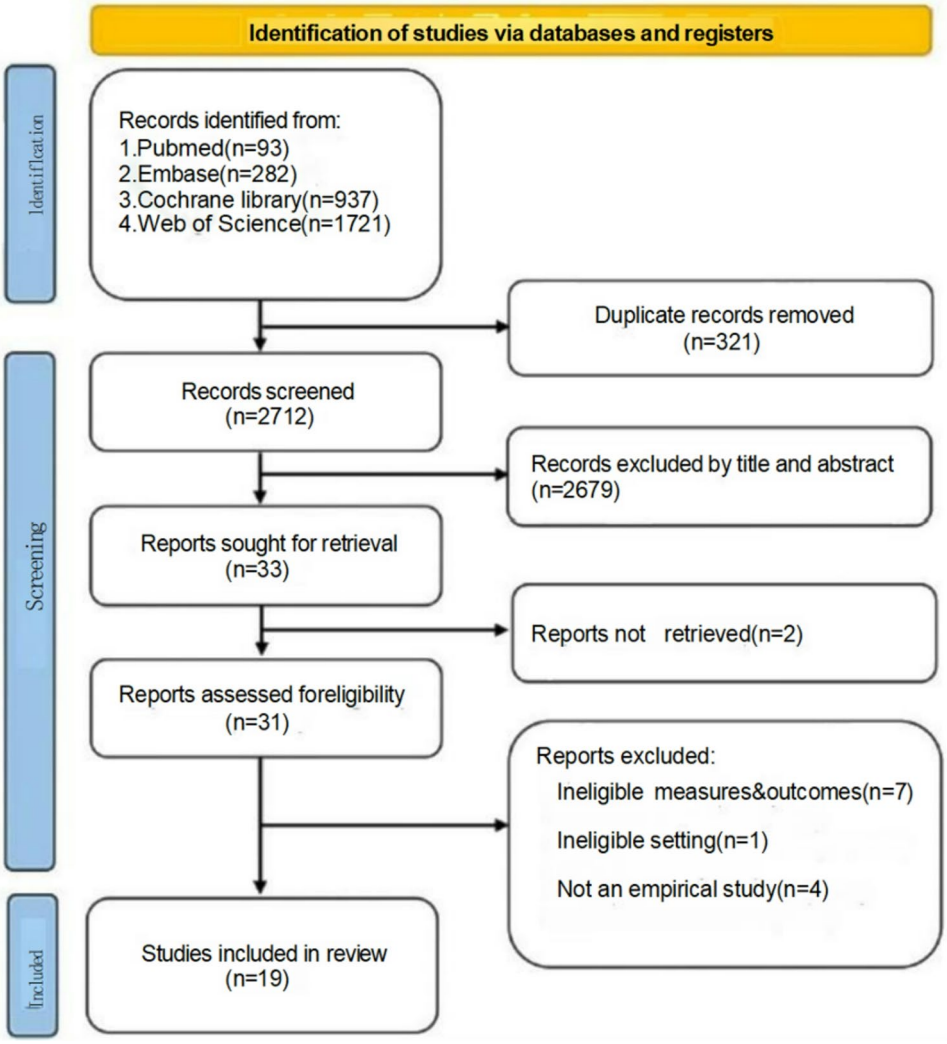


Fig. 1 PRISMA flowchart

GRADE assessment

The GRADE evidence profile is shown in Table S1. The certainty of evidence was very low for total and superficial or deep SSI rates after abdominal surgery, respectively. The certainty of evidence was moderate for SSI rate after gastrointestinal surgery, low for SSI rate after hepatic-biliary-pancreatic surgery, and very low for SSI rate after colorectal surgery and cesarean section, respectively. The certainty of the evidence was very low for SSI in clean-contaminated and moderate for SSI for contaminated or dirty wounds, respectively.

The risk of publication bias was examined using a funnel plot (Fig. 3). The asymmetry of this graph is caused by four studies [24–27].

Outcomes

A total of 4779 participants were involved in the 19 RCTs [13, 21, 22, 24–39], with 2376 patients in the With WP group and 2403 in the Without WP group. Regarding surgical types, colorectal surgery 13.1% (626 patients), appendectomy 13.9% (664 patients), cesarean Sect. 19.3% (920 patients), pancreaticoduodenectomy 6.2% (297 patients), gastrointestinal surgery 19.7% (939 patients), abdominal surgery 26.8% (1,281 patients). Most of the studies focused on abdominal surgery via an open approach while only one study by Lauscher JC [36] enrolled patients who underwent surgery via a laparoscopic approach. Another study by Baier P [21] enrolled patients via both the open and laparoscopic approaches. (Fig. 1)

The surgical sites include the gastrointestinal tract, appendix, uterus, colorectum, and hepatic-biliary-pancreatic system. Some of the studies mixed the surgical sites in different ranges due to the various purposes of these studies. The details of the characteristics of the studies are mentioned in Table 1.

Table 1 Characteristics of the included RCT studies in the meta-analysis

Study	Simple Size	Simple Size Calculation	Information on the WP	Surgical Approach	Types Of Surgery	Efficacy Of WP
Yoo N, 2024 [22]	457	Yes	Double-ring	Open	Gastrointestinal	Positive
Mothiba MS, 2023 [28]	207	Yes	Double-ring	Open	Cesarean section	Negative
Muniandy J, 2021 [29]	190	Yes	Double-ring	Open	Appendectomy	Negative
Salgado-Nesme N, 2020 [24]	41	Unclear	Double-ring	Open	Colorectal + Appendectomy	Positive
De Pastena M, 2020 [30]	190	Yes	Double-ring	Open	Pancreaticoduodenectomy	Negative
Kobayashi H, 2019 [31]	100	Unclear	Single-ring	Open	Colorectal	Positive
Bressan AK, 2018 [32]	107	Yes	Double-ring	Open	Pancreaticoduodenectomy	Positive
Scolari Childress KM, 2016 [33]	284	Yes	Double-ring	Open	Cesarean section	Negative
Hinkson L, 2016 [25]	198	Yes	Double-ring	Open	Cesarean section	Positive
Mihaljevic AL, 2014 [34]	546	Yes	Single-ring	Open	Abdominal	Positive
Pinkney TD, 2013 [35]	735	Yes	Single-ring	Open	Abdominal	Negative
Lauscher JC, 2012 [36]	93	Yes	Single-ring	Lap	Colorectal	Negative
Cheng KP, 2012 [26]	64	Yes	Double-ring	Open	Colorectal	Positive
Baier P, 2012 [21]	200	Yes	Single-ring	Open + Lap	Colorectal	Negative
Theodoridis TD, 2011 [27]	231	Yes	Double-ring	Open	Cesarean section	Positive
Reid K, 2010 [13]	130	Yes	Double-ring	Open	Gastrointestinal + Hepatic-biliary-pancreatic	Positive
Silva A, 2008 [39]	433	Yes	Double-ring	Open	Appendectomy	Positive
Horiuchi T, 2007 [37]	221	Unclear	Double-ring	Open	Colorectal	Negative
Sookhai S, 1999 [38]	352	Unclear	Single-ring	Open	Gastrointestinal	Positive

RCT: randomized controlled trials; WP: wound protector; Lap: laparoscopic

Total SSI rate in patients after abdominal surgery between with WP and without WP groups

Heterogeneity was at a moderate level among all the studies ($P = 0.001$, $I^2 = 57\%$). Overall, the result indicates that the application of WPs during abdominal surgery can significantly reduce the SSI rate (RR = 0.63, 95% CI: 0.50–0.80, $P < 0.0001$, very low certainty evidence) (Fig. 4).

As the WP is designed as a barrier between the wound edge and the operation area, it may potentially play a role in superficial or deep SSI prevention while not affecting organ-space SSI protection. Thus, we further investigated the superficial or deep SSI rate in these pooled patients. The results showed that there was a significant decrease in superficial or deep SSI rate in patients after abdominal surgery between With WP and Without WP groups (RR = 0.68, 95% CI: 0.50–0.91, $P = 0.009$, very low certainty evidence). The heterogeneity was at a moderate level among all the studies ($P = 0.01$, $I^2 = 54\%$). (Figure S2).

Subgroup analysis

SSI rate in different surgical sites

It is reported that the SSI rate varied from different types of surgeries in different surgical sites [28, 30, 31, 33, 40]. Thus, further subgroup analysis was performed according to the surgical site. Colorectal surgery, hepatic-biliary-pancreatic surgery, gastrointestinal surgery, and cesarean section were identified accordingly. Open appendicectomy (only two studies [29, 39]) was excluded from the subgroup analysis as laparoscopic appendectomy is the preferred approach in dealing with both complicated and uncomplicated appendicitis nowadays [41, 42]. Consequently, open appendicectomy is rarely performed, let al.one the application of WPs. For the studies with mixed surgical sites (e.g. gastrointestinal surgery site includes stomach, small bowel, and colorectum), the corresponding data was adopted when it was available.

The results showed that the implementation of WPs in colorectal (RR = 0.58, 95% CI: 0.38–0.91, $P = 0.02$, very low certainty evidence) and gastrointestinal (RR = 0.49, 95% CI: 0.36–0.67, $P < 0.00001$, moderate certainty evidence) surgery significantly reduced the SSI rate. However, the heterogeneity was still at a moderate level among all the studies in terms of colorectal surgery ($P = 0.09$, $I^2 = 47\%$) while was null within all the studies in terms of gastrointestinal surgery ($P = 0.64$, $I^2 = 0\%$). The implementation of WPs in the sesarean section(RR = 0.38, 95% CI:0.06–2.26, $P = 0.29$) and Hepatic-biliary-pancreatic (RR = 0.69, 95% CI: 0.34–1.39, $P = 0.30$) surgery showed no significant difference in the SSI rate. (Fig. 5)

SSI rate in different degrees of wound contamination

It is reported that the degree of wound contamination was associated with the SSI [5]. We further analyzed the SSI rate in different degrees of wound contamination in patients with or without WPs. The definition of degrees of wound contamination was consistent with the CDC definition [1]. Briefly, four degrees of wound contamination including clean, clean-contaminated, contaminated, and dirty were studied. Varies stratification strategies

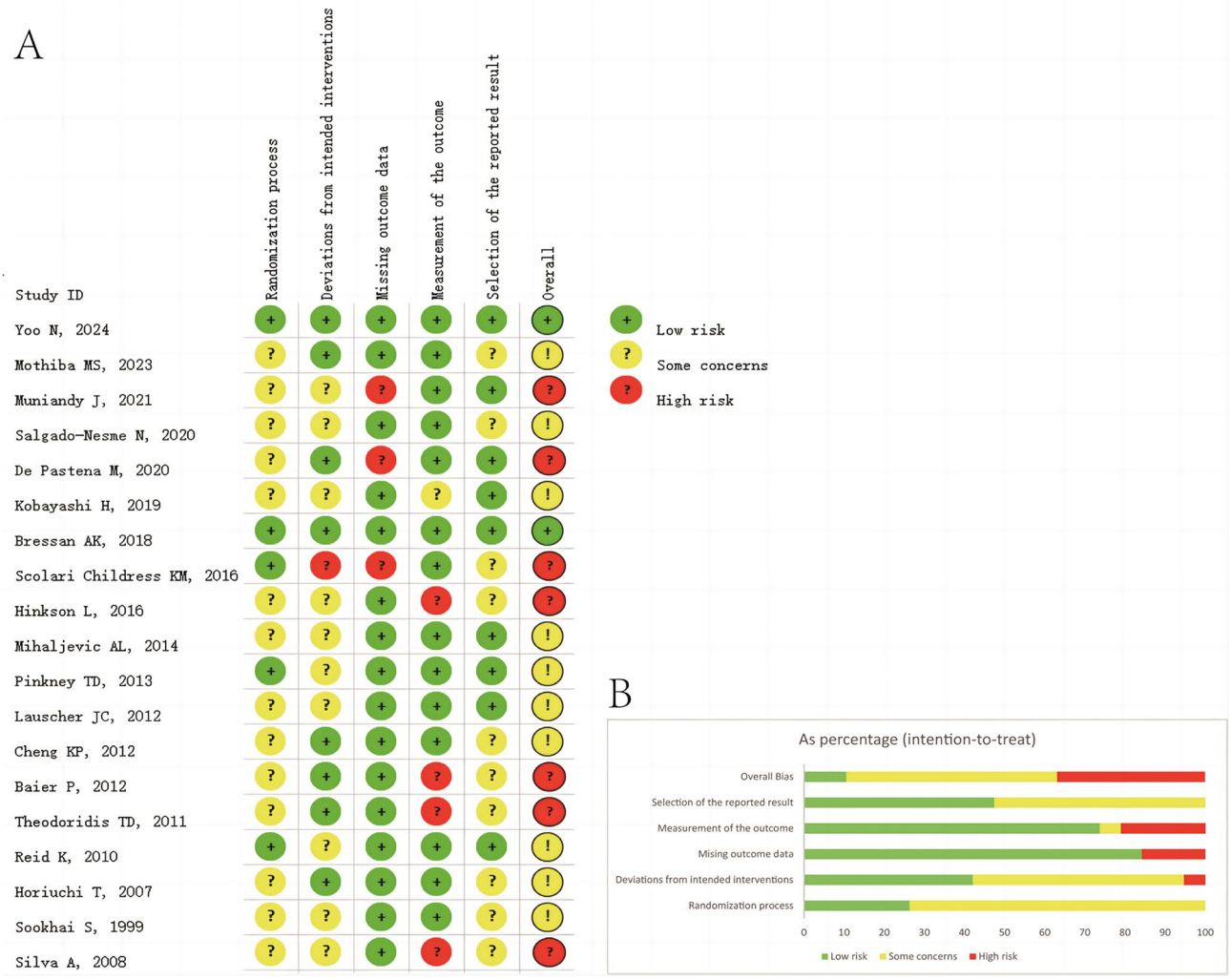


Fig. 2 The risks of the included studies. **A** Risk bias of graph for studies with intention-to treat (ITT), **B** Risk bias of graph for studies with pre-protocol (PP), C Risk bias of summary for all included studies

and incomplete data stopped us from conducting a more detailed subgroup analysis. The degree of wound contamination was stratified into clean-contaminated, contaminated or dirty in the current study. The corresponding data was used when it was available.

The results showed that the WPs significantly reduced the SSI rate in patients with a clean-contaminated wound (RR = 0.64, 95% CI: 0.46–0.89, $P = 0.008$, very low certainty evidence) ($P = 0.01$, $I^2 = 52\%$). Not surprisingly, the WPs also had a protective role in terms of SSI in the patient with a contaminated or dirty wound (RR = 0.61, 95% CI: 0.41–0.92, $P = 0.02$, moderate certainty evidence) ($P = 0.11$, $I^2 = 47\%$). (Fig. 6)

Discussion

In the current study, 19 RCTs were included in this meta-analysis. These results indicate a potential role of WPs in the incidence of SSI in abdominal surgery, especially in superficial and deep SSI. We further detected a protective effect of WPs in SSI in patients who underwent gastrointestinal and colorectal surgery, while this effectiveness was not clear in hepatic-biliary-pancreatic surgery and cesarean section. When considering the degree of wound contamination, our findings suggest WPs may had a reliable effect on clean-contaminated, contaminated, and dirty wounds.

A bundle of care is recommended to practitioners to prevent SSI after operations, while the application of WPs is suggested in some guidelines [8, 43–45]. However, it is still controversial due to the inconsistent results from different studies. Despite several meta-analysis studies confirming the role of WPs in SSI prevention [15–18, 46–55], the inherent cognitive limitations between studies over a decades-long history have hampered the interpretation of the results. Therefore, only the RCTs were included in our study to decrease the heterogeneity. Moreover, all the studies with available full text were carefully reviewed,

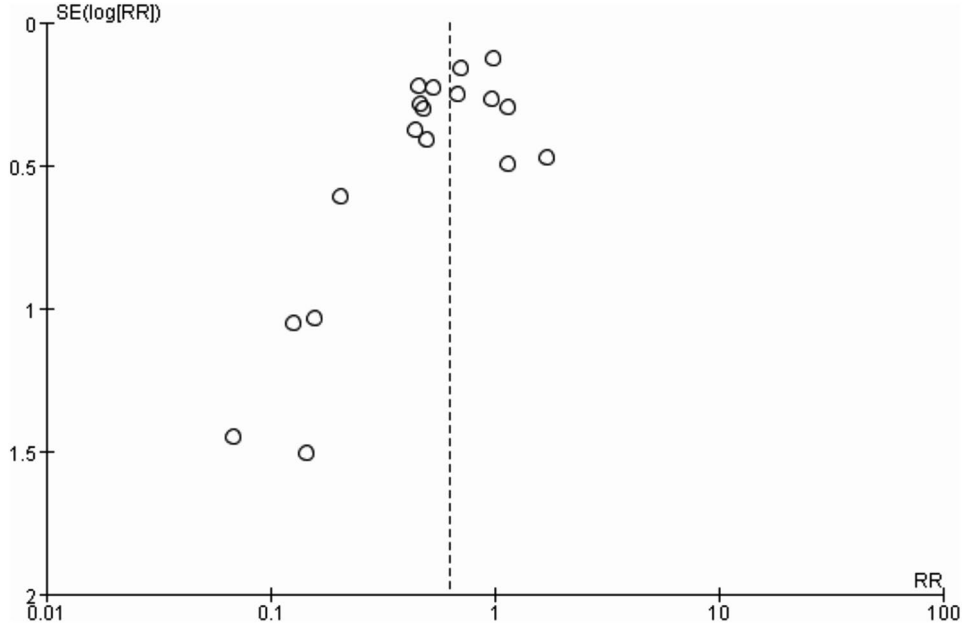


Fig. 3 Funnel plot of the included randomized controlled studies (random-effects model)

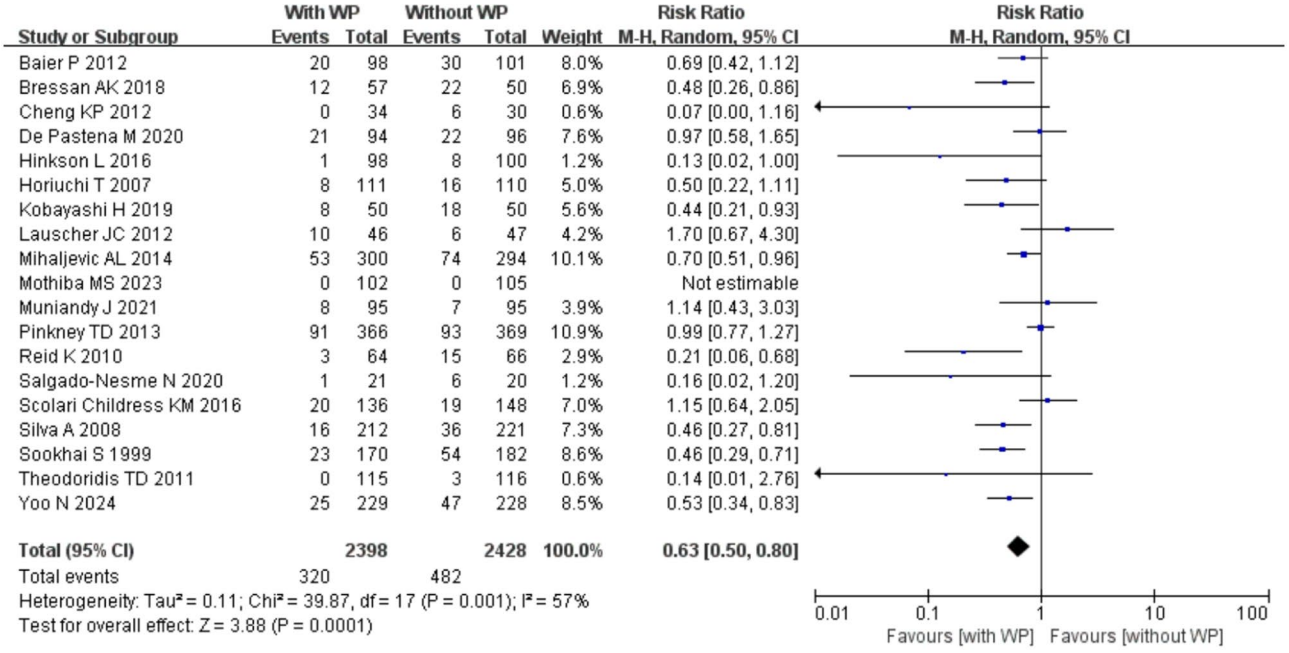


Fig. 4 Forest plots for the total surgical site infection rate

and those with inconsistent definitions of SSI proposed by the CDC were excluded [19, 20, 56–60].

In the present study, we detected a significant reduction in SSI rate in abdominal surgery after the application of WPs. However, caution must be paid when interpreting these results. Only two studies [34, 35] involved unselective abdominal surgeries, and a contradicting conclusion was made in each study. Despite pooled data showing a positive role of WPs, the extrapolation of this conclusion to unselective abdominal surgeries may not be suitable. Because it was only the gastrointestinal tract rather than any other sites that the WPs could work in SSI prevention in the following subgroup analysis. The reasonable explanation for this is that *Escherichia coli* and *Enterococcus faecalis* are the most common bacteria in the gastrointestinal tract while they are also part of the main pathogens to SSI. Therefore, an incision in gastrointestinal surgery is more fragile to pathogen contamination, causing

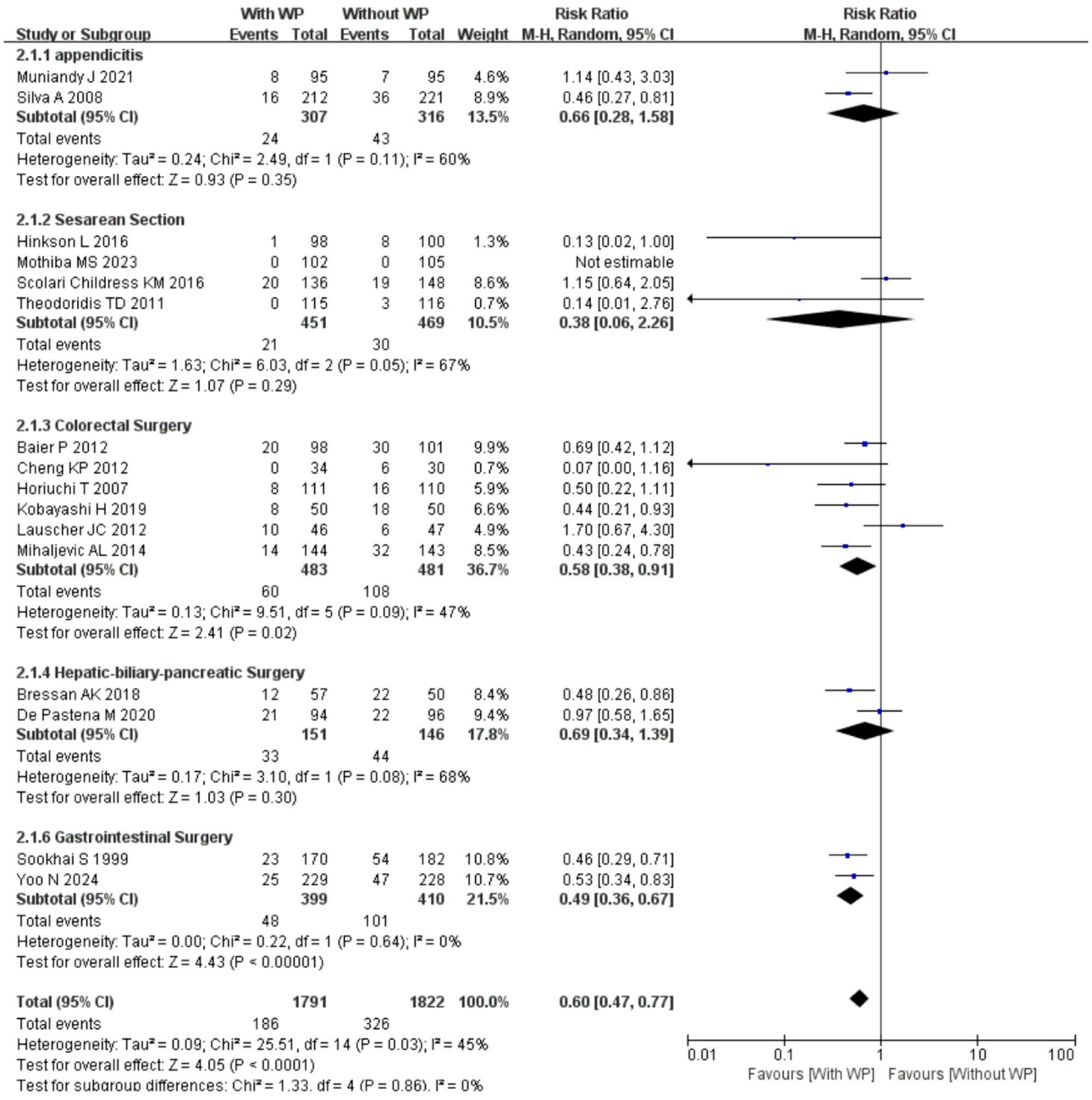


Fig. 5 Forest plots for the surgical site infection rate in different surgical sites

a higher rate of SSI. It is reported that the MBP + OAB could reduce the SSI rate after colorectal surgery [40, 61]. Based on such logic, a wound barrier shielding the incision from contamination by these gastrointestinal pathogens seems to be efficient too. Similarly, the extrapolation of this conclusion to all emergency abdominal surgeries may not be suitable. Due to the various designs in these studies, the enrollment of the emergency surgery in the elective surgery makes the study population mixed. It is well-known that the SSI increased in emergency surgeries when compared to elective surgeries.

Our results showed moderate certainty evidence that a protective role in terms of SSI in contaminated or dirty surgery. The evidence also supported the effectiveness of WPs in gastrointestinal surgery. In these operations, the wound is more susceptible to pathogens due to the inevitable spillage of the intestinal contents over the surgical area more or less. These results may boost surgeons' confidence in using WPs in contaminated or dirty procedures. However, overemphasizing the role of a single preventive method in contaminated or dirty procedures is detrimental. Following the aseptic technique, combining

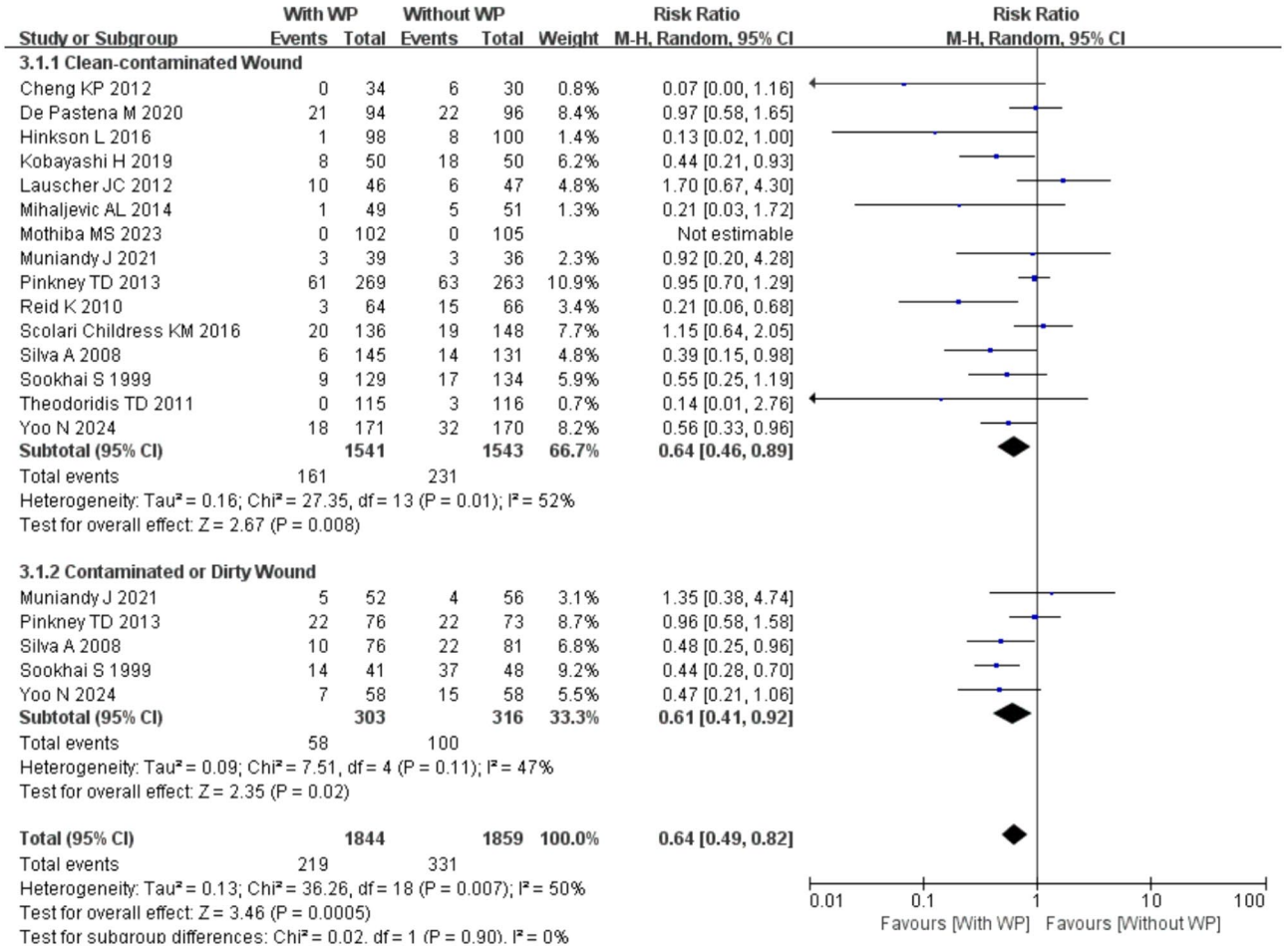


Fig. 6 Forest plots for the surgical site infection rate in different surgical sites

the WPs with multi-interventions, such as wound irrigation, subcutaneous drainage, or vacuum sealing drainage, should also be considered to minimize the incidence of SSI [62, 63].

There were many other terms referred to the WP, such as wound protection device, wound retractor, wound edge protector, Alexis ring, and so on. The variety of naming methods brings great difficulties to the current study. We recommend that the uniform naming of the WP should be taken into consideration by relevant associations, as has been done with the definition of SSI, to increase the availability of study data globally. The novel WP with an irrigation device is frequently reported in recent years [64–66], however, more studies, especially RCTs, are needed to determine the superiority.

A total of 19 RCTs were included in the current study, some are positive trials and some are negative trials. The inconsistent conclusions bring us back to the original intention of designing the WP, a barrier shielding the wound from bacterial cultivation at the surgical site. However, this well-established assumption that SSI is caused by intraoperative contamination events remains unproven [67, 68]. Thus, to further determine the role of WPs in SSI prevention, the underlying mechanism of surgical wound contamination related to SSI is in urgent need of disclosure. On the other hand, further clinical trials should continuously comply with the uniform conception of SSI, while implementing other recommended standard bundled care for SSI prevention as fully as possible.

Only one pure laparoscopic RCT was found in the current study [36]. it is reported that compared to open surgery, the incidence of SSI is much lower in laparoscopic surgery [69, 70]. More studies are needed to investigate the role of WPs in SSI reduction when applying it to patients undergoing laparoscopic surgery which has gradually become the preferred surgical approach in many types of surgery nowadays.

Finally, although our meta-analysis has provided valuable insights into the protective role of WP in reducing SSIs, it is essential to recognize the limitations of this study. Longer time spans between the included studies (from 1999 to 2024) may affect the homogeneity due to the progressive integration of newly validated

SSI prevention measures into standard care protocols over this period. We have taken some measures, such as including only RCTs and harmonizing the definition of SSI, but it is undeniable that we still cannot eliminate the impact. Additionally, the effectiveness of WPs should be interpreted within the framework of a comprehensive SSI prevention bundle rather than as an isolated intervention. This clarification underscores that our findings do not diminish the critical role of other established SSI prevention strategies but instead highlight the potential synergistic value of WPs when applied in conjunction with these measures, particularly in specific surgical contexts. Secondly, we don't have any restrictions on WP materials and formation. This is decided by the available resources in different studies. We don't think this will affect the principal role of the WP as a barrier. Thirdly, all the included studies lacked information about the wound length which may be a potential confounding factor when evaluating the efficacy of WPs. Future studies need to provide more comprehensive data collection to better understand the relationship between wound length and SSI, even the concern about cost-effectiveness and carbon emissions.

Conclusions

The results suggest a selective application of WPs in gastrointestinal, especially in colorectal surgery, is reasonable. A bundle of standard care plus WPs may effectively reduce the incidence of SSI in gastrointestinal surgery. Based on consideration of the cost and availability of WPs, we suggest that the WPs should not be used indiscriminately in unselected abdominal surgery until a conclusion with less heterogeneity emerges. For surgeries with contaminated or dirty incisions, WPs should be recommended. More studies are needed to determine the protective effect of WPs in minimally invasive wounds during laparoscopic surgery.

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s12893-025-02809-9.

Supplementary Material 1

Supplementary Material 2

Supplementary Material 3

Author contributions

Song Zhao designed the study; Bo Liu and Wenjing Sun performed the literature search; Juan Zhu and Jin Ye analyzed the data; Song Zhao and Bo Liu interpreted the results and drafted the manuscript. Wenjing Sun, Yang Yang and Jin Ye critically revised the manuscript for important intellectual content.

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Data availability

All data generated or analyzed during this study are included in this published article.

Declarations

Ethics approval and consent to participate

Not applicable.

Consent for publication

Not applicable.

Competing interests

The authors declare no competing interests.

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