Wound Protectors Reduce Surgical Site Infection

A Meta-Analysis of Randomized Controlled Trials

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Objective: A meta-analysis of randomized clinical trials (RCTs) was conducted to evaluate whether wound protectors reduce the risk of surgical site infection (SSI) after gastrointestinal and biliary tract surgery.

Background: The effectiveness of impervious wound edge protectors for reduction of SSI remains unclear.

Methods: A systematic review was conducted in Medline, EMBASE, and the Cochrane Library to identify RCTs that evaluate the risk of SSI after gastrointestinal and biliary surgeries with and without the use of an impervious wound protector. The pooled risk ratio was estimated with random-effect meta-analysis. Sensitivity analyses were performed to examine the impact of structural design of wound protector, publication year, study quality, inclusion of emergent surgeries, preoperative antibiotic administration, and bowel preparation on the pooled risk of SSI.

Results: Of the 347 studies identified, 6 RCTs representing 1008 patients were included. The use of a wound protector was associated with a significant decrease in SSI (RR = 0.55, 95% CI 0.31–0.98, $P = 0.04$). There was a nonsignificant trend toward greater protective effect in studies using a dual ring protector (RR = 0.31, 95% CI 0.14–0.67, $P = 0.003$), rather than a single ring protector (RR = 0.83, 95% CI 0.38–1.83, $P = 0.64$). Publication year ($P = 0.03$) and blinding of outcome assessors ($P = 0.04$) significantly modified the effect of wound protectors on SSI.

Conclusions: Our results suggest that wound protectors reduce rates of SSI after gastrointestinal and biliary surgery.

(*Ann Surg* 2012;256:53–59)

Surgical site infections (SSI) are a common and costly source of postoperative morbidity. They are the most common complications experienced after gastrointestinal and biliary tract surgery, occurring in 5% to 30% of patients.[1,2] SSI are associated with a twofold increased risk of in-hospital mortality, a 50% increase in intensive care admission, a 6-day mean increase in hospital stay, and a fivefold increased rate of readmission.[3] The estimated increased cost per SSI ranges from $1300 to $5000.[3,4] In addition, patients who develop SSI experience psychosocial distress, loss of income, and loss of productivity.[5] Prevention of SSI is therefore an important goal in delivering quality care to patients.

Wound protectors are devices designed to protect the abdominal wound edges from contamination and trauma during laparotomy.[1] A major reason for their conception and use is a theoretical reduction in risk of SSI. Various devices with similar intent have been described since the 1960s, falling into 2 main design categories: (1) those with an internal and external ring connected by impervious plastic and (2) those with a single, internal ring connected to a drape that extends outward, over the wound edges and onto the abdomen where they are affixed with adhesive or clips. The reduction of SSI afforded by wound protectors is supported by several studies.[2,6–13] However, other studies have obtained null results.[14–21] This discrepant evidence leaves significant uncertainty in the surgical community with regard to the efficacy of wound protectors in prevention of SSI.

The purpose of our study is to critically evaluate whether wound protectors reduce the risk of SSI after gastrointestinal and biliary tract surgery in a pooled analysis of randomized controlled trials (RCTs). To our knowledge, this meta-analysis is the first to address this important issue. Our secondary objectives are (1) to investigate whether risk reduction varies with structural design of wound protector, (2) to determine if the risk reduction is uniform in studies addressing elective operations only, compared to those including emergent surgeries, and (3) to determine if other factors such as preoperative antibiotic use, bowel preparation, publication year, or study quality are significant determinants of effect. The authors have no conflicts of interest to disclose.

METHODS

In accordance with a prespecified study protocol, Medline, EMBASE, and the Cochrane Central Register of Controlled Trials were systematically searched with the assistance of 2 independent reference librarians from the inception of all databases to March 31, 2011. The final search strategy used for each database included Medical Subject Heading terms and keywords reflecting "infection" and "wound protector." Search terms related to "gastrointestinal and biliary surgery" were found to limit the total number of articles retrieved; therefore, we omitted these terms from the final search strategy (Table 1). A manual search of the reference lists of relevant articles was performed, and an exploration of the gray literature was conducted with a systematic search of *Google Scholar*. Three reviewers (J.E., A.H., M.C.T.) independently evaluated all retrieved articles using prespecified eligibility criteria. Disagreements were resolved by consensus. All reasons for exclusion were documented systematically in a uniform log (Fig. 1). Experts in the field were also consulted to verify completeness of the search strategy and retrieved articles.

Eligibility Criteria

Studies meeting the following criteria were included: (1) Study design—randomized and controlled, (2) Population—patients undergoing non–trauma-related abdominal surgery with entry into the gastrointestinal and/or biliary tract, (3) Intervention—use of an occlusive barrier device to protect the laparotomy wound, (4) Comparator-–control group without an occlusive barrier device, (5) Outcome-—SSI defined as "any infection of the superficial/deep tissues or the organ/space affected by surgery, which occurs within 30 days of surgery when no prosthesis has been implanted" by the Centers for Disease Control and Prevention (CDC).[22] In accordance with this

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Disclosure: E.D. is supported by a Canadian Institutes of Health Research New Investigator Award. The remaining authors have no financial disclosures. None of the authors have any connection with the manufacturers of any of the products described in this report.

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ISSN: 0003-4932/12/25601-0053
DOI: 10.1097/SLA.0b013e3182570372

TABLE 1. Search Strategy Used to Identify Randomized Controlled Trials

Database	Search Terms
Central	(Protective devices/ or wound protective/ or Alexis/ or wound protector/ or plastic drape/ or plastic wound drape/ or wound protection/ or wound edge protector/ or wound guard/ or wound ring drape/ or plastic ring wound drape) AND (Infection/ or wound infection/ or infection/ or surgical wound infection/ or nosocomial/ or infections)
Medline	(Protective devices/ or wound protective/ or Alexis/ or wound protector/ or plastic drape/ or plastic wound drape/ or wound protection/ or wound edge protector/ or wound guard/ or wound ring drape/ or plastic ring wound drape) AND (Infection/ or wound infection/ or infection/ or surgical wound infection/ or nosocomial/ or infections)
EMBASE	(infection complication) or (infectious complication) or (hospital infection) or (cross infection) or (nosocomial) or (surgical infection) AND (wound protective) or (Alexis) or (plastic drapes) or (plastic wound drape) and (wound protections) or (wound edge protector) or (wound guard) or (wound ring drape) or (plastic ring wound drapes)

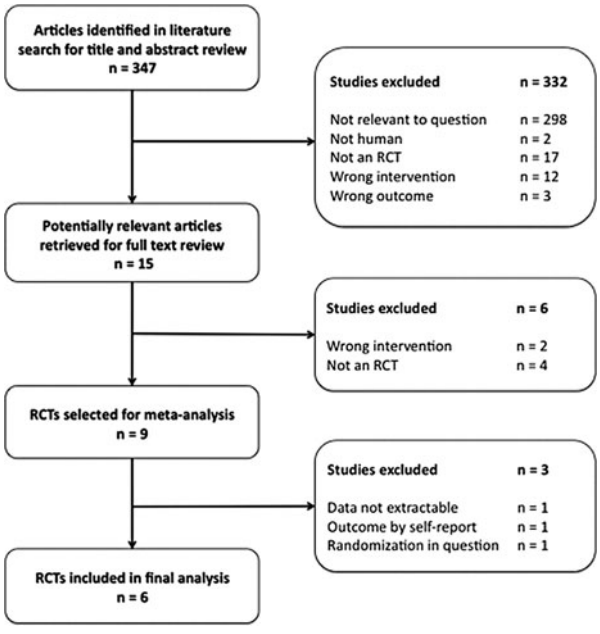

FIGURE 1. Quorum flow diagram depicting process of study selection.

definition, studies were required to adhere to one or more of the following criteria for identification of SSI: (1) purulent drainage, with or without laboratory confirmation, from the superficial incision, (2) organisms isolated from an aseptically obtained culture of fluid from the superficial incision, (3) at least one of the following signs or symptoms of infection: pain or tenderness, localized swelling, redness *and* superficial incision deliberately opened by surgeon, *unless* incision is culture-negative, or (4) diagnosis of SSI by a surgeon or attending physician.

No limits were placed on publication status or language. Translators were consulted as necessary for foreign language publications. We excluded studies with any of the following: nonhuman subjects, surgeries that did not involve entry into the gastrointestinal or biliary tract, nonrandomized study design, primary outcome not in accordance with the CDC definition of SSI, or interventions other than an occlusive, impervious wound protector. Studies from which raw data was not extractable and for which the authors could not be reached were also excluded. A criterion requiring patients to be older than 18 years was initially proposed, but as the majority of studies lacked an age restriction, we did not use an age criterion for inclusion in this meta-analysis.

Data Extraction

Three authors (J.E., A.H., M.C.T.) independently extracted data from each included RCT. Discrepancies were resolved by consensus. The data extracted included year of study publication, study country, surgeries included and excluded, patient inclusion and exclusion criteria, patient demographics for treatment and control groups (eg, gender distribution, mean age, body mass index, albumin), type of wound protector, timing of wound protector application and removal, quality indicators (eg, concealment of allocation, details of randomization, blinding of patients/outcome assessors/data analysts, intention-to-treat analysis, sample size calculation), length of follow-up, outcome assessment details, identity of outcome assessor, number of patients in treatment and control group, number of events in treatment and control group, patients lost to follow-up in each group, and covariates measured, and covariates adjusted for by individual studies. The use of preoperative antibiotics and bowel preparation, administration of preoperative high-level oxygen supplementation, efforts to minimize intravenous fluids, conclusions of each study, documentation of financial disclosure, and industry sponsorship were documented.

Statistical Methods

All statistical analyses were conducted using STATA Version 11.2. Treatment outcomes were expressed as risk ratios (RR) calculated from the raw data extracted from each study. Pooled RRs and 95% confidence intervals (CI) were estimated using a random effects model employing the DerSimonian-Laird method.[23] Forest plots were generated to demonstrate the individual and pooled RR and CI, and to allow visual inspection for study heterogeneity. The χ^2 test of homogeneity (Cochran Q-statistic) and I^2 statistic were also used to quantify heterogeneity. A $P > 0.05$ for the Q-statistic or an I^2 statistic $> 70\%$ indicated significant heterogeneity. The number needed to treat was calculated from the absolute risk reduction between the treatment and control groups.

Quality Assessment

To evaluate potential bias within studies, the quality of each trial was assessed using the component approach, a method that may overcome the weaknesses of alternative quality scores.[24] The quality components relevant for this study question included the following: concealment of allocation, blinding of outcome assessors to treatment assignment, intention-to-treat analysis, and the presence of a sample size calculation. Performance on each component was recorded as a binary variable for each study, and univariate meta-regression was performed for each quality component to evaluate any significant contributions to between-study heterogeneity. For those components found to be statistically significant in the meta-regression, stratified analyses were performed to establish whether effect estimates differed significantly in component subgroups.

Exploration of Heterogeneity

Several variables were identified a priori as potential contributors to between-study heterogeneity. These included type of wound protector, publication year, standard use of preoperative antibiotics, standard employment of mechanical bowel preparation, and inclusion of emergent surgeries. The type of protector employed was hypothesized to be a major source of heterogeneity with devices employing 1 of 2 main structural designs: (1) a dual ring design made up of an internal and an external ring connected by impervious plastic (Alexis Wound Protector, Applied Medical, CA) or (2) a single ring design with the lone internal ring connected to a drape which extends outward, over the wound edges and onto the abdomen where it is affixed with adhesive or clips (Vi-Drape Wound Protector, Parke Davis & Co, Detroit, MI; Op-Drape Wound Protector, Triplus, Sweden; Steri-Drape Wound Protector, 3M, St Paul, MN). As specified in the protocol, a planned subgroup analysis was performed according to structural design and univariate meta-regression. Cumulative meta-analysis and univariate meta-regression were used to examine the effect of publication year. Antibiotic use, mechanical bowel preparation, and elective only versus inclusion of emergent surgeries were examined with univariate meta-regression. Stratified analyses were carried out for all variables found to be statistically significant in the meta-regression phase.

Publication bias was evaluated by constructing a funnel plot with visual assessment of asymmetry. The results of the funnel plot were corroborated using Begg's adjusted rank correlation and Egger's linear regression methods.[25,26]

Influence analysis was performed to examine the robustness of the pooled RR to removal of individual RCTs. Sensitivity analysis was also performed to examine whether the effect estimate was robust to inclusion of the Williams and Nystrom studies, which had been excluded from the meta-analysis because of uncertain randomization and self-reported outcome assessment, respectively.[19,21]

RESULTS

The literature search yielded 347 studies. After the title and abstract of each citation were reviewed, a total of 15 studies met our eligibility criteria and were selected for full text review (Fig. 1). Of these 15 studies, 6 were excluded (2 involved interventions not specified in the inclusion criteria and 4 were not RCTs) to give a total of 9 studies for inclusion in the meta-analysis. There were no additional studies identified by cross-referencing the bibliographies of relevant and included articles. Of these 9 studies, we excluded one because the raw data was not extractable and the authors could not be reached to provide additional information.[20] Nystrom et al (1980) was excluded because of self-reported SSI by study participants via mail-in surveys,[19] and Williams et al was excluded because of a poorly defined randomization schema.[21] This left a final total of 6 studies for inclusion in the meta-analysis.

Study Characteristics

The characteristics of included studies are presented in Table 2. All 6 were RCTs that evaluated the risk of SSI with the use of wound edge protectors compared to controls. The trials varied with respect to preoperative antibiotic administration, bowel preparation, length of follow-up, brand of wound protector, and country of origin. Three studies employed a wound protector with a dual ring design (Alexis Wound Protector, Applied Medical).[2,6,7] The remaining 3 studies employed wound protectors composed of a single internal plastic ring and an impermeable plastic drape.[13,14,18] In all studies, the primary outcome was SSI, consistent with CDC criteria.[22] The length of follow-up for development of SSI was not reported for all studies. Reported length of follow-up varied from a minimum of 7 days to a maximum of 30 days.

Quality Assessment

The presence of the following methodological features was used to assess the quality of each included study: concealment of allocation, blinding of outcome assessors, intention-to-treat analysis, and sample size calculations (Table 3). Concealment of allocation, intention-to-treat analysis, and presence of sample size calculation were not significant sources of between-study heterogeneity ($P \geq 0.10$). The only statistically significant source of between-study heterogeneity was blinding of outcome assessors ($P = 0.04$). We therefore performed a subgroup analysis that demonstrated a difference in the pooled risk of SSI according to blinding status of outcome assessors. A significant reduction in SSI was seen in the blinded group (RR = 0.41, 95% CI 0.27–0.60, $P < 0.001$), whereas no significant effect was present in the nonblinded group (RR = 1.27, 95% CI 0.69–2.34, $P = 0.5$).

Pooled Analysis

Outcome data were available for all 6 included trials, representing 1008 patients. The L'Abbe plot confirmed that the RR was an appropriate effect measure to describe our data. Figure 2 illustrates the pooled analysis. Wound protector use was associated with a significant decrease in SSI (RR = 0.55, 95% CI 0.31–0.98, $P = 0.04$).

Exploration of Heterogeneity

Evidence of heterogeneity was observed among the 6 trials ($I^2 = 61.9\%$, $\chi^2 = 13.12$, df = 5, $P = 0.02$). As we had specified wound protector type to be a potential source of between study heterogeneity a priori, we conducted a subgroup analysis based on structural design of wound protector (dual ring versus not). The studies using a dual ring wound protector yielded a significant reduction in SSI (RR = 0.31, 95% CI 0.14–0.67, $P = 0.003$, $I^2 = 24\%$),[2,6,7] whereas studies using a single ring wound protector were not associated with a significant decrease in SSI (RR = 0.83, 95% CI 0.38–1.83, $P = 0.64$, $I^2 = 72\%$)[13,14,18] (Fig. 2). The difference between dual and single ring groups was not significant in univariate meta-regression ($P = 0.16$).

L'Abbe and Galbraith plots were used to identify other possible sources of heterogeneity. The trial by Gamble and Hopton was positioned outside the upper limit of the 95% CI for the unweighted regression line in the Galbraith plot and was a notable outlier in the L'Abbe plot.[14] Influence analysis was then conducted with systematic exclusion of each of the 6 RCTs. The omission of any individual study did not significantly change the overall effect estimate.

The sensitivity of our pooled effect estimate to exclusion of 2 RCTs was examined.[18,21] The reinclusion of these studies did not qualitatively change the pooled effect estimate, maintaining a significant reduction of SSI with the use of wound protectors (RR = 0.61, 95% CI 0.39–0.94; $I^2 = 49.8\%$).

Univariate meta-regression was carried out to evaluate publication year, antibiotic use, mechanical bowel preparation, and the inclusion of emergent surgeries as potential sources of heterogeneity. Although antibiotic use, mechanical bowel preparation, and inclusion of emergent surgeries were nonsignificant sources of heterogeneity ($P \geq 0.12$), publication year was a statistically significant source of heterogeneity ($P = 0.03$). Interestingly, cumulative meta-analyses suggested an unexpected transition from nonsignificance to a protective effect of wound protectors on risk of SSI (Fig. 3).

TABLE 2. Characteristics of Included Randomized Controlled Trials

Study	Year	Country	No. Patients	Surgical Procedure	Retractor Type	Mean Age (Yrs)		Male (%)		Follow-Up Time (d)	Study Design and Details
						Wound Protector	No Wound Protector	Wound Protector	No Wound Protector		
Gamble and Hopton[14]	1984	NR	56	Lower GI (elective only)	Single ring (Vi-Drape Wound Protector)	66	65	41	45	NR	RCT Mechanical bowel preparation used
Nystrom et al[18]	1984	Sweden	140	Lower GI (elective only)	Single ring (Op-Drape Wound Protector)	59	60	NR	NR	30	RCT Mechanical bowel preparation used Intention to treat analysis conducted
Sookhai et al[13]	1999	Ireland	352	Abdominal (elective and emergent)	Single Ring (Steri-Drape Wound Protector)	NR	NR	NR	NR	30	RCT Allocation concealed Assessor blinded Intention to treat analysis conducted
Horiuchi et al[2]	2007	Japan	221	Upper and lower GI	Dual ring (Alexis)	67	66	55	57	NR	RCT Assessor blinded Intention to treat analysis conducted
Lee et al[7]	2009	USA	109	Open appendix (emergent only)	Dual ring (Alexis)	35	33	62	64	21	RCT Allocation concealed Assessor blinded
Reid et al[6]	2010	Australia	130	Lower GI (elective only)	Dual ring (Alexis)	64	63	58	62	30	RCT Allocation concealed Assessor and analyst blinded Randomization by concealed envelope

T indicates treatment; C, control; GI, gastrointestinal; and NR, not reported.

TABLE 3. Quality Measure of Included Studies in the Meta-Analysis

Study (Year)	Concealment of Allocation	Blinding of Outcome Assessors	Intention-to-Treat Analysis	Sample Size/Power Calculation
Gamble and Hopton[14] (1984)	No	No	No	No
Nystrom et al[18] (1984)	No	No	Yes	No
Sookhai et al[13] (1999)	Yes	Yes	Yes	No
Horiuchi et al[2] (2007)	No	Yes	Yes	No
Lee et al[7] (2009)	Yes	Yes	No	Yes
Reid et al[6] (2010)	Yes	Yes	No	Yes

Publication Bias

The funnel plot was relatively symmetrical suggesting that publication bias was not present. Begg's test ($z = 0.75$, $P = 0.45$) and Egger's test ($P = 0.78$) were also not suggestive of publication bias.

DISCUSSION

We conducted a meta-analysis comparing risk of SSI with and without the use of an impervious plastic wound protector during gastrointestinal and biliary tract surgery. Our study suggests that the use of wound protectors decreases the risk of SSI by 45%. Our number needed to treat suggests that only 10 patients would have to be treated intraoperatively with a wound protector to prevent 1 SSI. To put this value into context, a meta-analysis evaluating the efficacy of aspirin therapy in the primary prevention of myocardial infarction suggests that 44 patients would have to be treated for 5 years to prevent a single incident case.[27] To our knowledge, this is the first meta-analysis examining efficacy of wound protectors in SSI prevention.

A recent narrative review of nonpharmacologic methods of SSI prevention found that the overall benefit of wound protectors in preventing SSI for abdominal surgery was equivocal.[1] Variability in the literature with respect to surgical procedure, wound protector

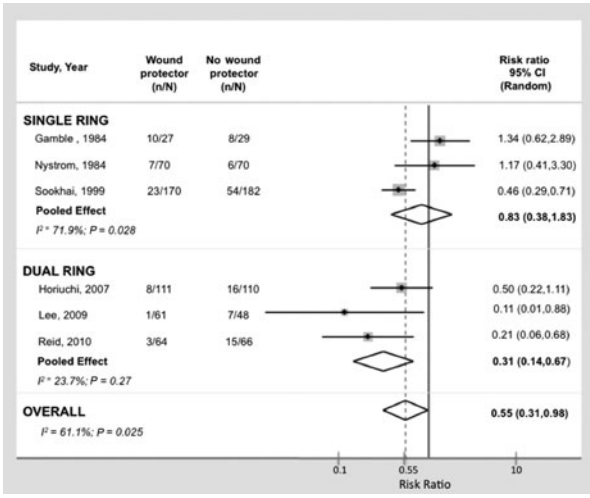

FIGURE 2. Forest plot depicting pooled random effects meta-analysis and stratified estimates according to dual versus single ring structure of wound protector.

type, stated conclusions, and the small numbers of RCTs were cited as reasons why uniform conclusions could not be drawn.[1] Thus, we investigated the effect of wound protectors on SSI by means of a systematic review and meta-analysis of RCTs, responding to these concerns with a statistical examination of the importance of various sources of heterogeneity. Our meta-analysis of rigorously chosen RCTs was sufficiently powered to detect a 10% *absolute* risk reduction in SSI. There are observational studies examining the association between wound protectors and SSI that could have been included in the analysis, but we restricted our protocol to RCTs to base our meta-estimate on the highest level of available evidence.[16,28]

Wound protector type was identified a priori as a potential source of between-study heterogeneity. When we stratify by structural design, there is a nonsignificant trend toward enhanced protection within the dual ring group, with a reduction in the risk of SSI of nearly 70% compared to controls. Although the dual ring structure hypothetically provides closer, more reliable approximation of the device to inner and outer surfaces of the abdominal wall, this observed trend may result from other between-study differences that have evolved concurrently with wound protection technology.

While single ring devices have been reported since the 1960s, dual ring wound protectors were not on the market until 2002 (Alexis Wound Protector, Applied Medical). Improvements in the quality and rigor of clinical research have, therefore, paralleled advances in device design. The trend toward enhanced protective effect in the dual ring group may be, in part, a reflection of the inextricable stratification on year of publication. This possibility is supported by one relatively recent study that employed a single-ring protector, yet demonstrated results consistent with studies employing a dual ring design (Fig. 2).[13] This study was larger (n = 352) than the other single ring wound protector studies (Nystrom: n = 140 and Gamble: n = 56) and scored better on assessment of quality components, making it more similar from those perspectives to the dual ring studies.

Two alternative explanations may explain these findings. Either the product itself differed (this study did use a different brand of single ring wound protector, the Steri-Drape, 3M), or the process by which the wound protector was implemented differentiated it from the other single ring studies. Although we classified wound protector type (dual-ring vs single-ring design) based on the logical division of gross appearance and biological plausibility, the effectiveness of a wound protector in reducing SSI is likely multifactorial and the dual-ring division may not be definitive.[29]

The importance of publication year as source of between-study heterogeneity is demonstrated in our cumulative analysis (Fig. 3). Typically, a cumulative analysis demonstrates exaggerated positive effects in small preliminary studies, with attenuation of the effect estimate and narrowing of the confidence intervals as the body of evidence grows.[30] The results of our cumulative analysis are contrary to what would be expected. One possible explanation is that factors other than use of wound protectors influence the association between intervention and outcome over time. If the wound protector actually has no effect on wound infection, the reduction in surgical site infection seen in more recent years could be attributed to factors such as improved aseptic technique and preoperative antibiotic use, which may be applied differentially in the group undergoing the "intervention."

Could the enhanced protective effect of wound protectors in later years be explained by the overall improvements in SSI prevention? A multinational review of hospital surveillance programs demonstrated a 25% to 57% overall reduction in surgical site infections over a 5- to 7-year observation period.[31] Improvements in the standards of surgical practice such as routine administration of preoperative antibiotics, maintenance of normothermia, control of hyperglycemia, and improved hospital infection control measures have been cited as important process measures, the widespread implementation of which have contributed to the significant reduction in SSI.[31,32] In this meta-analysis, pre-operative antibiotic use was not a significant modifier of effect estimate. We also attempted to analyze preoperative high-level oxygen supplementation and minimization of intravenous fluids as reflections of advancements in SSI prevention; however, this data was available in only one trial. With this said, we would not expect advancements in SSI prevention to enhance the *difference in risk* between those treated with wound protectors and controls, as these measures should not be differentially applied across treatment groups.

Other factors were considered as modifiers of the efficacy of wound protectors for reduction of SSI. Although studies including emergent surgeries did not differ significantly in their estimate of wound protector effect from those including elective operations only, there may indeed be differences not captured by the available evidence. We were able only to classify RCTs in a dichotomous fashion, based on *inclusion of any* emergent surgeries versus *exclusion of all* emergent cases. We were not able to quantify the proportion of emergent cases, nor the degree of contamination. As such, there may be residual confounding within the classification scheme to which we were constrained. Bowel preparation had no effect on the risk of SSI between treatment groups. Similarly, this finding may reflect the blunt classification allowed by our included RCTs. In addition, we planned to analyze on the basis of factors such as smoking status, nutritional status, immunosuppression, and comorbid diabetes, but these were inconsistently reported.

Quality components of each study were also formally evaluated as sources of heterogeneity. Blinding status of outcome assessors was a significant source of variation in effect estimate between studies. The blinding of outcome assessors is a powerful mechanism to circumvent investigator bias in any trial, and this finding should reinforce the importance of implementing this often inexpensive and simple step in surgical RCTs.[33]

We have identified some limitations of our study. Because of the long time period over which the included RCTs were conducted, it was impossible to separate the effect of publication year from that of improvements to the structural design of the wound protectors. Although we were able to show a significant reduction in

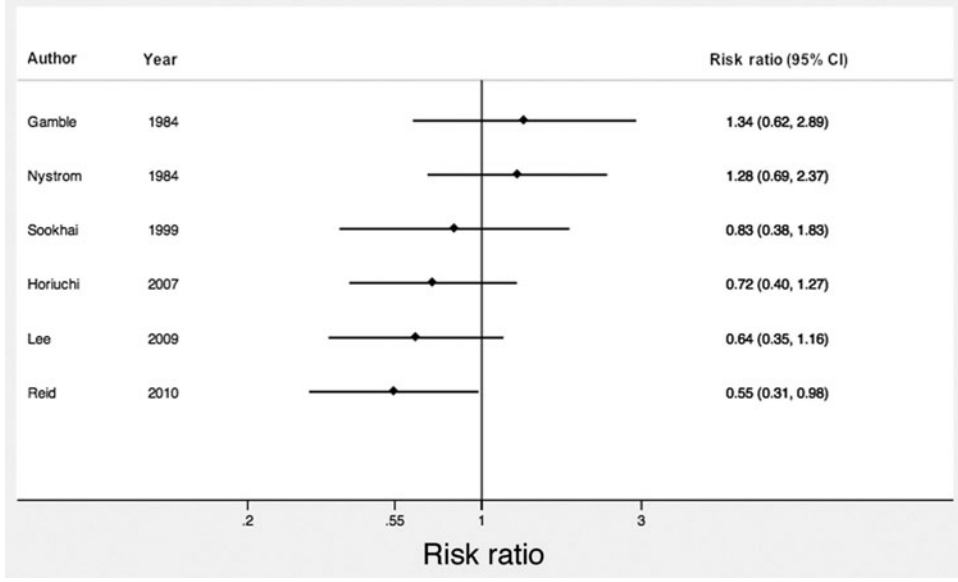

FIGURE 3. Cumulative meta-analysis detailing the evolution of the pooled effect estimate with addition of subsequent available trial data.

SSI in the pooled analysis, the stratification on structural design was nonsignificant. It is possible that the dual ring protectors provide enhanced protection over the single-ring designs and our study was underpowered for this subgroup analysis. Also, we were unable to evaluate the effects of other potential factors influencing would infection, such as smoking status, due to a lack of uniform reporting. This should not compromise the results of our study. We only included randomized trials that, when adequately powered, provide balance on measured and unmeasured confounders. Although few studies calculated sample size, the meta-regression on quality components found no difference in effect estimate based on presentation of such a calculation. Also, although each of our statistical tests can be justified, our study may be underpowered for the number of tests performed, potentially contributing to inconclusive results.

The strengths of this meta-analysis include the quality of evidence used and the rigor with which the evidence was evaluated. We selected only RCTs to maximize ability to infer causation between intervention and outcome. PRISMA guidelines were adhered to and advice was solicited from experts in both meta-analysis conduct and in subject matter.[30] Three authors independently reviewed the results of the search strategy and articles to minimize selection bias of articles (J.E., A.H., M.C.T.). In an effort to maximize reproducibility of results, the same 3 authors also independently extracted data from included studies.

The results of this meta-analysis have important implications for future surgical practice, as the application of an impervious plastic wound protector significantly reduces the risk of SSI after gastrointestinal and biliary tract surgery. The routine application of a wound protector should be considered for gastrointestinal and biliary tract surgery, especially because the intervention is relatively safe and the outcome of SSI is associated with significant postoperative morbidity and mortality.[3,5]

CONCLUSIONS

Impervious plastic wound protectors reduce the risk of SSI when employed in non–trauma-related gastrointestinal and biliary tract surgery. Wound protectors represent a safe and simple intervention that may reduce postoperative morbidity and mortality.

REFERENCES

1. Murray BW, Huerta S, Dineen S, et al. Surgical site infection in colorectal surgery: a review of the nonpharmacologic tools of prevention. *J Am Coll Surg*. 2010;211:812–822.
2. Horiuchi T, Tanishima H, Tamagawa K, et al. Randomized, controlled investigation of the anti-infective properties of the Alexis retractor/protector of incision sites. *J Trauma*. 2007;62:212–215.
3. Kirkland KB, Briggs JP, Trivette SL, et al. The impact of surgical-site infections in the 1990s: attributable mortality, excess length of hospitalization, and extra costs. *Infect Control Hosp Epidemiol*. 1999;20:725–730.
4. Dimick JB, Chen SL, Taheri PA, et al. Hospital costs associated with surgical complications: a report from the private-sector national surgical quality improvement program. *J Am Coll Surg*. 2004;199:531–537.
5. Zhan C, Miller MR. Excess length of stay, charges, and mortality attributable to medical injuries during hospitalization. *JAMA*. 2003;290:1868–1874.
6. Reid K, Pockney P, Draganic B, et al. Barrier wound protection decreases surgical site infection in open elective colorectal surgery: a randomized clinical trial. *Dis Colon Rectum*. 2010;53:1374–1380.
7. Lee P, Waxman K, Taylor B, et al. Use of wound-protection system and postoperative wound-infection rates in open appendectomy. *Arch Surg*. 2009;144:872–875.
8. Harrower HW. Isolation of incisions into body cavities. *Am J Surg*. 1968;116:824–826.
9. Nakagoe T, Sawai T, Tsuji T, et al. Minilaparotomy wound edge protector (lap-protector): a new device. *Surg Today*. 2001;31:850–852.
10. Batz W, Marcus D, Rothmund M. Value of ring drape and incision drape to prevent wound infection in colorectal surgery: a controlled randomized study. *Aktuel Chir*. 1987;22:149–152.
11. Redmond HP, Meagher PJ, Kelly CJ, et al. The use of an impervious wound edge protector to reduce postoperative wound infection rates. *IJMS*. 1994:522.
12. Sookhai S, Redmond HP, Deasy JM. Use of an impervious wound edge protector decreased postoperative wound infection. *Evidence-Based Med*. 2000;5:58.
13. Sookhai S, Redmond HP, Deasy JM. Impervious wound-edge protector to reduce postoperative wound infection: a randomised, controlled trial. *Lancet*. 1999;353:1585.

14. Gamble SS, Hopton DS. Plastic ring wound drapes in elective colorectal surgery. *J R Coll Surg Edinb*. 1984;29:232–233.
15. Katthagen BD, Zamani P, Jung W. Effect of surgical draping on bacterial contamination in the surgical field. *Z Orthop Ihre Grenzgeb*. 1992;130:230–235.
16. Kercher KW, Nguyen TH, Harold KL, et al. Plastic wound protectors do not affect wound infection rates following laparoscopic-assisted colectomy. *Surg Endosc*. 2004;18:148–151.
17. Maxwell JG, Ford CR, Peterson DE, et al. Abdominal wound infections and plastic drape protectors. *Am J Surg*. 1969;118:844–848.
18. Nystrom PO, Broome A, Hojer H, et al. A controlled trial of a plastic wound ring drape to prevent contamination and infection in colorectal surgery. *Dis Colon Rectum*. 1984;27:451–453.
19. Nystrom PO, Brote L. Effects of a plastic wound drape on contamination with enterobacteria and on infection after appendicectomy. *Acta Chir Scand*. 1980;146:65–70.
20. Psaila JV, Wheeler MH, Crosby DL. The role of plastic wound drapes in the prevention of wound infection following abdominal surgery. *Br J Surg*. 1977;64:729–732.
21. Williams JA, Oates GD, Brown PP, et al. Abdominal wound infections and plastic wound guards. *Br J Surg*. 1972;59:142–146.
22. Guideline for prevention of surgical site infection, 1999Mangram AJ, Horan TC, Pearson ML, et al.. Centers for Disease Control and Prevention (CDC) hospital infection control practices advisory committee. *Am J Infect Control*. 1999;27:97–132; quiz 133–134; discussion 96.
23. DerSimonian R, Laird N. Meta-analysis in clinical trials. *Control Clin Trials*. 1986;7:177–188.
24. Juni P, Altman DG, Egger M. Systematic reviews in health care: assessing the quality of controlled clinical trials. *BMJ*. 2001;323:42–46.
25. Begg CB, Mazumdar M. Operating characteristics of a rank correlation test for publication bias. *Biometrics*. 1994;50:1088–1101.
26. Egger M, Davey Smith G, et al. Bias in meta-analysis detected by a simple, graphical test. *BMJ*. 1997;315:629–634.
27. Sanmuganathan PS, Ghahramani P, Jackson PR, et al. Aspirin for primary prevention of coronary heart disease: safety and absolute benefit related to coronary risk derived from meta-analysis of randomised trials. *Heart*. 2001;85:265–271.
28. Horiuchi T, Tanishima H, Tamagawa K, et al. A wound protector shields incision sites from bacterial invasion. *Surg Infect (Larchmt)*. 2010;11:501–503.
29. Anthony T, Murray BW, Sum-Ping JT, et al. Evaluating an evidence-based bundle for preventing surgical site infection: a randomized trial. *Arch Surg*. 2011;146:263–269.
30. Egger M, Davey Smith G, Altman DG, eds. *Systematic Reviews in Health Care: Meta-Analysis in Context*. 2nd ed. London: BMJ Books; 2001.
31. Astagneau P, L'Heriteau F. Surveillance of surgical-site infections: impact on quality of care and reporting dilemmas. *Curr Opin Infect Dis*. 2010;23:306–310.
32. Berenguer CM, Ochsner MG, Jr, Lord SA, et al. Improving surgical site infections: using national surgical quality improvement program data to institute surgical care improvement project protocols in improving surgical outcomes. *J Am Coll Surg*. 2010;210:737–41, 741–3.
33. Hansson L, Hedner T, Dahlof B. Prospective randomized open blinded endpoint (PROBE) study: a novel design for intervention trials. prospective randomized open blinded end-point. *Blood Press*. 1992;1:113–119.