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Systematic review and meta-analysis of randomized controlled trials of the clinical effectiveness of impervious plastic wound protectors in reducing surgical site infections in patients undergoing abdominal surgery ☆

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ABSTRACT

Background: Surgical site infections are a common postoperative complication after abdominal surgery. Although impervious plastic wound protectors have been used in surgery to reduce surgical site infection rates, the effectiveness of impervious plastic wound protectors for reduction of surgical site infections remains unclear. This study aimed to determine the clinical effectiveness of impervious plastic wound protectors in reducing surgical site infection rates after abdominal surgery.

Methods: A systematic review of the PubMed, Embase, and Cochrane Library databases was performed to identify randomized clinical trials evaluating surgical site infection risk after abdominal surgeries with and without the use of impervious plastic wound protectors. The outcome of interest was a well-specified, clinically based definition of surgical site infections. No language or time restrictions were applied. The pooled risk ratio was estimated with random-effect meta-analysis. The quality assessment of the studies and the quantitative analyses were performed in line with the principles of the Cochrane Collaboration.

Results: Of the 400 studies identified, 14 randomized controlled trials representing 2,684 patients were included in this review. The pooled risk ratio under a random-effects model was 0.70 (95% confidence interval, 0.51–0.96; I^2, 56.8%), indicating a potentially significant benefit from impervious plastic wound protector use. There was a significant trend toward greater protective effect in studies using a dual ring protector (relative risk = 0.31; 95% confidence interval, 0.15–0.58), rather than a single ring protector (relative risk = 0.84; 95% confidence interval, 0.71–1.00). There was no significant between-study heterogeneity or publication bias.

Conclusion: This study suggests that impervious plastic wound protectors are efficient in reducing surgical site infection rates in patients undergoing abdominal surgery.

Introduction

Surgical site infection (SSI) is one of the most common hospital-acquired infections in the field of surgery. SSI leads to increased overall health care cost and is associated with a prolonged hospital stay, more complex wound care needs, more frequent visits to outpatient clinics, and higher rates of hospital readmission and morbidities.[1,2] Thus, SSI rates have been used to evaluate outcome measures of surgical quality worldwide.

Risk factors affecting the SSI rate can be categorized into 2 main groups: patient related and procedure related.[3] Patient-related factors include generally nonmodifiable factors such as patient age, body mass index, malnutrition, comorbidities (such as uncontrolled diabetes mellitus or anemia), and American Society of Anesthesiologists score. Meanwhile, procedure-related factors can be controlled to a degree and therefore may be modified in an effort to reduce the risk of SSI; these include the method of skin preparation, meticulous dissection and reduced operating time, use

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of minimally invasive surgery compared with conventional open surgery, and use of prophylactic antibiotics.

Physical wound protection can reduce the rate of SSI in patients undergoing abdominal surgery. Most abdominal surgeries are performed with a clean-contaminated or contaminated-incisional wound because these often require manipulation or resection of the bowel or biliary tract. In particular, emergency abdominal surgeries are more likely to consist of contaminated and dirty wounds. Therefore, in these cases, it is especially important to physically protect the incisional wound from sources of infection such as bowel content spillage to reduce the SSI rate. Impervious plastic wound protectors (IPWPs)—so-called wound edge protectors, circular wound edge protectors, plastic ring wound protectors, and so on—have been used to protect the incisional wound and reduce SSI rates for more than 40 years.[4] However, the effectiveness of IPWPs on reducing the SSI rate remains unclear. Despite the expected clinical benefit of IPWPs to reduce the rate of SSIs and the favorable results reported by several studies,[5–9] some prospective series and randomized clinical trials (RCTs) have reported disappointing results of the effect of IPWPs on reducing SSI rates in patients undergoing abdominal surgery.[10–14]

We hypothesized that IPWPs are effective in reducing SSI rate because of their physical protective effect on bacterial contamination, although there are disagreements based on the previous studies. Therefore, this meta-analysis study aimed to determine the clinical effectiveness of IPWPs in reducing SSIs in patients undergoing abdominal surgery.

Methods

Literature search

The literature was searched systematically using PubMed, Embase, and the Cochrane Library for studies from the inception of all databases to January 31, 2014. This systematic search was conducted according to the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines. The keywords were as follows: “wound protector,” “wound protective,” “wound protection,” “protective device,” “plastic drape,” “plastic wound drape,” “wound edge protector,” “wound edge protection,” “wound guard,” “wound ring drape,” “plastic ring wound drape,” “impervious wound protector,” “ring retractor,” or “Alexis” and “infection,” “wound infection,” “surgical wound infection,” “surgical site infection,” “wound complication,” or “postoperative infection.” The language or time was not restricted.

Selection criteria

We included only randomized controlled studies that met all of the following criteria: (1) a randomized control study; (2) a study comparing IPWP with nonuse of IPWP in abdominal surgery; (3) reported outcome measures with adjusted odds ratios or relative risks (RR) investigated and 95% confidence interval (CI). If we identified duplicated studies or data shared in more than a single study, the data in the first published paper were included in the analysis. Studies only presented as an abstract and not published as a complete academic paper in peer-reviewed journals were excluded.

Selection of relevant studies

Two authors (S.I.K. and H.K.O.) independently selected eligible studies from the database by reviewing those titles and abstracts. If there was disagreement between reviewers concerning the eligibility of studies, we discussed and reached a consensus.

Main and subgroup analyses

The main analysis examined the efficacy of IPWPs on reducing the rate of SSI. We investigated the associations between the use of (use versus no use) and the SSI rate. We also performed subgroup meta-analyses according to the ring type of IPWP (single ring versus dual ring).

Statistical analyses

Heterogeneity among studies including this meta-analysis was evaluated by using Higgins I^2. The I^2 results are between 0% and 100% and I^2 value >50% was considered to indicate substantial heterogeneity.[15] The presence of publication bias was evaluated by using the Cochrane risk of bias tool.[16] This tool evaluates selection bias (random sequence generation and allocation concealment), performance bias (blinding of participants and personnel), detection bias (blinding of outcome assessment), attrition bias (incomplete outcome data), reporting bias (selective reporting), and other biases between trials. Begg funnel plot and Egger test were also used to evaluate publication bias between included studies.

Random-effect models using DerSimonian and Laird methods and fixed-effect model using the Mantel-Haenszel method served as the basis for calculation of pooled RR with 95% CIs. The pooled RR with 95% CIs was reported based on the fixed-effects models if I^2 was less than 50% (without substantial heterogeneity). The summary estimates from the random-effects model were reported in cases with substantial heterogeneity. A forest plot was used to present the point estimates of effects with CIs and the pooled estimates with CIs found in individual studies. All statistical analyses were conducted using Stata 13.0 (Stata Corporation, College Station, TX) and RevMan Software Version 5.2 (Cochrane Collaboration, Copenhagen, Denmark).

Results

Trial selection

Of the 400 studies identified after searching PubMed ($n=95$), Embase ($n=252$), and the Cochrane Library ($n=53$), we excluded 69 duplicated articles and 295 articles that were not relevant to the selection criteria. The full texts of the remaining 36 articles were reviewed. Among them, 22 articles were excluded because of the following reasons: using bundle of interventions ($n=2$) or wrong interventions ($n=6$) for reducing SSI rate, non-RCTs ($n=12$), and not relevant to our question ($n=2$). Thus, 14 RCTs representing 2,684 patients were included in the final analysis.[4–14,17–19] Fig. 1 outlines the PRISMA flow chart showing the selection of articles for review.

Risk of bias assessment for included studies

Fig. 2, *A*, shows an overview of the risk of bias assessment according to the Cochrane risk of bias tool. Among the 14 trials, 2 trials had high risk of bias in the category of bias of blinding of participants and personnel and the category of the other biases. One trial was identified with high risk of bias in each of the remaining 5 evaluating categories of the Cochrane risk of bias tool. Begg funnel plots with pseudo–95% CI limits that seemed symmetric and Egger test ($P=.33$) indicated that there was no publication bias in the 14 studies (Fig. 2, *B*).

General characteristics of included trials

The included RCTs were published from 1972 to 2014 and were performed in the United States ($n=1$),[5] Malaysia ($n=1$),[6] Australia

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