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Wound-edge protection devices in gastrointestinal surgery: a meta-analysis

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ABSTRACT

Background: The role of wound-edge protection devices (WEPDs) in wound infection prevention is still controversial. The aim of this meta-analysis was to assess the protective efficiency of WEPDs in gastrointestinal surgery in a pooled analysis of randomized controlled trials.

Materials and methods: A variety of sources were searched for randomized controlled trials evaluating the protective efficiency of WEPDs in gastrointestinal surgery. Subgroup analysis and meta-regressions were conducted to investigate the possible influence of the type of WEPD on the size of intervention effect. This review was conducted in accordance with a prespecified protocol based on the guidance of the Cochrane Handbook and Preferred Reporting Items for Systematic Reviews and Meta-analyses statement.

Results: Sixteen studies with 3663 patients were included. The WEPDs usage led to a significant decrease in surgical wound infection (risk ratio [RR] = 0.64; 95% confidence interval [CI]: 0.46-0.87; $P = 0.005$; $I^2 = 63\%$), with the dual-ring design usage yielding a more significant reduction in surgical wound infection (RR = 0.24; 95% CI: 0.11-0.50; $P = 0.0002$; $I^2 = 29\%$), whereas the single-ring design usage yielding a nonsignificant result (RR = 0.78; 95% CI: 0.58-1.04; $P = 0.09$; $I^2 = 53\%$).

Conclusions: Double-ring WEPD, but not single-ring design, reduces wound infection rate significantly in gastrointestinal surgery. Therefore, the use of single-ring WEPD should be reconsidered.

Introduction

Since Joseph Lister introduced the antiseptic principles in 1865, there have been many advances in the area of infection prevention. However, as the frequency of surgical procedures has increased, surgical site infection (SSI) remains a leading cause of morbidity and mortality in modern health care settings, with an incidence of 2%-5% in USA, and 5%-6% in developing countries in patients receiving inpatient surgery.[1,2] The incidence of SSI varies depending on the type of surgical procedure, with the highest incidence in gastrointestinal procedures.[3]

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The Centers for Disease Control and Prevention definitions of SSI are as follows: any infection of the superficial, deep tissues, or organ space where surgery took place; the infection occurs 30 d after surgical operation if no implant is left in place or within 1 y if implant is in place; the infection appears to be related to the surgical operation. For abdominal surgery, two-thirds of these SSIs are confined to the superficial and deep tissues, which in practical terms is called wound infection.[4] It is believed that, unlike organ space infection which usually results from anastomosis leakage, wound infection is acquired by direct inoculation of endogenous and exogenous bacteria at the time of surgery and that the greater the number of contaminating bacteria, the greater the probability of infection after surgery.[5] Therefore, the impervious physical barriers were designed to prevent or minimize wound's exposure to bacterium. At present, two designs of wound-edge protector device (WEPD) are available commercially. The single-ring design is an impervious plastic drape circumferentially attached to a semi-rigid plastic ring which can be compressed sideways and inserted into the abdominal cavity. Being secured to surgical towels, the plastic drape can act as a barrier to bacteria and prevent desiccation of the wound edge. The other design, the Alexis WEPD, has one more ring outside the abdominal cavity and exerts more retraction strength to the wound to secure the drape and expose the surgical area. Although WEPDs have the aforementioned advantages, they are also believed to have some shortcomings: theoretically, contaminated intraperitoneal fluid may track up along the gap between the WEPD and abdominal well by capillary action and residual skin flora may proliferate beneath the drape due to a "greenhouse" effect.

Controversial results also come from clinical studies. Two meta-analyses published in the same year suggested that WEPDs reduced the rate of SSI after open abdominal surgery involving the digestive system.[6,7] Since then, great efforts have been made on this issue, with some of them showed unfavorable results.[8-10] However, some studies confused surgical wound infection with SSI and included organ space infection case as the event of interest.[11-13] Since WEPDs only cover the abdominal wound and leave the abdominal cavity to be exposed to potential bacterial contamination, it is deemed that WEPDs have no effect on organ space infection. Therefore, their results were unreliable and would mislead readers. The aim of our study was to assess the protective efficiency of WEPDs in gastrointestinal surgery on surgical wound infection in a pooled analysis of randomized controlled trials (RCTs) with effective data.

Materials and methods

This meta-analysis was conducted in accordance with a prespecified protocol based on the guidance of the Cochrane Handbook for Systematic Reviews of Intervention (version 5.1.0) and reported in line with Preferred Reporting Items for Systematic Reviews and Meta-analyses statement.

Eligibility criteria

Studies were considered eligible to be included if they met the following criteria: (1) study design: RCTs; (2) population: patients undergoing gastrointestinal surgery, both elective and emergency; (3) intervention: use of imperious surgical WEPDs in the intervention group; (4) comparison: the control group without WEPD but otherwise with the same standard protective procedures as the intervention group; (5) outcome: the incidence of surgical wound infection was set as the prespecified outcome. The definition of surgical wound infection was equal to the Centers for Disease Control and Prevention definition of superficial or deep tissue infection.

Those studies were excluded if they had any of the following: (1) non-RCT studies; (2) nonhuman subjects or surgeries not involving the digestive system; (3) interventions other than a WEPD; (4) since it is not the protective target of WEPDs, organ space infection data were extracted to be as a nonsurgical wound infection case, and if raw data were not extractable, the study would be excluded.

Laparoscopic or laparoscopic-assisted surgeries were not excluded from this meta-analysis. However, sensitivity analysis was conducted after excluding such surgical operations.

No language restrictions were applied. Any potentially relevant non-English publications were translated into English by consulting translators.

Search strategy

PubMed, EMBASE, and The Cochrane Central Register of Controlled Trials were searched in March 2015. No time restriction was applied. Highly sensitive search strategies were applied with both free-text words and MeSH terms for Medline, and Emtree terms for EMABSE, respectively, and all these words and terms were used to search within titles, abstracts, and keywords in The Cochrane Central Register of Controlled Trial. No publication type limit was applied.

For potentially relevant studies, in addition to the bibliographic databases, the references of the selected articles were hand-searched, and Google Scholar was searched for the articles citing them. A systematic search of Google Scholar was also conducted for gray literature. The search strategy used for PubMed is presented in Online Supplementary Table 1.

Study selection

Three independent reviewers examined the title and abstract of each report for potentially relevant articles of which full texts were retrieved and assessed according to the prespecified eligibility criteria. Multiple reports were excluded by checking the author names, location and setting, numbers of participants, or duration of the studies. Disagreements were resolved by discussion or arbitration by one expert. The reviewers were not blind to information about the reports in this procedure.

Assessment of risk of bias

The Cochrane collaboration's tool was used to assess the risk of bias of each included study. Since blinding was impossible for the surgeons who were involved in surgical operation and blinding of patients may not impact physiological outcomes, the blinding status of included studies only referred to the outcome assessors. Two reviewers assessed the risk of bias for