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# Adhesive incisional drapes during cesarean delivery for preventing wound infection: A systematic review and meta-analysis of randomized controlled trials

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ABSTRACT

*Objective:* To compare the incidence of wound infection after cesarean delivery in procedures conducted using adhesive incisional drapes verses no adhesive incisional drapes.
*Study Design:* Searches were performed in electronic databases (MEDLINE, ClinicalTrials.gov, the Cochrane Central Register of Controlled Trials, Scopus, OVID, EMBASE, and the PROSPERO International Prospective Register of Systematic Reviews). We included randomized controlled trials comparing adhesive incisional drapes to no adhesive incisional drapes during cesarean delivery. The primary outcome of this meta-analysis was wound infection. Meta-analysis was performed using the random effects model of DerSimonian and Laird, to produce relative risk (RR) with 95% confidence interval (CI).
*Results:* 52 publications were identified through initial search of databases and two randomized controlled trials were eligible and included in the meta-analysis. Our meta-analysis examined a total of 1943 subjects and showed a statistically significant increase in wound infections in patients in the adhesive incisional drape group when compared to the control group (RR: 1.29, 95% CI: 1.02–1.65).
*Conclusion:* Adhesive incisional drapes may increase the incidence of wound infections after cesarean delivery. Further studies are necessary to explore this relationship in the setting of current postoperative infection prophylaxis, including broad-spectrum antibiotic coverage, skin preparation and vaginal cleansing.


## Introduction

The incidence of Cesarean delivery (CD) has increased drastically in the past few decades making up nearly one third of all births and affecting an estimated 22.9 million women globally [1]. Wound infections are one of the most common causes of maternal morbidity after CDs with an incidence of 3–5% and are associated with a maternal mortality rate of up to 3% in some regions [2]. Given the high incidence of CDs, post-cesarean wound infections place large physical and financial costs to the patient and health care system [3].

Numerous trials have investigated the impact of various CD techniques in the prevention of wound infections [4]. For example, studies have examined the effect of antiseptic skin preparation [5,6], perineal hair removal [7], antibiotic prophylaxis [8,9], vaginal irrigation [10], and different skin closure techniques [11]. Studies have also investigated the use of various surgical apparatuses to reduce wound infection rates including O-ring retractors [12], the Lap-Protector [13], and adhesive incisional drapes [14,15]. Adhesive incisional drapes are used in numerous types of surgery including general or abdominal, orthopedic, and cardiac to limit wound infection. However, studies investigating the utility of adhesive incisional drapes in preventing infection are conflicting. A Cochrane review examining the use of preoperative skin preparation for CD found that there was no significant difference in wound infection rates when comparing adhesive incisional drapes to no adhesive incisional drapes (RR 1.29; 95% CI 0.97–1.71) [6]. However, another Cochrane review examining the

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use of adhesive incisional drapes in various types of surgeries found that there was no evidence that they reduced wound infections and that there is some evidence that they may instead increase rates of infection (RR 1.23; 95% CI 1.02–1.48, P = 0.03) [16]. Despite the potential increased risk of wound infections associated with adhesive incisional drapes, some providers prefer using these drapes for other theoretical clinical benefits. For example, adhesive incisional drapes may theoretically increase the accuracy of blood loss measurements during the procedure and these drapes may also reduce the risk of amniotic emboli by minimizing the contamination of amniotic fluid to the blood stream within the abdomen. Given these preferences as well as the conflicting existing data, we sought to compare the incidence of wound infection after CD in procedures conducted using adhesive incisional drapes verses no adhesive incisional drapes.

## Materials and methods

The meta-analysis was conducted following the PRISMA statement and checklist [17]. Searches were performed in electronic databases (MEDLINE, ClinicalTrials.gov, the Cochrane Central Register of Controlled Trials, Scopus, OVID, EMBASE, and the PROSPERO International Prospective Register of Systematic Reviews) from inception of databases until April 2018 using the MeSH terms and text words: “cesarean section”, “cesarean”, “drape”, “drapes”, “adhesive”, “adhesives”, “tissue adhesives”, “plastics”. The “AND” or “OR” operator was used to combine terms in different combinations (See Supporting Appendix A for search strategy). No restrictions for language or geographic location were applied. This search was performed by two health sciences reference librarians and two investigators independently. Before data extraction, the protocol was registered with PROSPERO International Prospective Register of Systematic Reviews (Registration number: CRD4201809489)

We included all randomized controlled trials (RCTs) that compared adhesive incisional drapes to no adhesive incisional drapes during cesarean delivery. Trials were excluded if they examined the use of adhesive incisional drapes in non-cesarean surgeries. We excluded articles that were observational studies, reviews, retrospective studies, or pseudo-RCTs. Trials were not excluded based on maternal age, gestational age, or fetal anomalies.

The intervention of adhesive incisional drapes was defined as surgical drapes with adhesive material applied over the skin of the surgical site so that the drape must be incised in order to incise the skin (Fig. 1). The control group was no adhesive incisional drapes (Fig. 1). The primary outcome was wound infection, as defined by each trial. Secondary outcomes included wound hematoma, wound seroma, wound separation, readmission for wound concerns, cellulitis, endometritis, and duration hospital stay in days.

The risk of bias was identified as either low, high, or unclear following the 7 categories outlined in the Cochrane Handbook for Systematic Review of Interventions: (1) Random sequence generation (selection bias) (2), Allocation concealment (selection bias) (3), Blinding of participants and personnel (performance bias) (4), Blinding of outcome assessment (detection bias) (5), Incomplete outcome data (attrition bias) (6), Selective reporting (reporting bias) and (7) Other Bias (any bias that did not fit into categories 1–6) [18]. The overall risk of bias was then graded by the level of evidence, using the Grading of Recommendations, Assessment, Development and Evaluation (GRADE) Working Group approach [19]. All authors were contacted for missing data.

Data abstraction was completed by two independent investigators (JQN, RE). Each investigator independently abstracted data from each study and analyzed data separately. The data analysis was completed independently by authors (GS, JQN, RE) using Review Manager 5.3 (The Nordic Cochrane Centre, Cochrane Collaboration, 2014, Copenhagen, Denmark). The completed analyses were then compared, and any differences were resolved with review of the entire data and independent analysis.

Data from each eligible study were extracted without modification of original data. A 2 by 2 table was assessed for the relative risk (RR); for continuous outcomes means ± standard deviations were extracted and imported into Review Manager v. 5.3 (The Nordic Cochrane Centre, Cochrane Collaboration, 2014, Copenhagen, Denmark).

Meta-analysis was performed using the random effects model of DerSimonian and Laird, to produce summary treatment effects in terms of RR or mean difference (MD) with 95% confidence interval (CI). The decision to use the random effects model versus the fixed effects model was determined a priori based on clinical heterogeneity. Subsequently, statistical heterogeneity was measured using I-squared (Higgins $I^2$). Potential publication biases were assessed statistically by using Begg’s and Egger’s tests if greater than 10 publications were analyzed. A p value <0.05 was considered statistically significant.

## Results

Fig. 2 shows the study selection flowchart. 52 publications were identified through initial search of databases. After removal of duplications, 35 records were checked against the pre-specified inclusion criteria focusing on title and abstract. Ultimately two RCTs were included in this meta-analysis consisting of 1943 subjects collectively (Table 1). Cordtz et al. [14] examined two

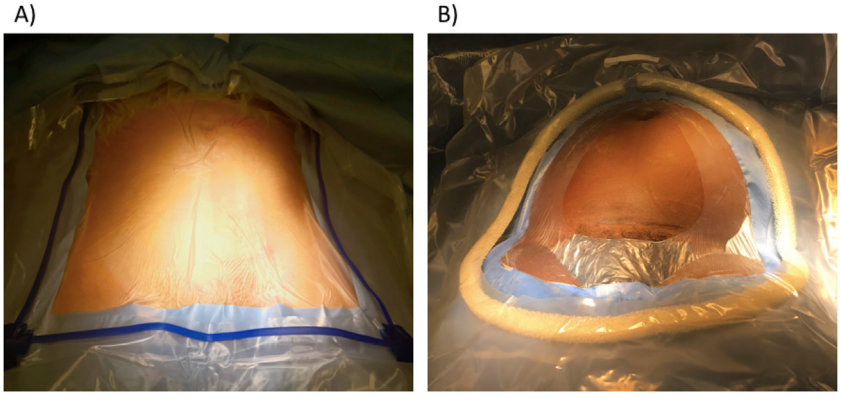


**Fig. 1.** Examples of drapes similar to those studied in this meta-analysis (A) adhesive incisional drapes (B) no adhesive incisional drapes.

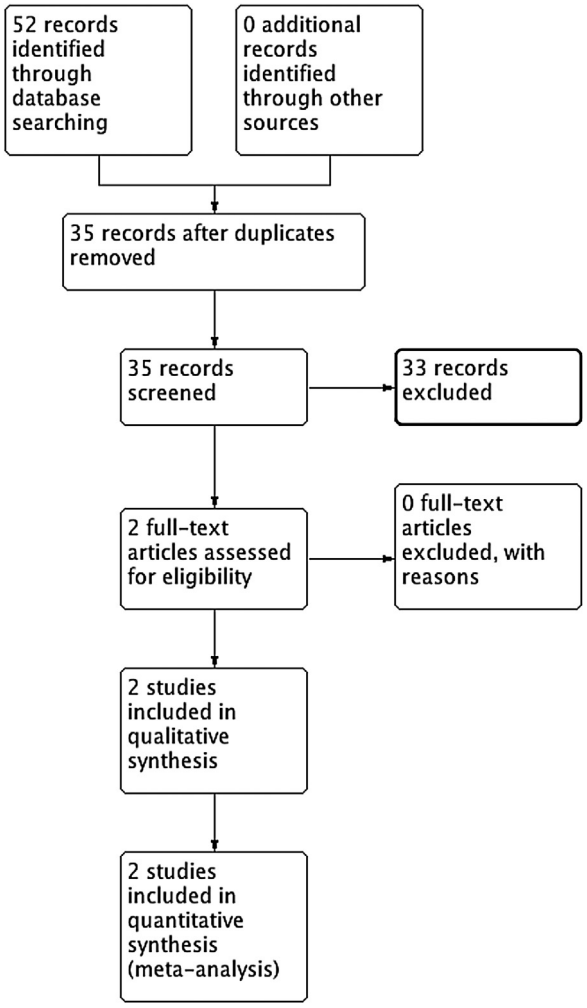


**Fig. 2.** PRISMA flowchart for study selection.

interventions, adhesive incisional drapes and skin re-disinfection, where skin was disinfected with 2.5% iodine in 70% ethanol shortly before skin closure [14]. Accordingly, the 1340 subjects in this trial were randomized into four arms (1) adhesive incisional drapes and skin re-disinfection (2) adhesive incisional drapes and no skin re-disinfection (3) no adhesive incisional drapes and skin re-disinfection (4) no adhesive incisional drapes and no skin re-disinfection (Table 1). Ward et al. [15] investigated the single intervention of adhesive incisional drapes and randomized 603 subjects into two arms (1) adhesive incisional drapes and (2) no adhesive incisional drapes (Table 1).

Fig. 3 summarizes our risk of bias according to the Cochrane Collaboration's tools [18]. Both studies have a high risk of performance bias as masking of surgeons to the intervention was not possible. The two studies also have a high risk of attrition bias as patients were not followed beyond 14 days in the Cordtz et al. study [14] and 5 days in the Ward et al. study [15] and there was no mention of intention-to-treat in either study. There was an unclear risk of selection bias, detection bias, and other bias in the Cordtz et al. [14] study as allocation concealment, outcome assessment, and baseline characteristics were not reported in the trial. All other forms of bias were determined to be low risk. Using the GRADE Working Group approach, the overall risk of bias for each study was graded as 1B, a strong recommendation with a moderate quality of evidence. This level of grade was selected as both studies were RCTs with important limitations (inconsistent results, methodologic flaws, indirect or imprecise). Therefore, further research (if performed) is likely to have an impact on our confidence in the estimate of benefit and risk and may change the estimate [19].

Numerous patient characteristics were not reported in one or both studies including maternal age, gestational age, gravity, parity, indication for CD, and number of scheduled, primary and emergency CD at randomization (Table 2). Many intraoperative risk factors for wound infection were also not described, such as BMI, diabetes, type of skin incision, closure of subcutaneous fat if $\geq$2 cm, method of skin closure, duration of membrane rupture, and duration of CD (Table 3). The primary outcome of wound infection was reported by each RCTs, but no other wound complications (hematoma, seroma, or readmission for wound concern) were reported as secondary outcomes (Table 3).

Neither of the two RCTs reported any benefit of using adhesive incisional drapes during CD in preventing infection. Cordtz et al. [14] showed a significant increase in wound infections in the adhesive incisional drape group compared to controls (RR 1.37; 95% CI: 1.03–1.82), while Ward et al. [15] showed that there was no significant difference in infections between groups (RR 1.11; 95%

**Table 1**
Characteristics of the included trials.

| | Cordtz 1989 | Ward 2001 |
|---|---|---|
| **Study location** | Copenhagen S, Denmark | Tygerberg, South Africa |
| **Number of Patients** | 1340 (662[a]/678[b]) | 603 (305/298) |
| **Inclusion criteria** | Cesarean delivery | Cesarean delivery |
| **Exclusion criteria** | NR | Clinically suspected ruptured uterus |
| **Primary outcomes** | Wound infection | Wound infection |
| **Definition of primary outcome** | Total infection rate: total of "*possible infected*" and "*infected*". "*Possible infected:* localized erythema and/or serous secretion without presence of pus. *Infected*: presence of pus irrespective of the results of bacteriological examination. Pus could be classified as superficially or subfascially located. Incision for drainage was also recorded." | "Infection was diagnosed if two of three features were present: 1. Erythematous cellulitis (erythematous induration either side of the incision line). 2. Seropurulent discharge from the wound. 3. Positive swab culture (organisms and leucocytes)." |
| **Intervention(s) studied** | Adhesive incisional drapes[c] | Adhesive incisional drapes |
| **Control(s)** | No adhesive incisional drapes[c] | No adhesive incisional drapes |
| **Follow up time period:** | 14 days postoperatively | 5 days postoperatively |

Abbreviations: NR, not recorded.
[a] The 662 subjects in adhesive incisional drape consisted of 325 with skin re-disinfection and 337 with no skin re-disinfection.
[b] The 678 subjects in the control consisted of 324 with skin re-disinfection and 354 with no skin re-disinfection.
[c] Two interventions: adhesive incisional drapes and skin re-disinfection. Two controls: no adhesive incisional drapes and no skin re-disinfection. The two interventions and two controls combined to create four arms: (1) adhesive incisional drapes and skin re-disinfection (2) adhesive incisional drapes and no skin re-disinfection (3) no adhesive incisional drapes and skin re-disinfection (4) no adhesive incisional drapes and no skin re-disinfection.

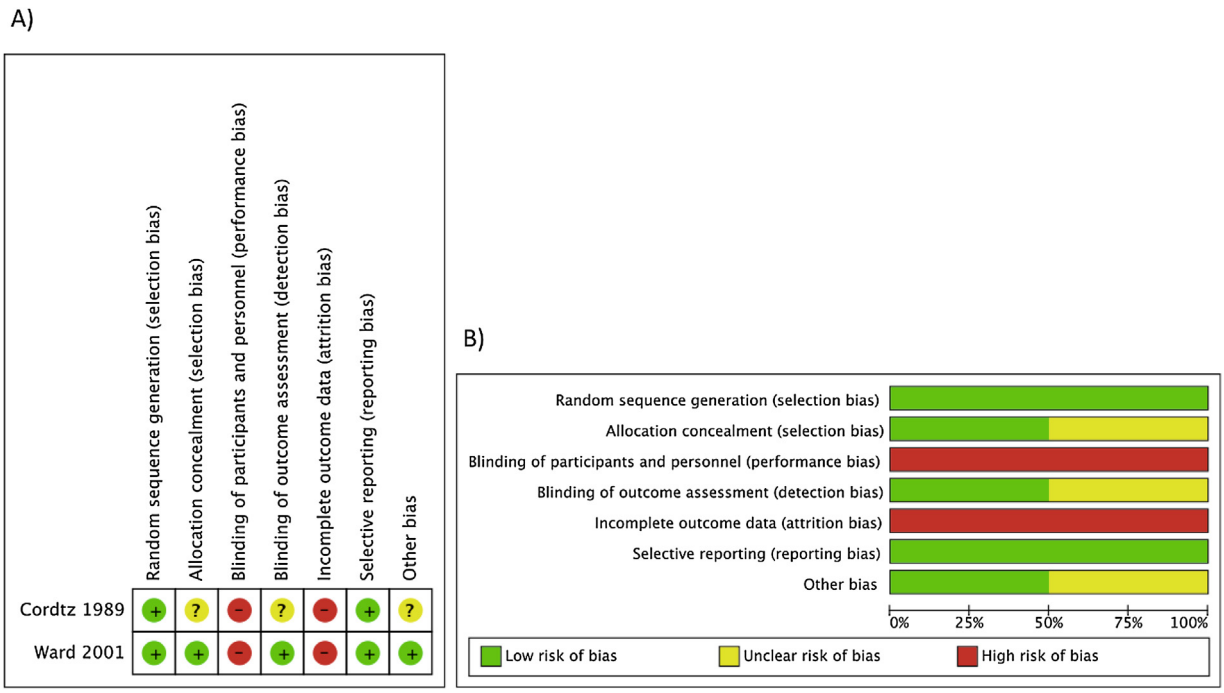


**Fig. 3.** Assessment of risk of bias. (A) Summary of risk bias for each trial; plus sign, low risk of bias; minus sign, high risk of bias; question mark; unclear risk of bias. (B) Risk of bias as a graph about each risk of bias item presented as percentages across all included studies.

**Table 2**
Characteristics of subjects at delivery.

| | Cordtz 1989 | | Ward 2001 | |
|---|---|---|---|---|
| | Adhesive Incisional Drapes | No adhesive Incisional Drapes | Adhesive Incisional Drapes | No adhesive Incisional Drapes |
| **Maternal age, y +/− sd** | NR | NR | 26.7+/−6.55 | 25.39+/−3.77 |
| **Gravity, n (range)** | NR | NR | 2 (1–9) | 2 (1–9) |
| **Parity, n (range)** | NR | NR | 1 (0–7) | 0.5 (0–8) |
| **Scheduled CD, %** | NR | NR | 89.2 | 88.6 |
| **Primary CD, n (%)** | NR | NR | 172/305 (56.39) | 200/298 (67.11) |
| **CD indication** | NR | NR | NR | NR |
| **Antepartum hemorrhage, %** | NR | NR | 2.3 | 4.2 |
| **Breech presentation, %** | NR | NR | 8.5 | 8.4 |
| **Cephalopelvic disproportion, %** | NR | NR | 27.5 | 27.2 |
| **Fetal distress, %** | NR | NR | 24.5 | 27.5 |
| **Malpresentation, %** | NR | NR | 2.6 | 1.7 |
| **Placenta previa, %** | NR | NR | 1.1 | 1.7 |
| **Prolapsed cord, %** | NR | NR | 0.7 | 0.7 |
| **≥2 previous CD, %** | NR | NR | 9.8 | 10.4 |
| **Slow progress, %** | NR | NR | 10.5 | 7.4 |
| **Other, %** | NR | NR | 12.1 | 11.1 |
| **Prophylactic antibiotics, n (%)** | 56/662 (8.46) | 54/678 (7.96) | 305/305 (100.0) | 298/298 (100.0) |

Abbreviations: CD, cesarean delivery; n, number; NR, not recorded; sd, standard deviation; y, year.

CI: 0.70–1.76) (Fig. 4). Our meta-analysis examined a total of 1943 subjects and demonstrated a significantly higher proportion of patients in the adhesive incisional drape group developed wound infection when compared to the control group (RR 1.29; 95% CI 1.02–1.65) (Table 3, Fig. 4).

## Comment

This study showed that the use of adhesive incisional drapes compared the use of no adhesive incisional drapes during CD may increase the incidence of wound infections. A recent Cochrane review evaluated the impact of adhesive incisional drapes on wound infections [16]. This meta-analysis included RCTs examining the use of adhesive incisional drapes in various types of surgeries, including general or abdominal surgeries [20–22], hip surgeries [23], and cardiac surgeries [24] in addition to CDs [14,15]. The review included seven RCTs [16], two of these RCTs used iodine-impregnated adhesive drapes [20,24] and five of these RCTs used adhesive incisional drapes that were not iodine-impregnated [14,15,21–23]. This meta-analysis showed no significant difference in the incidence of wound infection with the use of iodine-impregnated adhesive incisional drapes (RR 1.03; CI 0.66–1.6) and increased incidence of wound infection with the use of adhesive incisional drapes that were not iodine-impregnated (RR 1.23; CI 1.02–1.48) [16]. Our findings are consistent with the results of this review, as the two RCTs included in our meta-analysis used adhesive incisional drapes that were not iodine-impregnated and also found increased wound infection rates. Furthermore, the

**Table 3**
Intraoperative risk factors for wound infection and primary outcome for adhesive incisional drape and control.

| | Cordtz 1989 | | Ward 2001 | | RR (95% CI) |
|---|---|---|---|---|---|
| | Adhesive Incisional Drapes | No adhesive Incisional Drapes | Adhesive Incisional Drapes | No adhesive Incisional Drapes | |
| **Type of skin incision** | | | | | |
| **Pfannenstiel, %** | NR | NR | 35.1 | 37.6 | |
| **Midline vertical, %** | NR | NR | 63.9 | 62.4 | |
| **Closure of skin** | | | | | |
| **Sutures, %** | NR | NR | 5.9 | 4.4 | |
| **Staples, %** | NR | NR | 38.0 | 39.9 | |
| **Both, %** | NR | NR | 56.1 | 55.7 | |
| **In labor or ROM > 2 hrs, %** | NR | NR | 66.5 | 61.3 | |
| **Duration of ROM, hrs +/− sd** | NR | NR | 9.21 +/− 18.12 | 11.51 +/− 17.6 | |
| **Chorioamnionitis, %** | NR | NR | 1.3 | 2.4 | |
| **Scalp electrode used, %** | NR | NR | 9.2 | 8.1 | |
| **Duration of CD, mins +/− sd** | NR | NR | 37.03 +/− 11.16 | 35.87 +/− 11.73 | |
| **Re-disinfection of skin before closure, n (%)** | NR | NR | 305/305 (100) | 298/298 (100) | |
| **Primary outcome** | | | | | |
| **Wound Infection, n (%)** | 99/662 (15.0) | 74/678 (10.9) | 34/305 (11.1) | 30/ 298 (10.1) | 1.29, (1.02-1.65) |

Abbreviations: CD, cesarean delivery; CI, confidence interval; hrs, hours; mins, minutes; n, number; NR, not recorded; ROM, rupture of membranes; RR, relative risk; sd, standard deviation.

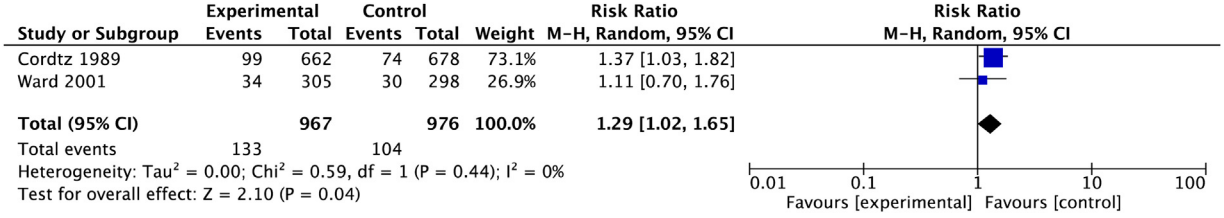


**Fig. 4.** Forest plot for the meta-analysis of the incidence of wound infection in patients using adhesive incisional drapes during cesarean delivery.

Cochrane review conclusions are in agreement with our study in finding that there was some evidence that adhesive incisional drapes may increase wound infection rates [16].

Another Cochrane review, which included the same studies [6,14,15], evaluated the effect of preoperative skin preparation during cesarean deliveries on wound infection rates, and adhesive incisional drapes were examined as an alternative form of skin preparation [6]. The two reviews found the same relative risk, yet confidence intervals differed between our meta-analysis and the Cochrane review (RR 1.29; CI 1.02–1.65 while the Cochrane reported RR 1.29; CI 0.97–1.71). This difference highlights the difference between fixed effects and random effects. We chose the random effects model as we determined the two RCTs are clinically heterogeneous based on differences in patient population characteristics and treatment effects. The studies represented populations of different countries (Denmark versus South Africa), the usage of prophylactic antibiotic greatly differed in each study (8.21% versus 100%), and the primary outcome of wound infection was measured for different durations (14 days versus 5 days) (Tables 1 and 2). In contrast, the Cochrane review used the fixed effects model assuming that the two RCTs estimated the same underlying population characteristics and treatment effects based on finding no substantial statistical heterogeneity ($Tau^2 > 0$, $I^2$ >30%, $P < 0.10$ in $Chi^2$ test for heterogeneity). However, the Cochrane review indicated that future updates should use the random effects model if clinical or substantial statistical heterogeneity is detected. Statistically heterogeneity testing was also found to be non-significant in our study, yet statistical heterogeneity does not preclude clinical heterogeneity and the decision to proceed with the random effects model was made a priori as indicated in our methods [25].

A strength of our study is that we adhered to the Cochrane Handbook for Systematic Review of Interventions PRISMA checklist [17] and preregistered our protocol in PROSPERO International Prospective Register of Systematic Reviews. Also, we contacted and received responses from authors of both RCTs and we were able to collect additional unpublished data from the Ward et al. study [15].

Our study is limited by the minimal available research on this subject and the age of the included studies, which were published in 1989 and 2001. Because of the time lapse that has occurred since publication, some of the CD techniques for prevention of postoperative wound infection have changed and these studies may not be representative of current risks. Another limitation of our study is that we were not able to synthesize other planned secondary outcomes as no common secondary outcomes were examined by the two studies. We were also unable to include and control for baseline characteristic and risk factors as this data was not published by both studies. Lastly, the intervention, control, and primary outcome of wound infection varied between the two trials.

Although each study's definition of the adhesive incisional drapes seems to align with our definition as described in the methods, there are a variety of adhesive incisional drape subtypes. For example, different brands of adhesive incisional drapes have different strength of adhesive properties and some drapes are impregnated with antibiotics or antimicrobial agents. It is unlikely that the two used the same type of drapes, as Ward et al. [15]

describes the adhesive incisional drapes used as “new generation” and this study was published over a decade after the Cordtz et al. trial [14]. Additionally, neither trial clearly defines the control group.

Each trial defined wound infection differently, with one study that followed patients for 5 days post-CD [15] and the other study that followed patients for 14 days post-CD [14] (Table 1). This short follow-up period for detecting wound infection is inconsistent with the CDC's definition of surgical site infection whereby infections can occur within 30 days postoperatively [26]. Although wound infections can be diagnosed within 30 days of CD, the majority of post-operative wound infections become clinically apparent between 4–7 days after CD [27]. However, one study found that the median time of wound infection diagnosis was 9.5 days (IQR: 6.5–11.5) when conducting complete 30-day post-CD surveillance [28]. Consequently, there is concern that our included trials may have underreported wound infection rates and wound infections occurring after the follow-up period may have differentially effected the intervention and control groups.

In summary, the results of our meta-analysis suggest that adhesive incisional drapes may increase the incidence of wound infections after CD. Further studies are necessary to explore the relationship of adhesive incisional drapes during CD in the setting of current postoperative infection prophylaxis, including broad-spectrum coverage, vaginal cleansing and skin preparation.

## Declaration of Competing Interest

All authors declare no conflicts of interest. The authors alone are responsible for the content and writing of this article.

## Acknowledgment

The authors have no grants or funding to report.

## Appendix A.

Pubmed MEDLINE Database Search Strategy: (("Cesarean Section"[Mesh] OR Cesarean)) AND ((((drape) OR drapes)) AND ((((("Tissue Adhesives" [Pharmacological Action] OR "Tissue Adhesives"[Mesh])) OR (adhesives OR adhesive)) OR "Plastics"[Mesh])).

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