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Advanced dressings for the prevention of surgical site infection in women post-caesarean section: a systematic review and meta-analysis

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Abstract

Objective(s): Surgical site infections (SSIs) are a common complication post-caesarean section. Advanced dressings aim to provide an optimal wound environment, primarily by physically or chemically controlling moisture, in order to promote timely healing. A systematic review and meta-analysis was conducted to evaluate the effectiveness of advanced dressings in SSI prevention post-caesarean section. Secondary effectiveness outcomes included superficial SSI, endometritis, wound dehiscence, rehospitalisation and length of rehospitalisation.

Study Design: We conducted a systematic review and meta-analysis according to PRISMA guidelines. A protocol was registered *a priori*. MEDLINE, EMBASE, CENTRAL and CINAHL databases were searched from inception to May 2021, without date or language restrictions. Keywords included: *caesarean section; bandages; dressing* and *surgical wound infection*. Randomised controlled trials (RCTs) were included if they investigated any advanced dressing in women post-caesarean section compared to simple dressings and assessed SSI incidence. Relative risks (RR), with 95% confidence intervals (CIs) and p-values, were calculated using Review Manager software (RevMan version 5.0, The Cochrane Collaboration). I^2 percentages were reported to assess heterogeneity and a funnel plot was produced to assess publication bias. Quality assessment was performed using the Cochrane Risk of Bias Assessment Tool. All data were double-extracted and discrepancies were finalised by a third reviewer.

Results: From 253 citations identified, six RCTs were included in the systematic review and meta-analysis. Two studies investigated dialkylcarbamoyl chloride (DACC)-impregnated dressings; two investigated silver-impregnated dressings; one investigated copper-impregnated dressings and one investigated chlorhexidine gluconate dressings. The overall meta-analysis showed that advanced dressings did not reduce SSI risk (RR 0.81 [95% CI 0.52-1.24; p=0.32]). However, subgroup analysis revealed that DACC-impregnated dressings reduced SSI risk (RR 0.33 [95% CI 0.14-0.77; p=0.01]). Silver-impregnated dressings caused a nonsignificant increase in SSI risk (RR 1.20 [95% CI 0.77-1.88; p=0.41]). All studies showed a high risk of bias.

Conclusion: This systematic review and meta-analysis suggests DACC dressings potentially reduce SSI. However we have shown no benefit of silver dressings. Further high-quality RCTs are required to recommend a change in clinical practice.

Keywords: Dialkylcarbamoyl chloride / Advanced dressing / Wound infection / Endometritis / Surgical site infection / Caesarean section

Introduction

Caesarean section (CS) is currently the most common major surgical procedure worldwide, with over 18.5 million operations per annum. [1] Global rates have increased rapidly over recent years. [2] The UK CS rate has mirrored this global surge, increasing rapidly from 19.7% in 2000 to 29% in 2021. [3,4,5] A number of maternal and neonatal complications are associated with CS, particularly surgical site infection (SSI). [6]

Defined by the Centers for Disease Control and Prevention (CDC), SSI is a wound infection occurring at the surgical incision site, within 30 days of the procedure. [6] SSI is a relatively common occurrence following CS, with an incidence of 9-11% in the UK alone. [7] The CDC classifies SSI according to the extent of tissue involvement: superficial SSIs are the most prevalent, involving only the skin and subcutaneous tissue; deep SSIs involve the deeper soft tissues such as fascia and muscle, and organ/space SSIs are characterised by infections of anatomical regions relevant to the specific operation. [6] With respect to CS, endometritis presents as the main organ/space SSI, presenting as pyrexia, fundal tenderness and purulent discharge from the uterus. [8,9]

SSI causes a significant increase in risk of maternal sepsis, wound dehiscence and maternal mortality. [10,11] Further consequences on maternal and fetal wellbeing are apparent, with an extended length of hospitalisation causing breastfeeding difficulties and hindering maternal-fetal bonding. [12] The economic burden of SSI also proves significant: for each patient, an average of 10 additional days were spent in hospital, costing the NHS approximately £5 million per annum. [13,14]

Several interventions, such as pre-incisional antibiotic prophylaxis and vaginal cleansing, have been trialled and implemented to reduce the risk of SSI post-CS. [15] With existing high SSI rates, further interventions must be established to improve maternal physical and mental wellbeing and lessen the economic burden on healthcare systems.

Advanced dressings are a relatively novel addition. The aim of this preventative measure is to control moisture levels, ensuring an optimal wound environment to promote timely wound healing. [16] Compared to simple dressings, such as basic wound contact or gauze dressings, advanced dressings have proven more effective for SSI prevention in diabetic foot ulcers, venous leg ulcers and burn wounds. [17-22]

We aim to assess the effectiveness of advanced dressings for SSI prevention in women post-CS, by conducting a systematic review and meta-analysis of all randomised controlled trials (RCTs).

2 Materials and methods

2.1 Registration

Prior to an electronic literature search and data extraction, a protocol for this systematic review was registered on PROSPERO (CRD42020220522). This review was performed according to PRISMA guidelines and recommendations by the Cochrane Handbook for Systematic Reviews of Interventions. [23]

2.2 Search strategy

The following electronic databases were searched from database inception to 24th May 2021: MEDLINE, EMBASE, CENTRAL and CINAHL. Reference lists of included studies and similar systematic reviews were also manually searched, as well as posters and conference abstracts. No date or language restrictions were applied. Study design was restricted to RCT only.

Search terms were formulated using our Population/Intervention/Comparator/Outcome (PICO) criteria. Within MEDLINE, a combination of MeSH terms and free-text terms were used, ensuring the incorporation of all spelling variations (**Table 1**). As controlled vocabulary search terms differed between each database, variations in search terms were used.

Table 1 - MEDLINE database search strategy

2.3 Primary and secondary outcomes

The primary outcome was SSI, defined using the CDC criteria as superficial, deep and/or organ/space SSI. [6] Secondary outcomes included: superficial SSI, endometritis, wound dehiscence, rehospitalisation, length of rehospitalisation, sepsis, maternal mortality and surgical scar pain.

2.4 Eligibility criteria

The inclusion criteria were based on our PICO: women undergoing CS (elective or emergency); advanced dressing (hydrogel, hydrocolloid, alginate, film, soft polymer, capillary-acting, odour absorbent or antimicrobial dressing); simple dressing (basic wound contact or gauze dressing); SSI (superficial, deep or organ/space). Only RCTs were included.

2.5 Study selection

Two reviewers (SW and RH) independently conducted title and abstract screening of the studies retrieved from our literature search. Full-text articles of studies deemed eligible were sought and independently screened. Studies confirmed to meet the eligibility criteria were consequently included in our systematic review. Any disagreements between the two reviewers were resolved by a third reviewer (VHM).

2.6 Data extraction

Two reviewers (SW and RH) independently extracted data from the included studies using an electronic data extraction form. This form detailed: (1) confirmation of the eligibility criteria being met; (2) time frame and population characteristics; (3) type of advanced dressing; (4) outcomes assessed; (5) raw data and statistical analyses. Any disagreements were resolved by a third reviewer (VHM).

2.7 Data analysis

Data was analysed using Review Manager software (RevMan version 5.0, The Cochrane Collaboration). For each outcome, 2x2 tables were constructed from the raw data. The relative risk (RR) with 95% confidence intervals (CIs) were calculated for dichotomous outcomes. Where meta-analyses could not be conducted, raw data was described.

Forest plots were produced, with I^2 values generated to assess statistical heterogeneity and p-values for statistical significance. Where heterogeneity was apparent, a random-effects model was used. A fixed-effects model was selected in instances of minimal heterogeneity. Subgroup analyses were also conducted, based on the type of advanced dressing.

Funnel plots indicating publication bias were synthesised for outcomes reporting at least five studies, which were assessed for visual asymmetry.

2.8 Quality assessment

Two reviewers (SW and RH) independently assessed the quality of included studies, using The Cochrane Risk of Bias Assessment Tool. [24] This assessed potential sources of bias across seven domains. Studies scoring a high risk of bias in at least one domain received an overall score of a high risk of bias. Any disagreements were resolved by a third reviewer (VHM).

3 Results

3.1 Characteristics of included studies

253 citations were identified from MEDLINE, EMBASE, CENTRAL and CINAHL (**Figure 1**). No additional records were identified from reference lists, posters or conference abstracts. From this, 74 duplicates were removed, leaving 179 articles to be screened for eligibility. After title and abstract screening, 158 were excluded as they were unrelated to the PICO. Full texts of the 21 remaining articles were retrieved. Exclusion of 15 full-text articles followed as they did not fit the inclusion criteria, resulting in the inclusion of six studies for the systematic review.

Figure 1 = PRISMA flow diagram

Six RCTs, conducted between 2010 and 2020, evaluated advanced dressings as their intervention compared to a simple dressing control group, in a total cohort of 2,295 women: 1,146 women randomised to receive an advanced dressing and 1,149 women randomised to receive a simple dressing (**Table 2)**. Individual study sample sizes ranged from recruitment of 142 women to 657 women. The studies were all conducted in hospital obstetric units in a variety of high-income countries. All studies were published in English. Choice of advanced dressing varied: two RCTs evaluated silver-impregnated dressings, two evaluated DACC-impregnated dressings, one evaluated copper-impregnated dressings and one evaluated chlorhexidine gluconate (CHG)-impregnated dressings. All studies included women of at least 18 years old undergoing either elective or emergency CS. Most included studies adequately reported participant characteristics and there were no significant differences between the baseline characteristics of the intervention and control groups in any study.

The primary outcome of SSI was reported by all six RCTs. Arendsen 2020 [25] and Saad 2020 [26] defined this outcome as any incidence of superficial or deep SSI within a 30-day period post-CS, consistent with CDC criteria. Stanirowski (a) 2016 [27] and Stanirowski (b) 2016 (pilot study) [28] defined the outcome of SSI as any incidence of superficial or deep SSI within a 14-day period post-CS. Connery 2019 [29] and Kellett 2015 [30] both reported an SSI outcome defined as any incidence of superficial SSI post-CS, with a follow-up period of 42 days and 7 days respectively.

Table 2 = Characteristics of included studies in the systematic review

3.2 Primary outcomes

The meta-analysis for SSI for all six RCTs demonstrated that application of an advanced dressing reduced the risk of SSI when compared to a simple dressing, although this reduction was statistically nonsignificant (RR: 0.81 [95% CI 0.52-1.24; p=0.32]) (**Figure 2**). There was evidence of moderate statistical heterogeneity (I^2= 40%).

Figure 2 = Forest plot demonstrating the efficacy of advanced dressings against surgical site infection post-caesarean section in randomised controlled trials

The funnel plot showed no obvious signs of visual asymmetry, indicating no significant publication bias (**Figure 3**).

Figure 3 = Funnel plot of randomised controlled trials investigating the efficacy of advanced dressings against surgical site infection post-caesarean section

Advanced dressings were further divided into their specific type. Subgroup meta-analysis for SSI for two RCTs investigating DACC-impregnated dressings (Stanirowski [a] 2016 [27], Stanirowski [b] 2016 [28]) showed a statistically significant reduction in SSI risk (RR: 0.33 [95% CI 0.14-0.77; p=0.01]). Studies showed no evidence of statistical heterogeneity (I^2=0%). Subgroup meta-analysis of two RCTs evaluating the application of silver-

impregnated dressings (Connery 2019 [29], Kellett 2015 [30]) for the reduction of SSI showed a statistically nonsignificant increase in SSI risk (RR: 1.20 [95% CI 0.77-1.88; p=0.41]). Studies showed no evidence of statistical heterogeneity (I^2=0%).

3.3 Secondary outcomes

For superficial SSI, meta-analysis of two RCTs (Connery 2019 [29], Kellett 2015 [30]) revealed the same results as the subgroup meta-analysis of two RCTs evaluating the application of silver-impregnated dressings for SSI (RR: 1.20 [95% CI 0.77-1.88; p=0.41]).

For endometritis, meta-analysis of three RCTs (Arendsen 2020 [25], Connery 2019 [29], Saad 2020 [26]) demonstrated that application of an advanced dressing caused a statistically nonsignificant increase in risk (RR: 1.43 [95% CI 0.09-23.92; p=0.80]). Significant heterogeneity between studies was observed (I^2= 77%).

For wound dehiscence, meta-analysis of four RCTs (Connery 2019 [29], Saad 2020 [26], Stanirowski [a] 2016 [27], Stanirowski [b] 2016 [28]) showed that application of an advanced dressing post-CS caused a nonsignificant reduction in risk (RR: 0.51 [95% CI 0.19-1.34; p=0.17]) (**Figure 4**). No evidence of statistical heterogeneity was observed between studies (I^2= 0%).

Figure 4 = Forest plot demonstrating the efficacy of advanced dressings against wound dehiscence post-caesarean section in randomised controlled trials

Further subgroup analysis by type of advanced dressing demonstrated that application of a DACC-impregnated dressing resulted in a nonsignificant reduction in the risk of wound dehiscence (RR: 0.43 95% CI [0.06-2.88; p=0.38]) (Stanirowski [a] 2016 [27], Stanirowski [b] 2016 [28]). No evidence of statistical heterogeneity was observed between studies (I^2=0%).

Meta-analysis of five RCTs (Arendsen 2020 [25], Kellet 2015 [30], Saad 2020 [26], Stanirowski (a) 2016 [27], Stanirowski [b] 2016 [28]) found a statistically nonsignificant reduction in risk of rehospitalisation for women receiving an advanced dressing post-CS (RR: 0.70 [95% CI 0.24-2.07; p=0.52]) (**Figure 5**). Studies showed no evidence of statistical heterogeneity (I^2=0%).

Figure 5 = Forest plot demonstrating the efficacy of advanced dressings against rehospitalisation post-caesarean section in randomised controlled trials

Subgroup meta-analysis of two RCTs (Stanirowski [a] 2016 [27], Stanirowski [b] 2016 [28]) demonstrated that application of a DACC-impregnated dressing resulted in a statistically nonsignificant reduction in the risk of rehospitalisation (RR: 0.20 95% CI 0.02-1.70; p=0.14]). Studies showed no evidence of statistical heterogeneity (I^2=0%).

Length of rehospitalisation was assessed in two RCTs (Arendsen 2020 [25], Stanirowski [a] 2016 [27]). Data showed similar lengths of rehospitalisation between copper-impregnated dressings and its comparator, however a significant decrease was seen with DACC-impregnated dressings.

No studies reported on the incidence of sepsis, maternal mortality or surgical scar pain.

3.4 Quality assessment

All studies scored a high risk of bias in at least one domain. There were concerns regarding allocation concealment in three studies (Arendsen 2020 [25], Stanirowski [a] 2016 [27], Stanirowski [b] 2016 [28]), potentially introducing selection bias. There were concerns regarding blinding of participants and personnel in three studies (Saad 2020 [26], Stanirowski [a] 2016 [27], Stanirowski [b] 2016 [28]), potentially introducing performance bias. Random sequence generation (Stanirowski [a] 2016 [27], Stanirowski [b] 2016 [28]), selective reporting (Connery 2019 [29], Kellet 2015 [30]) and other bias (Connery 2019 [29], Kellet 2015 [30]) were evident in two studies. Blinding of outcome assessment was present in one study (Saad 2020 [26]) (**Figures 6, 7**).

Figure 6 = Quality assessment of included studies in the systematic review
Figure 7 = Quality assessment summary graph

4 Discussion

4.1 Main findings

The results of our systematic review demonstrated that application of an advanced dressing did not significantly reduce SSI, wound dehiscence or rehospitalisation risks. This is consistent with the previous findings of Dumville et al [31], and the WHO systematic review [32], that concluded no significant benefit of advanced dressings for SSI prevention in all surgeries. However, this previous research was not conducted on the caesarean population, making direct comparison difficult.

Subgroup meta-analysis showed no demonstrable benefit of silver-impregnated dressings for superficial SSI prevention but highlighted the significant benefit of DACC-impregnated dressings in superficial and deep SSI prevention.

4.2 Strengths and limitations

The main strength of this systematic review and meta-analysis lies within its methodology; recommendations by PRISMA guidelines and the Cochrane Handbook for Systematic Reviews of Interventions were followed, and a protocol was registered *a priori*. Throughout

the process, two reviewers independently conducted screening, data extraction, analysis and quality assessment.

Limitations mainly relate to the individual studies: only six were included in our review, all with a high risk of bias identified. With one RCT (Stanirowski (b) 2016) a pilot of the full RCT (Stanirowski (a) 2016), despite no participant duplication, both studies used the same participant criteria, setting and methods. It is therefore difficult to ascertain whether findings for DACC-impregnated dressings are generalisable to the wider obstetric population. All included RCTs were conducted in high-income countries hence conclusions may not be generalisable to low-and middle- income countries. A number of core outcomes such as surgical scar pain, maternal mortality and sepsis were omitted by all included studies [33]. This may be due to all studies employing a follow-up period of less than 42 days. Although 30 days is required to be consistent with CDC criteria [6], shorter follow-up periods may have resulted in an inaccurate estimation of the incidence of SSI in the study populations.

4.3 Implications for research

Alongside the efficacy of DACC-impregnated dressings post-CS, other factors should be considered in decisions over their implementation. Stanirowski et al demonstrated that although DACC-impregnated dressings are 10-fold more expensive than simple dressings, the reduction in SSI risk and subsequent need for treatment outweighed the preventative costs, with an approximate saving of £119 per patient [34]. As DACC remains within the dressing, rather than being released into the wound, it is unlikely to contribute to antimicrobial resistance and no side effects have been reported in its use at the time of publication [19].

Our research has highlighted the deficit of high-quality primary research into advanced dressings in the caesarean population. As this review found DACC-impregnated dressings to be of significant benefit, a large, high-quality, multi-centre RCT is required, adhering to the core outcome set for infection prevention [33].

4.4 Implications for clinical practice

Our results suggest that DACC-impregnated dressings hold potential to reduce SSI post-CS. This agrees with the new NICE guidance, published in February 2021, also recommending their use [35].

Our results for silver-impregnated dressings, however, suggest that there may be an increased risk of SSI post-CS. Combined with evidence in other surgeries also highlighting this risk, and considering cost and side effects, we therefore recommend that silver dressings are not used for routine clinical practice [36-39].

With insufficient studies for copper-impregnated dressings and CHG-impregnated dressings, our results are insufficient to make conclusive recommendations for their use.

4.5 Conclusion

Our results demonstrated promise for the use of DACC-impregnated dressings. However, we have highlighted concerns regarding the use of silver dressings.

We acknowledge that the results of our systematic review are hindered by low-quality evidence and alone are insufficient to change clinical practice. We therefore encourage further research to be undertaken within this field of obstetrics to expand the existing evidence base.

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Declarations of interest
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