

INPLASY PROTOCOL

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A systematic review with meta-analysis on prophylactic negative pressure wound therapy versus standard dressing for obese women after cesarean section

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Review question / Objective: Population: obese women (BMI>30 kg/m²) after cesarean section for preventing wound complications. Intervention: negative pressure wound therapy. Comparison: standard dressings. Outcome: the primary outcome was the rate of surgical site infection after randomization; the secondary outcomes were the occurrence of overall complications, reoperation and readmission. Study design: two-arm RCTs. Objective: The aim of this systematic review is to compare negative pressure wound therapy and standard dressings in terms of efficacy and acceptability in obese women (BMI>30 kg/m²) after cesarean section for preventing wound complications to better inform clinical practice. To this end, the proposed systematic review will address the following question: Which is the best choice to reduce surgical site infection and overall complications in obese women after cesarean section, negative pressure wound therapy or standard dressings ?”

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 21 November 2022 and was last updated on 21 November 2022 (registration number INPLASY2022110106).

INTRODUCTION

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standard dressings. Outcome: the primary outcome was the rate of surgical site infection after randomization; the secondary outcomes were the occurrence of overall complications, reoperation and readmission. Study design: two-arm RCTs. Objective: The aim of this systematic

review is to compare negative pressure wound therapy and standard dressings in terms of efficacy and acceptability in obese women (BMI>30 kg/m²) after cesarean section for preventing wound complications to better inform clinical practice. To this end, the proposed systematic review will address the following question: Which is the best choice to reduce surgical site infection and overall complications in obese women after cesarean section, negative pressure wound therapy or standard dressings ?”

Condition being studied: The pre-pregnancy obesity was increasingly prevalent in women of different ages or races. Obese women whose pre-pregnancy body mass index >30kg/m² are considered to enter pregnancy with more risk, such as the performance of cesarean delivery. Previous research has found a link between obese women who had a cesarean section and an increased likelihood of surgical site infection, which leads to the prolonged hospital stay, additional surgical procedures and increased mortality. The high medical cost of SSI could also bring a significant financial burden on patients. Many wound therapies are applied to relieve surgical site infections. In addition to standard dressings, prophylactic negative pressure wound therapy is recently thought to be an effective procedure. Negative pressure wound therapy (NPWT) is acknowledged to accelerate wound healing by initiating a cascade of interrelated biological effects, including contracting the wound edges, stimulating angiogenesis and the granulation tissue formation. Nonetheless, some demerits of NPWT were also reported. Patients receiving NPWT are prone to develop adverse skin reactions compared with those receiving standard dressings. On the other hand, NPWT could be an expensive choice. Notably, NPWT versus standard dressing for obese women after cesarean section is in heated debate. The results of published meta-analyses and randomised controlled trials (RCTs) are subject to dispute. Tuuli et al published a RCT in JAMA concluded that using NPWT did not lower the risk of surgical site

infection significantly, compared with standard wound dressings. However, several meta-analyses reviewing RCTs suggested a significant decrease surgical site infection rate among obese women using NPWT compared with standard dressing . These inconsistencies are probably results from differences in study selection criteria, sample sizes, outcomes definition and assessing timepoint, or intervention methods or devices. The goal of our study is to offer an updated meta-analysis to further explore the effect of NPWT compared with standard dressing in obese women through a more comprehensive approach.

METHODS

Participant or population: Obese women (BMI>30 kg/m²) after cesarean section for preventing wound complications.

Intervention: Negative pressure wound therapy.

Comparator: Standard dressings.

Study designs to be included: Randomized controlled trial (RCT).

Eligibility criteria: The exclusion criteria included: 1. patients accepted surgeries except for cesarean section, patients with body mass index <30 kg/m²;2. no prophylactic use of NPWT or no comparison group, 3. outcomes did not involve wound infection or skin complications. 4. meta-analyses, reviews, case reports, protocols, and conference abstracts.

Information sources: PubMed, Embase, Web of Science, and the Cochrane Central Register of Controlled Trials.

Main outcome(s): The rate of surgical site infection after randomization, The occurrence of overall complications, reoperation and readmission.

Quality assessment / Risk of bias analysis: With the revised Cochrane risk of bias tool, two researchers independently assessed

the risk of bias in each study. The judgments concluded five domains of each randomized controlled trial study: (i) randomization process; (ii) missing outcome data; (iii) deviations from intended interventions; (iv) measurement of the outcome; (v) selection of the reported result. Each domain was evaluated as 'low risk', 'some concerns', and 'high risk'. Disagreements were determined by the third reviewer.

Strategy of data synthesis: Firstly, we evaluated the transitivity assumption by comparing the distribution of potential confounders (body mass index, maternal age, gestational age etc.) for all studies. With the Hartung-Knapp method, we calculated the risk ratio (RR) with the 95% confidence intervals (CIs) for dichotomized outcome data with a p-value <0.05 deemed as statistically significant. Then we tested the heterogeneity between studies by using I² statistics. The I² statistic was used to assess heterogeneity across studies, and. We chose the random-effects model to analyse the results with moderate and severe heterogeneity when the heterogeneity greater than 50% and fixed-effects model for the heterogeneity lower than 50%.

For SSI, we also conducted a Bayesian meta-analysis to investigate the robustness of the results with semi-informative prior as the "bayesmeta" package recommended. The semi-informative priors were based on zero mean and standard deviation 0.1 for the log RR and a Log-Normal heterogeneity distribution (mean -1.245, sd 0.76) specific for infection and pharmacologic versus control comparisons as proposed by Turner et al. The results were presented as 95% credible intervals (CrIs) for the Bayesian meta-analysis.

Subgroup analysis: Moreover, in order to investigate potential between-study heterogeneities and estimate potential confounding factors, we performed subgroup analyses for primary and secondary outcomes. The subgroup analyses were conducted according to the location of the infection, the type of skin incision and cesarean section, and body

mass index for SSI rate. Additionally, we conducted the contour-enhanced funnel plots to assess the publication bias. R software system v4.1.0. was used for the above statistical analyses, by using the packages: "meta", "metafor", "dmetar", and "bayesmeta".

Sensitivity analysis: None.

Country(ies) involved: China.

Keywords: cesarean section; meta-analysis; obesity; negative-pressure wound therapy; randomized controlled trial; nursing care.

Contributions of each author:

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