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Review Article

The impact of negative pressure wound therapy on surgical site infection rates in obese women following cesarean section: A systematic review and meta-analysis

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ABSTRACT

Background & Aim: This study aims to assess the surgical site infection (SSI) rate in obese women undergoing C-sections, comparing negative pressure wound therapy (NPWT) and standard dressings.

Methods & Materials: In this systematic review and meta-analysis, databases including Science Direct, Medline/PubMed, Web of Science, Scopus, and Cochrane Library were searched for articles published up to January 2024. The selection criteria included randomized controlled trials and cohort studies comparing the effect of (NPWT) with standard dressings on wound complications in women with obesity undergoing C-sections. Data collection and analysis Pooled effect sizes were calculated using random effects models based on heterogeneity.

Results: Out of 20 included studies, 18 reported SSI rates, which included 9243 cases and showed that NPWT reduces the rate of SSIs in obese women undergoing C-section (RR: 0.8, 95% CI: 0.66–0.96, I^2= 24.5%, P= 0.01). An in-depth examination of 13 high-quality studies, in which NPWT devices were used, reveals a pooled Mantel-Haenszel (M-H) Risk Ratio (RR) of 0.92 for Prevention- Reduction - Epithelialization- Vacuum- Environment- Negative pressure- Advanced (PREVENA) (95% CI: 0.67–1.26, I^2= 0%, P= 0.6) and 0.76 for Pressure-Incision- Closed- Optimization (PICO) (95% CI: 0.44–1.33, I^2= 15%, P= 0.05), with a significant difference among devices (P=0.05).

Conclusion: NPWT reduces the SSI rate in obese women undergoing C-sections, regardless of the type or device used. Economic evaluations are crucial to justify NPWT device costs against expenses for treating surgical infections, supporting its widespread use in infection prevention.

Introduction

Over the past few decades, the prevalence of concurrent medical conditions during pregnancy has increased in most populations, attributed to delayed fertility in women and an increase in the obesity rate (1). The rate of cesarean section (C-section) in overweight women is generally higher, with an elevated risk of both emergency and elective C-sections associated with an increase in Body Mass Index (BMI) (2). Although C-sections have contributed positively to diminishing maternal and neonatal mortality rates, postoperative Surgical Site Complications (SSCs), including Surgical Site Infections (SSIs), persist as a prevalent concern, impacting approximately one in every ten women (3). Risk factors for SSIs may include smoking, diabetes, high BMI, and the performance of emergency or repeat C-sections (4, 5). The rate of SSIs after C-section among normal weight population ranges from 3 to 20% (6), unadjusted risk estimates demonstrated that a 5-unit increase in BMI was associated with 13 % increased risk of SSI (7). In women with BMI>=40 kg/m2, the SSI rate reaches 50% (8). Additionally, SSIs are associated with delayed surgical incision healing, reduced quality of life (9), and a mortality rate exceeding 3% in C-section mothers (6).

The potential mechanisms linking elevated BMI to increased SSIs are not fully elucidated; however, it is believed that obese

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individuals typically have thicker subcutaneous fat layers that require higher retraction forces during surgery. This increases the risk of creating dead spaces after wound closure. These elements could result in heightened tissue necrosis and vascular perfusion deficiency, constraining bacterial clearance by neutrophils and culminating in wound infection. Furthermore, the excess adipose tissue in obese individuals acts as a reservoir for pro-inflammatory cytokines, contributing to insulin resistance and elevating the susceptibility to infection (10, 11). Various strategies have been recommended to reduce the SSI rate, including optimizing skin hygiene before surgery, preparing the skin during surgery, choosing the surgical incision type, employing appropriate surgical closure techniques, and timely administration of prophylactic antibiotics (12). In addition to these strategies, Negative Pressure Wound Therapy (NPWT) is an adjunctive treatment that has been employed in the past decade to reduce SSIs in women undergoing C-section with high BMI. However, it comes at a higher cost compared to standard dressings (13).

NPWT comprises a sealed system with a sealed dressing, including a sponge, a semi-occlusive barrier, and a fluid collection system. Through a tube connected to a small pump, a controlled negative pressure ranging from -50 to -200 mmHg is directly applied to the wound surface, drawing fluid from the incision site towards itself. Its four mechanisms involve macro deformation and micro deformation of tissues, removal of excess extracellular fluids, and stabilization of the wound environment. In surgical incisions, it enhances lymphatic clearance, reduces seroma formation, decreases lateral and shear stress on suture lines, increases blood flow, promotes oxygen exchange, and facilitates granulation tissue formation. The three main types of NPWT commonly used are PICO (Pressure- Incision- Closed- Optimization), simple NPWT such as PREVENA (Prevention- Reduction- Epithelialization- Vacuum- Environment- Negative pressure - Advanced), and iNPWT (installation Negative Pressure Wound Therapy) (1, 11, 14, 15). PICO is a portable, lightweight, and pocket-sized device that applies negative pressure up to -80 mmHg. Generally, it is more cost-effective than larger NPWT systems. Its exudate management is based on evaporation and does not require a canister, making it a single-use device. It is suitable for wounds with minimal exudate (16). PREVENA falls under the category of simple NPWT. It is portable but heavier due to the canister for collecting exudate. It applies negative pressure up to -200 mmHg. Its price varies depending on features like remote control and specialized settings. It uses bioactive dressings with antimicrobial properties for efficient exudate management. However, it does not have the feature of wound irrigation (17, 18). iNPWT is portable but heavier than PICO and PREVENA due to the washing feature. It applies negative pressure up to -200 mmHg. It includes mechanisms for wound irrigation and can deliver some medications and antibiotics to the wound surface through this feature, which is sometimes referred to as "soak" in some devices (1, 11, 14, 15).

The World Health Organization (WHO) recommends the use of incisional Negative Pressure Wound Therapy **(**iNPWT**)** for reducing SSIs in high-risk wounds, based on evidence (19). The National Institute for Health and Care Excellence (NICE) has suggested the use of the PICO device in high-risk patients to decrease the incidence of SSIs (20). While the Centers for Disease Control and Prevention (CDC) does not specifically mention iNPWT in its current guidelines (21), these recommendations lack strong endorsement due to uncertainty in evidence and the need to consider costs when implementing this preventive strategy (22). Based on two meta-analyses in obese women undergoing C-sections, NPWT led to a reduction in SSI rates, with no significant differences in hospital readmission, reoperation, and post-surgery

wound complication rates compared to standard care (23, 24). A 2023 meta-analysis found no differences between NPWT and standard dressings for superficial SSIs, deep SSIs, wound dehiscence, seroma, and hematoma (2). However, a 2023 study observed a significant reduction in SSIs and superficial SSIs with NPWT at -80 mmHg, but not at -125 mmHg (25). A 2022 meta-analysis noted a higher risk of blistering with NPWT (26), and another study reported increased skin reactions(23). Conversely, a 2023 meta-analysis found no significant difference in blistering between the groups (27). Another 2023 analysis showed a decrease in overall SSI incidence and wound complication rates with NPWT, with no significant differences based on C-section type (emergency/elective). PICO systems were more effective than PREVENA systems in reducing SSIs (28).

According to the results of the mentioned studies, several meta-analyses examining the impact of NPWT on SSIs in obese women during C-sections have yielded conflicting results. Discrepancies are attributed to limited sample sizes, variations in defining primary outcomes, included studies, and types of NPWT. Assessing the quality of these meta-analyses revealed challenges, including significant bias due to incomplete data reporting and information concealment from participants and personnel, with reported incompleteness reaching up to 50% (26). Furthermore, the latest meta-analysis in 2023 examined the effect of negative pressure therapy on the rate of SSI in all surgeries, combining cesarean sections with other abdominal surgeries without separate reporting (15). While SSIs in different types of abdominal surgeries vary, a new meta-analysis is needed that includes recent research, and detailed subgroup analyses, and considers the type of NPWT, different pressure levels, and various SSI levels (superficial-SSI, deep-SSI, organ-SSI), while also addressing the quality of the studies. Thus, this study was conducted to investigate the effectiveness of NPWT as a preventive treatment for SSIs in obese women after cesarean sections.

This study aims to assess the SSI rate in obese women undergoing C-section, comparing NPWT and standard dressings. Secondary objectives include comparing rates of wound complications, reoperations, and readmissions between the two groups. This study also compares the effectiveness of NPWT interventions based on the type of NPWT used.

Methods

This systematic review and meta-analysis were written following the guidelines outlined in the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement (29).

Search strategy

Comprehensive searches were conducted by "MA" from Mashhad University of Medical Science and "AK" from North Khorasan University of Medical Science in the databases of Science Direct, Medline/PubMed, Web of Science, Scopus, and the Cochrane Library up to January 2024, without language filter in search, to identify articles comparing the use of NPWT with standard dressings for preventing SSIs in obese women after C-sections. The search syntax in PubMed database and queries were based on the following terms and phrases: ("NPWT"[All Fields] OR "negative pressure wound therapy"[All Fields] OR "negative-pressure"[All Fields] OR "negative-pressure"[All Fields] OR "vacuum"[All Fields]) AND ("cesarean"[All Fields] OR "cesarean"[All Fields] OR "obstetric"[All Fields] OR "c-section"[All Fields] OR "abdominal delivery"[All Fields] OR "surgical delivery"[All Fields] OR "post cesarean"[All Fields]). The database search was complemented by manual searches of reference lists in included articles and Google Scholar.

Study selection

All search results were initially screened based on titles and abstracts, and

only relevant articles were retrieved to obtain the full text (30). Inclusion criteria based on PICOS were defined as follows: P-Participants: Women undergoing cesarean sections with a BMI more than 30 kg/m2. I-Intervention: Negative Pressure Wound Therapy (NPWT). C- Comparator: Standard dressings or regular wound care. O-Outcomes: Incidence of Surgical Site Infections (SSI), overall wound complications including SSIs, superficial SSIs, deep SSIs, and organ-specific SSIs. S-Study Design: Randomized Controlled Trials (RCTs) and cohort studies. Exclusion criteria comprised participants with a BMI less than 30 kg/m2, observational studies, duplicate studies, protocols, letters to the editor, and review articles.

Data extraction

Two independent reviewers conducted a thorough examination of the selected studies and extracted data. Any discrepancies were resolved through discussion and consensus. For unpublished literature, contact was made with the responsible author to obtain additional information regarding the study methodology, population demographics, and sample characteristics. In the case of non-response, only the abstract of that study was utilized, and the study could not achieve a high rating in the assessment (31). Information related to study authors, country, publication details, number of patients, patient characteristics such as age and BMI, type of NPWT, treatment duration, and study outcomes was collected. The primary outcome was the incidence of SSIs and their subtypes (superficial, deep, and organ). Additionally, secondary outcomes included overall wound complication rates and the occurrences of hospital readmission and reoperation.

Quality assessment

To assess the critical evaluation of the studies, a 5-item checklist derived from the JBI Critical Appraisal Checklist for cohort or RCT Studies (32) was employed. Both authors independently scrutinized each study against the checklist criteria, providing responses of "Yes," "No," or "Unclear." Each "Yes" earned a score of two, "Unclear" received a score of one, and "No" received no score. The total scores for each study were calculated. Quality classification based on this 5-item checklist was defined as high (7-10), moderate (3-6), and weak (3>).

Data analysis

Statistical analysis was conducted using Comprehensive Meta-Analysis (CMA) version 5.4 software and SPSS version 28 trial version. A random-effects model with the Mantel-Haenszel Risk Ratio (RR) statistical method was employed for the synthesis of outcome measures. M-H of RR with its variance and a 95% Confidence Interval (CI) were estimated. The heterogeneity among RRs was assessed using the I^2 statistic and reported. A sensitivity analysis was performed based on the included studies' quality, distinguishing between high and low-quality studies. Additionally, a subgroup analysis was conducted for different types of NPWT devices to assess their impact on the specified outcomes. Publication bias and small-sample bias were assessed through visual inspection of the funnel plot.

Results

Search process and study selection

Out of a total of 1511 studies identified through the systematic search, 163 studies were further examined for full-text evaluation after removing duplicates and irrelevant studies. Ultimately, 20 studies (17 full-text and 3 conference studies) were included in the meta-analyses. Three conference studies (33-35) published complete results, including tables, graphs, details of participant selection criteria, and analysis methods, in the form of posters. These studies were included in the analysis due to access to the full text of the posters, providing comprehensive data for review. The detailed process of study selection is illustrated in Figure 1.

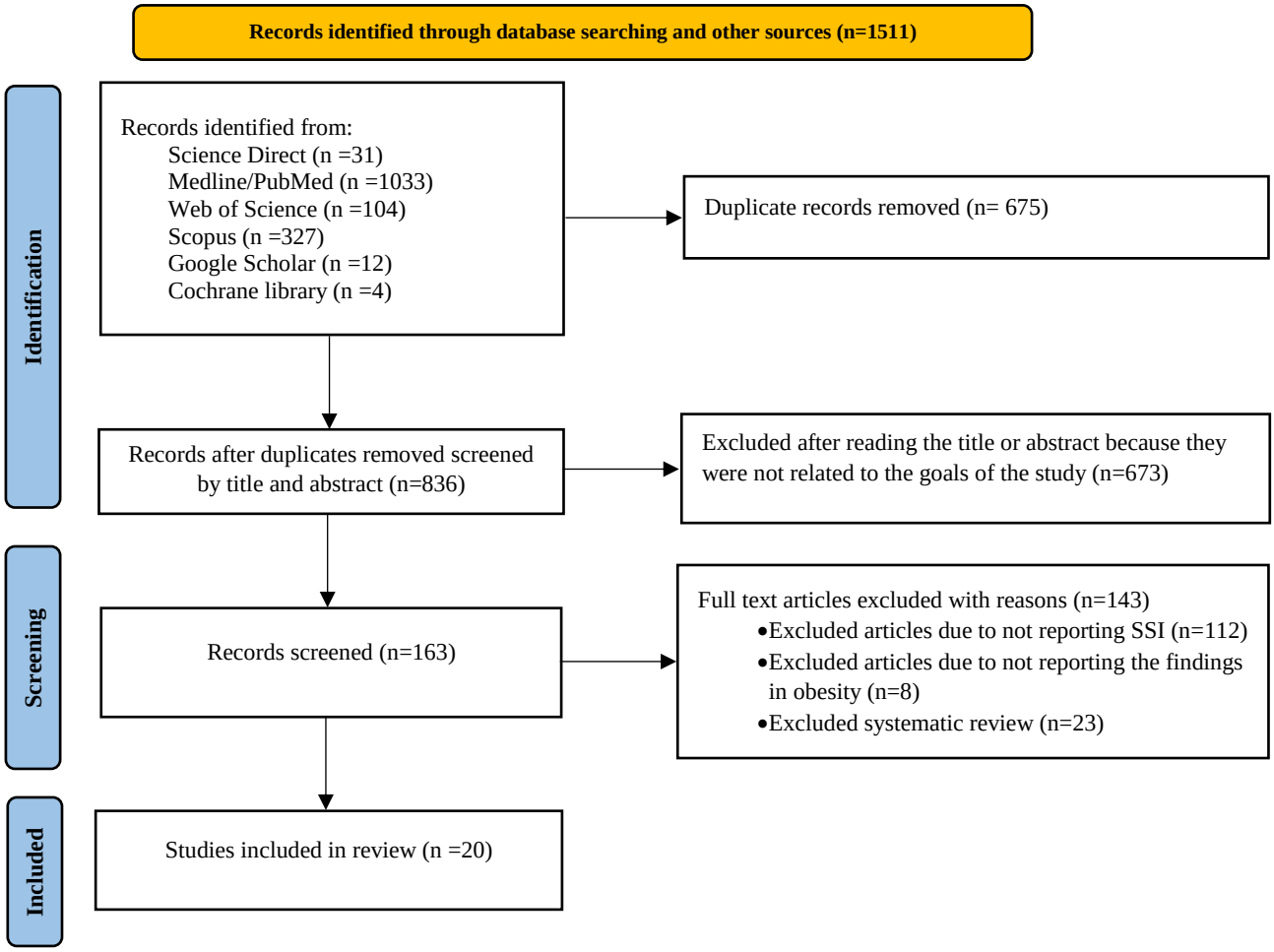


Figure 1. PRISMA flow diagram

Study characteristics

The meta-analysis included a total of 20 RCTs and cohort studies, comprising 9366 participants. Seventeen studies were published in full-text form, while three were presented as conference posters or oral presentations. The characteristics of the included studies are presented in Table 1. These studies were published between 2013 and 2023, with the majority conducted in the USA. The sample sizes across studies ranged from 54 to 2035 participants. Baseline characteristics were comparable between the intervention and control groups. All studies reported on obesity, with diabetes mellitus being the most frequently reported comorbidity. The predominant NPWT systems used were PICO or PREVENA. Treatment duration varied, spanning from 3 to 7 days, and follow-up periods ranged from 4 to 8 weeks. Two studies did not include numerical reports of SSIs and only analyzed wound complications following C-sections, so included in wound complications analysis (36, 37).

Primary outcome: SSI

Pooling the data from all relevant studies reporting SSI rates (18 studies involving 9,243 patients), it was observed that 262 out of 4,013 patients who received NPWT and 393 out of 5,230 patients who received standard care experienced SSIs. Irrespective of the specific NPWT device used, the analysis suggests that NPWT could statistically significantly reduce the occurrence of SSIs, with a pooled Risk Ratio (RR) for SSIs of 0.8 (P= 0.01) (95% CI: 0.66–0.96, I^2= 24.5%) (Figure 2A).

Table 1. Fundamental characteristics of the studies included in the meta-analysis

Reference	Year	Country	Type of study	Participant characteristics	NPWT system/ device	SSI criteria	Wound type	Number-Intervention/ Control	Age-Intervention	Age-Control	BMI-Intervention	BMI-Control
Stitely (37)	2013	USA	RCT	Weight > 199 lbs	NR	NR	Wound disruption, seroma, haematoma	28/26	NR	NR	NR	NR
Chabaoyer (43)	2014	Australia	RCT	BMI ≥ 30 kg/m2	PICO	CDC	Bleeding and bruising	44/43	30.6 ±5.5	30.7± 5.0	35.7 ± 4.5	36.8 ± 5.8
Mark (36)	2014	USA	Cohort	BMI ≥ 45 kg/m2	KCI	ICD-9	NR	21/48	26.1±4.2	29.5± 6.6	53.8 ± 11.1	51.3 ± 5.8
Swift (44)	2015	USA	Cohort	Not reported	PREVENA	NR	NR	110/209	30.8 ± 6.0	29.4 ±5.8	37.7 ± 9.0	33.6 ± 8.5
Orth (45)	2016	USA	Cohort	BMI ≥ or < 30 kg/m2	ENPDS	NR	seroma, hematoma, separation, or infection or a combination of these	102/866	31.0 ± 6	29.3 ± 6	43.3 ± 9	32.4 ± 6
Gunatilake (46)	2017	USA	RCT	BMI ≥ 35 kg/m2	PREVENA	NR	Seroma, haematoma, dehiscence, abscess	39/43	30.4 ± 5.7	29.7 ± 5	46.3 ± 7.3	46.8 ± 5.6
Ruhstaller (34)	2017	USA	RCT	BMI ≥ 30 kg/m2	PREVENA	CDC	Wound infection	61/58	27 ± 8	29 ± 10	36.1 ± 8.6	35.1 ± 9.5
Tuuli (35)	2017	USA	RCT	BMI ≥ 30 kg/m2	PICO	CDC	Seroma, haematoma	60/60	NR	NR	NR	NR
Villers (47)	2017	USA	Cohort	BMI ≥ 40 kg/m2	Not reported	CDC	infection, seroma, or hematoma	210/107	NR	NR	48.2	44.6
Kawakita (33)	2018	USA	Cohort	BMI ≥ 40 kg/m2	PICO	NR	NR	167/592	NR	NR	NR	NR
Looby (48)	2018	USA	Cohort	BMI ≥ 40 kg/m2	KCI	NR	NR	234/233	29.8±5.8	27.6±6.1	43.8±35.1	44.2±34.1
Roberts (49)	2018	USA	RCT		PREVENA	NR	NR	222/219	29.1±8.8	30.3±5.1	46.6 ± 6.0	45.8 ± 5.8
Wihbey (50)	2018	USA	RCT	BMI ≥ 35 kg/m2	PREVENA	CDC	infection, seroma, hematoma, wound dehiscence	80/81	31± 6	30.2±6	44.9 ± 8	43.4 ± 7
Hussamy (51)	2019	USA	RCT	BMI ≥ 40 kg/m2	PREVENA	CDC	Dehiscence, cellulitis	222/219	29.1± 6.1	30.3±6.1	46.6± 6.0	45.8± 5.8
Hyldig (4)	2019	Denmark	RCT	BMI ≥ 30 kg/m2	PICO	CDC	Wound exudate, minor wound dehiscence	432/444	32 ± 5	32 ± 5	34.7 ± 31.5	34.2 ±31.6
Tuuli (52)	2020	USA	RCT	BMI ≥ 30 kg/m2	PREVENA	CDC	Skin separation, seroma, haematoma, cellulitis	806/802	30.2 ± 5.6	30.5 ± 6.1	39.6 ± 7.7	39.5 ± 8.1
Brigid (53)	2021	Australia	RCT	BMI ≥ 30 kg/m2	PICO	CDC	Bleeding, dehiscence, haematoma, seroma	1017/1018	31 ±5.5	31 ± 5.4	NR	NR
Kawakita (54)	2021	USA	RCT	BMI ≥50 kg/m2	PICO	NR	Cellulitis, hematoma, seroma, dehiscence	73/106	30.8 ±4.9	27.5 ±5.9	55 ±50.8	52.8 ±50.3
Peterson (55)	2021	USA	RCT	BMI ≥40 kg/m2	PICO	CDC	Seroma, haematoma	55/55	31.5±6.3	31.2±5.3	49.3±6.6	47.8±6.9
Gonzalez (1)	2023	USA	RCT	BMI ≥ 30 kg/m2	PICO	CDC	NR	79/75	30.5 ± 6.1	31.9 ± 6.5	40.6 ± 8.6	39.3 ± 7.8

In the sensitivity analysis for SSIs, no significant differences were found in the pooled RR and 95% CI when each study was individually excluded. Analyzing 13 high-quality studies revealed that when studies were categorized based on the use of the PREVENA device (5 studies involving 2411 patients) or the PICO device (6 studies involving 3407 patients), the pooled RR for SSIs was 0.92 (95% CI: 0.67–1.26, I^2 = 0%, P= 0.6) and 0.76 (95% CI: 0.44–1.33, I^2= 15%, P= 0.05), respectively. After selecting

between-group analysis a statistically significant difference among NPWT devices in Mantel-Haenszel (M-H) of RR for SSIs was observed (P= 0.05), indicating that PICO was more effective in reducing SSI (Figure 2B and Table 2). Analysis of 18 studies showed that when the studies were classified by study type (5 cohort studies including 2830 patients) or (6 RCTs including 6413 patients), the pooled RR for SSIs was 0.60 (95% CI: 0.31–1.16, I^2= 68%, P= 0.13) and 0.80 (95% CI: 0.68–0.96, I^2 = 0%, P= 0.01), respectively. A statistically significant difference among types of study in terms of RR for SSIs was observed (P= 0.006) (Figure 2C and Table 2).

Figure 2: 2A. Forest plot for the effect of NPWT on SSIs after C-section, 2B. Forest plot for the effect of NPWT on SSIs after C-section in high-quality studies, 2C. funnel plots for the effect of NPWT on SSIs after C-section

Figure 2A. Forest plot for the effect of NPWT on SSIs after C-section

First author, year	Comparison	Events / Total NPWT	Events / Total Std Care	Statistics for each study: MH risk ratio	Lower limit	Upper limit	Relative weight
Orth, 2016	Other	2 / 102	11 / 866	1.544	0.347	6.867	15.61
Villers, 2017	Other	13 / 210	19 / 107	0.349	0.179	0.679	43.74
Looby, 2018	Other	11 / 234	19 / 233	0.576	0.281	1.184	40.66
Pooled		26 / 546	49 / 1206	0.540	0.279	1.042	
Prediction Interval				0.540	0.001	329.667	
Chabaoyer, 2014	PICO	10 / 44	12 / 43	0.814	0.394	1.684	10.06
Tuuli, 2017	PICO	3 / 60	2 / 60	1.500	0.260	8.658	1.94
Kawakita, 2018	PICO	16 / 167	47 / 592	1.207	0.703	2.072	16.43
Hyldig, 2019	PICO	20 / 432	41 / 444	0.501	0.299	0.842	17.57
Brigid, 2021	PICO	75 / 1017	99 / 1018	0.758	0.569	1.011	37.72
Kawakita, 2021	PICO	8 / 73	7 / 106	1.659	0.629	4.376	5.99
Peterson, 2021	PICO	7 / 55	7 / 55	1.000	0.376	2.661	5.89
Gonzalez, 2023	PICO	5 / 79	6 / 75	0.791	0.252	2.484	4.40
Pooled		144 / 1927	221 / 2393	0.829	0.647	1.061	
Prediction Interval				0.829	0.519	1.324	
Swift, 2015	PREVENA	3 / 110	24 / 209	0.238	0.073	0.771	5.94
Gunatilake, 2017	PREVENA	1 / 39	4 / 43	0.276	0.032	2.362	1.85
Ruhstaller, 2017	PREVENA	3 / 61	4 / 58	0.713	0.167	3.050	3.96
Roberts, 2018	PREVENA	21 / 222	25 / 219	0.829	0.478	1.435	23.36
Wihbey, 2018	PREVENA	12 / 80	12 / 81	1.013	0.484	2.118	14.10
Hussamy, 2019	PREVENA	21 / 222	25 / 219	0.829	0.478	1.435	23.36
Tuuli, 2020	PREVENA	31 / 806	29 / 802	1.064	0.647	1.748	27.44
Pooled		92 / 1540	123 / 1631	0.826	0.615	1.108	
Prediction Interval				0.826	0.493	1.382	
Pooled		262 / 4013	393 / 5230	0.801	0.668	0.961	
Prediction Interval				0.801	0.506	1.268	

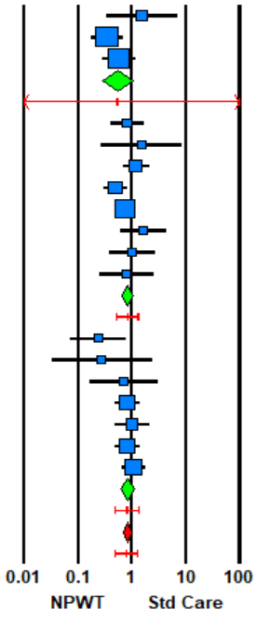


Figure 2B. Forest plot for the effect of NPWT on SSIs after C-section in high-quality studies

First author, year	Comparison	Events / Total NPWT	Events / Total Std Care	Statistics for each study: MH risk ratio	Lower limit	Upper limit	Relative weight
Orth, 2016	Other	2 / 102	11 / 866	1.544	0.347	6.867	27.12
Looby, 2018	Other	11 / 234	19 / 233	0.576	0.281	1.184	72.88
Pooled		13 / 336	30 / 1099	0.753	0.319	1.778	
Prediction Interval							
Chabaoyer, 2014	PICO	10 / 44	12 / 43	0.814	0.394	1.684	12.56
Tuuli, 2017	PICO	3 / 60	2 / 60	1.500	0.260	8.658	2.40
Hyldig, 2019	PICO	20 / 432	41 / 444	0.501	0.299	0.842	22.07
Brigid, 2021	PICO	75 / 1017	99 / 1018	0.758	0.569	1.011	48.18
Kawakita, 2021	PICO	8 / 73	7 / 106	1.659	0.629	4.376	7.46
Peterson, 2021	PICO	7 / 55	7 / 55	1.000	0.376	2.661	7.33
Pooled		123 / 1681	168 / 1726	0.768	0.583	1.011	
Prediction Interval				0.768	0.444	1.330	
Gunatilake, 2017	PREVENA	1 / 39	4 / 43	0.276	0.032	2.362	2.19
Ruhstaller, 2017	PREVENA	3 / 61	4 / 58	0.713	0.167	3.050	4.79
Wihbey, 2018	PREVENA	12 / 80	12 / 81	1.013	0.484	2.118	18.56
Hussamy, 2019	PREVENA	21 / 222	25 / 219	0.829	0.478	1.435	33.51
Tuuli, 2020	PREVENA	31 / 806	29 / 802	1.064	0.647	1.748	40.96
Pooled		68 / 1208	74 / 1203	0.923	0.672	1.269	
Prediction Interval							
Pooled		204 / 3225	272 / 4028	0.826	0.675	1.012	
Prediction Interval							

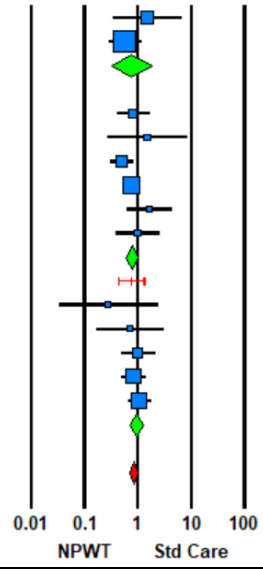


Figure 2C. Forest plot for the effect of NPWT on SSIs after C-section in RCT & Cohort studies

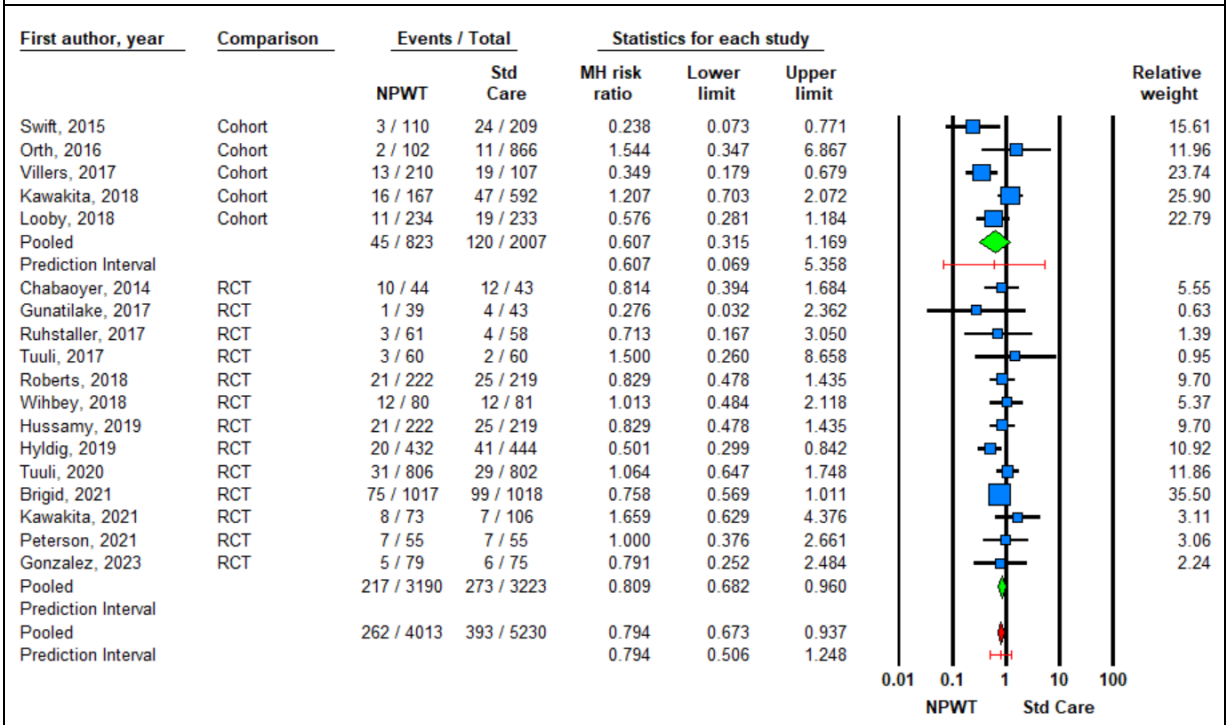


Figure 2D. Funnel plots for the effect of NPWT on SSIs after C-section

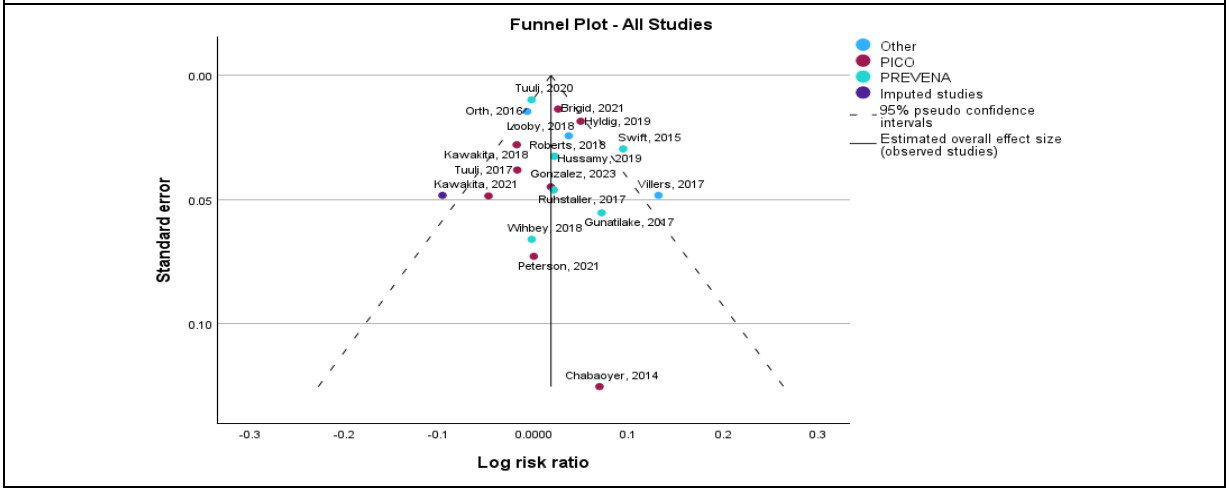


Table 2. Pooled RR and subgroup analysis of the effect of NPWT on SSIs after C-section

Variables	Groups	Number Studies	Effect size and 95% interval			Test of null (2-Tail)		Between-study		Other heterogeneity statistics			
			Point estimate	Lower limit	Upper limit	Z-value	P-value	Tau	TauSq	Q-value	df (Q)	P-value	I-squared
SSI	Other	3	0.54	0.27	1.04	-1.8	0.06	0.3	0.14	3.4	2	0.17	42.3
	PICO	8	0.82	0.64	1.06	-1.4	0.1	0.14	0.02	8.3	7	0.3	16.1
	PREVENA	7	0.82	0.61	1.1	-1.2	0.2	0.12	0.01	6.7	6	0.3	10.9
	Overall	18	0.8	0.66	0.96	-2.3	0.01	0.19	0.03	22.5	17	0.16	24.5
SSI	Cohort	5	0.6	0.31	1.1	-1.4	0.13	0.59	0.35	12	4	0.1	68
	RCT	13	0.8	0.68	0.96	-2.4	0.01	0.00	0.00	8.7	12	0.72	0.00
Superficial - SSI	Other	1	0.17	0.04	0.6	-2.7	0.007	0.00	0.00	0.00	0	1	100
	PICO	3	0.7	0.58	1	-1.8	0.05	0.00	0.00	0.3	2	0.8	0.00
	PREVENA	3	1	0.69	1.4	0.06	0.94	0.00	0.00	1.7	2	0.4	0.00
	Overall	7	0.8	0.64	1	-1.9	0.05	0.24	0.6	9.2	6	0.1	34

Deep- SSI	Other	1	0.8	0.26	2.9	-0.1	0.85	0.00	0.00	0.00	0	1	100
	PICO	4	1.4	0.42	5.2	0.6	0.5	0.9	0.8	6.9	3	0.07	56
	PREVENA	1	0.9	0.43	2.2	-0.01	0.9	0.00	0.00	0.0	0	1	100
	Overall	6	1	0.58	1.9	0.2	0.8	0.45	0.2	7.3	5	0.1	31
Organ-SSI	Other	1	0.25	0.6	0.99	-1.9	0.05	0.00	0.00	0.00	0	1	100
	PICO	4	0.64	0.27	1.5	-0.9	0.3	0.00	0.00	1.2	3	0.7	0.00
	PREVENA	3	0.72	0.19	2.7	-0.48	0.6	0.00	0.00	1.7	2	0.4	0.00
	Overall	8	0.5	0.28	1.02	-1.8	0.05	0.00	0.00	4.5	7	0.7	0.00
Readmission	PICO	3	1.6	0.8	3.1	1.5	0.1	0.00	0.00	0.3	2	0.8	0.00
	PREVENA	3	1.1	0.5	2.3	0.4	0.6	0.00	0.00	1.8	2	0.4	0.00
	Overall	6	1.4	0.8	2.2	1.4	0.1	0.00	0.00	2.6	5	0.7	0.00
Reoperation	PICO	2	0.9	0.2	3.2	-0.04	0.9	0.00	0.00	0.5	1	0.4	0.00
	PREVENA	2	1.3	0.6	2.8	0.77	0.4	0.00	0.00	0.04	1	0.8	0.00
	Overall	4	1.2	0.6	2.3	0.6	0.5	0.00	0.00	0.8	3	0.8	0.00
Wound complication	Other	4	1.7	0.9	3.3	1.8	0.06	0.4	0.1	5.7	3	0.12	47
	PICO	7	1.09	0.7	1.6	0.4	0.6	0.4	0.2	23	6	0.001	74
	PREVENA	6	0.88	0.6	1.1	-1	0.3	0.00	0.00	3.6	5	0.5	0.00
	Overall	17	0.9	0.8	1.2	-0.07	0.9	0.38	0.1	46	16	0.00	65
Other: iNPWT or type of NPWT not specified in the study													

Superficial-SSI

Pooling data from all relevant studies reporting superficial surgical site infection (Superficial-SSI) rates (7 studies involving 4,759 patients), it was observed that 135 out of 2,434 patients who received NPWT and 165 out of 2,325 patients who received standard care experienced Superficial-SSIs. Regardless of the specific NPWT device used, the analysis indicates that NPWT could statistically significantly reduce the occurrence of Superficial-SSIs, with a pooled Risk Ratio (RR) for Superficial-SSIs of 0.8 (P= 0.05) (95% CI: 0.64-1, I^2 = 34%) (Figure 3A and Table 2). In the sensitivity analysis for Superficial-SSIs, no significant differences were found in the pooled RR and 95% CI when each study was individually excluded. When studies were categorized based on the use of the PREVENA device (3 studies involving 2210 patients) or the PICO device (3 studies involving 2232 patients), the pooled RR for Superficial-SSIs was 1 (95% CI: −0.69, I^2= 0%, P= 0.9) and 0.7 (95% CI: 1–0.58, I^2= 0%, P= 0.05), respectively. A statistically significant difference among NPWT devices in terms of RR for Superficial-SSIs was observed (P= 0.04), indicating that PICO was more effective in reducing Superficial-SSIs.

Deep- SSIs

Pooling data from all relevant studies reporting the rate of deep surgical site infections (deep-SSIs) (6 studies involving 4,985 patients), it was observed that the rate of deep-SSIs did not significantly differ between patients who used NPWT (32 out of 2,317 patients) and patients who received standard care (29 out of 2,668 patients) (P= 0.8) (95% CI: 0.58–1.9, I^2= 31%, RR= 1). In the sensitivity analysis, where each study was individually removed, and in the analysis based on the quality of studies, study type (RCT, cohort), and device type for deep-SSIs between the two groups, no significant difference in the pooled RR and 95% CI was observed (P>0.05) (Figure 3B and Table 2).

Organ-SSIs

Pooling data from all relevant studies reporting the rates of organ-SSIs (8 studies involving 5587 patients), it was observed that (14 out of 2619) received NPWT, and (37 out of 2968) experienced organ-SSIs with standard care. Regardless of the type of NPWT device, the analysis indicated that NPWT could significantly reduce the occurrence of organ-SSIs, with a pooled RR for SSI of 0.5 (P= 0.05) (95% CI: 0.28–1.02, I^2=0%) (Figure 3C, Table 2).

Figure 3: 3A. Forest plot for the effect of NPWT on superficial-SSIs after C-section, 3B. Forest plot for the effect of NPWT on deep-SSIs after C-section, 3C. Forest plot for the effect of NPWT on Organ-SSIs after C-section

Figure 3A. Forest plot for the effect of NPWT on superficial-SSIs after C-section

First author, year	Comparison	Events / Total		Statistics for each study			Relative weight
		NPWT	Std Care	MH risk ratio	Lower limit	Upper limit	
Villers, 2017	Other	3 / 210	9 / 107	0.170	0.047	0.614	100.00
Pooled		3 / 210	9 / 107	0.170	0.047	0.614	
Prediction Interval							
Chabaoyer, 2014	PICO	5 / 44	7 / 43	0.698	0.240	2.031	6.64
Brigid, 2021	PICO	70 / 1017	93 / 1018	0.753	0.559	1.015	85.45
Peterson, 2021	PICO	7 / 55	7 / 55	1.000	0.376	2.661	7.91
Pooled		82 / 1116	107 / 1116	0.767	0.582	1.009	
Prediction Interval							
Wihbey, 2018	PREVENA	12 / 80	8 / 81	1.519	0.656	3.516	20.60
Hussamy, 2019	PREVENA	20 / 222	25 / 219	0.789	0.452	1.378	46.70
Tuuli, 2020	PREVENA	18 / 806	16 / 802	1.119	0.575	2.180	32.70
Pooled		50 / 1108	49 / 1102	1.012	0.692	1.482	
Prediction Interval							
Pooled		135 / 2434	165 / 2325	0.805	0.646	1.003	
Prediction Interval				0.805	0.399	1.622	

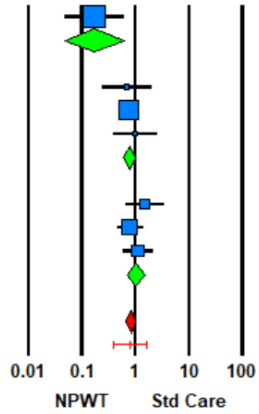


Figure 3B. Forest plot for the effect of NPWT on deep-SSIs after C-section

First author, year	Comparison	Events / Total		Statistics for each study			Relative weight
		NPWT	Std Care	MH risk ratio	Lower limit	Upper limit	
Villers, 2017	Other	7 / 210	4 / 107	0.892	0.267	2.979	100.00
Pooled		7 / 210	4 / 107	0.892	0.267	2.979	
Prediction Interval							
Chabaoyer, 2014	PICO	2 / 44	4 / 43	0.489	0.094	2.530	25.71
Kawakita, 2018	PICO	4 / 167	4 / 592	3.545	0.896	14.024	29.63
Brigid, 2021	PICO	4 / 1017	6 / 1018	0.667	0.189	2.358	31.38
Kawakita, 2021	PICO	4 / 73	0 / 106	13.014	0.711	238.094	13.29
Pooled		14 / 1301	14 / 1759	1.499	0.427	5.268	
Prediction Interval				1.499	0.011	205.186	
Tuuli, 2020	PREVENA	11 / 806	11 / 802	0.995	0.434	2.282	100.00
Pooled		11 / 806	11 / 802	0.995	0.434	2.282	
Prediction Interval							
Pooled		32 / 2317	29 / 2668	1.063	0.583	1.939	
Prediction Interval				1.063	0.231	4.897	

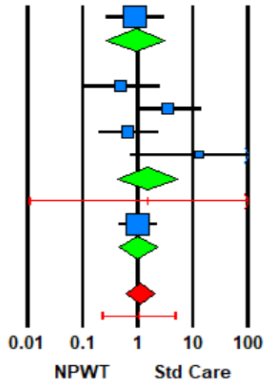
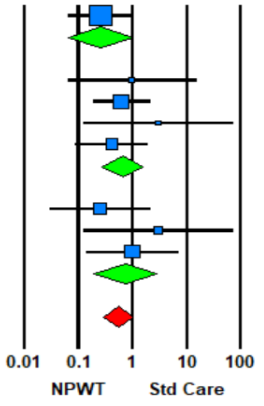


Figure 3C. Forest plot for the effect of NPWT on Organ -SSIs after C-section

First author, year	Comparison	Events / Total		Statistics for each study			Relative weight
		NPWT	Std Care	MH risk ratio	Lower limit	Upper limit	
Villers, 2017	Other	3 / 210	6 / 107	0.255	0.065	0.999	100.00
Pooled		3 / 210	6 / 107	0.255	0.065	0.999	
Prediction Interval							
Chabaoyer, 2014	PICO	1 / 44	1 / 43	0.977	0.063	15.131	10.03
Kawakita, 2018	PICO	3 / 167	17 / 592	0.626	0.186	2.109	50.98
Brigid, 2021	PICO	1 / 1017	0 / 1018	3.003	0.122	73.628	7.36
Kawakita, 2021	PICO	2 / 73	7 / 106	0.415	0.089	1.941	31.63
Pooled		7 / 1301	25 / 1759	0.645	0.271	1.536	
Prediction Interval							
Wihbey, 2018	PREVENA	1 / 80	4 / 81	0.253	0.029	2.216	37.19
Hussamy, 2019	PREVENA	1 / 222	0 / 219	2.960	0.121	72.259	17.14
Tuuli, 2020	PREVENA	2 / 806	2 / 802	0.995	0.141	7.047	45.67
Pooled		4 / 1108	6 / 1102	0.721	0.192	2.707	
Prediction Interval							
Pooled		14 / 2619	37 / 2968	0.540	0.284	1.024	
Prediction Interval							



Secondary outcomes

Overall wound complications

Pooling data from all relevant studies reporting the rates of overall wound complications (17 studies involving 6493 patients), it was observed that the overall wound complications rate between patients who used NPWT (374 of 2676 patients) and patients who received standard care (469 of 3817 patients) did not show a significant difference (P=0.9), (95% CI: 0.8-1.2, I^2 = 65%, RR= 0.9). In the sensitivity analysis, when each study was removed individually, and in the analysis based on the quality of studies and the type of studies (RCT, Cohort) and the type of device for overall wound complications between the two groups, there was no significant difference in the pooled RR and 95% CI (P>0.05) (Fig.4A, Table 2).

Hospital readmission

Pooling data from all relevant studies reporting the hospital readmission rate (6 studies involving 4442 patients), it was observed that the hospital readmission rate differed between patients who used NPWT (42 of 2224 patients) and patients who received standard care (29 of 2218 patients) with no significant difference (P= 0.1), (95% CI: 0.8-2.2, I^2= 0%, RR= 1.4). In the sensitivity analysis, when each study was excluded individually, and in the analysis based on the type of device for hospital readmission between the two groups, there was no significant difference in the pooled RR and 95% CI (P>0.05) (Fig.4B, Table 2).

Reoperation

Pooling data from all relevant studies reporting the reoperation rate (4 studies involving 2747 patients), it was observed that the reoperation rate differed between patients who used NPWT (20 of 1374 patients) and patients who used standard care (16 of 1373 patients) with no significant difference (P = 0.5) (95% CI: 0.6-2.3, I^2 = 0%, RR = 1.2). In the sensitivity analysis, when each study was excluded individually, and in the analysis based on the type of device for reoperation between the two groups, there was no significant difference in the pooled RR and 95% CI (P>0.05) (Figure 4C, Table 2).

Figure 4: 4A. Forest plot for the effect of NPWT on wound complications after C-section, 4B. Forest plot for the effect of NPWT on hospital readmission after C-section, 4C. Forest plot for the effect of NPWT on reoperation after C-section

Figure 4A. Forest plot for the effect of NPWT on wound complications after C-section

First author, year	Comparison	Events / Total		Statistics for each study			Relative weight
		NPWT	Std Care	MH risk ratio	Lower limit	Upper limit	
Stitely, 2013	Other	15 / 28	10 / 26	1.393	0.767	2.528	37.45
Mark, 2014	Other	0 / 21	5 / 48	0.202	0.012	3.504	4.38
Orth, 2016	Other	13 / 102	37 / 866	2.983	1.641	5.423	37.38
Villers, 2017	Other	14 / 210	4 / 107	1.783	0.602	5.286	20.79
Pooled		42 / 361	56 / 1047	1.791	0.963	3.333	
Prediction Interval				1.791	0.187	17.162	
Chabaoyer, 2014	PICO	6 / 44	6 / 43	0.977	0.342	2.794	10.01
Tuuli, 2017	PICO	0 / 60	1 / 60	0.333	0.014	8.023	1.74
Kawakita, 2018	PICO	19 / 167	26 / 592	2.591	1.471	4.563	17.04
Hyldig, 2019	PICO	154 / 410	206 / 417	0.760	0.649	0.891	23.19
Kawakita, 2021	PICO	26 / 73	26 / 106	1.452	0.922	2.288	18.98
Peterson, 2021	PICO	9 / 55	14 / 55	0.643	0.304	1.360	14.01
Gonzalez, 2023	PICO	14 / 79	13 / 75	1.022	0.515	2.029	15.03
Pooled		228 / 888	292 / 1348	1.094	0.707	1.691	
Prediction Interval				1.094	0.298	4.018	
Gunatilake, 2017	PREVENA	2 / 39	9 / 43	0.245	0.056	1.065	2.70
Ruhstaller, 2017	PREVENA	3 / 61	4 / 58	0.713	0.167	3.050	2.76
Roberts, 2018	PREVENA	37 / 222	42 / 219	0.869	0.582	1.297	36.39
Wihbey, 2018	PREVENA	25 / 80	24 / 81	1.055	0.661	1.683	26.75
Hussamy, 2019	PREVENA	16 / 222	17 / 219	0.928	0.481	1.790	13.54
Tuuli, 2020	PREVENA	21 / 806	25 / 802	0.836	0.472	1.481	17.85
Pooled		104 / 1430	121 / 1422	0.881	0.692	1.122	
Prediction Interval							
Pooled		374 / 2679	469 / 3817	0.993	0.813	1.213	
Prediction Interval				0.993	0.426	2.316	

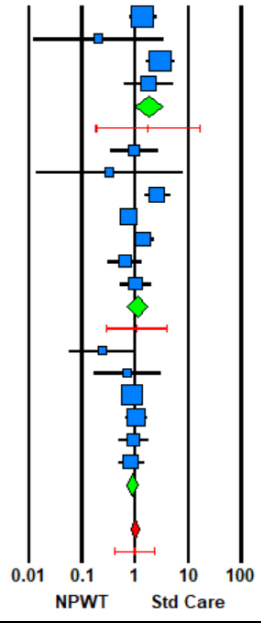


Figure 4B. Forest plot for the effect of NPWT on hospital readmission after C-section

First author, year	Comparison	Events / Total		Statistics for each study			Relative weight
		NPWT	Std Care	MH risk ratio	Lower limit	Upper limit	
Chabaoyer, 2014	PICO	1 / 44	1 / 43	0.977	0.063	15.131	5.41
Brigid, 2021	PICO	23 / 1017	13 / 1018	1.771	0.902	3.477	89.21
Peterson, 2021	PICO	1 / 55	1 / 55	1.000	0.064	15.588	5.38
Pooled		25 / 1116	15 / 1116	1.663	0.879	3.145	
Prediction Interval							
Wihbey, 2018	PREVENA	3 / 80	5 / 81	0.608	0.150	2.458	25.28
Hussamy, 2019	PREVENA	12 / 222	9 / 219	1.315	0.566	3.059	69.35
Tuuli, 2020	PREVENA	2 / 806	0 / 802	4.975	0.239	103.468	5.36
Pooled		17 / 1108	14 / 1102	1.162	0.575	2.346	
Prediction Interval							
Pooled		42 / 2224	29 / 2218	1.415	0.882	2.268	
Prediction Interval							

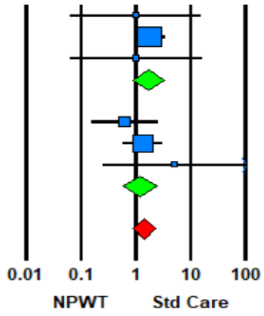
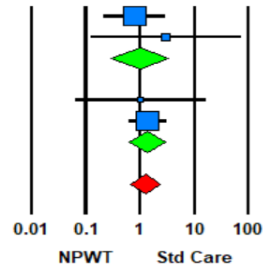


Figure 4C. Forest plot for the effect of NPWT on reoperation after C-section

First author, year	Comparison	Events / Total		Statistics for each study			Relative weight
		NPWT	Std Care	MH risk ratio	Lower limit	Upper limit	
Brigid, 2021	PICO	4 / 1017	5 / 1018	0.801	0.216	2.974	85.45
Peterson, 2021	PICO	1 / 55	0 / 55	3.000	0.125	72.076	14.55
Pooled		5 / 1072	5 / 1073	0.970	0.289	3.263	
Prediction Interval							
Wihbey, 2018	PREVENA	1 / 80	1 / 81	1.013	0.064	15.910	7.60
Hussamy, 2019	PREVENA	14 / 222	10 / 219	1.381	0.627	3.042	92.40
Pooled		15 / 302	11 / 300	1.349	0.631	2.882	
Prediction Interval							
Pooled		20 / 1374	16 / 1373	1.229	0.646	2.340	
Prediction Interval							



Publication bias

Publication bias was investigated using Egger's test. Moreover, graphical funnel plots were symmetry and showed no evidence of bias (Figure 2D).

Discussion

The results of the analysis indicate that the use of NPWT in obese women undergoing cesarean sections reduces the rate of SSIs. Based on the results of this study, NPWT did not demonstrate a significant positive effect in reducing overall wound complications, reoperation, and readmission. Biologically, the preventive efficacy of NPWT in reducing and preventing infections at the surgical site has been conclusively established. These findings align with the results of a meta-analysis of 11 RCTs conducted on 5746 obese women undergoing C-sections (15). Two meta-analyses in obese women undergoing C-sections, one based on 9 RCTs involving 5529 patients (26), and another including 8 RCTs with 1972 patients, also support these findings (24). In another meta-analysis covering 44 RCTs with 5693 patients undergoing primarily closed surgical wounds (without restrictions on sex and type of surgery), NPWT was found to reduce the SSIs rate by approximately 40% compared to standard dressings. This study also indicated a statistically significant reduction in the rates of wound dehiscence and wound seroma (38). In the present study, the average length of hospital stay, as reported in all studies providing this information, was 3 days, with no significant difference observed between the two groups. However, in another meta-analysis that used the single-use NPWT device PICO with negative pressure of -80 mmHg compared to standard dressings, the duration of hospitalization was reduced across all types of surgeries (orthopedic, abdominal, intestinal, or cesarean). This study suggests a potential reduction in socioeconomic consequences (39).

In the current study, when studies using the PREVENA device with pressures ranging from -125 to -200 mmHg (5 studies, involving 2411 patients) or PICO with pressures ranging from -50 to -80 mmHg (6 studies, involving 3407 patients) were grouped, a statistically significant difference among NPWT devices in

terms of RR for SSIs was observed (P= 0.05). PICO demonstrated greater effectiveness in reducing SSIs. In this regard, one study examined 11 RCTs involving 5,847 obese women undergoing cesarean sections (6 studies with a device set at -80 mm Hg pressure and 5 studies with a device set at -125 mm Hg pressure). A statistically significant improvement in the SSIs rate was observed with the device set at -80 mm Hg pressure (PICO) compared to a standard dressing, while this effect was not observed with the device set at -125 mm Hg pressure (PREVENA or iNPWT) (25). PICO has demonstrated superior effectiveness in reducing SSIs compared to the PREVENA device. PICO's standout portability enables patients to maintain daily activities during therapy, enhancing compliance with negative pressure therapy and ensuring completion of treatment, thereby reducing infection risks. Furthermore, the lower pressure applied by the PICO device enhances patient tolerance and efficacy, particularly in wounds with lower exudate levels such as cesarean sections, further reducing the likelihood of infection (17, 18).

In the present study, the use of NPWT, compared to standard dressing, in obese women undergoing C-section resulted in a significant decrease in superficial-SSIs and organ-SSIs rates. Additionally, the PICO device was more effective in reducing the superficial-SSIs rate than PREVENA. In another meta-analysis, prophylactic use of NPWT reduced the incidence of superficial infection in closed sections of abdominal surgery but had no effect on deep infection or organ space (40). Based on another meta-analysis of obese women undergoing C-section, the results showed that there was no difference in the outcomes of superficial-SSIs, deep-SSIs, wound dehiscence, hematoma, or seroma between obese women after cesarean section who received NPWT and those who used standard dressing (2). The findings of this study align with the WHO guidelines for the prevention of surgical site infection, published in 2018 and based on a systematic review of the literature, including observational data up to 2015. Considering the low quality of evidence, the WHO issued a conditional recommendation for the use of NPWT in high-risk adults with closed primary wounds. Due to the high cost of NPWT and the resulting limited access, it is not feasible to use it for all surgical wounds (19). The application of meta-analysis enhances precision and statistical power when assessing disparities between NPWT and standard treatment, surpassing the capabilities of individual RCTs. Nonetheless, existing meta-analyses are constrained by limited sample sizes, primarily stemming from the relatively low incidence of results. For NPWT to be established as more effective than standard dressings, a meta-analysis should demonstrate a 50% reduction in SSIs rate an outcome not yet achieved in any meta-analysis. The outcomes propose two potential scenarios: 1) NPWT might not yield a clinically significant reduction in SSI rates; or 2) NPWT may provide smaller risk reductions that elude detection in this analysis, with implications that may or may not hold clinical significance (41). Although all studies involved obese women undergoing C-section in the abdominal region, variations in underlying anatomical structures and baseline patient characteristics were present. Undoubtedly, differences in surgical techniques, types of incisions, and conditions of patients for abdominal wall reconstruction may limit the effectiveness and efficiency of selective care for wound closure (42). Various studies have also utilized different techniques for sealing NPWT. Additionally, the type of polyurethane foams used and the devices employed have varied, which could impact the effectiveness of the results.

Due to its relatively high cost, most studies on NPWT have been conducted in the USA. However, it is also popular in other countries, especially in Iran and Arab countries, but has not yet been scientifically reported. When performing NPWT, it should be noted that this treatment is prescribed by the attending physician and administered by a trained nurse. Informed consent must be obtained from the patient before the procedure, and the patient should be educated on the details of the procedure and psychologically prepared to accept and continue the treatment. In this study,

a greater number of randomized controlled trials (RCTs) have been included in the analysis, compared to previous research. These studies have been analyzed based on two main groups: adverse events and surgical site infections (SSIs). Additionally, the types of studies, both RCTs and cohort studies, as well as the quality of included studies and the type of devices used, have been examined. These evaluations assist physicians and nurses in making better decisions in selecting treatment methods using negative pressure. This comprehensive analysis clearly demonstrates the extent of new and effective information obtained and how it can improve medical decision-making.

Conclusion

Despite potential limitations, the current meta-analysis suggests a reduction in the SSIs rate in obese women undergoing C-section with the use of NPWT, regardless of the C-section type or device. Variations in underlying anatomical structures and patient characteristics undoubtedly influence the efficacy of surgical techniques, incision types, and conditions for abdominal wall reconstruction. The effectiveness of the selective care method for limited wound closure is also impacted. Moreover, differences in meta-analysis results can be attributed to selective reporting methods, industry financial support, potential reporter bias, diverse definitions of SSIs, and variations in wound complications and NPWT device types. Strengthening the evidence supporting NPWT use can be achieved by incorporating randomized studies with consistent definitions of surgical infection, duration of NPWT device use, follow-up time, and precise device types and pressures. To promote the widespread adoption of NPWT for preventing surgical infections, it is essential to conduct an economic comparison, considering factors such as antibiotics, readmission, reoperation, and length of hospital stay.

Acknowledgments

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Conflict of interest

The authors declare that they have no conflicts of interest.

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