Centre universitaire de santé McGill

McGill University Health Centre

Technology Assessment Unit (TAU) of the McGill University Health Centre (MUHC)

December 16, 2024

Negative Pressure Wound Therapy in Cesarean Section Patients with Obesity

Health Technology Assessment Report

Report no. 96

Report prepared for the Technology Assessment Unit (TAU) of the McGill University Health Centre (MUHC)

by

Eva Suarthana, MD, PhD, Thiphavone Oudanonh MSc and Nisha Almeida, PhD

Mission Statement

The MUHC Health Technology Assessment Unit (TAU) advises hospital administrators and clinical teams in difficult resource allocation decisions. Using an approach based on independent, critical evaluations of the available scientific evidence and a transparent, fair decision-making process, novel and existing medical equipment, drugs and procedures used by healthcare professionals are prioritized on a continuous basis ensuring the best care for life with the best use of resources.

TAU Policy Committee

Declaration of Conflicts of Interest

Members of TAU's research staff and policy committee declare no conflicts of interest.

Suggested citation

Suarthana E, Oudanonh T and Almeida N. The Negative Pressure Wound Therapy in Cesarean Section Patients with Obesity. Montreal (Canada): Technology Assessment Unit (TAU) of the McGill University Health Centre (MUHC); 2024 September 23. Report no. 96. 54 pages.

Report available from https://muhc.ca/tau

ACKNOWLEDGEMENTS

The expert assistance of the following individuals is gratefully acknowledged for providing background information:

- Loïca Ducheine, BScN, Nursing Advisor of the Products, Nursing Directorate of the MUHC
- Sophia Kapellas, RN, MSc(A), advanced practiced nurse in obstetrics, Women's Health Mission of the MUHC
- Jennifer Pepin, RN, BScN, Clinical administrative Coordinator, Women's Health Mission of the MUHC
- Dr. Fady Mansour, MD, FRCSC, Division Director for Obstetrics and Colposcopy Royal Victoria Hospital, MUHC

REPORT REQUESTOR

This report was requested by Loïca Ducheine, Nursing advisor in the Products Procurement division of the Nursing directorate of the MUHC. The final report will be shared with her and the clinical team within the obstetrics and gynaecology division of the MUHC.

TYPES OF RECOMMENDATIONS ISSUED BY THE TAU COMMITTEE

Type of recommendation	Explanation
Approved	• Evidence for relevant decision criteria, including efficacy, safety, and cost, as well as context-specific factors such as feasibility, is sufficiently strong to justify a recommendation that the technology be accepted, used and funded through the institutional operating budget
Approved for evaluation	• There is a reasonable *probability* that relevant decision criteria, including efficacy, safety, and cost, as well as context-specific factors such as feasibility, are favorable but the evidence is not yet sufficiently strong to support a recommendation for permanent and routine approval. • The evidence is sufficiently strong to recommend a *temporary* approval in a restricted population for the purposes of evaluation, funded through the institutional operating budget.
Not approved	• There is insufficient evidence for the relevant decision criteria, including efficacy, safety, and cost; • The costs of any use of the technology (e.g. for research purposes) should not normally be covered by the institutional budget.

DISCLAIMER

The Technology Assessment Unit ("TAU") of the McGill University Health Centre ("MUHC") was created in order to prepare accurate and trustworthy evidence to inform decision-making and when necessary to make policy recommendations based on this evidence. The objective of the TAU is to advise the hospitals in difficult resource allocation decisions, using an approach based on sound, scientific technology assessments and a transparent, fair decision-making process. Consistent with its role within a university health centre, it publishes its research when appropriate, and contributes to the training of personnel in the field of health technology assessment.

The information contained in this report may include, but is not limited to, existing public literature, studies, materials, and other information and documentation available to the MUHC at the time it was prepared, and it was guided by expert input and advice throughout its preparation. The information in this report should not be used as a substitute for professional medical advice, assessment and evaluation. While MUHC has taken care in the preparation of this report to ensure that its contents are accurate, complete, and up to-date, MUHC does not make any guarantee to that effect. MUHC is not responsible for any liability whatsoever, errors or omissions or injury, loss, or damage arising from or as a result of the use (or misuse) of any information contained in or implied by the information in this report.

We encourage our readers to seek and consult with qualified health care professionals for answers to their personal medical questions. Usage of any links or websites in the report does not imply recommendations or endorsements of products or services.

TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

LIST OF ABBREVIATIONS

BMI	Body mass index
CADTH	Canada's Drug and Health Technology Agency
CI	Confidence interval
ICER	Incremental cost-effectiveness ratio
I^2 statistic	The percentage of variation across studies in a meta-analysis that is due to heterogeneity rather than chance
LOS	Length of stay
MUHC	McGill University Health Center
NICE	National Institute for Health and Care Excellence
NPWT	Negative pressure wound therapy
OR	Odds ratio
POD	Post-operative day
RCT	Randomized clinical trial
RR	Relative risk
SOC	Standard of care
SSI	Surgical site infection
SSO	Surgical site outcomes
TAU	MUHC Technology Assessment Unit

ABSTRACT

- Negative pressure wound therapy (NPWT) is a wound healing technology that produces a negative pressure (a vacuum), premised on the hypothesis that a vacuum-sealed environment improves healing and reduces the risk of infection. There are two commonly available devices that differ by level of negative pressure: the Smith & Nephew PICO system (-80 mmHg) and the 3M™ Prevena system (–125 mmHg).
- There is interest in extending use of this technology to high-risk patients following caesarean sections, including at the McGill University Health Centre (MUHC). However, questions still remain on the clinical and economic impact of expanding use of the technology to this population.
- The objectives of this report were to evaluate the following in patients with a BMI >30 kg/m^2 who undergo cesarean section:
    1. the impact of NPWT compared to standard care on clinical outcomes including surgical site infections (SSI);
    2. the impact of NPWT compared to standard care on clinical outcomes in a subgroup of patients with a BMI >40 kg/m^2 who undergo cesarean section
    3. the impact of the level of negative pressure (-80 mmHg vs –125 mmHg) on clinical outcomes ;
    4. the budget impact of adopting NPWT in this population at the MUHC.
- Results from our meta-analysis:
    - **Objective 1**: Moderate quality evidence from 10 RCTs (417 events among 5,639 subjects) indicates that in patients with a BMI >30 kg/m^2 who undergo cesarean section, NPWT reduces composite surgical site infections (SSI), on average, by 20% compared to standard dressing (RR=0.79, 95% CI: 0.66, 0.95, I^2=0%). Low quality evidence indicates there is no benefit of NPWT on composite wound complications (RR=0.90, 95% CI: 0.73, 1.09), hospital readmission (RR=1.41, 95% CI: 0.88, 2.27), or reoperation (RR=1.23, 95% CI: 0.65, 2.34).
    - **Objective 2**: Low-quality evidence from 2 RCTs (33 events of 2,476 subjects) shows no benefit of NPWT on composite SSI among cesarean patients with BMI ≥ 40 kg/m^2 (RR=0.87, 95% CI: 0.54, 1.40)
    - **Objective 3**: We did not find any studies of direct head-to-head comparisons between the PICO and the Prevena devices. A statistical test of an indirect comparison of the two devices indicated no evidence one was superior to the other in reducing SSI.
    - **Objective 4**: The budget impact of using the PICO device at $200 per patient to treat 200 patients would be $40,000 per year, assuming the device price contributed to all the additional costs of the procedure.

- The rate of post-cesarean section SSI in the past five years at the MUHC ranged from 1.47% to 2.8%. Therefore, using the pooled estimate derived from our meta-analysis of a 20% SSI reduction using NPWT compared to the standard, we projected that 3 to 5 SSI cases could be prevented annually with the use of NPWT in cesarean patients at the MUHC.
- Given this very low rate of post-caesarean section SSI at the MUHC, and that there is no evidence of effectiveness of the device on more serious complications and readmissions, the opportunity for impact on clinical benefit and cost savings is minimal.

RÉSUMÉ

- La thérapie par pression négative (TPN) est une technologie de cicatrisation des plaies qui produit une pression négative (un vide), fondée sur l'hypothèse selon laquelle un environnement sous vide améliore la guérison et réduit le risque d'infection. Il existe deux appareils couramment disponibles qui diffèrent par le niveau de pression négative : le système PICO de Smith & Nephew (-80 mmHg) et le système Prevena de 3M^{TM} (–125 mmHg).

- L'élargissement de l'utilisation de cette technologie aux patientes à haut risque après une césarienne suscite de l'intérêt, notamment au Centre universitaire de santé McGill (CUSM). Cependant, des questions demeurent quant à l'impact clinique et économique de l'extension de l'utilisation de cette technologie à cette population.

- Les objectifs de ce rapport étaient d'évaluer les éléments suivants chez les patients ayant un IMC >30 kg/m^2 qui subissent une césarienne :

    1. l'impact de la TPN par rapport aux soins standards sur les indicateurs cliniques, y compris les infections au site chirurgical;
    2. l'impact de la TPN par rapport aux soins standards sur les indicateurs cliniques dans un sous-groupe de patients avec un IMC >40 kg/m^2 qui subissent une césarienne;
    3. l'impact du niveau de pression négative (-80 mmHg vs -125 mmHg) sur les indicateurs cliniques;
    4. l'impact budgétaire de l'adoption de la TPN dans cette population au CUSM.

- Résultats de notre méta-analyse :

    - **Objectif 1** : Des données probantes de qualité modérée provenant de 10 ECR (417 événements parmi 5639 sujets) indiquent que la TPN réduit le critère composite d'infections au site chirurgical, en moyenne, de 20% par rapport au pansement standard (RR=0,79, 95% IC: 0,66 - 0,95, I^2=0 %) chez les patientes ayant un IMC >30 kg/m^2 qui ont eu une césarienne. Des données probantes de faible qualité indiquent que la TPN n'apporte aucun bénéfice sur le critère composite de complications des plaies (RR=0,90, 95% IC: 0,73 - 1,09), la réadmission à l'hôpital (RR=1,41, 95% IC: 0,88 - 2,27) ou la réopération (RR=1,23, 95% IC: 0,65 - 2,34).

    - **Objectif 2** : Des données probantes de faible qualité provenant de 2 ECR (33 événements sur 2476 sujets) ne montrent aucun bénéfice de la TPN sur le critère composite d'infections au site chirurgical chez les patientes ayant subi une césarienne avec un IMC ≥ 40 kg/m^2 (RR=0,87, 95% IC: 0,54 - 1,40).

- **Objectif 3** : Nous n'avons trouvé aucune étude comparant directement les appareils PICO et Prevena. Un test statistique comparant indirectement les deux appareils n'a pas montré que l'un était supérieur à l'autre dans la réduction des infections au site chirurgical.
- **Objectif 4** : L'impact budgétaire de l'utilisation de l'appareil PICO à 200$ par patient pour traiter 200 patients serait de 40 000$ par année, en supposant que le prix de l'appareil contribuait à tous les coûts supplémentaires de la procédure.

- Au cours des cinq dernières années au CUSM, le taux d'infections au site chirurgical post-césarienne variait entre 1,47% et 2,8%. Par conséquent, en se basant sur l'estimation agrégée de notre méta-analyse de 20% réduction des infections au site chirurgical en utilisant la TPN par rapport aux soins standards, nous avons projeté que 3 à 5 cas d'infection au site chirurgical pourraient être évités chaque année grâce à l'utilisation de la TPN chez les patientes ayant subi une césarienne au CUSM.
- Compte tenu du très faible taux d'infections au site chirurgical post-césarienne au CUSM et du fait qu'il n'existe aucune preuve probante de l'efficacité de l'appareil sur les complications plus graves et les réadmissions, la possibilité d'impact sur les bénéfices cliniques et les économies de coûts est minime

EXECUTIVE SUMMARY

BACKGROUND

Negative pressure wound therapy (NPWT) is a wound healing technology that incorporates an airtight seal cover and a pump to produce negative pressure (a vacuum), thereby providing an environment for improved healing and a lower risk of infection. Based on the level of negative pressure, there are two commonly available devices: the PICO system (Smith & Nephew) that uses a pressure of -80 mmHg and the Prevena system (3M^{TM}) with a pressure of –125 mmHg.

There is interest in extending use of this technology to high-risk patients following caesarean sections, including at the McGill University Health Centre (MUHC). The Product Management team of the Nursing Directorate requested an evaluation by TAU to determine clinical benefit of the technology in this population.

Policy question

Should NPWT be used in patients with a BMI >30 kg/m^2 who undergo cesarean section at the MUHC?

Evaluation questions (Objective of this report)

The objectives of this report were to evaluate

1. the impact of NPWT compared to standard care on clinical outcomes in patients with a BMI >30 kg/m^2 who undergo cesarean section
2. the impact of NPWT compared to standard care on clinical outcomes in patients with a BMI >40 kg/m^2 who undergo cesarean section
3. whether there is a difference between the level of negative pressure (-80 mmHg vs –125 mmHg) on clinical outcomes in patients with a BMI >30 kg/m^2 who undergo cesarean section
4. the budget impact of adopting NPWT in patients with a BMI >30 kg/m^2 who undergo cesarean section at the MUHC

METHODS

We conducted a systematic review and meta-analysis on NPWT compared to standard dressing in pregnant patients with a BMI >30 kg/m^2 who undergo cesarean section by searching PubMed and ClinicalTrials.gov. The primary outcome was composite surgical site infection (SSI), while secondary outcomes included composite wound complications excluding SSI, hospital readmissions related to wounds, and reoperations. We estimated the burden of illness, the budget impact and incremental cost-effectiveness ratio using local SSI rates.

RESULTS

We identified ten relevant RCTs to be included in our meta-analysis.

Objective 1: What is the impact of NPWT vs. standard dressing on clinical outcomes in women with a BMI >30 kg/m2 who undergo cesarean section?

Surgical site infections (SSI):

- Our meta-analysis (10 RCTs; 417 events among 5,639 subjects) found that, when compared to standard dressing, NPWT reduces composite SSI by 20% on average (RR=0.79, 95% CI: 0.66, 0.95, I^2=0%).
- This evidence was of moderate quality, and was mainly impacted by lack of blinding in personnel and outcome assessors, which may have biased the results.

Composite wound complications:

- Pooled estimates from our meta-analysis (10 RCTs, 861 events of 5,590 subjects) found no evidence of benefit of NPWT on composite wound complications (RR=0.90, 95% CI: 0.73, 1.09).
- This evidence was of low quality due to lack of blinding in patients, personnel and outcome assessors.

Hospital readmission and reoperation:

- Pooled estimates (6 RCTs; 71 events of 4,442 subjects) found no evidence of benefit of NPWT on hospital readmission (RR=1.41, 95% CI: 0.88, 2.27) or reoperation (4 RCTs; 36 events of 2,747 subjects) (RR=1.23, 95% CI: 0.65, 2.34). The quality of evidence for both outcomes was low because of low number of events.

Patient-reported outcomes:

- Patient-reported outcomes were measured heterogeneously, precluding pooled analyses. Most studies reported comparable patient satisfaction, self-rated health status, pain score, wound concerns, and proportions of breastfeeding at discharge in the NPWT and standard care groups.
- There was no evaluation of patient compliance with using the device at home.

Objective 2: What is the impact of NPWT vs. standard dressing on clinical outcomes in women with a BMI >40 kg/m^2 who undergo cesarean section?

- Our meta-analysis (2 RCTs, 60 events of 551 subjects) found no evidence that NPWT reduces composite SSI in women with BMI>40 kg/m2 post-cesarean section (RR=0.87, 95% CI: 0.54, 1.40) when compared to standard dressing.
- This evidence was of low quality and mainly impacted by the low number of events in the included studies.

Objective 3: Is there a difference between the level of negative pressure (-80 mmHg vs –125 mmHg) on clinical outcomes in patients with a BMI >30 kg/m2 who undergo cesarean section?

- Pooled estimates from 5 studies (417 events of 3,228 subjects) found that the PICO device (–80 mmHg) reduced composite SSI by 28% (RR 0.72, 95% CI 0.58, 0.91, I2= 0%), compared to standard dressing. This result was driven by the largest study.
- In contrast, pooled results from 5 studies (141 events of 2,441 subjects) found that the Prevena device (–125 mmHg) was not associated with a reduction in composite SSI (RR 0.93 95%CI 0.68, 1.28, I^2=0%), compared to standard dressing.
- While there were no studies assessing direct head-to-head comparisons of PICO vs Prevena, a statistical test of an indirect comparison of PICO vs. Prevena indicated that the impact of PICO on SSIs was not significantly different from that of Prevena.
- The quality of this evidence was low and was impacted by the low number of events in the Prevena subgroup.
- We therefore cannot conclude that either device is superior to the other in terms of preventing SSIs in this population.

Objective 4: What is the budget impact of adopting NPWT in patients with a BMI >30 kg/m2 who undergo cesarean section at the MUHC?

- At the MUHC, the post-cesarean section SSI rate in the past five years ranged from 1.47% to 2.8%. Using the pooled estimate derived from our MA of a 20% SSI reduction using NPWT compared to the standard of care in cesarean section patients with BMI >30, we subsequently projected that 3 to 5 SSI cases could be prevented annually with the use of NPWT at the MUHC.
- The budget impact of using the PICO device at $200/patient would be $40,000 per year to treat 200 patients, assuming device price contributed to all the additional costs of the procedure.
- We calculated an incremental cost-effectiveness ratio (ICER) of $11,173, i.e. it would cost $11,173 to prevent one additional SSI case by using this device in this population.

CONCLUSIONS

- Moderate quality evidence indicates that NPWT reduces SSI in patients with BMI ≥30 kg/m^2 undergoing cesarean section. However, there was no evidence of benefit for other outcomes including composite wound complications, hospital readmissions and reoperation. Low quality evidence indicates PICO and Prevena were not statistically different in terms of their impact on SSI.
- The quality of the evidence was mainly impacted by the lack of blinding in personnel and outcome assessors, which may have biased the results.
- The rate of post-cesarean section SSI in the past five years at the MUHC ranged from 1.47% to 2.8%. Therefore, we projected that 3 to 5 SSI cases could be prevented annually with the use of NPWT in cesarean patients at the MUHC. The incremental cost effectiveness ratio (ICER) indicates that it would cost $11,173 to prevent one additional case of an SSI by using this device in this population.
- Given this very low rate of post-caesarean section SSI at the MUHC, and that there is no evidence of effectiveness of the device on more serious complications and readmissions, the opportunity for impact on clinical benefit and cost savings is minimal.

BEST PRACTICE RECOMMENDATIONS

Given that:

- The best available evidence does not show an impact of NPWT on readmission and reoperation rates,
- Our calculations estimate a small benefit (3 to 5 cases per year) in prevented surgical site infection cases,

We recommend that any pilot of this device ensure the prospective collection of the following variables:

- Number of patients who receive the device;
- Patient selection criteria (BMI, indication for caesarean section, surgical history, history of uncontrolled diabetes, preeclampsia, autoimmune/inflammatory disease, immunosuppression);
- Clinical outcomes (SSIs, complications, readmissions)
- Patient-reported outcomes including compliance with use; and
- Associated costs (training time, OR time, need for additional supplies).

SOMMAIRE

Contexte

Le traitement par la thérapie par pression négative (TPN) est une technologie de cicatrisation des plaies qui intègre un couvercle hermétique et une pompe pour produire une pression négative (un vide), offrant ainsi un environnement propice à une meilleure cicatrisation et un risque d'infection plus faible. Il existe deux appareils couramment disponibles selon le niveau de pression négative : le système PICO (Smith & Nephew) qui utilise une pression de -80 mmHg et le système Prevena (3M^{TM}) avec une pression de -125 mmHg.

Il existe un intérêt à étendre l'utilisation de cette technologie aux patientes à haut risque après une césarienne, y compris au Centre universitaire de santé McGill (CUSM). L'équipe de gestion des produits de la Direction des soins infirmiers a demandé à TAU de procéder à une évaluation afin de déterminer les avantages cliniques de la technologie dans cette population.

Question décisionnelle

Devrait-on utiliser la thérapie par pression négative (TPN) chez les patientes ayant un IMC >30 kg/m^2 qui subissent une césarienne au CUSM ?

Questions d'évaluation (Objectifs du rapport)

Les objectifs de ce rapport étaient d'évaluer

1. l'impact de la TPN par rapport aux soins standard sur les résultats cliniques chez les patientes ayant un IMC >30 kg/m^2 qui subissent une césarienne
2. l'impact de la TPN par rapport aux soins standard sur les résultats cliniques chez les patientes ayant un IMC >40 kg/m^2 qui subissent une césarienne
3. s'il existe une différence selon le niveau de pression négative (-80 mmHg vs -125 mmHg) sur les résultats cliniques chez les patientes ayant un IMC >30 kg/m^2 qui subissent une césarienne
4. l'impact budgétaire de l'adoption de la TPN chez les patientes ayant un IMC >30 kg/m^2 qui subissent une césarienne au CUSM

Méthodologie

Nous avons réalisé une revue systématique et méta-analyse sur la TPN comparé au pansement standard chez les patientes enceintes avec un IMC >30 kg/m^2 qui subissent une césarienne en effectuant une recherche sur PubMed et ClinicalTrials.gov. Le résultat principal était le critère composite d'infections du site chirurgical, tandis que les résultats

secondaires incluaient le critère composite de complications des plaies (excluant l'infections du site chirurgical), les réadmissions à l'hôpital liées aux plaies et les réopérations. Nous avons estimé le fardeau de la maladie, l'impact budgétaire et le rapport coût-efficacité différentiel en utilisant les taux locaux d'infections du site chirurgical.

Résultats

Nous avons identifié dix ECR pertinentes à inclure dans notre méta-analyse.

Objectif 1 : Quel est l'impact de la TPN par rapport au pansement standard sur les résultats cliniques chez les femmes ayant un IMC >30kg/m^2 qui subissent une césarienne ?

Infections du site chirurgical :

- Notre méta-analyse (10 ECR, 417 événements parmi 5 639 sujets) a révélé que, par rapport au pansement standard, la TPN réduit le critère composite d'infections du site chirurgical de 20% en moyenne (RR=0,79, 95% IC : 0,66 - 0,95, I^2=0%).
- Ces données probantes étaient de qualité moyenne et étaient principalement affectées par le fait que les études n'ont pas été réalisées à l'insu des évaluateurs des résultats, ce qui peut avoir biaisé les résultats.

Complications des plaies :

- Les estimations agrégées de notre méta-analyse (10 ECR, 861 événements sur 5 590 sujets) n'ont pas mis en évidence de bénéfice de la TPN sur le critère composite de complications des plaies (RR=0,90, 95% IC : 0,73 - 1,09).
- Ces données probantes étaient de faible qualité en raison de l'absence des conditions d'insu chez les patients, le personnel et les évaluateurs des résultats.

Réadmission à l'hôpital et réopération :

- Les estimations agrégées (6 ECR, 71 événements sur 4 442 sujets) n'ont pas mis en évidence de bénéfice de la TPN sur la réadmission à l'hôpital (RR=1,41, 95% IC: 0,88 - 2,27) ou la réopération (4 ECR, 36 événements sur 2 747 sujets) (RR=1,23, 95% IC: 0,65 - 2,34). La qualité des données probantes pour les deux résultats était faible en raison du nombre peu élevé d'événements.

Résultats rapportés par les patients :

- Les résultats rapportés par les patients ont été mesurés de manière hétérogène, ce qui a empêché de faire des analyses agrégées. La plupart des études ont rapporté des résultats comparables pour la satisfaction des patients, l'état de santé auto-évalué, le score de douleur, les préoccupations concernant les plaies et

les proportions d'allaitement à la sortie de l'hôpital dans les groupes de TPN et de soins standards.
- Aucune évaluation n'a été effectuée sur la conformité des patients à l'utilisation de l'appareil à domicile.

Objectif 2 : Quel est l'impact de la TPN par rapport au pansement standard sur les résultats cliniques chez les femmes ayant un IMC >40kg/m^2 qui subissent une césarienne ?

- Notre méta-analyse (2 ECR, 60 événements sur 551 sujets) n'a pas mise en évidence que la TPN réduise le critère composite des infections du site chirurgical chez les femmes avec un IMC >40 kg/m^2 après une césarienne (RR=0,87, 95% IC : 0,54 - 1,40) par rapport au pansement standard.
- Ces données probantes étaient de faible qualité et principalement affectées par le nombre peu élevé d'événements dans les études incluses.

Objectif 3 : Existe-t-il une différence selon le niveau de pression négative (-80 mmHg vs -125 mmHg) sur les résultats cliniques chez les patientes ayant un IMC >30kg/m^2 qui subissent une césarienne ?

- Des estimations agrégées de 5 études (417 événements sur 3 228 sujets) ont révélé que l'appareil PICO (-80 mmHg) réduit le critère composite des infections du site chirurgical de 28% (RR=0,72, 95% IC : 0,58 - 0,91, I^2=0%), par rapport au pansement standard. Ce résultat est influencé par la plus grande étude incluse.
- En contrepartie, les résultats agrégés de 5 études (141 événements sur 2 441 sujets) ont révélé que l'appareil Prevena (-125 mmHg) n'était pas associé à une réduction du critère composite des infections du site chirurgical (RR=0,93, 95% IC: 0,68 - 1,28, I^2=0%), par rapport au pansement standard.
- Bien qu'aucune étude n'ait évalué les comparaisons directes entre PICO et Prevena, un test statistique comparant indirectement PICO et Prevena a indiqué que l'impact de PICO sur les infections du site chirurgical n'était pas significativement différent de celui de Prevena.
- La qualité de ces données probantes était faible et a été affectée par le nombre peu élevé d'événements dans le sous-groupe Prevena.
- Nous ne pouvons donc pas conclure qu'un appareil est supérieur à l'autre en termes de prévention des infections du site chirurgical dans cette population.

Objectif 4 : Quel est l'impact budgétaire de l'adoption de la TPN chez les patientes ayant un IMC >30 kg/m^2 qui subissent une césarienne au CUSM ?

- Au CUSM, le taux d'infections du site chirurgical post-césarienne au cours des cinq dernières années variait entre 1,47% et 2,8%. En se basant sur l'estimation agrégée de notre méta-analyse de 20% réduction des infections du site chirurgical grâce à la TPN par rapport aux soins standards chez les patientes ayant subi une césarienne avec un IMC >30 kg/m^2, nous avons ensuite projeté que 3 à 5 cas d'infections du site chirurgical pourraient être évités chaque année grâce à l'utilisation de la TPN au CUSM.
- L'impact budgétaire de l'utilisation du dispositif PICO à 200 $/patient serait de 40 000 $ par année pour traiter 200 patients, en supposant que le prix de l'appareil contribue à tous les coûts supplémentaires de la procédure.
- Nous avons calculé un rapport coût-efficacité différentiel (ICER en anglais) de 11 173$, c'est-à-dire qu'il en coûterait 11 173 $ pour prévenir un cas supplémentaire d'infections du site chirurgical en utilisant cet appareil dans cette population.

Conclusions

- Des données probantes de qualité modérée indiquent que le traitement par la TPN réduit les infections du site chirurgical chez les patientes ayant un IMC ≥30 kg/m^2 subissant une césarienne. Cependant, il n'y a aucune évidence de bénéfice pour les autres indicateurs, y compris le critère composite de complications aux plaies, les réadmissions à l'hôpital et la réopération. Des données probantes de faible qualité indiquent que PICO et Prevena n'étaient pas statistiquement différents en termes d'impact sur les infections du site chirurgical.
- La qualité des données probantes a été principalement affectée par l'absence des conditions d'insu chez les personnels et les évaluateurs des résultats, ce qui peut avoir biaisé les résultats.
- En termes d'impact budgétaire, l'utilisation de l'appareil PICO à 200$/patient entraînerait un coût supplémentaire de 40 000$ par an pour traiter 200 patientes. Le rapport coût-efficacité différentiel (ICER en anglais) indique qu'il en coûterait 11 173$ pour prévenir un cas supplémentaire d'infections du site chirurgical en utilisant cet appareil dans cette population.
- Étant donné le très faible taux d'infection du site chirurgical (1,47% à 2,8%) après une césarienne au CUSM et l'absence de données probantes de l'efficacité de l'appareil sur les complications plus graves et les réadmissions, la possibilité d'impact sur les avantages cliniques et les économies de coûts est minime.

Recommendations

RECOMMANDATIONS DE MEILLEURES PRATIQUES

Étant donné que :

- Les meilleures données disponibles ne montrent pas d'impact du TPN sur les taux de réadmission et de réopération,
- Nos calculs estiment un faible bénéfice (3 à 5 cas par an) dans les cas d'infection du site chirurgical évités;

Nous recommandons que tout pilote de ce dispositif assure la collecte prospective des variables suivantes :

- Nombre de patients qui reçoivent le dispositif ;
- Critères de sélection des patients (IMC, indication de césarienne, antécédents chirurgicaux, antécédents de diabète non contrôlé, prééclampsie, maladie auto-immune/inflammatoire, immunosuppression) ;
- Résultats cliniques (infections, complications, réadmissions) ;
- Résultats rapportés par les patients, y compris l'observance de l'utilisation ; et
- Coûts associés (temps de formation, temps de bloc opératoire, besoin de fournitures supplémentaires).

Negative Pressure Wound Therapy in Cesarean Section Patients with Obesity

1. BACKGROUND

1.1 What is Negative Pressure Wound Therapy?

Negative pressure wound therapy (NPWT) is a wound healing technology using three components: a wound dressing, an airtight seal cover, and a pump to produce negative pressure. Reticulated open-pore polyurethane foam is used in modern NPWT to distribute equal negative pressure throughout the entire wound surface. In theory, NPWT can increase blood flow, granulation tissue, and flap survival, with decreased bacterial growth (1). It has been used for closed wounds since 2006 as an additional treatment to improve wound healing and prevent surgical site infections (SSI) and wound complications (1). Based on the level of negative pressure, there are two commonly available devices: the Smith & Nephew PICO system (-80 mmHg) and the 3M™ Prevena system (–125 mmHg).

The Society for Healthcare Epidemiology of America (SHEA), the Infectious Diseases Society of America (IDSA), and the Association for Professionals in Infection Control and Epidemiology (APIC) have recommended the use of negative pressure wound therapy as an additional approach to prevent surgical site infection (SSI) (2). To date, available evidence suggests that this strategy is most likely effective in specific procedures (e.g. abdominal procedures) and/or specific patients (e.g. increased body mass index) (2).

1.2 Context of the current report

The Obstetrics and Gynaecology Division of the McGill University Health Centre (MUHC) would like to adopt this technology for patients with obesity post-caesarean section. The Product Management team of the Nursing Directorate requested an evaluation by TAU to determine the clinical benefit of the technology in this population.

Recent systematic reviews addressing the use of NPWT in patients with obesity post-caesarean section have been heterogeneous: some included both RCTs and observational studies (lower quality of evidence); others combined various types of outcomes, while others combined different patient populations (3-9). We therefore decided to conduct our own systematic review and meta-analysis.

2. POLICY AND EVALUATION QUESTIONS

2.1 Policy Question

Should NPWT be used in patients with a BMI >30 kg/m^2 who undergo caesarean section at the MUHC?

2.2 Evaluation Questions (Objectives of this report)

The objectives of this report were to evaluate:

1. the impact of NPWT compared to standard care on clinical outcomes in patients with a BMI >30 kg/m^2 who undergo cesarean section;
2. the impact of NPWT compared to standard care on clinical outcomes in patients with a BMI >40 kg/m^2 who undergo cesarean section;
3. whether there is a difference between the level of negative pressure (-80 mmHg vs –125 mmHg) on clinical outcomes in patients with a BMI >30 kg/m^2 who undergo cesarean section;
4. the budget impact of adopting NPWT in patients with a BMI >30 kg/m^2 who undergo cesarean section at the MUHC.

3. METHODS

3.1 Literature Search and Meta-analysis

We searched PubMed and ClinicalTrials.gov using the following search terms: ("negative pressure wound therapy" OR "negative-pressure wound therapy" OR "negative pressure") AND (cesar* OR cesarean section* OR caesar*) from inception until February 15, 2024. We excluded non-English, non-human, and non full-text articles. We also manually searched relevant studies from the references.

3.1.1 PICO components

Our inclusion criteria for the population, intervention and outcomes targeted are shown below.

	Inclusion Criteria
Population	Pregnant patients with BMI >30 kg/m^2 undergoing cesarean sections
Intervention	NPWT, either using the -80 mmHg device (PICO) or -125 mmHg device (PREVENA)
Comparator	Standard of care (SOC) using standard dressing
Outcomes	Primary: composite surgical site infection (SSI), defined as the sum of number of superficial SSI, deep SSI and/or organ SSI, when available, or the overall SSI.
	Secondary: • composite wound complications excluding SSI, defined as the sum of number of complications such as seroma, hematoma, blisters, erythema, bleeding and/or dehiscence, when available; • hospital readmissions related to wound, defined as the number of wound-related hospital readmissions; • reoperations, defined as returned to surgery after caesarean section because of wound complications; • patient-reported outcomes (pain, satisfaction, and compliance)

3.1.2 Data extraction

Study selection and data extraction were done independently by 2 reviewers and any discrepancies were resolved by consensus. The following variables were collected:

- Study characteristics: first author, year of publication, study design, country, source of funding
- Patient characteristics: age, BMI and when it was measured, diabetes status, smoking status
- Surgery-related characteristics: antibiotics used during surgery, cesarean section type
- Total number of patients per group (NPWT, standard dressing)
- Duration of NPWT and standard dressing application

- Absolute number of events for the following outcomes: SSI (superficial, deep, organ), individual wound complications (such as seroma, hematoma, blister, erythema, bleeding, dehiscence), reoperation, hospital readmission related to wound complications, and patient-reported outcomes (pain, satisfaction, and compliance)

3.1.3 Assessment of Bias and Quality of Evidence

Risk of bias

Two reviewers independently assessed the risk of bias for the included studies using the Cochrane Risk of Bias Tool for Randomized Trials (RoB 1.0).(10)

The tool covers eight domains: the randomisation sequence, allocation concealment, blinding of the patients, personnel, and assessors, as well as selective reporting and other bias. Each domain was graded as high, moderate (some concerns or unclear) or low.

- We considered a high overall risk of bias when: (a) at least two domains had a high risk of bias, or (b) one domain had a high risk of bias and at least two other domains had a moderate risk of bias. A study is considered as having a low overall risk of bias when all domains have a low risk. Other situations will be considered as moderate risk of bias.
- For lack of blinding domains, the risk of bias is considered low for SSI if they inquired about the use of antibiotics in their definition (as this is a more objective measure), moderate if they used a standardized definition, and high if they did not use a standard definition. Similarly, for composite complications, the risk of bias due to lack of blinding is considered moderate if they used a specific objective indicator (eg. wound dehiscence >1 cm, required packing, etc); and high if they were patient-reported without a specific indicator. Despite the lack of blinding, the risk of readmission and reoperation outcomes were considered low risk of bias because they are hard outcomes. For incomplete data domains, studies that were terminated early were considered to have a high risk of bias.

Quality of the evidence

We rated the overall quality of evidence as high, moderate or low for each outcome using an in-house decision tree (Appendix A:):

- We incorporated the following dimensions to evaluate the evidence quality:
  i. Overall risk of bias of the included studies, as described above
  ii. Number of events (i.e. imprecise results)
  iii. Weak or inappropriate study design (e.g. no control group)
  iv. Inappropriate statistical tests
  v. Insufficient information provided on patient characteristics

- **Low quality evidence:** Quality of the evidence for outcomes that included studies with a high overall risk of bias was, by default, considered low quality of evidence. This indicates that our confidence in the overall effect estimate is limited.(11)
- **Moderate quality evidence**: Included studies with a low or moderate overall risk of bias could be downgraded and considered a lower quality of evidence if they (a) showed imprecision (ie. wide confidence intervals), (b) a small number of events, (c) weak study design (ie. no control group), (d) used inappropriate statistical tests, or (e) provided insufficient information on patients' characteristics. Moderate quality evidence suggests that we are moderately confident in the effect estimate; the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.(11)
- **High quality evidence:** When studies are not downgraded for any of the elements considered above and overall risk of bias is low, this would indicate an overall high quality of evidence and that we are very confident that the true effect lies close to that of the estimate of the effect.(11)

3.1.4 Data synthesis

Meta-analysis to combine effect estimates

- Pooled effect sizes of the included studies were estimated as risk ratios (RR) with their 95% confidence intervals (CI). A random-effects model (DerSimonian and Laird) was used since preliminary literature review showed that the populations, interventions and definition of outcomes was not sufficiently similar across the trials.
- Individual and pooled estimates with their 95% CI were presented in forest plots by outcome. The corresponding traffic light for the risk of bias assessment was added to these forest plots.
- We assessed the heterogeneity in the effect estimates and between-study by calculating I^2 and τ^2 statistics, as well as by inspecting the forest plots. The presence of substantial heterogeneity was defined as $I^2 > 50$ and possible sources of heterogeneity were investigated, when applicable.
- Sensitivity analyses were performed to assess the robustness of the results. Given that some RCTs were terminated before recruitment was completed, we tested their influence by excluding these studies. Sensitivity analysis was also done by excluding studies with the heaviest weight.
- P-values and confidence intervals were used to assess statistical significance. All analyses were performed with software R v4.3.3.

3.2 Burden of Illness at the MUHC

We estimated the burden of illness using the annual cesarean section rates and overall SSI rates post-cesarean section provided from the obstetrics and gynecology dashboard (personal communication, Sophia Kapellas, advanced practiced nurse in obstetrics of the Women's Health Mission of the MUHC).

3.3 Cost components

We corresponded with Loïca Ducheine, Nursing Advisor – Products, Nursing directorate of the MUHC, about the unit cost of the device to estimate the budget impact. The incremental cost-effectiveness ratio (ICER) was calculated as the ratio of the cost difference between using vs. not using NPWT and the difference in clinical effectiveness (measured as a reduction in SSI) of using NPWT.

4. RESULTS

4.1 Systematic Review and Meta-Analysis

We identified 124 studies from the databases and 3 from other sources (Figure 1). Ten relevant RCTs were included in our meta-analysis: Chaboyer (2014)(12), Gillespie (2021)(13), Gunatilake (2017)(14), Hussamy (2019)(15), Hyldig (2019)(16), Peterson (2021)(17), Ruhstaller (2017)(18), Tuuli (2017)(19), Tuuli (2020)(20), and Wihbey (2018)(21). The characteristics of the studies are displayed in Table 1.

4.1.1 Objective 1: What is the impact of NPWT vs. standard dressing on clinical outcomes in women with a BMI >30 kg/m2 who undergo cesarean section?

Surgical site infections (SSI):

- Pooled estimates from our meta-analysis (10 RCTs; 417 events of 5,639 subjects) found that, when compared to standard dressing, NPWT reduces composite SSI by 20% on average (RR=0.79, 95% CI: 0.66, 0.95, I^2=0%) (Figure 2).
- This evidence was of moderate quality and was mainly impacted by lack of blinding in personnel and outcome assessors, which may have biased the results (Table 2).
- A sensitivity analysis by excluding the terminated studies (Peterson 2021, Tuuli 2020, and Wihbey 2018) yielded similar results (RR=0.72, 95% CI: 0.58, 0.89) (Figure 3). Another sensitivity analysis by excluding the study with the largest

weight (Gillespie 2021) yielded an RR of 0.81 with a wider 95% CI 0.64 to 1.04 (Figure 4).

Composite wound complications:

- Pooled estimates from our meta-analysis (10 RCTs, 861 events of 5,590 subjects) found no evidence of benefit of NPWT on composite wound complications (RR=0.90, 95% CI: 0.73, 1.09) (Figure 5).
- This evidence was of low quality, because the overall risk of bias was high in six RCTs (due to lack of blinding in patients, personnel and outcome assessors), and/or incomplete outcomes caused by early termination of the trials (Table 2).

Hospital readmission and reoperation:

- Pooled estimates from 6 studies (71 events of 4,442 subjects) show that there was no evidence of benefit of NPWT on hospital readmission (RR=1.41, 95% CI: 0.88, 2.27) (Figure 8).
- Similarly, analysis from 4 studies (36 events 2,747 subjects) on reoperation showed no evidence of benefit of NPWT (RR=1.23, 95% CI: 0.65, 2.34) (Figure 11).
- Both outcomes had a moderate risk of bias, mostly due to incomplete outcome data caused by early termination of the trials. The quality of evidence for both outcomes was low because of a low number of events (Table 2).
- Sensitivity analyses by excluding the terminated studies and by excluding studies with the largest weight yielded similar results. (Figure 6, Figure 7, Figure 9, Figure 10, Figure 12 and Figure 13)

Patient-reported outcomes:

- For patient-reported outcomes, studies used different indices and tools and hence, we could not pool the estimates (Appendix B:). Gunatilake reported significantly lower incisional pain with pressure, while other studies showed comparable outcomes between the NPWT and SOC groups. Comparable patient satisfaction was reported by Hussamy and Tuuli; self-rated health status by Hyldig; pain score and wound concerns by Ruhstaller; and breastfeeding at discharge by Wihbey.
- Regarding patient compliance, in RCTs by Gunatilake, Hyldig, and Peterson, some patients kept NPWT after being discharged from the hospital on post-operative day (POD)-3 or 4 and were removed on POD6 or 7. However, there was no evaluation of patient compliance at home. Patience compliance and the difficulty of daily living activities while using NPWT at the hospital were evaluated by Chaboyer and Ruhstaller, respectively. Unfortunately, no results were reported. Nevertheless, Hussamy reported 10% of patients in the NPWT and 7% in the SOC groups reported dressing interfered with caring for infants (p=0.19). Only 6%

patients in the NPWT and 7% in the SOC groups reported dressing interfered with feeding the infants (p=0.6), which in turn would enhance compliance.

4.1.2 Objective 2: What is the impact of NPWT vs. standard dressing on clinical outcomes in women with a BMI >40 kg/m^2 who undergo cesarean section?

- Our meta-analysis (2 studies, 60 events of 551 subjects) showed that, when compared to standard dressing, there is no evidence that NPWT reduces composite SSI women with BMI>40 kg/m2 post cesarean section (RR=0.87, 95% CI: 0.54, 1.40) (Figure 14).
- This evidence was of low quality due to moderate risk of bias and low number of events (the pooled estimated included only 2 studies evaluating 2 different devices); therefore, our confidence in the effect estimate is limited (Table 2).

4.1.3 Objective 3: Is there a difference between the level of negative pressure (-80 mmHg vs –125 mmHg) on clinical outcomes in patients with a BMI >30 kg/m^2 who undergo cesarean section?

- In sub-group analysis by level of negative pressure, our meta-analysis (5 studies; 417 events of 3,228 subjects) found that, compared to standard dressing, the use of the PICO device (–80 mmHg) reduced composite SSI by 28% (RR 0.72, 95% CI 0.58, 0.91, I2= 0%) (Figure 15). This result was driven by the largest study; exclusion of this study resulted in a pooled estimate that was no longer statistically significant (Figure 16).
- In contrast, pooled estimates of 5 studies (141 events of 2,441 subjects) evaluating Prevena (–125 mmHg) demonstrated that, compared to standard dressing, the use of Prevena was not associated with a reduction in composite SSI (RR 0.93 95%CI 0.68, 1.28, I^2=0%) (Figure 15).
- While there were no studies assessing direct head-to-head comparisons of PICO vs. Prevena, a statistical test of an indirect comparison of the two devices indicated that the impact of PICO on SSIs was not significantly different from that of Prevena.
- Pooled estimates by type of NPWT device also indicated that NPWT did not reduce any of the secondary outcomes: composite wound complications (Figure 17), hospital readmission (Figure 18) or reoperation (Figure 19) when compared to standard dressing.
- The quality of this evidence was low and was impacted by the low number of events in the Prevena subgroup (Table 2).
- We therefore cannot conclude that either device is superior to the other in terms of preventing SSIs in this population.

4.1.4 Publication bias

The funnel plot of all studies assessing the risk of composite SSI is presented in Figure 20. The Egger's test for plot asymmetry yielded a p-value of 0.8737, confirmed no publication bias. Likewise, the funnel plot of all studies assessing the risk of composite wound complications showed no publication bias (confirmed by the Egger's test for plot asymmetry yielded a p-value of 0.3016) (Figure 21).

4.2 Published Guidelines

In 2018, the British Royal College of Obstetrics and Gynaecology (22) stated in their guidelines that "there is a lack of good-quality evidence to recommend the routine use of negative pressure dressing therapy, barrier retractors and insertion of subcutaneous drains to reduce the risk of wound infection in patients with obesity requiring caesarean sections". They did not cite any of the RCTs identified in our systematic review.

In 2019, the National Institute for Health and Care Excellence of the UK published their recommendation on the use of PICO negative pressure wound dressings for closed surgical incisions (23). They evaluated six types of surgery: orthopaedic, colorectal, obstetrics, plastic/breast, vascular, and cardiothoracic surgeries. Although they found PICO significantly reduced the SSI rates compared to standard dressing for all surgeries, sub-group analysis by types of surgery showed that the reduction was only significant in obstetric surgery (OR 0.48, 95% CI 0.30 to 0.76; p=0.002) and orthopaedic surgery (OR 0.45, 95% CI 0.22 to 0.91; p=0.03). For the evaluation of PICO use in cesarean section patients, they cited RCTs by Chaboyer, Gillespie, and Hyldig.

Finally, Canada's Drug and Health Technology Agency published a rapid response on NPWT use in cesarean sections (24). They did not do a meta-analysis or make any recommendations. They only identified five RCTs (Chaboyer, Gunatilake, Hyldig, Ruhstaller, and Wihbey), which concluded that compared to standard dressing, NPWT reduced SSI in cesarean section patients with obesity, although the findings were not significant.

4.3 Burden of illness and budget impact at the MUHC

4.3.1 Objective 4: What is the budget impact of adopting NPWT in patients with a BMI >30 kg/m^2 who undergo cesarean section at the MUHC?

- At the MUHC, the SSI rate post-cesarean section in the past five years ranged from 1.47% to 2.8% (Figure 22). Using the pooled estimate derived from our meta-analysis of a 20% reduction in SSI with the use of NPWT compared to standard care in cesarean

section patients with a BMI >30, we subsequently projected that 3 to 5 SSI cases could be prevented annually with the use of NPWT at the MUHC.

- In the US, there is a large price difference: $200 USD per PICO unit and $500 USD per Prevena unit (Tuuli 2017 (19)). The same price difference applies here in Quebec. The budget impact of using the PICO device at $200/patient would be $40,000 per year to treat 200 patients, assuming device price contributed to all the additional costs of the procedure.
- The incremental cost-effectiveness ratio (ICER), calculated as the ratio of the difference in cost ($200) to the difference in effectiveness of preventing SSIs (derived from the pooled estimates of the 10 RCTs as 1.79%) was $11,173, i.e. it would cost $11,173 to prevent one additional case of an SSI by using this device in this population (Table 3). Moreover, we would need to treat 56 women with NPWT to avoid one additional case of SSI in women with BMI>30.

4.4 Published cost-effectiveness analyses

NICE concluded that NPWT was cost-saving for highly invasive surgery with a higher incidence of SSI (such as colorectal, small bowel, gastric, cardiothoracic, and vascular surgeries) where a higher additional cost attributable to SSI balanced the NPWT device cost. For surgery in a relatively healthier population such as cesarean section and orthopedic surgery, PICO did not seem to be cost-saving (23).

CADTH's rapid response summarized three studies (Hyldig 2019, Heard 2017, and Tuffaha 2015) evaluating the cost of NPWT in cesarean section patients with obesity compared to standard dressing. Heard and Tuffaha concluded that NPWT was cost-effective, while Hyldig found no difference in cost and QALYs (24).

5. CONCLUSIONS

- Moderate quality evidence indicates that NPWT reduces SSI in patients with BMI ≥30 kg/m2 undergoing cesarean section. However, there was no evidence of benefit for other outcomes including composite wound complications, hospital readmissions and reoperation. Low quality evidence indicates PICO and Prevena were not statistically different in terms of their impact on SSI.

- The quality of the evidence was mainly impacted by the lack of blinding in personnel and outcome assessors, which may have biased the results. In terms of budget impact, the use of the PICO device at $200/patient would result in an additional $40,000 per year to treat 200 patients. The ICER indicates that it would

cost $11,173 to prevent one additional case of an SSI by using this device in this population.

- Given the very low rate of surgical site infection (1.47% to 2.8%) post-caesarean section at the MUHC, and that there is no evidence of effectiveness of the device on more serious complications and readmissions, the opportunity for impact on clinical benefit and cost savings is minimal.

6. BEST PRACTICE RECOMMENDATIONS

Given that:

- The obstetrics team at the MUHC has decided to procure the PICO device for use in an as yet undefined patient population;
- The best available evidence does not show an impact of NPWT on readmission and reoperation rates;
- Our calculations estimate a small benefit (3 to 5 cases per year) in prevented surgical site infection cases;

We recommend that prospective local data be collected to monitor:

- Number of patients who receive the device;
- Patient selection criteria (BMI, indication for caesarean section, surgical history, history of uncontrolled diabetes, preeclampsia, autoimmune/inflammatory disease, immunosuppression);
- Clinical outcomes (SSIs, complications, readmissions)
- Patient-reported outcomes including compliance with use; and
- Associated costs (training time, OR time, need for additional supplies)

FIGURE

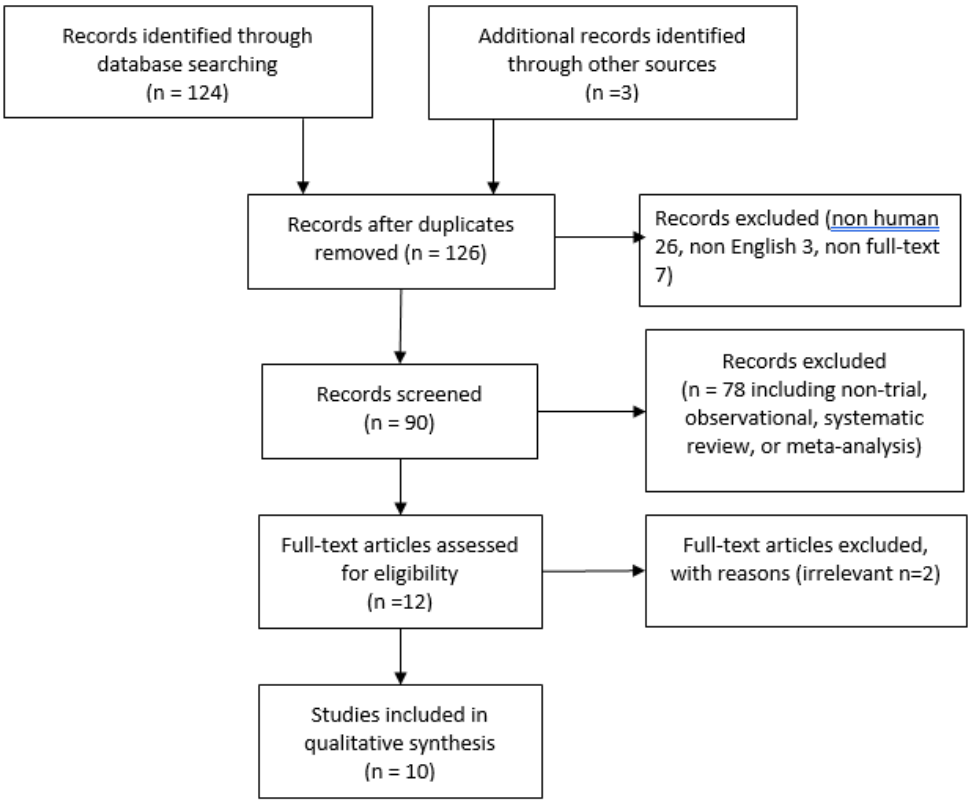


Figure 1. PRISMA flowchart of the literature

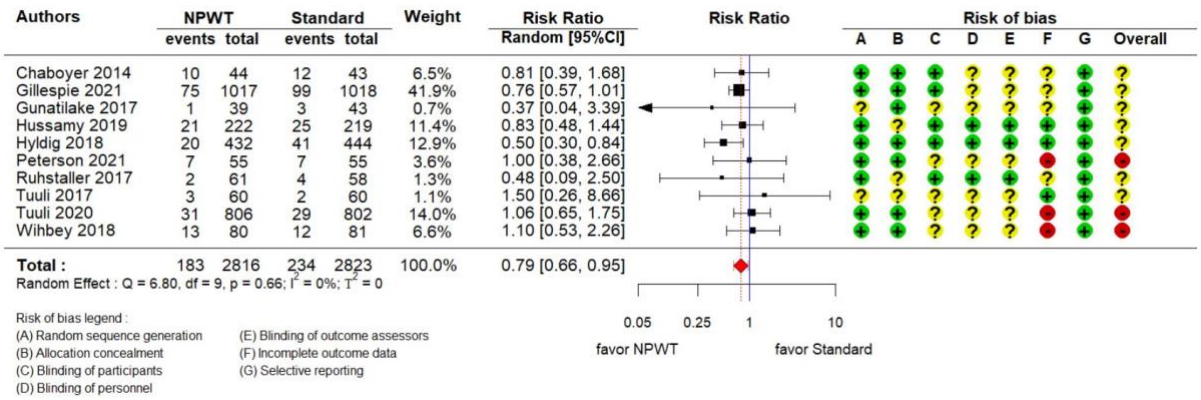


Figure 2. Forest plot of studies assessing the risk of composite SSI in patients with BMI ≥30 kg/m^2 after cesarean section using NPWT compared to standard dressing

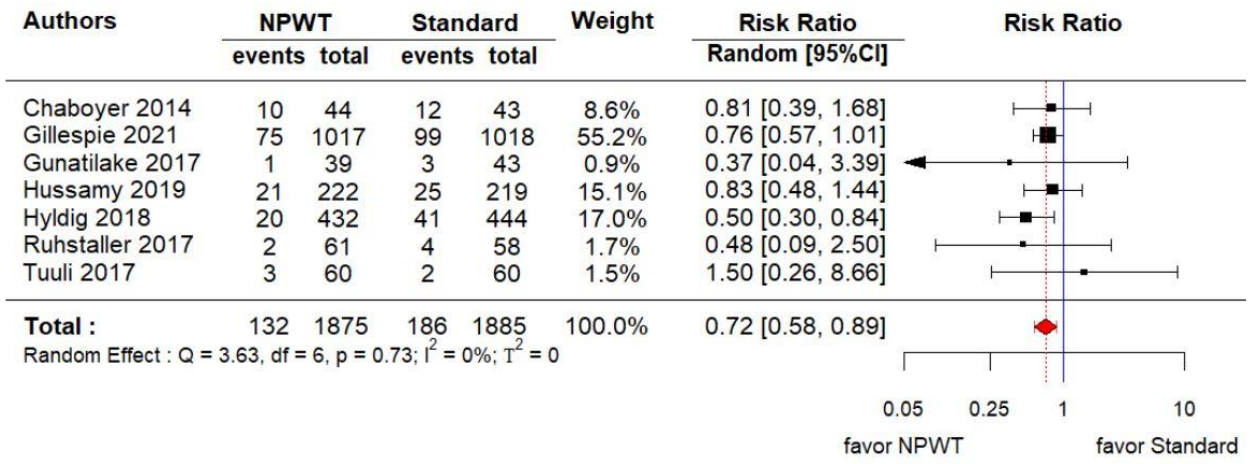


Figure 3. Forest plot of non-terminated studies assessing the risk of composite SSI in patients with BMI ≥30 kg/m^2 after cesarean section using NPWT compared to standard dressing

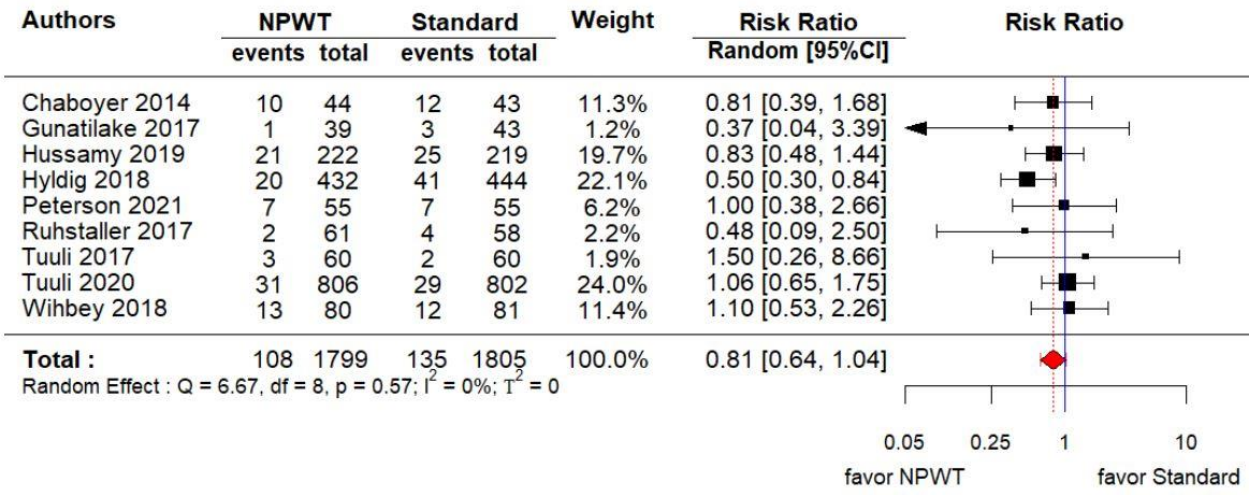


Figure 4. Forest plot of studies (excluding Gillespie) assessing the risk of composite SSI in patients with BMI ≥30 kg/m^2 after cesarean section using NPWT compared to standard dressing

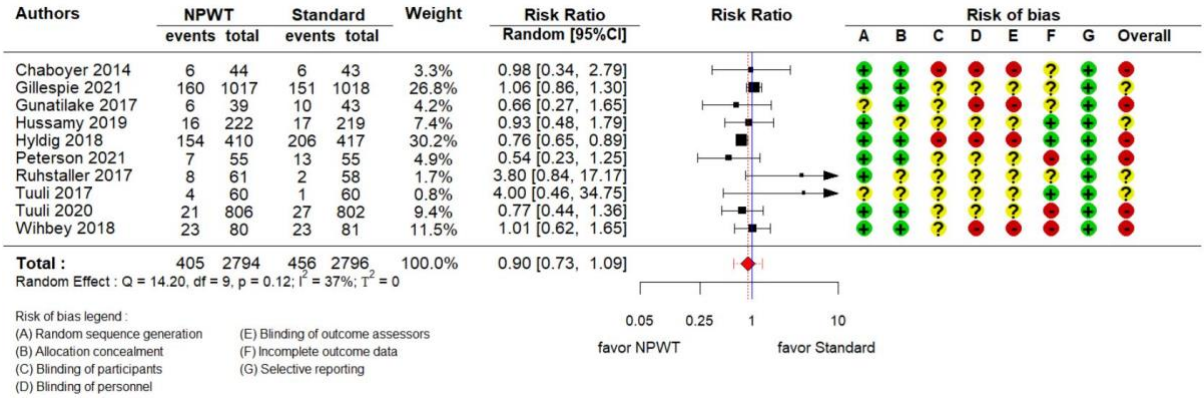


Figure 5. Forest plot of studies assessing the risk of composite wound complication in patients with BMI ≥30 kg/m^2 after cesarean section using NPWT compared to standard dressing

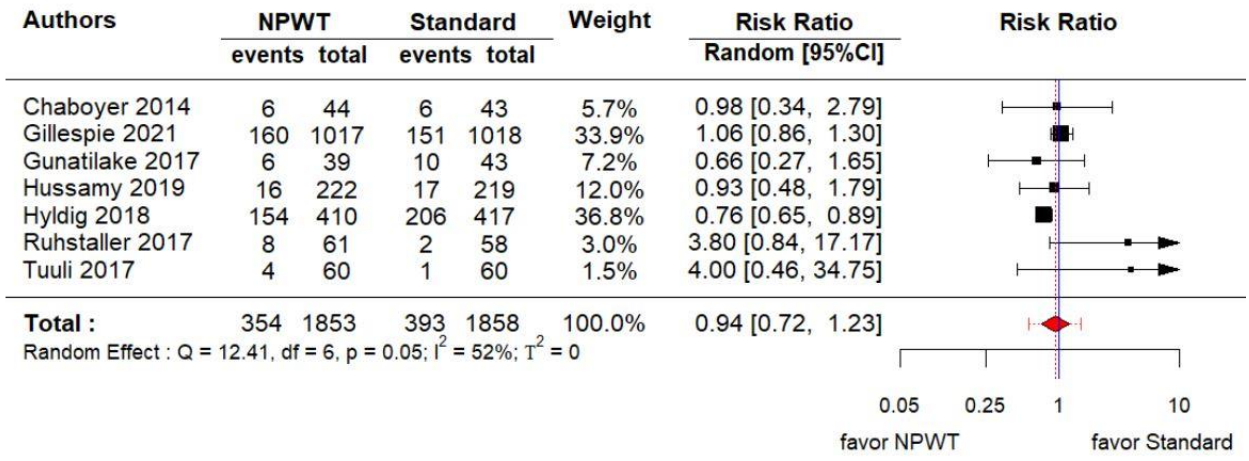


Figure 6. Forest plot of non-terminated studies assessing the risk of composite wound complication in patients with BMI ≥30 kg/m^2 after cesarean section using NPWT compared to standard dressing

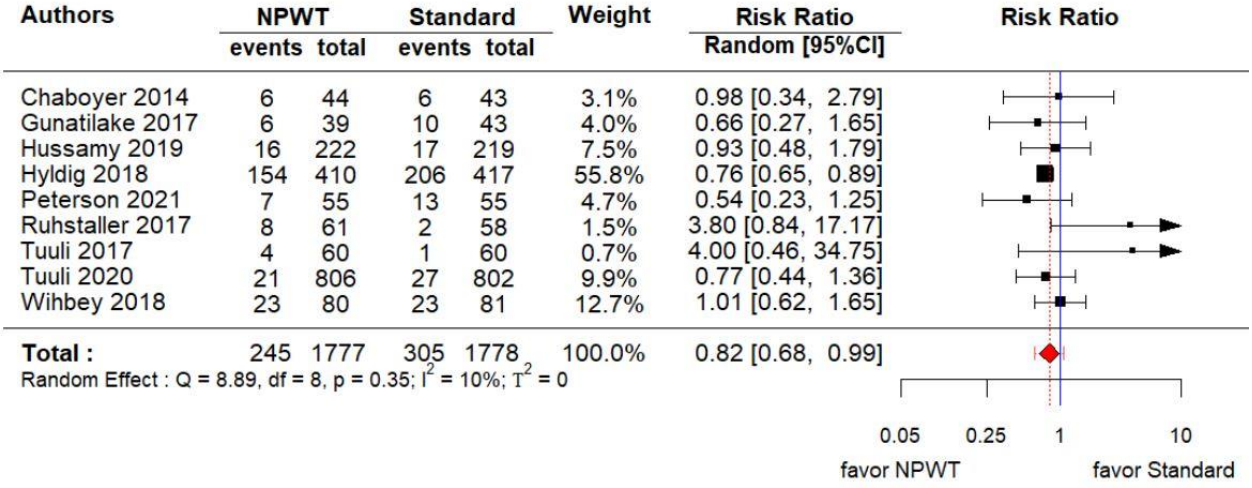


Figure 7. Forest plot of studies (excluding Gillespie) assessing the risk of composite wound complication in patients with BMI ≥30 kg/m^2 after cesarean section using NPWT compared to standard dressing

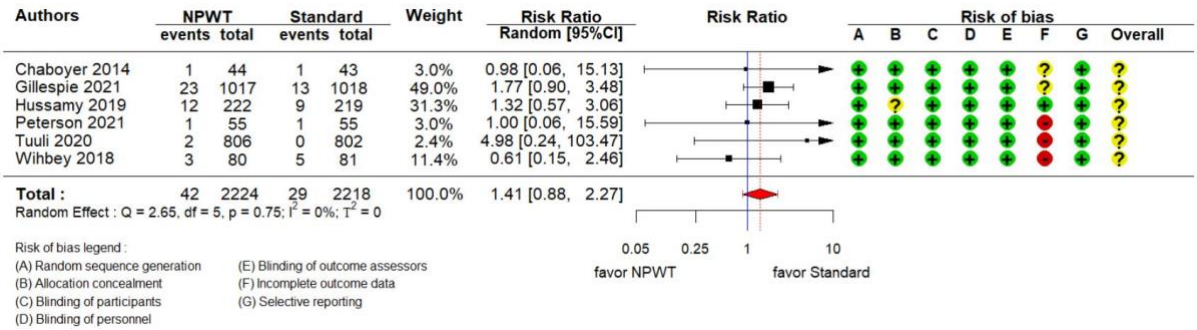


Figure 8. Forest plot of studies assessing the risk of hospital readmission in patients with BMI ≥30 kg/m^2 after cesarean section using NPWT compared to standard dressing

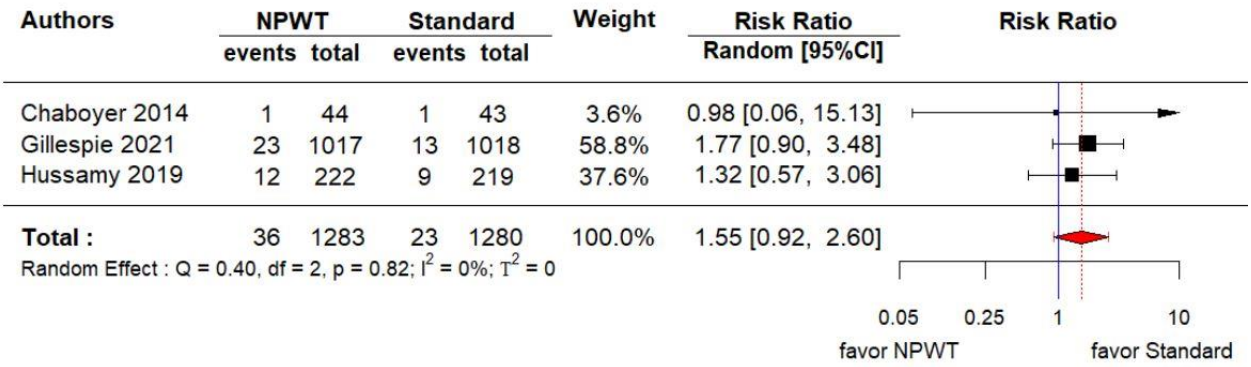


Figure 9. Forest plot of non-terminated studies assessing the risk of hospital readmission in patients with BMI ≥30 kg/m^2 after cesarean section using NPWT compared to standard dressing

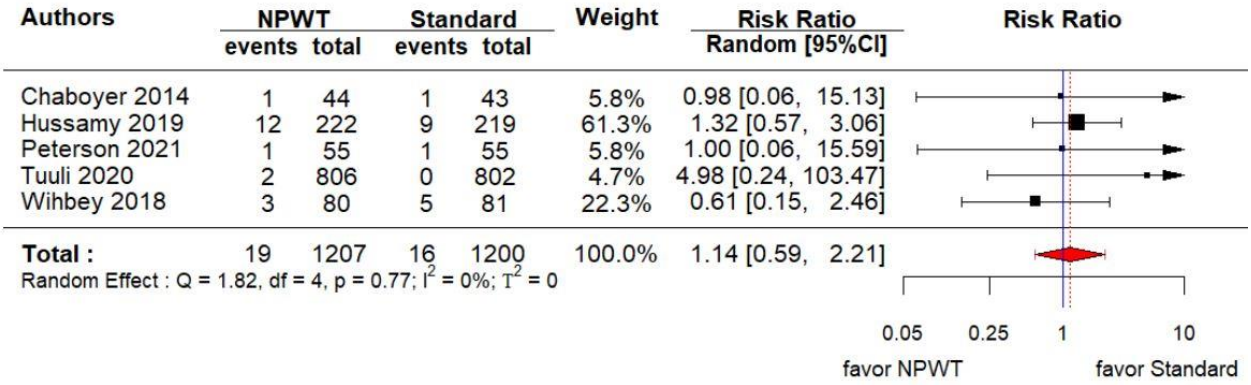


Figure 10. Forest plot of studies (excluding Gillespie) assessing the risk of hospital readmission in patients with BMI ≥30 kg/m^2 after cesarean section using NPWT compared to standard dressing

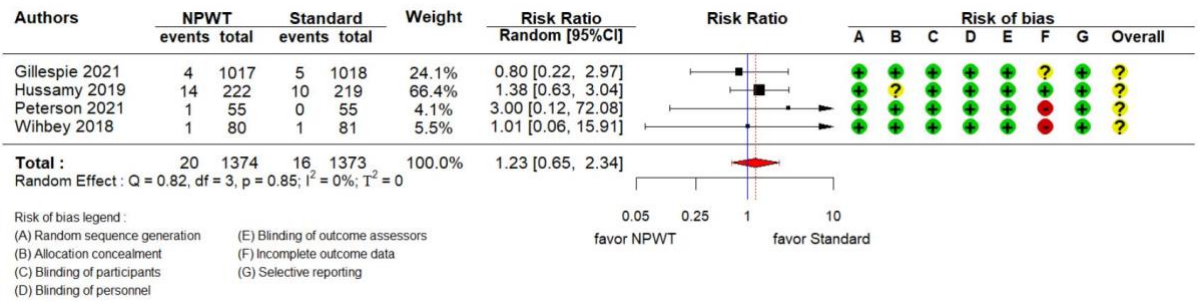


Figure 11. Forest plot of studies assessing the risk of reoperation in patients with BMI ≥30 kg/m^2 after cesarean section using NPWT compared to standard dressing

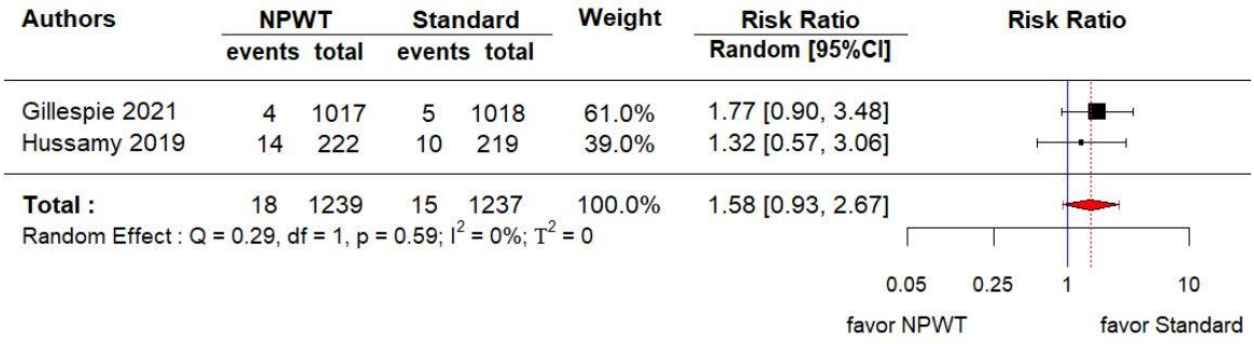


Figure 12. Forest plot of non-terminated studies assessing the risk of re-operation in patients with BMI ≥30 kg/m^2 after cesarean section using NPWT compared to standard dressing

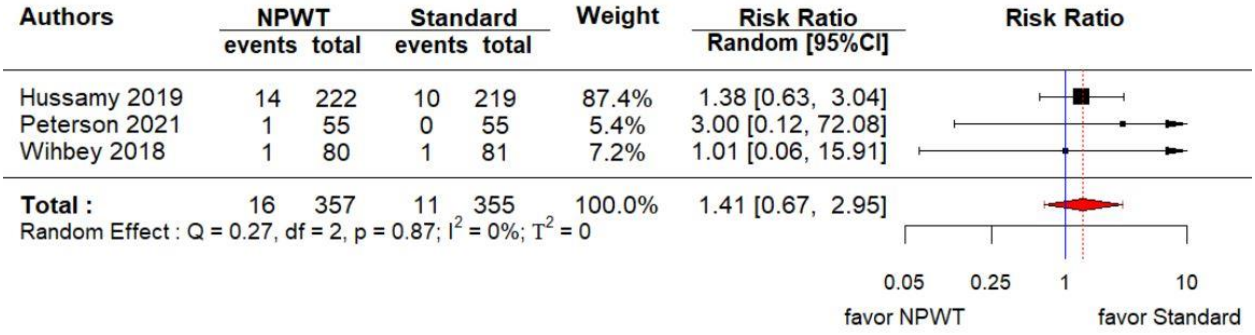


Figure 13. Forest plot of studies (excluding Gillespie) assessing the risk of reoperation in patients with BMI ≥30 kg/m^2 after cesarean section using NPWT compared to standard dressing

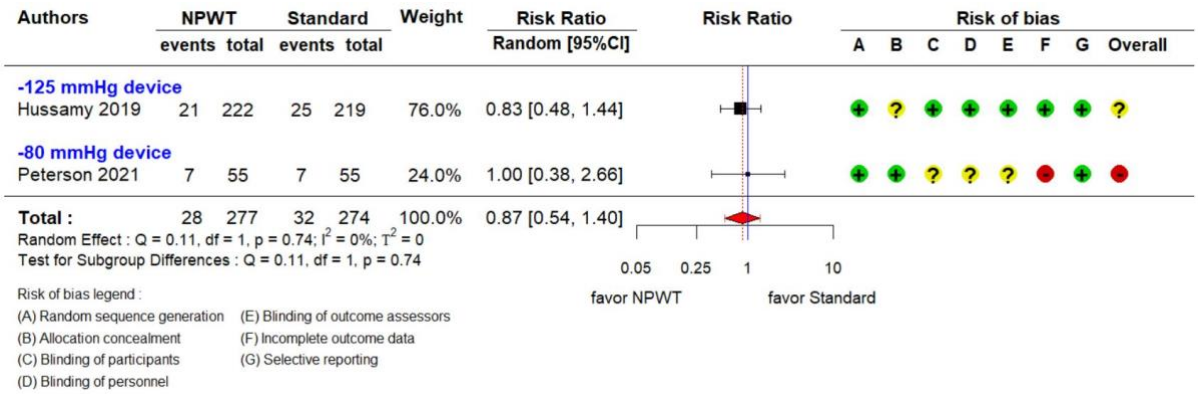


Figure 14. Forest plot of studies assessing the risk of SSI in patients with BMI ≥ 40 kg/m² by device type after cesarean section using NPWT compared to standard dressing

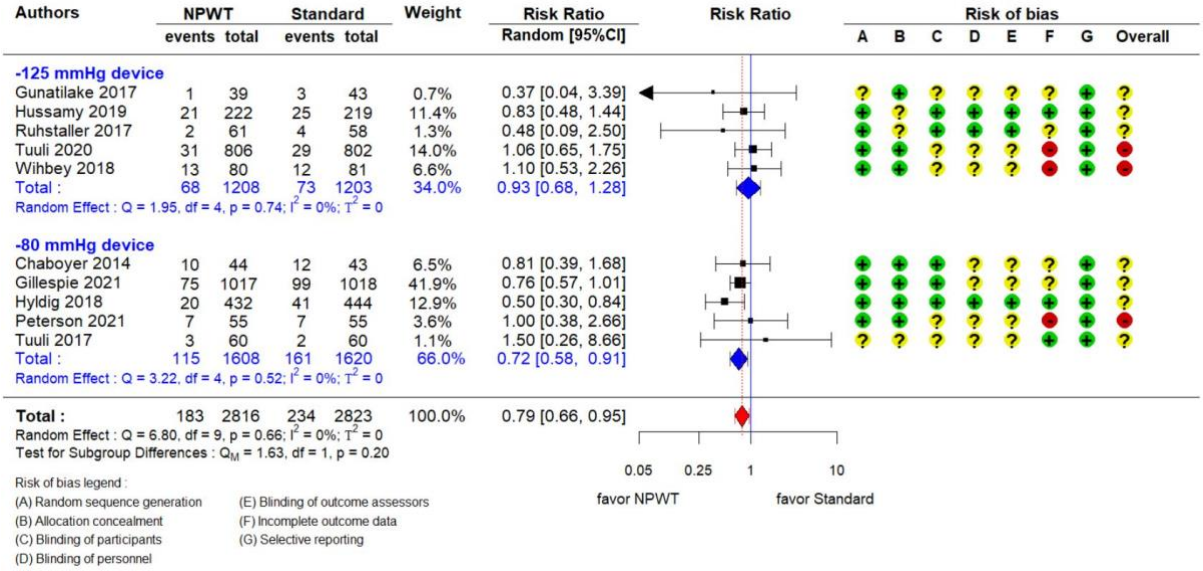


Figure 15. Forest plot of studies assessing the risk of composite SSI by type of NPWT devices in patients with BMI ≥30 kg/m² after cesarean section compared to standard dressing

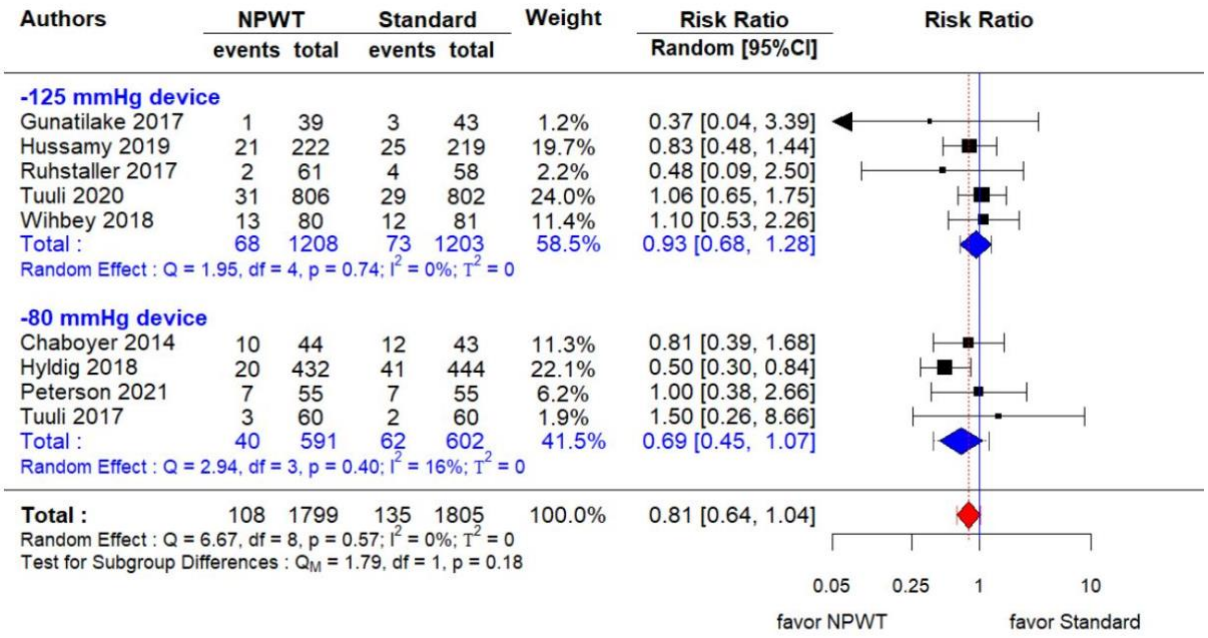


Figure 16. Forest plot of studies (excluding Gillespie) assessing the risk of composite SSI by type of NPWT devices in patients with BMI ≥30 kg/m² after cesarean section compared to standard dressing

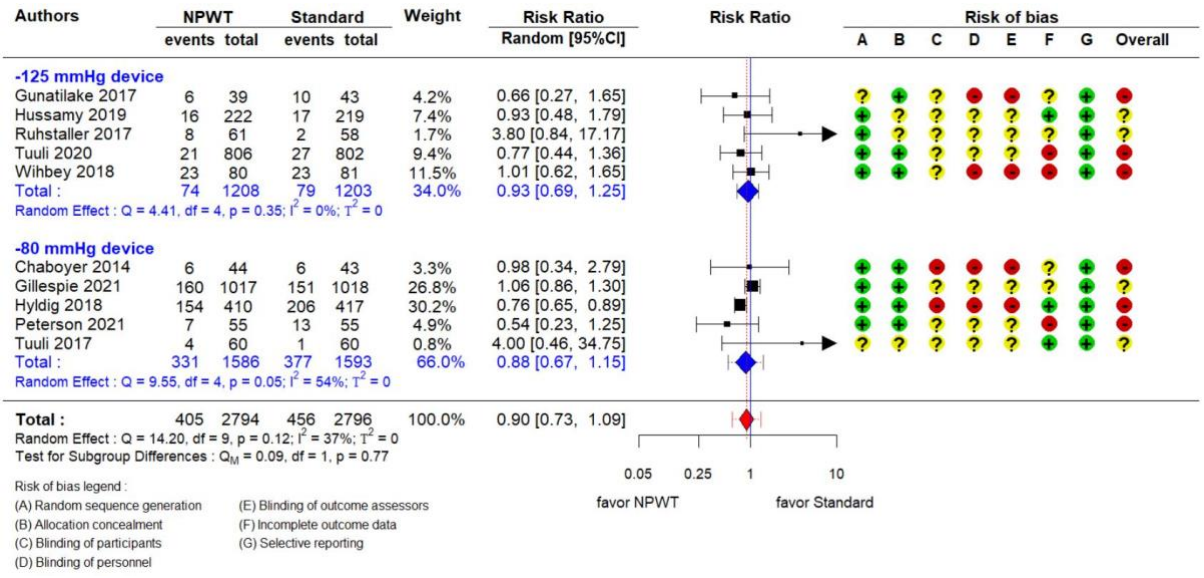


Figure 17. Forest plot of studies assessing the risk of composite wound complications by type of NPWT devices in patients with BMI ≥30 kg/m² after cesarean section compared to standard dressing

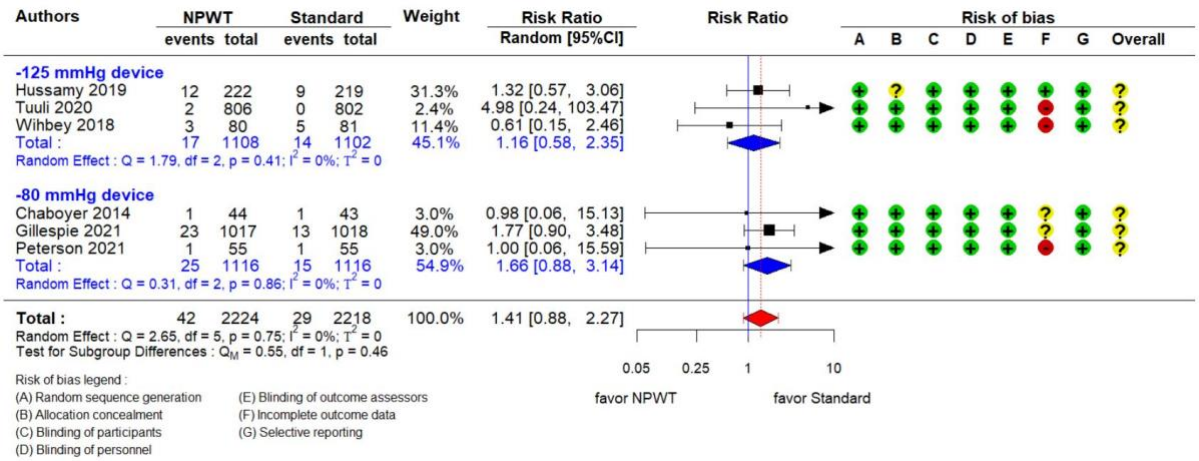


Figure 18. Forest plot of studies assessing the risk of hospital readmission by type of NPWT devices in patients with BMI ≥30 kg/m^2 after cesarean section compared to standard dressing

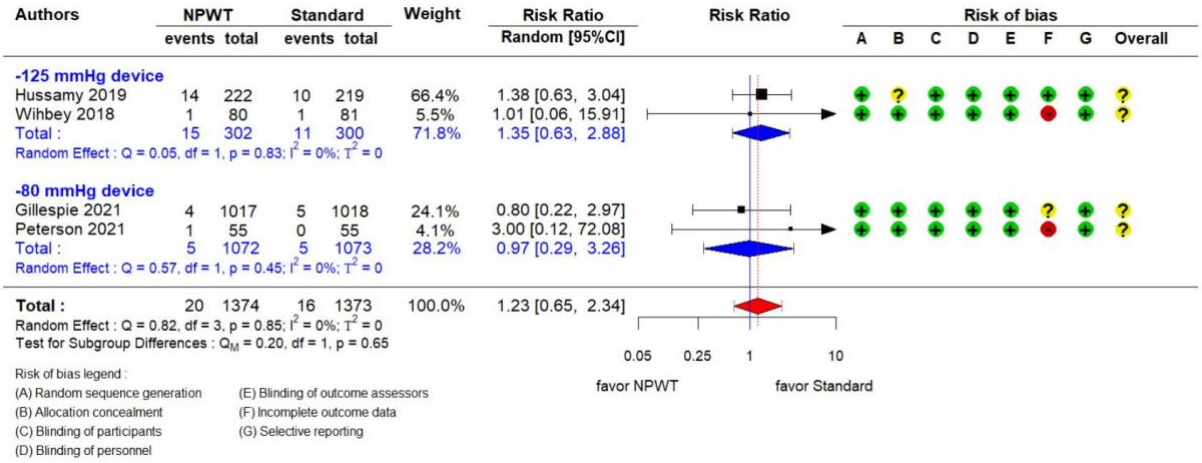


Figure 19. Forest plot of studies assessing the risk of reoperation by type of NPWT devices in patients with BMI ≥30 kg/m^2 after cesarean section compared to standard dressing

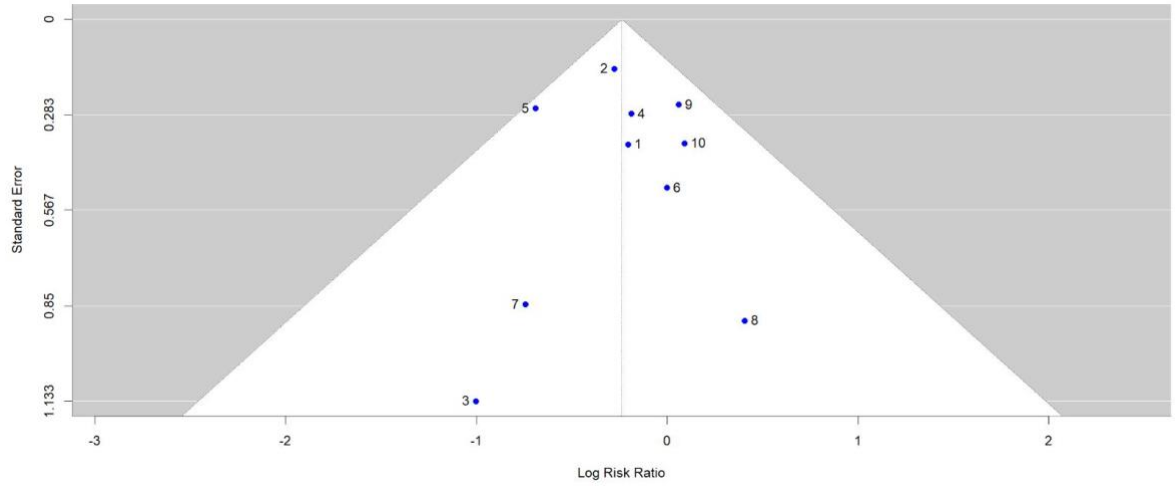


Figure 20. Funnel plot of studies assessing the risk of composite SSI in patients with BMI ≥30 kg/m^2 after cesarean section using NPWT compared to standard dressing. Egger's Test for plot asymmetry: p-value = 0.8737

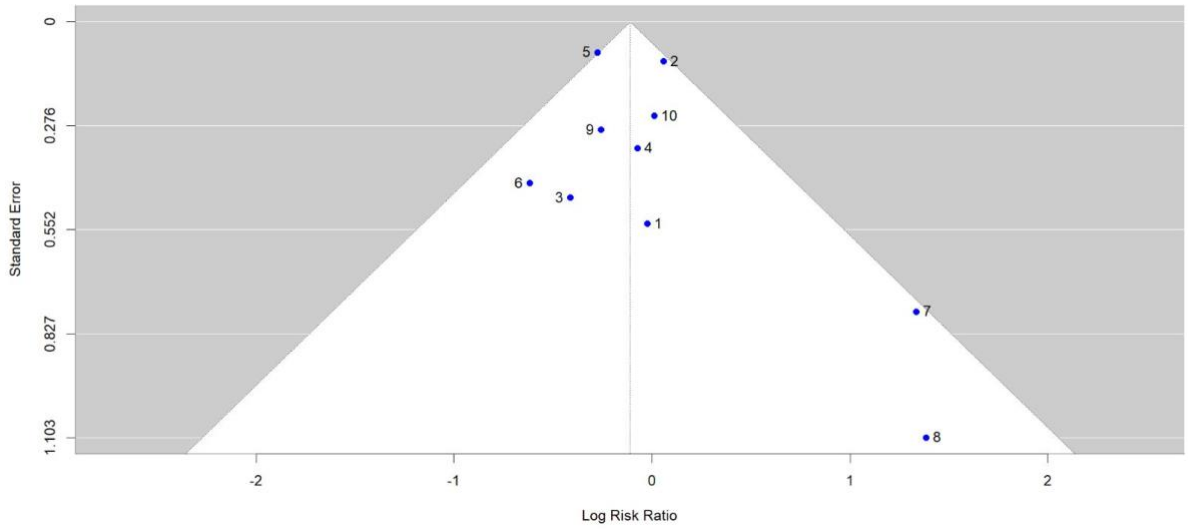


Figure 21. Funnel plot of studies assessing the risk of composite wound complications in patients with BMI ≥30 kg/m^2 after cesarean section using NPWT compared to standard dressing. Egger's Test for plot asymmetry: p-value = 0.3016

	Annual Cesarean section rates	Annual SSI rates post Cesarean section		SSI cases prevented with NPWT
	2022-23	2022-23	Upper range	
MUHC rates	33.6%	1.47%	2.8%	
Burden of illness	33.6%* 2831=951	1.47%*951 =**14**	2.8%*951 =**27**	20%*14=**3**

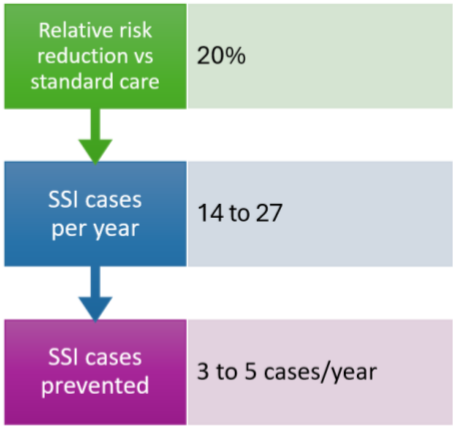


Figure 22. The burden of illness. The estimated SSI cases prevented with NPWT in cesarean patients at the MUHC

TABLES

Table 1 Characteristics of the RCTs

Author	Country	Centres	Funding	BMI	BMI when	Cesarean Section type	Antibiotics	Device	Duration	% lost to follow up	Risk factors/ potential confounders
Chaboyer 2014	Australia	Single university hospital	Academic	≥30	pre-pregnancy	Elective	unspecified	-80 mmHg PICO dressing (Smith & Nephew UK) vs. standard dressing (Comfeel Plus®)	Both NPWT and SOC were kept on for 4 days	5%	Diabetes was present in 29.5% NPWT and 26.9% of SOC
Gillespie 2021	Australia	Four large public hospitals	Government	≥30	pre-pregnancy	Elective, semi-urgent (not life-threatening)	majority	-80 mmHg PICO dressing (Smith & Nephew UK) vs. standard dressing	NPWT and SOC were left intact for five to seven days	# lost to follow-up or withdrew: 9 in NPWT and 19 in control	One-third of women (657; 32%) across the sample had either gestational diabetes or diabetes mellitus
Gunatilake 2017	USA	Single university hospital	Sponsored by manufacturer	≥35	delivery	Elective	all	-125 mmHg PREVENA dressing (Acelity) vs. standard dressing	NPWT was kept 5-7 days, SOC was kept 1-2 days. On average, patients were discharged on POD 3-4 and returned on POD6±1 day to remove the device	7 of 96 did not develop SSO before discontinued	Diabetes was present in 17% of the enrolled women in both groups
Hussamy 2019	USA	Single university hospital	Device provided by the manufacturer	≥40	pregnancy	Both	all	-125 mmHg PREVENA dressing (Acelity) vs. standard dressing	NPWT was kept until discharged, SOC were kept on for 1 day (POD1)	6 lost to follow up	Diabetes was present in 16% NPWT and 11% of SOC

Author	Country	Centres	Funding	BMI	BMI when	Cesarean Section type	Antibiotics	Device	Duration	% lost to follow up	Risk factors/ potential confounders
Hyldig 2018	Denmark	Three tertiary referal centers, two university hospitals	Academic, but device and operating grant from the manufacturer	≥30	pre-pregnancy	both, transverse abdominal	all	-80 mmHg PICO dressing (Smith & Nephew UK) vs. standard dressing	NPWT was kept up to POD5; SOCs were kept for at least 24 hours. On average, patients were discharged on POD 3. On POD6 nurse visited to remove the device	None? All extracted from the national database	Diabetes was present in 2.6% NPWT and 2.5% of SOC. Gestational diabetes was present in 15.1% NPWT and 15.5% of SOC
Peterson 2021	USA	Single university tertiary hospital	Academic	≥40	unspecified	both	all	- 80 mmHg PICO dressing (Smith & Nephew UK) vs. standard dressing	NPWT was changed once on POD3/4 by the discharging physicians and removed on POD7 by the patient at home; SOCs were kept on for 1 day (POD1)	Early termination at 45% enrolment because 2 large RCTs did not show the benefit of NPWT compared to SOC. Two lost to follow-up.	Diabetes was present in 16% NPWT and 11% of SOC. Gestational diabetes was present in 27% NPWT and 36% of SOC
Ruhstaller 2017	USA	Single university tertiary hospital	Academic, but device from the manufacturer	≥30	pregnancy	emergency	majority	-125 mmHg PREVENA dressing (Acelity) vs. standard dressing	NPWT was kept up to POD3, SOCs were kept on for 24 hours.	Lost to follow up 11/69 in NPWT and 6/67 in control	Diabetes was present in 8% NPWT and 7% of SOC
Tuuli 2017	USA	Single university hospital	Academic	≥30	delivery	elective	unspecified	-80 mmHg PICO dressing vs. standard dressing	NPWT was removed at discharge usually on POD4, SOC was removed after 24 hours	None	NA

Author	Country	Centres	Funding	BMI	BMI when	Cesarean Section type	Antibiotics	Device	Duration	% lost to follow up	Risk factors/ potential confounders
Tuuli 2020	USA	Four university hospitals	Government, but the manufacturer partially funded the study. Some key investigators received grants from the manufacturer	≥30	pre-pregnancy or early pregnancy	both	majority	-125 mmHg PREVENA dressing (Acelity) vs. standard dressing	NPWT was removed at discharge (usually on POD4) or kept up to POD7 for longer hospitalized patients; SOCs were removed after 24 hours	Of 1624 women randomized, 16 (1.0%) withdrew; 10 in NPWT and 6 in SOC group. No loss to follow up. Early termination at 50% of the planned sample size	Gestational diabetes was present in 11.9% NPWT and 12.3% of SOC
Wihbley 2018	USA	A rural tertiary care center and a community hospital	Devices provided by the manufacturer	≥35	At delivery	Both	majority	-125 mmHg PREVENA dressing (Acelity) vs. standard dressing	NPWT was kept up to POD5-7, SOC was kept until POD2	Lost to follow up 5/86 in SOC, baseline characteristics were unbalanced. Early termination due to low enrolment	Gestational diabetes was present in 15% NPWT and 25% of SOC

NPWT: negative pressure wound therapy, POD: post-operative day, SOC: standard of care

Table 2. Quality of Evidence Assessment

№ of studies	Certainty assessment						Effect			Quality of Evidence
	Study design	Risk of bias	Imprecision	Number of events	Statistical tests used	Information on patients' characteristics	№ of events	№ of individuals	Rate (95% CI)	
Outcome: NPWT impact on SSI in patients with BMI>30										
10	RCTs, no downgrading	Moderate	No downgrading	No downgrading	No downgrading	No downgrading	417	5,639	RR=0.79, 95% CI: 0.66, 0.95	Moderate
Outcome: NPWT impact on composite wounds in patients with BMI>30										
10	RCTs, no downgrading	High	No downgrading	No downgrading	No downgrading	No downgrading	861	5,590	RR=0.90, 95% CI: 0.73, 1.09	Low
Outcome: NPWT impact on readmission in patients with BMI>30										
6	RCTs, no downgrading	Moderate	Wide confidence interval	Low number of events	No downgrading	No downgrading	71	4,442	RR 1.41, 95% CI: 0.88, 2.27	Low
Outcome: NPWT impact on reoperation in patients with BMI>30										
4	RCTs, no downgrading	Moderate	Wide confidence interval	Low number of events	No downgrading	No downgrading	36	2,747	RR=1.23, 95% CI: 0.65, 2.34	Low
Outcome: NPWT impact on SSI in patients with BMI>30 by types of devices										
10	RCTs, no downgrading	Moderate	Wide confidence interval	Low number of events	No downgrading	No downgrading	PICO: 417 Prevena: 141	3,228 2,411	RR 0.72, 95% CI 0.58, 0.91 RR 0.93 95% CI 0.68, 1.28	Low
Outcome: NPWT impact on SSI in patients with BMI>40										
2	RCTs, no downgrading	Moderate	Wide confidence interval	Low number of events	No downgrading	No downgrading	60	551	RR 0.87, 95% CI: 0.54, 1.40	Low

Table 3. Incremental case effectiveness ratio and the number needed to treat

	Additional cost per patient[1]	SSI rate[2]	Δ Efficacy[3] (SSI risk difference)	ICER[4]	NNT[5]
Without NPWT		8.29%			
With NPWT	$200	6.50%	0.0179	$11,173	56

[1] Delta cost = difference in cost between the 2 procedures (assuming the device prices contributes to all the additional cost)

[2] The SSI rates were derived from the pooled estimates of the 10 RCTs included in our meta-analysis.

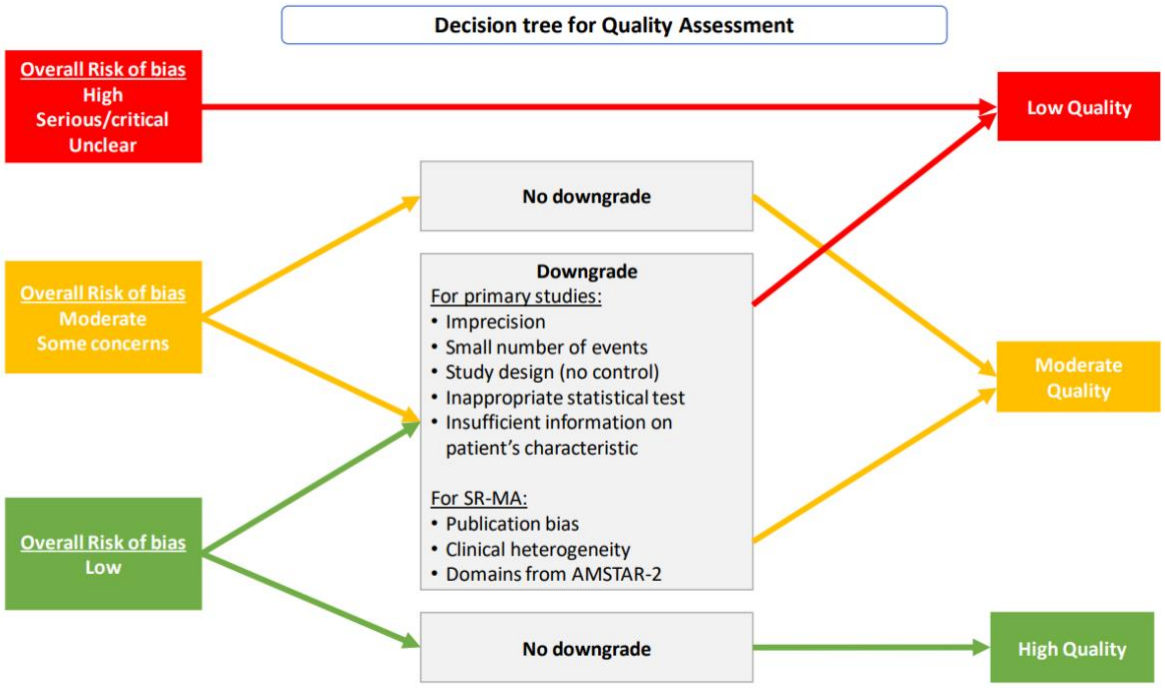
[3]Delta efficacy = risk difference between the 2 procedures.

[4]Incremental case effectiveness ratio (ICER)= delta cost / delta efficacy = (NPWT cost- Standard of care cost)/ SSI rate difference = 200/0.0179= $11,173

[5]Number needed to treat (NNT)=1/0.0179=56

APPENDICES

APPENDIX A: QUALITY ASSESSMENT ALGORITHM



APPENDIX B: PATIENT REPORTED OUTCOMES

Author	Patient Reported Outcomes (pain, satisfaction, compliance measures)	NPWT group	SOC group	P-value
Chaboyer 2014	Daily assessment of protocol compliance	No result		
Gillespie 2021	Research nurses evaluated patients' satisfaction with the NPWT dressing on POD2	No result		
Gunatilake 2017	Incisional pain with pressure using the Wong-Baker Faces Scale (% reported a value of >2 or any pain) days 1-7	37%	85%	p<0.001
Hussamy 2019	A brief patient satisfaction survey about wound healing (% satisfied)	89%	92%	n/a
	Reported "Dressing interfered with feeding OR caring infant".	10%	7%	p=0.19
	Reported "Dressing interfered with feeding for infants"	6%	7%	p=0.6
Hyldig 2018	The overall self-rated health status measured with EQ-VAS (better indicated by higher values) (mean, 95% CI)	83 (82-85)	82 (80-83)	p=0.25
Ruhstaller 2017	Sharp pain score (0-10) on POD2 (median, interquartile range)	6 (4-8)	5.5 (3-8)	p=0.56
	Telephone survey on wound concerns at week 2	22%	20%	p=0.99
	Evaluation of difficulty with of daily living activities on POD2 (0 for "no difficulty" and 4 for "so much difficulty I could not do it"	No result		
Tuuli 2020	Patient satisfaction scores (0 for least satisfied to 10 for most satisfied) at discharge (median (interquartile range [IQR])	10 (8-10)	9 (7-10)	0.8 (0.3-1.3) p<0.001
	Patient satisfaction scores postoperative day 30 score (median (interquartile range [IQR])	10 (9-10)	10 (8-10)	0.2 (-0.01-0.4), p=0.07
Wihbey 2018	Breastfeeding at discharge	65%	73%	p=0.31

NPWT: negative pressure wound therapy, POD: post-operative day, SOC: standard of care

REFERENCES

1. Joshi C, Hsieh J, Hassan A, Galiano R. Application of Negative Pressure Wound Therapy on Closed Incisions. In: Ahmad M, editor. Wound Healing: IntechOpen; 2020.

2. Calderwood MS, Anderson DJ, Bratzler DW, Dellinger EP, Garcia-Houchins S, Maragakis LL, et al. Strategies to prevent surgical site infections in acute-care hospitals: 2022 Update. Infect Control Hosp Epidemiol. 2023;44(5):695-720.

3. Angarita AM, Jayakumaran J, Di Mascio D, Berghella V. Prophylactic negative pressure wound therapy on wound complications after cesarean delivery in women with obesity: a meta-analysis of randomized controlled trials. Am J Obstet Gynecol MFM. 2022;4(3):100617.

4. Goldman T, Costa B. A Systematic Review and Meta-analysis of Two Negative Pressure Wound Therapy Devices to Manage Cesarean Section Incisions. Am J Perinatol. 2023.

5. Groenen H, Jalalzadeh H, Buis DR, Dreissen YEM, Goosen JHM, Griekspoor M, et al. Incisional negative pressure wound therapy for the prevention of surgical site infection: an up-to-date meta-analysis and trial sequential analysis. EClinicalMedicine. 2023; 62:102105.

6. Guo C, Cheng T, Li J. Prophylactic negative pressure wound therapy on surgical site infection in obese women after cesarean section: A systematic review and meta-analysis. Int J Gynaecol Obstet. 2022;158(3):502-11.

7. Smid MC, Dotters-Katz SK, Grace M, Wright ST, Villers MS, Hardy-Fairbanks A, et al. Prophylactic Negative Pressure Wound Therapy for Obese Women After Cesarean Delivery: A Systematic Review and Meta-analysis. Obstet Gynecol. 2017;130(5):969-78.

8. Tian Y, Li K, Zeng L. A systematic review with meta-analysis on prophylactic negative pressure wound therapy versus standard dressing for obese women after caesarean section. Nurs Open. 2023;10(9):5999-6013.

9. Yu L, Kronen RJ, Simon LE, Stoll CRT, Colditz GA, Tuuli MG. Prophylactic negative-pressure wound therapy after cesarean is associated with reduced risk of surgical site infection: a systematic review and meta-analysis. Am J Obstet Gynecol. 2018;218(2):200-10.e1.

10. Higgins JP, Altman DG, Gotzsche PC, Juni P, Moher D, Oxman AD, et al. The Cochrane Collaboration's tool for assessing risk of bias in randomised trials. BMJ. 2011;343:d5928.

11. Schünemann HJ, Higgins JP, Vist GE, Glasziou P, Akl EA, Skoetz N, et al. Completing 'Summary of findings' tables and grading the certainty of the evidence. In: Higgins JP, Thomas J, Chandler J, Cumpston M, Li T, Page MJ, et al., editors. Cochrane Handbook for Systematic Reviews of Interventions. Version 6.2 (updated February 2021): Cochrane; 2021.

12. Chaboyer W, Anderson V, Webster J, Sneddon A, Thalib L, Gillespie BM. Negative Pressure Wound Therapy on Surgical Site Infections in Women Undergoing Elective Caesarean Sections: A Pilot RCT. Healthcare (Basel). 2014;2(4):417-28.

13. Gillespie BM, Thalib L, Ellwood D, Kang E, Mahomed K, Kumar S, et al. Effect of negative-pressure wound therapy on wound complications in obese women after caesarean birth: a systematic review and meta-analysis. Bjog. 2022;129(2):196-207.

14. Gunatilake RP, Swamy GK, Brancazio LR, Smrtka MP, Thompson JL, Gilner JB, et al. Closed-Incision Negative-Pressure Therapy in Obese Patients Undergoing Cesarean Delivery: A Randomized Controlled Trial. AJP Rep. 2017;7(3):e151-e7.

15. Hussamy DJ, Wortman AC, McIntire DD, Leveno KJ, Casey BM, Roberts SW. Closed Incision Negative Pressure Therapy in Morbidly Obese Women Undergoing Cesarean Delivery: A Randomized Controlled Trial. Obstet Gynecol. 2019;134(4):781-9.

16. Hyldig N, Vinter CA, Kruse M, Mogensen O, Bille C, Sorensen JA, et al. Prophylactic incisional negative pressure wound therapy reduces the risk of surgical site infection after caesarean section in obese women: a pragmatic randomised clinical trial. BJOG. 2019;126(5):628-35.

17. Peterson AT, Bakaysa SL, Driscoll JM, Kalyanaraman R, House MD. Randomized controlled trial of single-use negative-pressure wound therapy dressings in morbidly obese patients undergoing cesarean delivery. Am J Obstet Gynecol MFM. 2021;3(5):100410.

18. Ruhstaller K, Downes KL, Chandrasekaran S, Srinivas S, Durnwald C. Prophylactic Wound Vacuum Therapy after Cesarean Section to Prevent Wound Complications in the Obese Population: A Randomized Controlled Trial (the ProVac Study). Am J Perinatol. 2017;34(11):1125-30.

19. Tuuli MG MS, Stout MJ, Steiner HL, Harper LM, Longo S, AG Cahill, AT Tita, GA Macones. Pilot randomized trial of prophylactic negative pressure wound therapy in obese women after cesarean delivery. Am J Obstet Gynecol. 2017;216(1):S245.

20. Tuuli MG, Liu J, Tita ATN, Longo S, Trudell A, Carter EB, et al. Effect of Prophylactic Negative Pressure Wound Therapy vs Standard Wound Dressing on Surgical-Site Infection in Obese Women After Cesarean Delivery: A Randomized Clinical Trial. JAMA. 2020;324(12):1180-9.

21. Wihbey KA, Joyce EM, Spalding ZT, Jones HJ, MacKenzie TA, Evans RH, et al. Prophylactic Negative Pressure Wound Therapy and Wound Complication After Cesarean Delivery in Women With Class II or III Obesity: A Randomized Controlled Trial. Obstet Gynecol. 2018;132(2):377-84.

22. Denison FC AN, Keag O, Hor K, Reynolds RM, Milne A, Diamond A, on behalf of the Royal College of Obstetricians and Gynaecologists. Care of Women with Obesity in Pregnancy. 2018.

23. NICE. PICO negative pressure wound dressings for closed surgical incisions. 2018.

24. CADTH. Summary of Abstracts Negative Wound Pressure Therapy for Caesarean Sections: Clinical Effectiveness, Cost Effectiveness and Evidence Based Guidelines. 2019.