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Cost-utility analysis of negative pressure wound therapy in high-risk cesarean section wounds

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ABSTRACT

Background: Obese women undergoing cesarean section are at increased risk of post-operative infection. There is growing interest in negative pressure wound therapy (NPWT) to prevent closed surgical incision complications including surgical site infection; however, the evidence on the effectiveness and cost-effectiveness of this technology is limited. The objective of this study was to evaluate the cost-effectiveness of NPWT compared with that of standard dressing in preventing surgical site infection in obese women undergoing elective cesarean section based on current evidence and to estimate the value and optimal design of additional research to study this technology.

Methods: The analysis was from the perspective of Queensland Health, Australia, using a decision model. Parameters were obtained from the published literature, a pilot clinical trial, and expert opinion. Monte Carlo simulation was performed to calculate the net monetary benefit, characterize decision uncertainty, and estimate the value of additional research. Comparing the expected monetary benefits and costs of alternative trial sample sizes informed the optimal future study design.

Results: The incremental net monetary benefit of NPWT was Australian dollars 70, indicating that NPWT is cost-effective compared with that of standard dressing. The probability of NPWT being cost-effective was 65%. The estimated value of additional research to resolve decision uncertainty would be Australian dollars 2.7 million. The optimal sample size of a future trial investigating the relative effectiveness of NPWT would be 200 patients per arm.

Conclusions: Based on the current evidence, NPWT is cost-effective; however, there is high uncertainty surrounding the decision to adopt this technology. Additional research is worthwhile before implementation.

1. Introduction

The increasing prevalence of obesity in women of childbearing age is a major health problem. Studies from the United States, England, and Australia reported around 25% of women of childbearing age are obese with a body mass index (BMI) of $\geq$30 kg/m^2 [1–4]. Maternal obesity poses serious complications during and after pregnancy to both the affected mothers and

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their babies, including gestational diabetes, hypertensive disorders of pregnancy, and stillbirth [5]. Obesity also increases the need for cesarean delivery with the risk of a cesarean section (CS) being two to three times higher among obese compared with pregnant women of normal weight [6–8]. Obese women undergoing CS are at increased risk of complications particularly postoperative infection [5,9]. In a meta-analysis of six studies, the pooled odds ratio for obese CS women having an infection was three times higher compared with that for nonoverweight women [5]. A common postoperative complication is surgical site infection (SSI), which occurs after surgery in the area of the body where the surgery took place [10]. Controlling SSI is a health-care quality indicator because it results in significant morbidity, reduced quality of life, occasional death, and increased costs [11–13]. One case of SSI may cost up to $30,000, depending on its severity [12,14,15]. Despite the advances in infection control practices, ventilation systems in the operating rooms, sterilization methods, surgical technique, preoperative antimicrobial prophylaxis, and wound dressings, SSI remains common in obese women undergoing CS with an estimated incidence between 16 and 30% [11,16,17].

Since its introduction two decades ago, negative pressure wound therapy (NPWT) has been used to promote the healing of acute and chronic wounds as well as skin grafts (Table 1) [19–21]. It is based on a closed sealed system that applies negative pressure to the wound surface resulting in increased blood circulation, decreased edema, enhanced granulation tissue formation, and reduced bacterial colonization [21,22]. There is growing interest in extending the use of NPWT to closed surgical incision to prevent wound complications including SSI [21,22]. Unfortunately, the available evidence on the effectiveness and cost-effectiveness of NPWT in surgical incisions is limited [23]. This is expected in surgical practice, where innovations in technologies and equipment often outpace supporting evidence. Recent systematic reviews have identified three small randomized controlled trials (RCTs) that investigated the incidence of SSI in NPWT compared with that of standard wound dressing [22,23]. Those trials showed a reduction in SSI with NPWT although all trials reported that the reductions were not statistically significant [23–26]. None of the trials involved patients undergoing CS.

Given the cost of NPWT can reach $100 a day, it is essential to evaluate the cost-effectiveness of this technology before its wide implementation. Nevertheless, with the limitations in the available evidence, the results of a cost-effectiveness analysis may not be certain enough to inform a decision. Clearly, conducting additional research would reduce this uncertainty and better inform decisions. But, there is a cost associated with obtaining further evidence in terms of the direct costs of conducting clinical trials and the opportunity cost of delaying the implementation of an effective intervention awaiting research results. An analytical approach known as value of information analysis has been developed and used in health-care interventions to inform whether the available evidence is sufficient to support a decision on a given technology or if additional research study is worthwhile [27,28]. It is based on the notion that information is valuable because it reduces the uncertainty surrounding the available evidence and subsequently the potential cost of making wrong decisions based on that uncertain evidence [27,28]. In other words, the expected value of information is the expected cost of error. Furthermore, value of information analysis has been proposed as an alternative to the standard hypothesis testing approach, which is based on type 1 and type 2 error and the minimum clinically important difference, in determining sample sizes for RCTs [29–31]. Under this economic approach, researchers consider the sample sizes that maximize the expected net benefit of research, which is the difference between the expected monetary benefit of a given trial design and its expected cost [29,30].

The aim of this study was to conduct a cost-effectiveness analysis of NPWT in preventing SSI in obese women undergoing CS compared with that of standard dressing based on currently available evidence and to perform a value of information analysis to estimate the value and optimal sample size of a larger RCT to support this technology.

2. Methods

The approach to achieve the study aim was to: 1) conduct a cost-effectiveness analysis of NPWT compared with standard dressing using a decision analytic model and; 2) perform

Table 1 – Description of commonly used negative pressure devices [18].

Product name	Prevena	VAC-VIA	PICO
Manufacturer	Kinetic Concepts Inc	Kinetic Concepts Inc	Smith and Nephew
Clinical indications	• Chronic wounds • Acute wounds • Traumatic wounds • Subacute wounds • Dehisced wounds • Partialthickness burns • Flaps and grafts	Clean, closed incisions that continue to drain after closure.	• Acute • Flaps and grafts • Incision sites • Partial thickness burns • Subacute wounds • Traumatic • Ulcers (e.g.,pressure)
Pressure settings	−75 to −125 mm Hg	−125 mm Hg	−80 mm Hg
Therapy duration, d	7	2–7	5
Cost	AUD875	AUD395	AUD175

mm HG = millimeter mercury.