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Clinical study

Cost-effectiveness analysis alongside a pilot study of prophylactic negative pressure wound therapy

Christopher Heard [a], Wendy Chaboyer [b, c], Vinah Anderson [b, c], Brigid M. Gillespie [b, c], Jennifer A. Whitty [a, b, c, d, *]

[a] School of Pharmacy, Faculty of Health and Behavioural Sciences, The University of Queensland, St Lucia, Queensland, Australia
[b] NHMRC Centre of Research Excellence in Nursing, Griffith University, Gold Coast, Queensland, Australia
[c] Menzies Health Institute Queensland, Gold Coast, Queensland, Australia
[d] Norwich Medical School, University of East Anglia, Norwich, Norfolk, UK

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ABSTRACT

Background: Negative pressure wound therapy (NPWT) is increasingly used prophylactically following surgery despite limited evidence of clinical or cost-effectiveness.
Objective: To evaluate whether NPWT is cost-effective compared to standard care, for the prevention of surgical site infection (SSI) in obese women undergoing elective caesarean section, and inform development of a larger trial.
Methods: An economic evaluation was conducted alongside a pilot randomised controlled trial at one Australian hospital, in which women were randomised to NPWT (n = 44) or standard care (n = 43). A public health care provider perspective and time horizon to four weeks post-discharge was adopted. Cost-effectiveness assessment was based on incremental cost per SSI prevented and per quality-adjusted life year (QALY) gained.
Results: Patients receiving NPWT each received health care costing AU$5887 (±1038) and reported 0.069 (±0.010) QALYs compared to AU$5754 (±1484) and 0.066 (±0.010) QALYs for patients receiving standard care. NPWT may be slightly more costly and more effective than standard care, with estimated incremental cost-effectiveness ratios (ICERs) of AU$1347 (95%CI dominant- $41,873) per SSI prevented and AU$42,340 (95%CI dominant- $884,019) per QALY gained. However, there was considerable uncertainty around these estimates.
Conclusions: NPWT may be cost-effective in the prophylactic treatment of surgical wounds following elective caesarean section in obese women. Larger trials could clarify the cost-effectiveness of NPWT as a prophylactic treatment for SSI. Sensitive capture of QALYs and cost offsets will be important given the high level of uncertainty around the point estimate cost-effectiveness ratio which was close to conventional thresholds.
Australian and New Zealand trial registration number: ACTRN12612000171819.

1. Introduction

Surgical site infection (SSI) is the third most commonly reported type of hospital-acquired infection, and a major impediment to surgical wound healing [1]. SSIs can cause higher resource use (and hence higher healthcare costs), patient distress and poor physical, emotional or economic outcomes [2]. Thus, SSI prevention is an important perioperative care objective.

Negative pressure wound therapy (NPWT) was developed in the 1990s to aid wound healing [3] and is increasingly used prophylactically to prevent wound complications, including SSIs, particularly in obese patients or those with difficult-to-heal wounds [4]. This is despite a lack of understanding about the mechanisms by which NPWT aids wound healing (experimental evidence suggests

Abbreviations: NHMRC, National Health and Medical Research Council; NPWT, Negative Pressure Wound Therapy; SSI, Surgical Site Infection; QALY, Quality-Adjusted Life Year; ICER, Incremental Cost-Effectiveness Ratio; QoL, Quality of Life; PBS, Pharmaceutical Benefits Scheme.

* Corresponding author. Health Economics Group, Norwich Medical School, Faculty of Medicine and Health Sciences, University of East Anglia, Norwich Research Park, Norwich, NR4 7JT, UK.
E-mail address: Jennifer.Whitty@uea.ac.uk (J.A. Whitty).

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several factors may be involved [3]) and limited evidence of efficacy [4]. There have been a number of reviews of NPWT [4–8], with some favouring NPWT over standard dressings [5,6] and others failing to find convincing evidence of benefit [4,7,8]. The majority of these focus either primarily or entirely on studies of NPWT in the treatment setting [5–8], although a Cochrane review of NPWT for prophylactic postoperative use concluded that the evidence for effectiveness was unclear [4].

The cost-effectiveness of NPWT is also unclear. One study developed a decision model combining information from the literature with data from a small pilot study and professional assessments [9,10]. The authors concluded that NPWT achieves lower overall costs and superior outcomes compared to standard treatment for severe pressure ulcers [9,10]. Other researchers have concluded that NPWT is cost-effective compared to standard treatment in retrospective chart reviews [11] and comparative case-studies [12]. The results of these studies are highly uncertain and generalisability is limited by the heterogeneity of patients receiving NPWT [6]. Additionally, most cost-effectiveness studies have focused on the treatment of chronic, difficult-to-heal wounds [6,10,11]. NPWT is increasingly used prophylactically following surgery for high-risk clean wounds [13], particularly in obese patients at greater risk of developing SSIs [14]. As obesity is a growing problem in Australia and other developed countries understanding the clinical effectiveness and cost-effectiveness of interventions for preventing SSIs in obese patients is important. Previous findings that NPWT may be cost-effective in the treatment of difficult-to-heal wounds do not necessarily support prophylactic use.

Given the increasing prophylactic use of NPWT despite limited evidence of benefit, a study of the clinical effectiveness and cost-effectiveness of prophylactic NPWT is urgently required. One previous study constructed a decision-analytic model of prophylactic NPWT following caesarean section and concluded that it was not cost-effective, however that study was not limited to overweight patients and did not consider quality of life (QoL) [15]. In this study, our aim was to evaluate whether NPWT is cost-effective compared to standard care for the prevention of SSIs in obese women undergoing elective caesarean section. Obese women are at greater risk of SSI following caesarean section compared to women who are not overweight [16].

2. Methods

2.1. Study design

We estimate the cost-effectiveness of NPWT compared to standard care, based on data from a pilot study of NPWT use in obese women following elective caesarean section. Cost-effectiveness assessment was based on incremental cost (AU$) per SSI prevented and per quality-adjusted life year (QALY) gained.

The design of the pilot study has been described in detail elsewhere [17]. The pilot study was a prospective, single site randomised controlled trial (RCT). Obese (BMI>30 kg/m^2) women were recruited during the scheduled pre-operative visit before elective caesarean section booked prior to the commencement of labour. Informed consent was obtained from all patients. Randomisation occurred after recruitment and prior to surgery. Patients were allocated to two treatment arms in a 1:1 ratio using simple randomisation; NPWT PICO™ (disposable unit from Smith and Nephew, Hull, UK) (n = 44) or standard care (n = 43) which consisted of Comfeel Plus® dressing (Coloplast, Denmark). Data were collected on resource use, clinical outcomes and health-related QoL during the hospital stay and at weekly intervals for four weeks post-discharge. Total costs, SSI incidence and QALYs were compared across the two treatment arms and an incremental cost-effectiveness ratio (ICER) was calculated to describe the cost of additional QALYs gained by utilising NPWT for prophylaxis compared to standard care.

2.2. Setting and perspective

The perspective taken was that of the public health care provider. The setting was the obstetrics unit of a large Australian tertiary teaching hospital. A standard surgical technique was used for all procedures but the treating health professionals were able to administer antibiotics or other medicines at their discretion. Follow-up occurred daily while the women were in hospital and via telephone once per week for four weeks post-discharge. No discounting was applied to costs or outcomes due to the short time horizon.

2.3. Data collection

Data describing in-hospital resource use and clinical outcomes were collected by direct observation or chart audit by a research assistant (RA) using report forms specifically developed for the trial. Data describing post-discharge resource use, clinical outcomes and QoL were collected during the weekly post-discharge telephone follow-ups with patients.

The allocated dressings were applied by the operating obstetrician and their surgical assistant following wound closure.

2.4. Resource unit costs

Resources were valued in Australian dollars (AU$) at 2014 values (AU$1~ US$0.82 ~ €0.66 at 17 December 2014). Resources recorded and their unit costs are given in Table 1. The total cost per resource was calculated for each patient by multiplying the per-unit cost of the resource by the number of units used. Each individual's total cost of treatment was calculated as the sum of the individual's total costs per resource over all resources.

2.5. Outcome measures: SSI and quality of life

SSI incidence measurement is described by Chaboyer et al. [17]. Briefly, SSIs were assessed by an independent assessor blinded to treatment allocation in accordance with the Centres for Disease Control and Prevention definition [1]. Health related QoL data were collected using the SF-12v2® survey which is a multi-attribute health status classification system that assigns a single QoL index (utility weight) based on responses to 12 questions [22]. The SF-12v2® instrument was administered at baseline (prior to surgery) and at each of the four weekly post-discharge follow-ups.

2.6. Economic analysis

All patients had complete outcome (QALY) data and were included in the analysis. Descriptive statistics were used to describe resource use, costs and QoL. SF-12v2® QoL indices (utility weights) were calculated using the method of Brazier and Roberts [22]. QALYs were estimated from the utility weights using the standard area under the curve method. We assumed that the change from the baseline to the first post-discharge weight was linear and occurred over the period of hospitalisation, that the first post-discharge weight applied to the full first week following discharge and that the transition between post-discharge weights was linear. Additional days at the fourth post-discharge weight were added where necessary to ensure an equal number of days were considered for each patient, regardless of length of hospital stay. QALYs were adjusted for differences in baseline SF-12v2®