

The use of negative pressure wound therapy dressing in obese women undergoing caesarean section: a pilot study

Vinah Anderson¹ MHP, BHScN, RN. Wendy Chaboyer² PhD, MNurs, BSc, RN. Brigid Gillespie³ PhD, BHth Sc, RM, RN. Jennifer Fenwick⁴ PhD, MNgST, BHSc, RM.

1. Senior research assistant, NHMRC Centre of Research Excellence in Nursing Centre for Health Practice Innovation, Griffith Health Institute, Griffith University, Gold Coast campus, Southport, Queensland 4222 Australia. Email: v.anderson@griffith.edu.au
2. Professor and director, NHMRC Centre of Research Excellence in Nursing Centre for Health Practice Innovation, Griffith Health Institute, Griffith University, Gold Coast campus, Southport, Queensland 4222 Australia. Email: w.chaboyer@griffith.edu.au
3. Senior research fellow, NHMRC Centre of Research Excellence in Nursing Centre for Health Practice Innovation, Griffith Health Institute, Griffith University, Gold Coast campus, Southport, Queensland 4222 Australia. Email: b.gillespie@griffith.edu.au
4. Professor of midwifery and clinical chair, Gold Coast Hospital and Griffith University, Logan Campus, University Drive, Meadowbrook, Queensland 4131 Australia. Email: j.fenwick@griffith.edu.au

This project received financial support from the Office of Health and Medical Research, Queensland Health. The inclusion of this paper in the RCM's journal does not imply any endorsement or support for the products used in the study.

Abstract

Background. Obese women undergoing caesarean section (CS) are at increased risk of surgical site infection (SSI). Negative pressure wound therapy (NPWT) is growing in use as a prophylactic approach to prevent wound complications such as SSI, yet there is little evidence regarding its benefits. The aim of this pilot study was to evaluate the feasibility of undertaking a randomised controlled trial using NPWT in obese women undergoing elective CS.

Method. Obese women undergoing elective CS were recruited from the antenatal clinic in a metropolitan hospital in Queensland, Australia, between 2012 and 2013. Using parallel 1:1 randomisation, 18 of these women received the intervention following closure of their wound in operating room (NPWT, PICO™ dressing) and 17 women received standard care (Comfeel Plus® dressing). Pre-defined criteria used to assess feasibility included: recruitment (>75% participation), loss to follow-up (<10%), intervention fidelity (≥95%), and interrater reliability (kappa ≥0.8). Ethics approval was granted by the hospital and university human research ethics committees.

Results. Of the 55 women approached, 48 (87%) consented to participate, 35 (63.6%) were randomised and 33 (94%) women completed post-discharge follow-up. All women received the intended dressing with the exception of one (2.8%) who later crossed over during dressing change. A kappa score of 0.87 (p<.0001) for SSI (yes/no) and an intraclass correlation coefficient score of 0.95 (p<.0001) for type of SSI were achieved.

Conclusion. As shown in this study, careful planning and study site selection is critical to the success of the overall study. The results indicate that women with newborns are willing to participate in trials involving interventions and short-term follow-up.

Key words: Obesity, surgical site infection, caesarean section, feasibility, pilot study, evidence-based midwifery

Introduction

The proportion of people who are overweight or obese is increasing. Worldwide, 1.6 billion adults are overweight with a further 400 million more classified as obese (WHO, 2006). In Australia, the population's weight, indicated by body mass index (BMI), has also been steadily increasing (Australian Bureau of Statistics, 2007). BMI, a calculation of weight (kg) divided by height (m²) is the internationally recommended measurement for obesity and classifies adult body weight as: underweight <18.5; normal range 18.5 to 24.9; overweight ≥25; and obese ≥30 (WHO, 2006). According to the Australian Bureau of Statistics, 68% of males and 55% of females over the age of 18 years are overweight or obese – an increase of 4% and 6%, respectively, since 2001.

Although in general the rates of overweight and obesity are higher in older age groups, there has been a greater increase in the childbearing women (Women's Health Australia, 2009). The association between rising levels of obesity in pregnant women, adverse maternal and neonatal outcomes and increased interventions such, as caesarean section (CS), has also been reported in several studies worldwide (Callaway et al, 2006; Weiss et al, 2004; Rode et al, 2005).

Recent meta-analyses have shown an overall increased risk of CS and repeat elective CS in obese women (Poobalan et al, 2009; MacDorman et al, 2008; Chu et al, 2007).

While elective CS is considered a 'clean' and relatively safe surgical technique in resource-rich countries, such as Australia, surgical delivery is still associated with increase morbidity (Liu et al, 2007). For example, obese women undergoing CS are at greater risk of developing postoperative infections than non-obese women (Tran et al, 2000).

Surgical site infections (SSI) are defined as occurring after surgery in the part of the body where the surgery took place (Horan et al, 2008). SSIs are classified as: 1a) superficial incisional primary; 1b) superficial incisional secondary; 2a) deep incisional primary; 2b) deep incisional secondary and; 3) organ/space infection. All three classifications include infections diagnosed within 30 days without implant and/or one year including implant following operation (Horan et al, 2008). Factors associated with SSI in women undergoing CS include: type of abdominal incision, subcutaneous thickness and closure, preoperative antibiotic use, use of subcutaneous drains, and patient temperature regulation (Tipton et al, 2011). A study by Olsen et al (2008) involving a large cohort of women (n=1605) identified subcutaneous

haematoma, use of staples for closure, increased surgery time and the operation performed by a university teaching facility as significant independent risk factors for SSI. Comorbidities, such as diabetes, and prolonged use of steroids also contributed significantly to poorer wound healing following this type of surgery (de Vivo et al, 2010).

Wound management is also thought to play a role in rates of SSI (National Collaborating Centre for Women's and Children's Health, 2008). It is assumed that sterile dressings applied to the wound in the operating room (OR) act as a barrier and protect the surgical incision from environmental factors, such as skin contamination, irritation from external clothing and/or equipment. In addition, dressings contain exudate and thus provide comfort for the patient. More recently, there has been an increase in the use of vacuum-assisted dressing which is referred to as negative pressure wound therapy (NPWT). This type of closure is thought to aid healing (Kanakaris et al, 2007; Molnar et al, 2005) by increasing local blood flow and granulation of tissue, as well as reducing bacterial contamination, wound area, oedema, exudate, and changes to the micro-environment of the wound (Banwell and Téot, 2003). The use of NPWT has been recommended for a diverse range of chronic lesions or difficult-to-heal wounds (Stannard et al, 2012; Bovill et al, 2008), and, more recently, for clean surgery in obese patients (Dragu et al, 2011) with prophylactic intent.

The evidence around wound dressing or management practices, however, remains somewhat problematic. A Cochrane review concluded that there was no evidence to suggest covering of surgical wounds healing by primary intention with wound dressings reduces the risk of SSI (Dumville et al, 2011). Conversely, the trials included in this review were small and of poor quality and were, therefore, at high or unclear risk of bias. Given the lack of scientific evidence supporting the plethora of dressings available, which include those that use NPWT, Webster et al (2012) suggest that high-quality trials are needed. A recent integrative review supports this recommendation, noting that there remains minimal high-quality evidence addressing wound management practices in obese women undergoing CS (Anderson et al, 2013). Before large scale trials can be undertaken that demonstrate the effectiveness of various dressings, pilot studies are required.

Aim and objectives

To evaluate the feasibility of undertaking a randomised controlled trial (RCT) using prophylactic NPWT in obese women undergoing an elective surgical delivery.

Feasibility was assessed against four pre-defined criteria: 1) Recruitment: at least 75% of eligible women would agree to participate; 2) Loss to follow-up of those women randomised (no more than 10%); 3) Fidelity: at least 95% of participants will receive the treatment they were allocated; 4) Interrater reliability: a kappa score of at least 0.8 between two clinicians experienced in recognising SSI.

Method

Pilot studies are synonymous with feasibility, and thus are intended as a pre-requisite to a larger trial to test methods and

procedures involving issues around recruitment, retention, missing data and fidelity (Conn et al, 2010; Thabane et al, 2010). As such, the purpose of a pilot study is not to test hypotheses (Thabane et al, 2010).

The pilot was conducted in accordance with the *Good clinical practice* guidelines (Mathieu, 2011) and the *Consort statement* (Schulz et al, 2010) at a single site using a parallel 1:1 randomised controlled design (Schultz et al, 2010). Study participants received either NPWT PICO™ (Smith and Nephew, Victoria Australia) (intervention) or Comfeel® Plus (Coloplast, Denmark) (usual care) following closure of their wound in the OR. Ethics approval was granted by the hospital and university human research ethics committees.

Sample and setting

The setting for this pilot study was a 450-bed metropolitan hospital in Queensland, Australia. The hospital's maternity unit included labour ward, postnatal ward and antenatal clinic. At the time of study inception, approximately 27% of women had an elective CS (Perinatal Data Collection Queensland Health, 2012). Women were recruited if they met the following inclusion criteria: 1) pre-pregnancy BMI $\geq 30\text{kg/m}^2$ at booking visit; 2) booked for elective CS; 3) able to provide written informed consent. Exclusion criteria were: 1) previous participation in this trial; 2) existing infection; 3) unable to speak or understand English with no interpreter.

Women were approached following triage by midwives and obstetricians in the antenatal clinic. Women received a participant information sheet and were provided with an opportunity to ask questions and seek further clarification. The majority of women consented to the study at this time. Women who requested further discussion with family members prior to consenting were only contacted prior to the pre-admission anaesthetic visit if verbal consent was provided to do so.

Following informed consent, study identification numbers were allocated to women who agreed to participate. This number was used to randomise the woman to either the intervention or control arm on the day of surgery.

Women who consented to participate were subsequently excluded prior to randomisation if they spontaneously went into labour (for example: ruptured membranes), required emergency CS or if they were being treated at time of surgery for a concurrent infection.

A block randomisation technique (blocks of four) was utilised to allocate the women to either the intervention (NPWT, PICO™) and or usual care (Comfeel®) groups in the OR via a central web-based service prior to the start of elective CS surgery by the research team member. To ensure allocation concealment, OR staff including medical and nursing staff were blinded to type of dressing until wound closure. On completion of wound closure, the PICO™ or Comfeel® dressing was applied as per manufacturer recommendations and under sterile conditions.

Intervention

The intervention used in this study was NPWT also known as vacuum-assisted closure. The NPWT device used in this

study was a single use PICO™ dressing consisting of a small pump, two lithium batteries, two gauze-based dressings and 10 fixation strips (Smith and Nephew, Victoria, Australia). The wound surface was covered with a gauze-based dressing and sealed with fixation strips applied to the dressing borders under sterile conditions in the OR by a member of the surgical team. Once the dressing was fixed in place, the battery-operated device was attached to the tubing and continuous negative pressure was delivered at 80mmHg. This single unit device has a seven-day battery life and a secondary dressing available for dressing change if required such as excessive oozing at wound site.

Education and training on the NPWT device and study protocol was provided to medical staff, OR nurses and midwives involved in the care of these women prior to the start of the study. Ongoing education continued throughout the study to address staff turnover. This ensured consistency in application and care of dressing in situ. The control group received usual care and the application of a Comfeel Plus® (Coloplast) dressing at the completion of surgery following wound closure by OR staff under sterile conditions.

Data collection

A specifically designed data collection tool was developed and modified in the initial phase of data collection. This tool comprised of five components: 1) screening; 2) recruitment and baseline; 3) OR surgery; 4) post-operative daily wound data; and 5) weekly telephone follow-up. At time of consent, baseline data were collected including, contact details, height, weight, BMI, co-morbidities, and recent infections.

Data on CS surgical technique, type of anaesthetic and score were collected in the OR during the CS by the research team member. Daily visits to the postnatal ward were necessary to collect post-operative wound data for all outcomes. Following discharge, the women from both groups were contacted weekly for four weeks via telephone to collect outcome data on evidence of SSI. These data were collected using hard copy and were entered into an electronic database. The dressings of both groups were removed by the community midwives ranging from days five to seven post discharge depending on the availability of human resources.

Due to the nature of the intervention used, blinding of patients and clinical staff involved in their care was not possible. The education and training of staff on application of dressings used promoted consistency throughout the study and reinforced standardised practice. Performance bias is always a possibility when staff or study participants cannot be blinded (Kearney and Simonelli, 2006), however, use of an ongoing education programme minimised the risk of this occurring. It was impossible to blind the research team members collecting the data, but the laboratory staff assessing any wound swabs and the two clinicians analysing the data to determine SSI were blinded to group allocation.

Data analysis

Raw data entered into the Predictive Analysis Software Package (Version 21, IBM Chicago, IL) were checked for accuracy. The types of statistics used were based on the level

and the distribution of the data. Descriptive statistics were used to describe sample characteristics using absolute (n) and relative (%) frequencies for the following variables; co-morbidities, gestational diabetes (GDM), type two diabetes, hypertension (HTN), anaemia and number of previous CS within two groups.

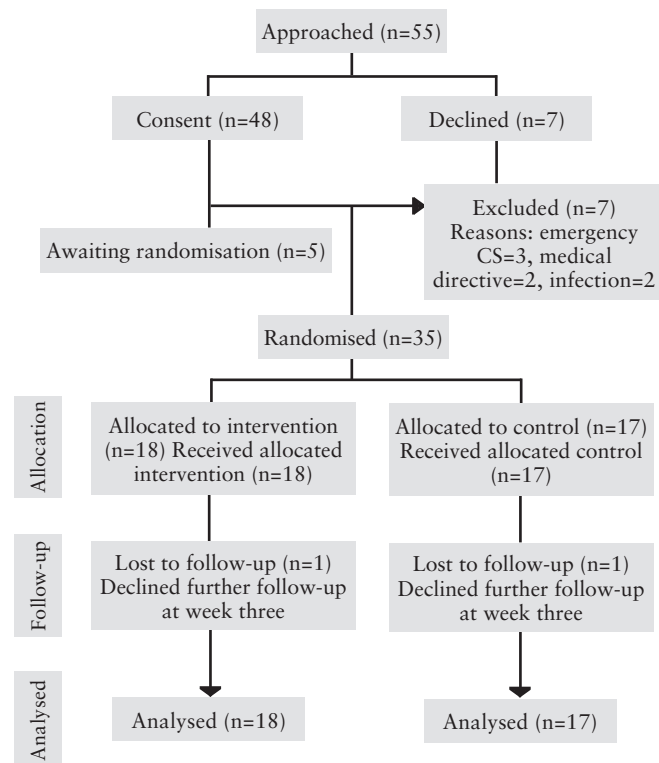
Inferential statistics, including chi-square and Mann-Whitney U tests, were chosen as the most suitable non-parametric measures to detect group differences and explore the relationships between the variables age, BMI, length of surgery in minutes, and hospital length of stay in days. A p-value of <0.05 was considered significant. An interrater reliability analysis using the kappa statistic was performed for SSI (yes/no) and intraclass correlation coefficient (ICC) score was calculated for type of SSI (superficial, deep, organ space) to determine consistency among raters (ordinal data). A kappa value of 0.81 to 1.00 indicates very good agreement (Altman, 1991), while an ICC coefficient of ≥0.70 is considered acceptable (Polit, 2010).

Results

The process from enrolment, intervention allocation, and follow-up and data analysis of this pilot trial with two groups of women is described in Figure 1.

A total of 55 potential participants received study information in the antenatal clinic between the end of June 2012 and January 2013 (a nine-month period). Seven (14.5%) women declined to participate. The most common reasons given for non-participation were: too busy, anxiety about the birth, and unsure of intervention. A total of 48 (87%) women provided written consent to participate, thus

Figure 1. Participant enrolment flow diagram



the recruitment target was exceeded. Seven (12%) women were excluded prior to randomisation due to a change in their medical status, which placed them into one of three exclusion criteria categories; 1) emergency, 2) concurrent infection and 3) medical directive. One woman withdrew from the study on the day of surgery.

A total of 35 (57%) women were randomised. Of these, 18 (51%) women received the intervention (PICO™) and 17 (48.5%) women received the control (Comfeel®), as per randomisation in the OR. A 100% fidelity was achieved in the OR. During an unplanned dressing change, one woman 'crossed over' into the control group following NPWT. Two (5.7%) women dropped out of the study at week three phone follow-up (one from each group) without a reason.

Of the 18 women who were allocated and received the PICO™ device, 12 (66.6%) NPWT dressings were applied by the registrar, four (22.2%) by the surgeon, one (5%) by the scrub nurse and one (5%) jointly by the scrub nurse and resident doctor. In the control group (Comfeel®), 10 (62.5%) were applied by the registrar, three (17.6%) by the surgeon and four (23.5%) by the scrub nurse-resident. The registrar was the most likely member of the team in both intervention and control group to apply the dressing in the OR.

The age range of the women was 18 to 40 years and the BMI ranged from 30 to 56kg/m² using pre-pregnancy measurements. Table 1 displays further demographic and

clinical data on the sample. Non-parametric tests, Mann-Whitney U test and chi-square were chosen to compare the two groups to assess differences in these characteristics. The only significant difference found between the two groups was length of surgery (p=0.026).

The kappa score was calculated as 0.87 (p<0.001) for the chart audits for the assessment of SSI (yes/no). ICC was calculated for the type of SSI, and was 0.95 (p<0.001). Both results suggest a high level of agreement between the two raters in determining the presence and the type of SSI.

Discussion

This pilot study addressed four main feasibility criteria prior to undertaking a larger randomised controlled study: 1) recruitment; 2) loss to follow-up; 3) fidelity; 4) interrater reliability. Important lessons can be learned from undertaking pilot studies, which may lead to an improvement in the design and execution of a larger trial (Thabane et al, 2010). This pilot study allowed the researchers to refine some of our processes, including making modifications to the data collection tool. Only minor changes to the data collection tool were necessary during the conduct of the study. These changes mainly involved refinement of the surgical technique questions, but the design of the chart audit tool was also adjusted to reduce confusion surrounding SSI indicators. Summary of the enablers and barriers to recruitment, loss to follow-up and fidelity are presented in Table 2.

Recruitment

The recruitment process proved to be time-consuming and subsequently expensive at the chosen site. Over the nine months of the study, the elective CS rate decreased by one third, which impacted heavily on the number of eligible women available. The environmental aspects, such as the confined physical workspace, and the existing processes created barriers to accessing potential women. The medical clinics were 'themed' to promote a more streamlined service but, despite this, women would be transferred in and out of clinics. This prevented a more selective targeting of potential participants. As others have noted, these issues only became evident once recruitment strategies were actually implemented (Jairath et al, 2000). Uncovering organisational change issues, such as the loss of the triage midwife role, using feasibility criteria which may impact on the progress of the study can only strengthen the larger trial (van Teijlingen and Hundley, 2002).

Ongoing education seminars and product training was provided to midwives, medical staff and OR nurses at the start, and for the duration of, the study, as staff regularly rotated through the hospital. Thus, through this pilot, the researchers identified the need for ongoing training resources to be allocated for the duration of the trial.

Table 1. Sample demographic and clinical data

Demographic characteristic	Intervention n=18		Control n=17		p-value
	Median	IQR	Median	IQR	Mann-Whitney U
Age	30.0	10.0	34.0	8.0	0.145
BMI	34.3	7.6	34.0	7.5	0.765
Length of surgery (mins)	45.5	19.0	53.0	16.0	0.026
Hospital length of stay (days)	3.00	1.00	3.00	1.0	0.957
	Frequency	Percentage	Frequency	Percentage	Chi-square
No of co-morbidities					
Gestational diabetes	3	16.7	3	17.6	0.939
Type 2 diabetes	0	0	2	11.8	0.134
HTN	1	5.6	2	11.8	0.512
Anaemia	3	16.7	1	5.9	0.316
No of previous CS					
0	3	16.7	2	11.8	0.499
1	9	50.0	11	64.7	
2	4	22.2	4	23.5	
3	2	11.1	0	0	

Table 2. Discussion summary

	Enablers	Barriers
Recruitment	Continuity with one research assistant (RA); RA – a trained health professional; education seminars for all staff	Environment – confined physical workspace; existing processes – reliant on midwife and doctor referrals; loss of triage midwife; rotating medical trainees; lack of support from delivery suite; organisation – midwifery model of care; participants – anxiety re treatment; clinicians' concerns
Loss to follow-up	Establishing positive relationships; home visiting; team education	Exclusion criteria; post discharge phone contact; GP follow-up of wound
Fidelity	Presence of RA in the OR; rapport with OR staff	Application of dressing – variety of medical trainees

The reduction in the elective CS rate from 27.0% to 19.5% during the study impacted on recruitment rates. The unexpected reduction in elective CS was an important finding in this study for the future larger trial and supports the rationale for undertaking pilot studies. The study revealed a specific maternity unit strategy that has the potential to impede or facilitate sample acquisition in a larger study (Levine et al, 2002).

Some of the barriers to participation were: perceived additional demands on the woman following birth, preference for a particular treatment, worry about the uncertainty of intervention, and clinicians' concerns about treatment. Similar barriers were uncovered in a systematic review of RCTs/feasibility studies by Ross et al (1999).

Loss to follow-up

In this group, the researchers managed to achieve less than 10% loss to follow-up, which is considered acceptable (Hertzog, 2008). The 5.7% drop-out rate in the combined groups can be explained by the research assistant's (RA) effort in establishing positive relationships with these women. Continuity assists with engagement and is vital to achieving such a high retention rate following randomisation. Similar findings have been demonstrated in studies of childbearing women by Gamble et al (2005).

Inclusion criteria also affected the number of women randomised, as women could only remain in the study if they were booked for an elective CS and, at the time of randomisation, were not medically treated for a concurrent infection. The unpredictable nature of the study population presented some retention issues. Weekly telephone calls for four weeks following discharge of women was necessary to obtain information regarding SSI. It was not always possible to obtain this information on day seven each week, due to difficulties in contacting the women.

The researchers' reliance on the home visiting team to

collect wound data following dressing removal proved challenging. It was only clarified during the study, that those women who did not receive a second home visit by their midwife, were referred to their GP for removal of the dressing. Similar issues were identified during the piloting of a Scottish national births survey and their solution was to engage midwives early in the process and sustain support through ongoing collaboration (van Teijlingen and Hundley, 2002).

Fidelity

The presence of the RA in the OR undertaking the central web-based randomisation process reduced the risk of incorrect group allocation of dressing at skin closure. Close monitoring of the application of intervention in the OR maintained treatment integrity, an important step in the research process (Kearney and Simonelli, 2006). Although there was a high success rate in the receipt of allocated dressing, variability did occur among the personnel applying the dressing. These are some of the inherent challenges of undertaking a study in a training facility. This study reflects the real-world setting and clinical practice variation, as opposed to the rigidity and sterility of RCTs in an artificial environment. Arguably, it may be that having more than one person applying the dressing affected the final outcome. However it was not uncommon for two persons to apply the NPWT (PICO™) dressing due to the apparent difficulties associated with surgical procedures in the obese client.

Conclusion

This systematic approach to the analysis of feasibility revealed significant issues with recruitment in the study site. Recruitment was time-intensive and costly due to the difficulties in identifying eligible women in the antenatal clinic. The unanticipated reduction in the number of elective CS during the conduct of the study led to a slower recruitment rate. Despite this, the researchers managed to maintain a relatively low attrition rate during follow-up (<10%). It is unknown whether these difficulties would have been faced in other sites, but it indicates the need for a comprehensive assessment of each setting for a multi-site trial.

A different approach to education and training of clinical personnel needs to be considered, due to busy ward schedules and a high turnover of rotating medical staff. Consideration should be given to identifying resource persons in the wards and antenatal clinic to act as study champions and conduits of communication. These persons could assist unfamiliar staff with any issues surrounding study protocol during the post-operative period and the antenatal clinic during the women's health assessment for eligibility into the study. The provision of educational DVDs and DVD players for midwives and medical personnel would result in improved access to training resources. Developing a strong rapport with specialist and trainee doctors is essential to gaining access to eligible women. Building strong collaborative relationships between researchers and clinicians is vital for the success of the study. In conclusion, undertaking pilot studies is a necessary prerequisite to a larger RCT, as demonstrated in this study.

References

- Altman D. (1991) *Practical statistics for medical research*. Chapman & Hall: London.
- Anderson V, Chaboyer W, Gillespie B. (2013) The relationship between obesity and surgical site infections in women undergoing caesarean sections: an integrative review. *Midwifery* **29**(1): 1331-8.
- Australian Bureau of Statistics. (2007) *Australian social trends: overweight and obesity*. Commonwealth of Australia: Canberra.
- Banwell PE, Téot L. (2003) Topical negative pressure (TNP): the evolution of a novel wound therapy. *Journal of Wound Care* **12**(1): 22-8.
- Bovill E, Banwell PE, Téot L, Eriksson E, Song C, Mahoney J, Gustafsson R, Horch R, Deva A, Whitworth I. (2008) Topical negative pressure wound therapy: a review of its role and guidelines for its use in the management of acute wounds. *International Wound Journal* **5**(4): 511-29.
- Callaway L, Prins J, Chang A, McIntyre D. (2006) The prevalence and impact of overweight and obesity in an Australian obstetric population. *Medical Journal of Australia* **184**(2): 56-9.
- Chu SY, Kim SY, Schmid C, Dietz P, Callaghan W, Lau J, Curtis K. (2007) Maternal obesity and risk of caesarean delivery: a meta-analysis. *Obesity Reviews* **8**(1): 385-94.
- Conn V, Algate D, Rawl S, Zerwic J, Wyman J. (2010) Publishing pilot intervention work. *Western Journal of Nursing Research* **32**(8): 994-1010.
- de Vivo A, Mancuso A, Giacobbe A, Priola A, De Dominicis R, Savasta L. (2010) Wound length and corticosteroid administration as risk factors for surgical-site complications following caesarean section. *Acta Obstetrica et Gynecologica* **89**(1): 355-9.
- Dragu A, Schnürer S, Unglaub F, Wolf M, Beier J, Kneser U, Horch R. (2011) Wide topical negative pressure wound dressing treatment for patients undergoing abdominal dermolipectomy following massive weight loss. *Obesity Surgery* **21**(1): 1781-6.
- Dumville JC, Walter CJ, Sharp CA, Page T. (2011) Dressings for the prevention of surgical site infection. *Cochrane Database Syst Rev* **7**: CD003091.
- Gamble J, Creedy D, Moyle W, Webster J, McAllister M, Dickson P. (2005) Effectiveness of a counselling intervention after a traumatic childbirth: a randomised controlled trial. *Birth* **32**(1): 11-9.
- Hertzog M. (2008) Considerations in determining sample size for pilot studies. *Res Nurs Health* **31**(1): 180-91.
- Horan T, Andrus M, Dudeck M. (2008) CDC/NHSN surveillance definition of healthcare-associated infection and criteria for specific types of infections in the acute care setting. *American Journal of Infection Control* **36**(5): 309-32.
- Jairath N, Hogerney M, Parsons C. (2000) The role of the pilot study: a case illustration from cardiac nursing research. *Applied Nursing Research* **13**(2): 92-6.
- Kanakaris NK, Thanasis C, Keramaris N, Kontakis G, Granick MS, Giannoudis PV. (2007) The efficacy of negative pressure wound therapy in the management of lower extremity trauma: review of clinical evidence. *Injury* **38**(suppl 5): S9-S18.
- Kearney M, Simonelli C. (2006) Intervention fidelity: lessons learned from an unsuccessful pilot study. *Applied Nursing Research* **19**(1): 163-6.
- Levine E, Olander C, Lefebvre C, Cusick P, Biesiadecki L, McGoldrick D. (2002) The team nutrition pilot study: lessons learned from implementing a comprehensive school-based intervention. *Journal of Nutrition Education and Behavior* **34**(1): 109-16.
- Liu S, Liston R, Joseph KS, Heaman M, Sauve R, Kramer M. (2007) Maternal mortality and severe morbidity associated with low-risk planned caesarean delivery versus planned vaginal delivery at term. *Canadian Medical Association Journal* **176**(4): 455-60.
- MacDorman M, Declercq E, Menacker F, Malloy M. (2008) Neonatal mortality for primary caesarean and vaginal births to low-risk women: application of an 'intention-to-treat' model. *Birth* **35**(1): 3-8.
- Mathieu M. (2011) *Good clinical practice: a question and answer reference guide*. Barnett International: Needham, Massachusetts.
- Molnar JA, Simpson JL, Voignier DM, Morykwas MJ, Argenta LC. (2005) Management of an acute thermal injury with subatmospheric pressure. *Journal of Burns and Wounds* **4**(e5): 83-92.
- National Collaborating Centre for Women's and Children's Health (UK). (2008) *Surgical site infection: prevention and treatment of surgical site infection*. NICE Clinical Guidelines No 74. Appendix C: wound dressings for surgical site infection prevention. RCOG Press: London.
- Olsen M, Butler A, Willers D, Devkota P, Gross G, Fraser V. (2008) Risk factors for surgical site infection after low transverse caesarean section. *Infection Control and Hospital Epidemiology* **29**(6): 477-84.
- Polit D. (2010) *Statistics and data analysis for nursing research*. Pearson Education: Upper Saddle River, New Jersey.
- Poobalan A, Aucott L, Gurung T, Smith W, Bhattacharya S. (2009) Obesity as an independent risk factor for elective and emergency caesarean delivery in nulliparous women – systematic review and meta-analysis of cohort studies. *Obesity Reviews* **10**(1): 28-35.
- Rode L, Nilas L, Wøjdemann K, Tabor A. (2005) Obesity-related complications in Danish single cephalic term pregnancies. *Obstetrics and Gynecology* **105**(3): 537-42.
- Ross S, Grant A, Counsell C, Gillespie W, Russell I, Prescott R. (1999) Barriers to participation in randomised controlled trials: a systematic review. *Journal of Clinical Epidemiology* **52**(12): 1143-56.
- Schulz K, Altman D, Moher D. (2010) Consort 2010 statement: updated guidelines for reporting parallel group randomised trials. *Annals of Internal Medicine* **152**(11): 1-8.
- Stannard JP, Gabriel A, Lehner B. (2012) Use of negative pressure wound therapy over clean, closed surgical incisions. *International Wound Journal* **9**(suppl 1): 32-9.
- Thabane L, Ma J, Chu R, Cheng J, Ismaila A, Rios L, Reid R, Thabane M, Giangregoria L, Goldsmith Charles. (2010) A tutorial on pilot studies: the what, why and how. *BMC Medical Research Methodology* **10**(1): 1-10.
- Tipton A, Cohen S, Chelmsow D. (2011) Wound infection in the obese pregnant woman. *Seminars in Perinatology* **35**(6): 345-9.
- Tran T, Jamulitrat S, Chongsuvivatwong V, Geater A. (2000) Risk factors for post-caesarean surgical site infection. *Obstetrics and Gynecology* **95**(3): 367-71.
- van Teijlingen E, Hundley V. (2002) The importance of pilot studies. *Nursing Standard* **16**(40): 33-6.
- Webster J, Schuffham P, Sherriff K, Stankiewicz M, Chaboyer W. (2012) Negative pressure wound therapy for skin grafts and surgical wounds healing by primary intention. *Cochrane Database Syst Rev* **4**: CD009261.
- Weiss JL, Malone FD, Emig D, Ball RH, Nyberg DA, Comstock CH, Saade G, Eddleman K, Carter SM, Craigo SD, Carr SR, D'Alton ME, FASTER Research Consortium. (2004) Obesity, obstetric complications and caesarean delivery rate: a population-based screening study. *American Journal of Obstetrics and Gynecology* **190**(1): 1091-7.
- Women's Health Australia. (2009) *The Australian longitudinal study on women's health*. See: alswh.org.au/images/content/pdf/technical_reports/report_32_alswh.pdf (accessed 4 February 2014).
- World Health Organization. (2006) *Obesity: preventing and managing the global epidemic*. World Health Organization: Geneva.

Reproduced with permission of the copyright owner. Further reproduction prohibited without permission.