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A randomised study of negative pressure dressings for lower limb amputations

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Abstract

Background: *Negative pressure wound dressings have become commonplace in the management of open surgical wounds. This study investigates the potential advantage of negative pressure wound dressings for lower limb amputation wounds.*

Methods: *A randomised study of conventional wound dressing (wool and crepe) versus negative pressure wound dressing (PICO) in patients undergoing lower limb amputation in a tertiary level teaching hospital department of vascular and endovascular surgery. All wounds were closed in a standard fashion with Vicryl to fascia and interrupted nylon to the skin. The dressing was left intact for 5 days following surgery and then followed with conventional wound dressings. The primary end point was the need for any surgical intervention to the amputation within 3 months of the index procedure. Secondary end points included wound infections within 6 weeks.*

Results: *Over a 30-month period, 63 patients underwent a below or above knee amputation. Of these, 50 patients were recruited and completed the study, 25 in the PICO group and 25 in the wool and crepe group. The two groups were well matched in terms of sex (16 males in wool and crepe and 17 in PICO), age (mean age of wool and crepe group = 63 years and PICO group 69.7 years), comorbidities and indications for surgery. The primary end point occurred in 3 patients in each group, 2 conversions of below knee amputation to above knee amputation in each group, one shortening of an amputation in the PICO group and one haematoma wash out in the wool and crepe group. There was no difference in wound infections between the two groups (28% vs 16% p 0.306)*

Conclusion: *This small randomised study suggests that there is no advantage to negative pressure wound dressings for lower limb amputation wounds closed primarily.*

Keywords: *negative pressure, wound dressing, amputations, peripheral arterial disease*

Introduction

Despite advances in techniques and increased frequency of both conventional open bypass surgery and endovascular procedures for lower limb ischaemia, major lower limb amputations are still performed in vascular units around the world. A major lower limb amputation is defined as any amputation above the level of the ankle, most commonly a below knee (BKA) or above knee (AKA) amputation. The incidence of such procedures varies globally, ranging between 3.6 - 68.8 per 100 0000 in the general population and between 5.6 - 600 per 100 0000 in the diabetic population [1]. Diabetic men are more likely to undergo amputation when compared to women, but women have a higher mortality related to these procedures [2]. Major lower limb amputation remains a morbid procedure associated with both a high mortality and morbidity rate. Wound infection can occur in up to 34.6% and in many of these patients a surgical revision is required [3]. The incidence of reoperations for wound complications can be as high as 17.5% [4].

There is growing interest in the use of negative pressure wound dressings for surgical wounds. Negative pressure dressings have made a big impact in the management of open wounds and seem to aid wound healing by secondary intention. A Cochrane review concluded that there was “an urgent need for trials to evaluate the effects of the newer Negative Pressure Wound Therapy products on clean, closed surgical incisions and that such trials should focus initially on wounds that may be difficult to heal.” [5]. The Pico wound management system (Smith and Nephew, London, UK) is one such negative pressure wound dressing system. The aim of this study was to investigate the potential advantages of the Pico wound management system on major lower limb amputation wound complications in a randomised trial.

Methods

DThis was a randomised study in patients undergoing major lower limb amputation in a vascular and endovascular surgery department of a small tertiary referral, teaching hospital. Patients scheduled to undergo a major lower limb amputation were approached for inclusion in the study. We excluded patients who were not willing to consent to be involved in the study. In those patients with dementia, consent was sought from their guardian who was providing consent for surgery.

All operations were performed by a consultant vascular surgeon or a vascular surgery trainee under direct supervision of a consultant. The type of anaesthetic was left to the discretion of the anaesthetists and no nerve catheters were used in this study. Patients received per and post-operative antibiotics according to

the hospital protocol, unless they were already on antibiotics. All wounds were closed with Vicryl (Ethicon, Johnson and Johnson, US) to the deep fascia and interrupted nylon sutures to the skin. At this point, a sealed envelope was opened to reveal the dressing type to be applied. The study patients had a Pico dressing applied and control patients had jelonet applied directly to the wound, followed by a wool bandage and then finally a firm crepe bandage. Dressings were left intact for 5 days at which time the dressing was removed, the wound inspected. Thereafter, conventional wound dressings were applied according to the consultant's preference.

The primary outcome for this study was the need for surgical revision of the stump within 3 months of surgery. Secondary outcomes included whether the dressing was left intact for 5 days following the operation and wound infection.

The study received local research and ethics committee approval. However, this committee were concerned that we would not be able to recruit adequate numbers for a full trial and thus approved only a pilot of 50 patients in total.

Results

Figure 1 shows the consort diagram for the study. As per the research and ethics committee limitation, 50 patients were recruited to the study. Following randomisation, the groups were well matched as shown in Table 1 except that there were more diabetic patients in the wool and crepe group (13 vs. 5 p = .018).

Table 2 shows the results of the study. There was no difference in the primary outcome although there was a trend towards fewer infections in the PICO group (16% vs 28%).

There were 7 deaths in each group at a mean of 5 months following surgery.

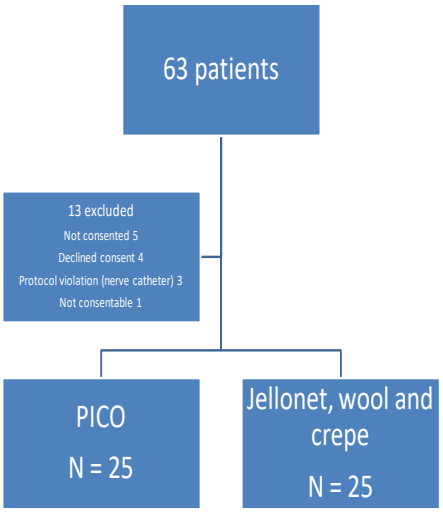

Figure 1. *Consort diagram*

Discussion

Since the inception of this study, reports have emerged on the potential benefits of negative pressure dressings for surgical wounds. In particular, Lee has reported that in a randomised study of 102 patients classified as having high risk groin wounds following vascular surgery, negative pressure dressings reduced the incidence of wound infection from 19% to 11%. Hospital stay was also reduced with negative pressure dressings (8.9 days vs 6.4 days) [6].

	PICO group	**Wool and crepe group**	**p**
Males n =	17 (68%)	16 (64%)	0.76#
Mean age	69.76 years	63.16 years	0.11*
History of stroke n =	3	1	0.30#
History of dementia n =	5	2	0.22#
Diabetes n =	5	13	0.018#
History of ischaemic heart disease n =	12	9	0.39#
eGFR less than 60	7	8	0.76#
Indication for amputation Gangrene Infection plus gangrene Infection Pain	 4 5 13 3	 4 5 10 6	
Mean Pre-operative haemoglobin g/l	109.1	114.9	0.37*
Mean pre-operative white cell count /nl	11.4	11.6	0.91*
Mean pre-operative albumin g/l	30.5	27.5	0.2*
Amputation side = right n =	16	11	0.156#
BKA:AKA	16:09	15:10	
General anaesthetic:regional anaesthetic	14:11	17:08	
#Chi squared test; * Students T Test			

Table 1. *Pre-operative demographics and clinical features of study groups.*

	PICO group	Wool and crepe	P
Requirement for surgical revision. N =	3	2	0.637#
Dressing removed before day 5 n =	2	2	1
Wound infection n =	4	7	0.306#

Table 2. *Results of study*

Unfortunately, this study has failed to show a statistical difference in revision surgery for patients undergoing major lower limb amputation but there may be a trend towards fewer wound infections. Although a larger randomised study might produce a statistically significant result, it would seem that an obvious clinical advantage might not be realised. One unexpected observation from this study was the superior appearance of the wound upon removal of the PICO dressing when compared to the wool and crepe dressing. As this was not anticipated before commencement of the trial and is a very subjective observation, this has not been reported in the results section.

It is interesting to note that the patient cohort in this study was very similar to the much larger cohort presented in a recent publication by Phair et al in which they looked at risk factors for unplanned readmission and stump complications after major lower extremity amputation [7]. The only exception to this was the lower incidence of diabetes in the PICO group presented in this

study versus a 72.1% incidence of diabetes in the Phair cohort. The distribution of AKA to BKA (38%) was the same in these two studies.

This study also reminds us of the severity of illness in this patient cohort with a 28% mortality at a mean of 5 months.

In conclusion, negative pressure dressings for major lower limb amputation do not reduce the risk of wound revision.

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