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# Use of Negative Pressure Wound Therapy for Lower Limb Bypass Incisions

Kah Wei Tan, MBBS,<sup>1</sup> Zhiwen Joseph Lo, MBBS, B Med Sci, MMed (Surg), FRCSEd, FAMS, FICS,<sup>2</sup> Qiantai Hong, MBBS, MMed, MRCS,<sup>2</sup> Sriram Narayanan, MBBS, MS, FRCS,<sup>2</sup> Glenn Wei Leong Tan, MBChB, FRCS (Glasg), MMed (Surg), FRCSEd (Gen),<sup>2</sup> and Sadhana Chandrasekar, MBBS, MS, FRCS<sup>2</sup>

**Objective**: The use of negative pressure wound therapy (NPWT) for post-surgical cardiothoracic, orthopedic, plastic, and obstetric and gynecologic procedures has been described. However, there are no data regarding its use for lower limb bypass incisions. We aimed to investigate the outcomes of NPWT in preventing surgical site infection (SSI) in patients with lower limb arterial bypass incisions.

**Materials and Methods**: We retrospectively used data of 42 patients who underwent lower limb arterial bypass with reversed great saphenous vein between March 2014 and June 2016 and compared conventional wound therapy and NPWT with regard to preventing SSI.

**Results**: Twenty-eight (67%) patients underwent conventional wound therapy and 14 (33%) underwent NPWT. There were no statistical differences regarding patient characteristics and mean SSI risk scores between the two patient groups (13.7% for conventional wound therapy vs. 13.4% for NPWT; P=0.831). In the conventional group, nine instances of SSI (32%) and three (11%) of these required subsequent surgical wound debridement, whereas in the NPWT group, there was no SSI incidence (P=0.019). Secondary outcomes such as the length of hospital stay, 30-day readmission rate, and need for secondary vascular procedures were not statistically different between the two groups.

**Conclusion**: The use of NPWT for lower limb arterial bypass incisions is superior to that of conventional wound therapy because it may prevent SSIs.

*Keywords:* negative pressure wound therapy, lower limb bypass, surgical site infection, critical limb ischemia, PICO

<sup>1</sup>Yong Loo Lin School of Medicine, Singapore <sup>2</sup>Vascular Surgery Service, Department of General Surgery, Tan Tock Seng Hospital, Singapore

Received: May 26, 2017; Accepted: July 27, 2017 Corresponding author: Zhiwen Joseph Lo, MBBS, B Med Sci, MMed (Surg), FRCSEd, FAMS, FICS. Vascular Surgery Service, Department of General Surgery, Tan Tock Seng Hospital, 11 Jalan Tan Tock Seng, Singapore 308433 Tel: +65-9017-7634, Fax: +65-6252-7282 E-mail: zhiwen@gmail.com

#### Introduction

Surgical site infection (SSI) is a common complication among patients who undergo infra-inguinal lower extremity bypass. SSIs can lead to prolonged hospital stays, increased healthcare expenditures, readmission, graft failure, and limb loss and is recognized as an important cause of postoperative morbidity and mortality.<sup>1,2</sup>) Negative pressure wound therapy (NPWT) has emerged as a method for reducing the risk of SSIs and is the wound dressing of choice in many vascular procedures.<sup>3</sup>)

NPWT is a therapeutic technique in which subatmospheric pressure is applied to a wound using a sealed wound dressing that is connected to a vacuum pump,<sup>4</sup>) which can be intermittently or continuously applied. NPWT facilitates wound healing by decreasing the bacterial burden; promoting granulation tissue formation, capillary blood flow, endothelial proliferation, and angiogenesis; and restoring the integrity of the capillary basement membrane.<sup>5–7</sup>)

The clinical efficacy of NPWT for closed incisions has been extensively studied in surgical disciplines such as orthopedics, cardiothoracics, and plastic surgery, and its use in promoting wound healing and improving patient outcomes has been validated.<sup>8–10)</sup> The use of vacuum-assisted closure dressings for infected bypass grafts in vascular surgery has also been previously reviewed.<sup>11,12)</sup> However, there is currently no evidence that supports the use of NPWT for lower limb bypass incisions. Therefore, we aimed to investigate the outcomes of NPWT in preventing SSIs in patients with lower limb arterial bypass incisions.

#### **Materials and Methods**

We retrospectively reviewed 42 patients who underwent lower limb arterial bypass with reversed great saphenous vein (tunneled subfascia) that was performed from March 2014 to June 2016. Postoperatively, 28 patients received conventional wound therapy (OpSite<sup>®</sup>, Smith & Nephew, London, UK) whilst 14 patients received NPWT (PICO<sup>®</sup>,



Annals of Vascular Diseases Vol. 10, No. 4 (2017)

**(C) BY-NC-SA** This article is distributed under the terms of the Creative Commons Attribution License, which permits use, distribution, and reproduction in any medium, provided the credit of the original work, a link to the license, and indication of any change are properly given, and the original work is not used for commercial purposes. Remixed or transformed contributions must be distributed under the same license as the original. Smith & Nephew, London, UK) for their closed incision sites after great saphenous vein harvesting (Fig. 1). The decision to use either conventional wound therapy or NPWT was based on surgeon's preference.

PICO<sup>®</sup> is a disposable, single-use pump without a canister that generates an effective, non-adjustable, negative pressure of -80 mmHg and that can be used for up to 7 days.<sup>13)</sup> It incorporates leak detection and low battery indicators and is connected to a 4-layer absorbent dressing that primarily removes wound exudates through evaporative loss. The mechanism of action has been postulated to occur because of the combined effects of a reduction in the frequency of dressing changes, a reduction in stress concentration in the tissue surrounding the incision, and an enhancement in the appositional strength of the incision line, thus reducing dead space and minimizing the risk of wound contamination.<sup>14)</sup> PICO<sup>®</sup> has also been demonstrated to enhance lymphatic clearance and decrease the risk of hematomas or seromas.<sup>15)</sup>

According to the local institution antimicrobial guidelines, patients who underwent elective bypass received a perioperative dose of intravenous cefazolin. For patients who underwent emergency bypass secondary to foot ulcers were administered targeted antibiotic therapy based on cultures from ulcerated tissues, and this was continued postoperatively, in consultation with the Department of Microbiology.

Data collected included patient demographics, comorbidities, and SSI risk score (SSIRS). SSIRS was designed by the University of Ottawa to estimate an individual risk of SSI within 30 days of surgery for a broad range of surgeries.<sup>16)</sup> The tool uses a model and risk score that were developed using a point system comprising various risk factors determined to have an independent association with SSI risk. This tool can be used to estimate SSI risk of individual patients and was validated in 181,146 patients with a c-statistic value of 0.8 and a 95% confidence interval (CI) of 0.776–0.786.

The primary outcomes in our study were SSIs and the need for subsequent surgical debridement. SSI was defined according to definition by the US Center for Disease Control and Prevention. Superficial incisional SSI is diagnosed



Fig. 1 Use of NPWT for femoral-posterior tibial bypass.

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when an infection occurs within 30 days of operation, involves only the skin and subcutaneous tissue, and if the patient has one of the following: purulent discharge, positive culture, or signs of inflammation.<sup>17)</sup> Other secondary outcomes evaluated include the length of hospital stays, need for 30-day readmission, and need for secondary vascular surgical procedures.

Statistical analysis was performed using SPSS for Mac (Ver. 21.0, SPSS Inc., Chicago, IL, USA). Continuous variables were analyzed using Student's t-test, and categorical variables were analyzed using Fisher's and chi-square tests. A P value of <0.05 was considered to be statistically significant.

#### Results

Between March 2014 and June 2016, 42 patients underwent lower limb arterial bypass with reversed great saphenous vein (Table 1). Of 42 patients, 13 (31%) underwent femoral-popliteal bypass and of 42 patients, 13 (31%) underwent femoral-popliteal bypass and 28 (67%) underwent femoral-distal bypass. Twenty-five patients (60%) underwent the procedure in an emergency setting. The median age of the patients was 66 (range, 41-81) years, and 67% of the study population was males. Baseline characteristics such as patient demographics, Rutherford classification, and comorbidities were not significantly different between patients in the conventional wound therapy and those in the NPWT group (Table 2). The mean SSIRS also showed no statistical difference between the two groups (13.7% for conventional wound therapy vs. 13.4% for NPWT; P = 0.831).

SSIs developed in nine patients (32%) of the conventional wound therapy group, whereas no SSIs developed in any patient of the NPWT group (P=0.019). All nine patients with SSIs underwent femoral-distal bypass. In

| <b>Table 1</b> Characteristics of lower limb arterial bypass | Characteristics of lower limb arterial bypass |  |
|--|---|--|
|--|---|--|

| Characteristics                | Bypass patients<br>(n=42) |
|--------------------------------|---------------------------|
| Types of bypass                |                           |
| Femoral popliteal              | 13 (31%)                  |
| Femoral distal                 | 28 (67%)                  |
| Tibioperoneal trunk            | 4 (10%)                   |
| Anterior tibial                | 6 (14%)                   |
| Posterior tibial               | 15 (36%)                  |
| Peroneal                       | 3 (7%)                    |
| Popliteal distal               | 1 (2%)                    |
| Urgency of operative procedure |                           |
| Emergency                      | 25 (60%)                  |
| Elective                       | 17 (40%)                  |
| Conduit                        |                           |
| Long saphenous vein            | 42 (100%)                 |

#### Table 2 Comparison of patient characteristics and SSI risk

|                           | Bypass patients (n=42) |                                   |                          |  |
|---------------------------|------------------------|-----------------------------------|--------------------------|--|
|                           | NPWT (n=14)            | Conventional wound therapy (n=28) | P value<br>(Fisher's χ²) |  |
| Demographics              |                        |                                   |                          |  |
| Male: Female              | 8 (67%):6 (33%)        | 20 (71%):8 (29%)                  | 0.490                    |  |
| Chinese: Malay: Indian    | 6 (43%):1 (7%):7 (50%) | 18 (64%):3 (11%):7(25%)           | 0.266                    |  |
| Mean age (range), years   | 66 (41–81)             | 66 (52–80)                        | 0.716                    |  |
| Comorbidities             |                        |                                   |                          |  |
| Smoker                    | 8 (57%)                | 15 (54%)                          | 0.213                    |  |
| Type 2 diabetes mellitus  | 13 (93%)               | 26 (93%)                          | 1.000                    |  |
| Mean HbA1C (%) (range)    | 8.9 (6.6–13.4)         | 7.9 (5.0–12.4)                    | 0.314                    |  |
| Hypertension              | 13 (93%)               | 25 (89%)                          | 1.000                    |  |
| Hyperlipidemia            | 14 (100%)              | 26 (93%)                          | 0.545                    |  |
| Ischemic heart disease    | 5 (36%)                | 16 (57%)                          | 0.326                    |  |
| History of stroke         | 3 (21%)                | 8 (29%)                           | 0.723                    |  |
| End-stage renal failure   | 1 (7%)                 | 5 (18%)                           | 0.645                    |  |
| Previous amputation       | 4 (29%)                | 10 (36%)                          | 0.738                    |  |
| Rutherford classification |                        |                                   |                          |  |
| Rutherford 3              | 2 (14%)                | 0 (0%)                            | 0.106                    |  |
| Rutherford 4              | 1 (7%)                 | 2 (14%)                           | 1.000                    |  |
| Rutherford 5              | 7 (50%)                | 20 (71%)                          | 0.193                    |  |
| Rutherford 6              | 4 (29%)                | 6 (21%)                           | 0.707                    |  |
| Mean SSI risk (%) (range) | 13.4 (10.2–19.1)       | 13.7 (7.7–24.0)                   | 0.831                    |  |

NPWT: negative pressure wound therapy

#### Table 3 Outcomes after lower limb arterial bypass

|   | Bypass patients (n=42) |  |         |                          |
|---|------------------------|--|---------|--------------------------|
|   | NPWT (n=14)            | =14) Conventional wound therapy (n=28) |         | P value<br>(Fisher's χ²) |
| Primary outcome                                 |                        |  |         |                          |
| Surgical site infection                         | 0 (0%)                 | 9 (32%)                                |         | 0.019                    |
|   |                        | Subsequent surgical debridement        | 3 (11%) |                          |
|   |                        | Antibiotics with wound care            | 6 (21%) |                          |
| Secondary outcomes                              |                        |  |         |                          |
| Mean length of hospital stay in<br>days (range) | 30 (6–217)             | 52 (6–166)                             |         | 0.186                    |
| 30-Day readmission                              | 5 (36%)                | 10 (36%)                               |         | 1.000                    |
| Need for secondary procedures                   | 9 (64%)                | 17 (61%)                               |         | 0.314                    |

NPWT: negative pressure wound therapy

the conventional wound therapy group, three patients (11%) underwent subsequent surgical debridement for SSI (**Table 3**). Secondary outcomes such as the average length of hospital stay, 30-day readmission, and postoperative complications (graft thrombosis and wound dehiscence) were not statistically different between the conventional wound therapy and NPWT groups.

Among 26 patients (62%) who required secondary vascular procedures after lower limb bypass surgery, 21 (50%) required further wound debridement or amputation for treating their initial tissue loss. Eleven patients re-

quired 30-day readmission for further surgical procedures related to postoperative complications after lower limb bypass surgery; of the 11 patients, eight (19%) had graft thrombosis and three (7%) had wound dehiscence.

#### Discussion

This is the first study to present data regarding the use of NPWT in preventing SSI in patients with lower limb arterial bypass incisions. NPWT has been extensively used for closed incisions in other disciplines such as orthopedic, plastic, and cardiothoracic surgery<sup>8–10)</sup> but has not been described for closed incisions during vascular lower limb bypass. In cardiothoracic surgery, studies have investigated the use of NPWT for sternotomy incisions in patients with coronary artery bypass graft (CABG).<sup>8)</sup> Although most patients with CABG require lower limb incisions for harvesting the great saphenous veins, which is similar to our study population, no study has reviewed the use of NPWT for lower limb incisions.

Our study also validates the use of NPWT over conventional wound therapy for reducing SSI (0% in the NPWT group compared with 32% in the conventional wound therapy group; P=0.019). Although the mechanism of action of NPWT remains unclear, many studies have suggested that NPWT reduces SSI by increasing blood flow, promoting granulation, and reducing edema and bacterial colonization.<sup>5–7,18,19)</sup> PICO<sup>®</sup>, the NPWT type used in our study, can generate an effective negative pressure of -80 mmHg and can be used for up to 7 days.

Two systematic reviews and meta-analysis that were conducted to evaluate the efficacy of NPWT for closed surgical incisions also confirmed its efficacy in reducing the SSI rates.<sup>20,21)</sup> In the study by Semsarzadeh et al.,<sup>20)</sup> there was a 29.4% relative reduction in the SSI rate in the negative pressure therapy group compared with that in the control group. Hyldig et al.<sup>21)</sup> also found that NPWT was associated with a significant reduction of wound infection rates [relative risk (RR), 0.54; 95%CI, 0.33–0.89] and seroma formation rates (RR, 0.48; 95%CI, 0.27–0.84).

An in vivo study revealed that applying subatmospheric pressure to a wound increases the rate of granulation tissue formation and reduces tissue bacterial counts.<sup>22)</sup> Reducing bacterial count is important in lower extremity wounds of patients with diabetes, who have poor healing rates owing to high bacterial burden<sup>23</sup>; this possibly occurs because of altered glucose metabolism and oxidative stress, resulting in phagocytic dysfunction.<sup>24)</sup> Similarly, NPWT helps in relieving endothelial dysfunction and subsequent edema in patients with critical limb ischemia (CLI)<sup>25)</sup> by promoting angiogenesis and reducing edema. Angiogenesis is critical for tissue repair, and patients with diabetes have reduced angiogenic response that leads to delayed wound healing.<sup>26)</sup> NPWT has also been postulated to enhance angiogenesis by establishing a hypoxic gradient, with the highest levels of vascular endothelial growth factors being detected at the foam-wound edge interface, which is an area of relative hypoxia.<sup>27</sup>)

Type 2 diabetes mellitus (T2DM) is a well-established risk factor for wound infections,<sup>28)</sup> particularly in patients with CLI. In patients who undergo lower limb procedures for CLI, the reported rates of SSI range from  $3\%^{29}$  to 40%.<sup>30)</sup> This variance is probably because of the differences in the proportion of patients with T2DM within the

study population, which ranged from 44%<sup>29</sup> to 64%.<sup>30</sup> With 93% of our study population having T2DM, our SSI rate of 32% in the conventional wound therapy group concurs with those previously reported with a similar proportion of patients with T2DM.<sup>30</sup> Hence, the use of NPWT in these patients will help lower the risk of SSI and surgery-related morbidity.

Our study has some limitations such as its retrospective nature, inherent bias, and a relatively small study population that can lead to probable sampling bias. Because the decision to use conventional wound therapy or NPWT depended on the surgeon's preference, there may have been a degree of selection bias, although similar SSIRSs between the two groups suggest otherwise. Finally, we could not evaluate cost differences between the two types of wound therapy.

## Conclusion

The use of NPWT for lower limb arterial bypass incisions is superior to that of conventional wound therapy because it may prevent SSI, particularly in patients with CLI and T2DM.

## **Disclosure Statement**

This study did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

## **Author Contributions**

Study conception: ZJL, QH, SN GWLT, SC Data collection: KWT, QH Analysis: KWT, QH, ZJL Investigation: KWT, QH, ZJL Writing: KWT, ZJL Funding acquisition: nil Critical review and revision: all authors Final approval of the article: all authors Accountability for all aspects of the work: all authors

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