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Original Article

Effect of Negative Pressure Wound Therapy for Soft Tissue Injuries of Foot and Ankle in Patients at a Tertiary Care Hospital

Roqayyh Munawwer Khursheed, Faisal Akhlaq Ali Khan, Hyder Ali, Zaara Zahid, Saba Kiran, *Muhammad Kamran Ullah Ansari

Dow University of Health Sciences Civil Hospital, Karachi Pakistan, *Abbasi Shaheed Hospital, Karachi Pakistan

ABSTRACT

Objective: To determine the effect of Negative Pressure Wound Therapy (NPWT) in patients with foot and/or ankle injury compared with conventional dressing techniques.

Study Design: Randomized controlled trial (Trial No: NCT04569305).

Place and Duration of Study: Department of Plastic Surgery, Dr Ruth K.M. Pfau Civil Hospital, Karachi Pakistan, from Dec 2019 to Oct 2020.

***Methodology*:** All patients with foot and ankle injury resulting in soft tissue injury with or without bones and tendons exposed were included. Thirty-five patients were randomized into the NPTW-Group and 35 into the Conventional Treatment Group using the lottery method. NPTW was applied to an injured foot and ankle area after debridement and cleaning the necrosed tissue. The effect of the technique was assessed by measuring the wound surface area covered with healthy granulation tissue measured in a centimetre square on follow-up.

***Results*:** Mean wound grade at the start of treatment was estimated as 3.20±0.71 in the NPWT-Group and 3.14±0.73 in the Control-Group, and at the end of treatment as 1.20±0.53 in the NPWT-Group and 1.71±0.78 in the Control Group. The mean wound size at the start of treatment was estimated as 52.74±21.92 cm2 in the NPWT-Group and 54.08±23.28 cm2 in Controls. At the end of treatment, an average wound size was estimated as 21.61±13.46 in NPTW and 30.40±16.50 in controls. NPTW significantly reduced wound grade and size more effectively than the conventional technique (p<0.05).

Conclusion: Negative pressure wound therapy was more effective for soft tissue injury of the foot and/or ankle injury than the conventional dressing technique.

Keywords: Conventional dressing technique, Negative pressure wound therapy, Soft tissue injury, Wound size, Wound grade.

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INTRODUCTION

A common outcome of foot or ankle injury is the exposure of tendons, bones and soft tissue.[1] Acute injuries can lead to exposed tendons and even bones depending on the type and severity of the injury. In the conventional way of treatment, these wounds with exposed tendons or/and bones are covered with skin graft following the formation of healthy granulation tissue assisted by VAC dressings.[2] This conventional way of treatment, although it improves the healing process, however, may take a longer period resulting in a serious loss of functionality among the patients.[1,3]

Patients treated with this VAC may experience severe pain mainly because of prolonged treatment and multiple changes of dressings.[3] In addition to these problems, the formation of healthy granulation tissue is impaired by VAC dressings in case tendons/bones or implants are exposed due to injury. Therefore, there is a requirement for free flap surgery requiring much more effort in addition to the problem of donor site healing issues.[4,5]

Argenta *et al*. introduced, for the first time, what was called Negative Pressure Wound Therapy (NPWT).[5,6] The technique covers major soft tissue defects and even exposed bones, sparing the need for much more frequent dressing changes, thus reducing not only the burden on health care system but also reducing the chances of infections.[7,8] This technique also optimizes wound blood supply and reduces oedema, enhancing and improving healthy granulation tissue formation. Several studies have reported the use of NPWT at different sites of the body, including the abdomen, chest and extremities.[9,10]

Despite this evidence, the efficacy of this technique is very little reported in foot wounds and reconstructive ankle surgeries. The scientific evidence on the efficacy of NPWT is especially important because most of the injury in this region results in exposure of bones and tendons. In addition, it is also important to generate scientific evidence on the efficacy of NPWT in this region, as, among geriatric

Correspondence: Dr Roqayyh Munawwer Khursheed, Department of Plastic Surgery Dow University of Health Sciences Karachi Pakistan.
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patients and those with chronic ulcerative diseases, conventional regular dressing is not always very practical. Therefore, the purpose of this study was to evaluate the efficacy of NPWT in patients with foot and/or ankle injury with or without exposing bones and tendons compared with the conventional dressing technique.

METHODOLOGY

This randomized controlled trial was conducted at the Department of Plastic Surgery, Dr Ruth K.M. Pfau Civil Hospital, Karachi Pakistan, from December 2019 to October 2020, (Trial registration number: NCT04569305). The sample size was calculated using the previously reported effects of NPWT by McCallum *et al*,[11] as days to heal in NPWT as 22.84±17.4 days and in the control arm as 42.8±32.5 days. The minimum required sample size was calculated to be 54 (27 in each arm) at a 95% confidence level and 80% power. However, this study enrolled 70 patients (35 in each arm) using a non-probability consecutive sampling technique.

Inclusion Criteria: All patients aged 18 years or above with foot and ankle injury resulting in soft tissue injury with or without bones and tendon exposure were included in the study.

Exclusion Criteria: Patients with uncontrolled diabetes mellitus and multiple fractures were excluded from the study.

The potential research participants were approached by the OPD of Dr Ruth K.M Pfau Civil Hospital, Karachi Pakistan and informed in detail regarding the research. Informed and written consent was obtained and randomized into whether the NPWT-Group or the Conventional Treatment Group using the lottery method. In the Conventional Group, simple dressing with normal saline-soaked gauze was performed. In the NPWT-Group, the negative pressure technique was applied to an injured area of the foot and ankle after debridement, cleaning the necrosed tissue, and using Vacuum Assisted Closure (VAC) consisting of an evacuation tube, vacuum pump, collecting canister, and a multiporous polyurethane sponge was performed. Multiporous polyurethane foam dressings are used over wounds and are cut to size to fit wounds. The foam dressing was applied, filling the wound. An evacuation tube was placed over the foam then an Opsite was applied over the top to create a seal around the dressing. The evacuation tube was then connected to a wall-mount suction canister. Once the dressing was sealed, the vacuum pump was set to deliver continuous or intermittent pressures, with pressure levels varying between −125 and −75 mmHg, depending on the patient tolerance. The effect of the technique was assessed by measuring the wound surface area covered with healthy granulation tissue measured in centimetre square on follow-up and wound grading (Figure-1).

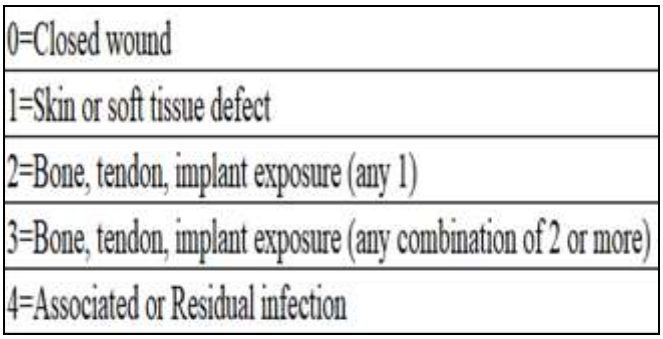

Figure-1: Wound Grading

Data were entered and analysed using Statistical Package for Social Sciences (SPSS) version 23:00. Descriptive statistics were calculated for all continuous and categorical variables. Pre and post-mean wound grade and size were compared using paired t-tests. In addition, the comparison was made between NPWT and Conventional Dressing Groups in terms of mean change in wound size and grade using an independent t-test. The *p*-value of ≤0.05 was considered statistically significant.

RESULTS

Of 70 patients, the mean age of the study sample was estimated as 36.46±18.66 years (Range: 15-78 years). Most patients were males (n=59,84.3%), and 11(15.7%) were females. The wound was located on the dorsum foot in 32(45.7%) patients, on the plantar in 19(27.1%) patients, on the medial side in 9(12.9%) patients, on the lateral side and ankle in 5(7.1%) patients respectively. The majority of the patients experienced pedestrian traffic accident (PTA) (n=29,41.4%), followed by spoke wheel/motorcycle (n=25, 35.7%), a crush injury (n=10,14.3%) and fall (n=6,8.6%) respectively (Table-I).

The mean duration of treatment in the NPWT-Group was estimated as 15.8±4.95 days ranging from 10 to 27 days, whereas in the Control-Group as 16.09±4.29 days ranging from 10-24 days. Mean wound grade at the start of treatment was estimated as 3.20±0.71 in the NPWT-Group and 3.14±0.73 in the Control-Group and at the end of treatment as 1.20±0.53 in the NPWT- Group and 1.71±0.78 in the Control-

Group. Hence, the wound grade was significantly reduced in both Groups (p<0.05). However, NPWT was more effective in reducing wound grade than the Control-Group (p=0.01).

Table-I: Descriptive Statistics of Study Population (n=70)

Descriptive Statistics	n (%)
Age in years	
Mean±SD	36.46±18.66
Gender	
Male	59 (84.3)
Female	11 (15.7)
Site of Injury	
Dosral	32 (45.7)
Plantar	19 (27.1)
Medial	9 (12.9)
Lateral	5 (7.1)
Ankle	5 (7.1)
Mechanism of Injury	
Pedestrian traffic accident	29 (41.4)
Crush	10 (14.3)
Fall down	6 (8.6)
Spoke wheel/motorcycle	25 (35.7)

Mean wound size at the start of treatment was estimated as 52.74±21.92 cm2 in the NPWT Group and as 54.08±23.28 cm2 in controls, and at the end of treatment, average wound size was estimated as 21.61±13.46 in NPWT and as 30.40±16.50 in controls. Hence, the wound size was significantly reduced in both Groups (p<0.05). However, NPWT was more effective in reducing wound size than the Control Group (p=0.001) (Table-II).

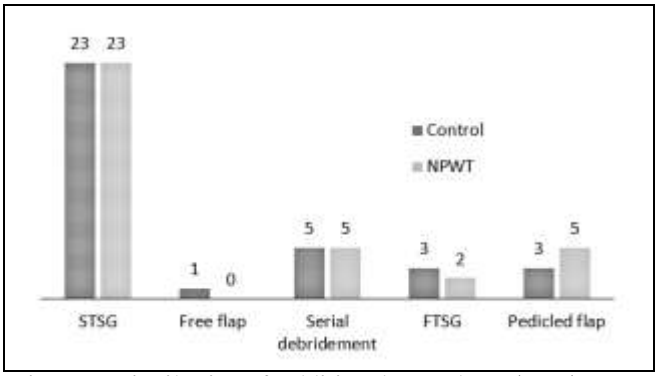

Figure-2: Distribution of Additional Procedures (n=70)

DISCUSSION

Soft tissue injuries to the foot or ankle are typically correlated with a substantial loss of skin, resulting in exposure of joints, tendons, or hardware and related wound management problems.[12] Such injuries are similar in many respects to persistent diabetic foot ulcerative lesions. The gradual development of granulation tissues and blood vessels is essential for healing such wounds. Conventionally, frequent changes of wet dressing, i.e., 3 to 4 times a day, are used to manage this kind of case, but such treatment is painful, and lengthy.[2,13,14] In addition, the interstitial fluid from the contaminated wound inhibits the blood supply as well as the healing process of the wound due to the metalloproteinase and collagenase constituents.[15] Through this view, NPWT is more effective at removing interstitial fluids and provides

Table-II: Comparison of Wound Outcomes in Negative Pressure Technique Group and Control Group (n=70)

Groups	Wound Grade		p-value	Change
	Pre (Mean±SD)	Post (Mean±SD)		Mean±SD
Negative Pressure Technique (n=35)	3.20±0.71	1.20±0.53	0.001	2.00±0.90
Control (n=35)	3.14±0.73	1.71±0.78	0.001	1.42±0.91
Groups	**Wound Size**		**p-value**	**Change**
	Pre (Mean±SD)	**Post (Mean±SD)**		**Mean±SD**
Negative Pressure Technique (n=35)	52.74±21.92	21.61±13.46	0.001	31.12±13.43
Control (n=35)	54.08±23.28	30.40±16.50	0.001	23.68±13.50

Post NPWT, a Split thickness skin graft (STGS) was performed in 22 cases to cover granulation tissue and a full thickness skin graft (FTSG) in six cases. In the Control Group, STGS was done in 23 cases and FTSG in three cases (Figure-2). Scar contracture occurred in five patients in the Conventional Group and four in the NPWT Group. No other complication, such as bleeding or deep infection, was reported.

advantages such as angiogenesis relaxation, wound drainage, proteinase excretion and decreased systemic and local bacterial loads.[16]

In the present trial, the mean time of NPWT use was 15.8±4.95 days, and the mean time of conventional therapy was 16.09±4.29 days. The research by Jones *et al*,[16] revealed similar results; the meantime of NPWT was 22.5 days which is lesser than the use of conven-

tional therapy for six weeks for infected wound.[3,17,18] In another study by Tarek Abulezz, also showed the meantime for granulation tissue in NPWT was significantly lesser than conventional therapy (18.5 days vs 28 days).[19]

Blume *et al*. in their study found a significant reduction in wound size in the NPWT Group as compared to Controls (43.2% vs 28.9%).[20] Tarek Abulezz, also found higher efficacy of NPWT than conventional therapy (77.8% vs 46.1%).[19] In our study we also found a significant reduction in mean wound size and grade in NPWT which was higher than conventional therapy (p<0.05), due to the early effect of NPWT in reducing bacterial load. DeFranzio *et al*.[21] revealed that NPWT was efficient in granulation formation in more than 80% of the patients in contrast with a conventional wet dressing. Additionally, it was also observed that NPWT gives continuous physical stimulus that improves the formation of new granulation tissues and vessels.[22]

Usually, soft tissue or injury in the ankle or foot area needs free flap surgery when a skin graft method is not applicable because of the limited formation of granulation tissue. STSG is not considered and recommended for wounds with involvement of weight-bearing surface of the foot or exposed bone or neurovascular structures.[23] In a study where comparison of NPWT and conventional dressings for foot lawnmower injuries was found to decrease the need for free flap surgery by 30%.[24] A significant decrease in need of additional operation is supposed to be a great benefit of NPWT.[7] In another study by Demond *et al*. It was also reported that a grade III wound with an associated open tibial fracture healed without additional operation, like a free flap.[25] Lee *et al*. also observed that open wound grades significantly decreased after NPWT. Only one patient required a free flap to cover the exposed tendon and bone.[15] In the present study, only five patients needed additional operations, such as a free flap to cover granulation. Only one patient needed a free flap in the Conventional Therapy Group.

NPWT also reduces the complications like deep infection, bleeding or disuse atrophy. In addition, with the reduced period of therapy and early mobility, NPWT restricts the requirement for post-operative physiotherapy.[15-17,22] In the present study, only four patients in the NPWT Group experienced scar contracture who underwent skin grafting, while no complications such as worsening infection or severe bleeding which could be specifically related to NPWT use were observed. Scar contracture occurred in four patients in the NPWT Group. No other complication, such as bleeding or deep infection, was reported.

LIMITATIONS OF STUDY

The present research has several limitations, such as a small sample size. Therefore, we recommend a multicentre study with a larger sample size to increase the generalizability of findings.

CONCLUSION

NPWT was more effective for soft tissue injury of the foot and/or ankle injury than the conventional dressing technique.

Conflict of Interest: None.

Author's Contribution

Following authors have made substantial contributions to the manuscript as under:

RMK & FAAK: Conception, drafting the manuscript, critical review, approval of the final version to be published.

HA & ZZ: Study design, data interpretation, critical review, approval of the final version to be published.

SK & MKUA: Data acquisition, data analysis, data interpretation, critical review, approval of the final version to be published.

Authors agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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