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Original article

Impact of negative pressure wound therapy on open diaphyseal tibial fractures: A prospective randomized trial

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ABSTRACT

Introduction: Open tibial fractures are associated with a high incidence of mainly osteomyelitis. Negative pressure wound therapy (NPWT) is a novel form of treatment that uses subatmospheric pressure to effect early wound healing.

Objectives and study design: To determine the effect of NPWT on incidence of deep infections/osteomyelitis after open tibial fractures using a prospective randomized study design.

Materials and methods: Ninety-three open tibial fractures were randomized into two groups receiving NPWT and the second group undergoing periodic irrigation, cleaning and debridement respectively. The wounds were closed or covered on shrinkage in size and sufficient granulation. Evidence of infection was sought during the course of treatment and follow up. Also serial cultures were sent every time the wound was cleaned.

Results and conclusions: Patients in the control group developed a total of 11 infections (22%) as opposed to only 2 (4.6%) in the NPWT group ($p < 0.05$). The relative risk was 5.5 (95% confidence interval) suggesting patients who received NPWT were 5.5 times less likely to develop infection. Twenty patients developed positive growth when samples were sent for culture with 3 (6.9%) in the NPWT group and 17 (34%) in the control group ($p < 0.05$). Only 5 patients (25%) went on the develop osteomyelitis, all being a part of the control group. Thus negative pressure wound therapy is indeed beneficial for preventing the incidence of both acute infections and osteomyelitis in open fractures. However a significant difference was not seen in the time required for the wound to be ready for delayed primary closure or coverage.

1. Introduction

Open fractures are a commonly encountered problem in orthopaedic practice. They are associated with a high rate of deep infections and osteomyelitis. Many studies have reported an infection rate in the tune of 16–66% in open fractures.[1–8] With modern treatment protocols and availability of better antibiotics, this percentage has decreased significantly but still amounts to a sizeable chunk. This scenario is worse for open diaphyseal tibial fractures as they are associated with a higher contamination, soft tissue damage and skin loss.

Negative pressure wound therapy (NPWT) is a novel form of treatment that uses subatmospheric pressure (vacuum) to effect early wound healing.[9–16] Its efficacy in reducing infections in open fractures has not been conclusively established. We aim to elucidate the effect of this therapy with respect to incidence of deep infections in open diaphyseal tibial fracture in this prospective randomized study.

2. Materials and methods

This study evaluated the role of negative pressure therapy on the incidence of deep infections in open tibial diaphyseal fractures. This study was commenced after clearance of the departmental review board and institutional ethics committee of our centre. Patients were included in the study only after their due consent. Adult patients (greater than 18 years) suffering from an open tibial fracture who were willing to be a part of the trial were included. Patients whose wounds could be closed at the index surgery, patients not needing repeated debridements and dressing, patients less than 18 years of age and those not willing to give consent were excluded from the study. Also, patients with periarticular tibial

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fractures, those needing amputations and those with wounds on which it would not be possible to use negative pressure therapy were also excluded.

All fractures were classified using the Gustilo Anderson classification system used for open fractures.[1] All Grade I and most of Grade II fractures had to be excluded from the study as the wounds could be closed after debridement during the primary surgery itself. The majority of the fractures that were included were Grade II and Grade IIIA fractures with heavy contamination and severe soft tissue and bony injury along with all Grade IIIB and Grade IIIC fractures. All patients underwent a thorough intraoperative debridement with stabilization of the fractures commonly with an external fixator. All patients received perioperative antibiotic coverage as per the institutional protocol which included a third generation cephalosporin, an aminoglycoside and clindamycin. These antibiotics were continued post-operatively.

The patients were randomized into two groups: the first group receiving VAC (vacuum assisted closure) dressing and the second group receiving daily cleaning, dressing and debridement. The VAC dressing consisted of a custom cut open cell foam and gauze that was put over the wound under an adhesive occlusive dressing. As per our institutional protocol, a negative pressure of about 125 mmHg was applied intermittently. Several studies have shown intermittent pressure mode to be more efficacious compared to continuous negative pressure.[20] The wound was opened every fourth day for reapplication of dressing and swab was sent for aerobic and anaerobic culture every time the wound was opened. Once the wound had sufficient granulation tissue such that it could undergo skin grafting or the wound had contracted to such a size that it could surgically closed, it was either closed or covered with skin graft. Serial irrigation and debridement was continued till the wounds were ready for closure or coverage.

Confounding factors such as nutrition and mobilization protocol were standardized as per the institutional guidelines and kept same. Basic demographic data of the patients was collected and tabulated. Also noted was the presence of comorbidities like Diabetes mellitus, chronic kidney disease and any immunosuppressive medications that the patient was receiving. History of smoking was also elicited as smoking has a clear negative impact on wound healing. The serum albumin levels of patients in both groups were noted. The distribution of these factors in the two groups was analyzed to remove bias. All patients were followed up regularly to look for presence of any delayed infection. Any patient who developed signs of acute wound infection like pyrexia, raised total leucocyte count and local signs like pus discharge from the wound with erythema of skin edges within 1 week of primary debridement was considered to have an acute infection. Deep infections included cases developing features of chronic osteomyelitis like a discharging sinus, fixed puckered overlying soft tissue and radiological changes consistent with chronic osteomyelitis. A case was considered to be culture positive if even a single culture out of the serial analysis showed quantitative bacterial growth.

Continuous variables were analyzed and tabulated using arithmetic mean, standard deviations and range. An unpaired t test was used to determine if the occurrence of various confounding factors in the two groups was significant. The relative risk was calculated using 95% confidence intervals. The differences in the incidence of infection in the two groups were calculated using Fischer exact test and probability (p value) less than 0.05 was considered significant.

3. Results

A total of 95 patients were enrolled in the study of which two required amputation as primary mode of treatment on the operating surgeon's discretion. These two patients were excluded. Using a random number generator, 50 patients were allotted to the control group and 43 to the group receiving negative pressure therapy. A total of 60 males and 33 females were randomly distributed in the two groups. The mean age of the patients receiving negative pressure therapy was 34.8 years while that of the ones in the control group was 37.4 ($p > 0.1$). Most of the patients presented to us within 48 h of trauma; however, there were some patients having delayed presentation. The mean interval between the time of injury and presentation to our institute was 4.6 days in the trial group compared to 4.3 days in the control group. A total of 8 patients were known cases of diabetes mellitus on medical treatment. They included 3 (6.9%) patients in the trial group and 5 (10%) patients in the control group. This difference was not statistically significant. A total of 25 patients were smokers being distributed as 25.5% and 28% in the trial and control groups respectively ($p > 0.05$). Only 2 patients, both in the trial group, had chronic renal disease while one patient in the trial group was on immunosuppressive medications in view of rheumatoid arthritis. Serum albumin is an important factor in wound healing especially in countries where malnourishment is rampant. The mean serum albumin was 2.4 and 2.52 in trial and control groups respectively highlighting the effective randomization and nutrition depleted status of these patients (Table 1).

The wound characteristics were also studied in detail. Majority of the fractures in the study belonged to Gustilo Anderson Grade IIIA and IIIB open fractures. 15 (34.8%) fractures and 14 (28%) fractures were Grade IIIA and 22 (51.1%) fractures and 27 (54%) fractures were Grade IIIB in the NPWT and control groups respectively. No Grade I fractures and very few Grade II and IIIA fractures were included as most underwent internal fixation with primary closure of the wound after debridement. Hence, only heavily contaminated wounds in these groups that required further debridements were possible to be included (Table 2). The average time required for the wound to be ready for grafting or delayed closure was 8.3 days and 9.8 days in the two groups respectively. This difference was not statistically significant ($p > 0.05$).

Wound dimensions were measured with the help of a ruler and were similar in both groups. The mean dimension in the group receiving NPWT was 10.4 cm × 6.1 cm × 1.6 cm. The average dimension of the wound in the group undergoing cleaning, debridement and dressing was 12.1 cm × 6.2 cm × 1.6 cm. Most of the wound in both groups underwent delayed closure while a total of 16 patients (eight in each group) needed skin grafting. Only three required a flap procedure for coverage (Table 3). One patient required a delayed amputation in view of unsalvageable soft tissue damage distal to the fracture. However, data from this patient was retained in view of the index wound being proximal to the amputation site. All patients were followed up at regular intervals with the mean follow-up being around 23 weeks ± 6 weeks.

Patients in the control group developed a total of 11 infections (22%) as opposed to only 2 (4.6%) in the group who received NPWT.

Table 1
Patient data and demographics.

	NPWT	Control group
Total	43	50
Male	28	32
Female	15	18
Age (mean)	34.8	37.4
Diabetes mellitus	3 (6.9%)	5 (10%)
Serum albumin levels	2.4 ± 0.4	2.52 ± 0.4
Chronic kidney disease	2 (4.6%)	–
Immunosuppressive therapy	–	1 (2%)
Smoking	11 (25.5%)	14 (28%)

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