Result of negative pressure wound therapy in open fracture

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Abstract

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

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

Materials and methods: Ninety-five open 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 19 infections (42.21%) as opposed to only 5 (10%) in the NPWT group. FOURTY SEVEN patients developed positive growth when samples were sent for culture with 5 (4.75%) in the NPWT group and 42 (39.9%) in the control group. Only 21 patients (22.2%) went on to develop osteomyelitis, among them 5(10%) patients are in npwt grup and 16(35.55%) are in 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 seen in the time required for the wound to be ready for delayed primary closure or coverage.

Keywords: Hip fracture; bone turnover markers; CTX; PINP; vitamin D

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. With modern treatment protocols and availability of better antibiotics, this percentage (5-40%) has decreased significantly. This scenario is worse for open 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 sub atmospheric early wound healing. 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 and retrospective randomized study.

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2. Materials and method: This study evaluated the role of negative pressure therapy on the incidence of deep infections (osteomyelitis) on open fractures. Patients were included in the study only after their due consent.

Inclusion criteria
1. Adult patients (greater than 18 years) suffering from an open fracture who were willing to be a part of the trial were included.
2. Patients with periarticular fractures, those needing amputations and those with wounds on which possible to use negative pressure therapy were also included.

Exclusion criteria
1. Patients whose wounds could be closed at the index surgery, patients not needing repeated debridement’s and dressing, patients less than 18 years of age and those not willing to give consent were excluded from the study.
2. All fractures were classified using the Gustilo Anderson classification system used for open fractures. 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 NPWT (Negative pressure wound therapy) dressing and the second group receiving daily clean dressing and debridement.
- Since its introduction 19 years ago by Argenta and Morykwas, negative pressure wound therapy (NPWT) has emerged as a common treatment for open fracture. In simple terms, NPWT refers to any device that tightly seals the wound creating a near airtight environment to which a vacuum can be applied resulting in a series of biological reactions that enhance wound healing. The terms Vacuum Assisted Closure (VAC) and microdeformational wound therapy (MDWT) are sometimes used interchangeably with NPWT. VAC now commonly refers to a family of devices using a highly porous foam based on the first commercially available NPWT device. Much of the clinical and basic science literature is based on these early devices. “Negative pressure” is somewhat of a misnomer as technically all pressure values should be positive. The VAC dressing consisted of a custom cut open cell foam of pore size of 400 -600 micromillimeter 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. The wound was opened every 7th 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 analysed 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 analysed 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.

3. Result
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 included. Using a random number generator, 45 patients were allotted to the control group and 50 patient to the group receiving negative pressure therapy. A total of 68 males and 37 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 7 patients were known cases of diabetes mellitus on medical treatment. They included 4 (3.8%) patients in the trial group and 3 (2.85%) patients in the control group. This difference was not statistically significant. A total of 35 patients were smokers being distributed as 22.8% and 10.45% in the trial and control groups respectively. Only 2 patients, both in the trial group, had chronic renal disease while one patient in the control 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 2.3 and 2.52 in trial and control groups respectively. An unpaired t test was used to determine if the occurrence of various confounding factors in the two groups was significant.

Table 1: Patient Data and Demographics

| Characteristic                     | NPWT  | Control Group |
|------------------------------------|-------|---------------|
| Total                              | 50    | 45            |
| Male                               | 33    | 35            |
| Female                             | 17    | 20            |
| Age (mean)                         | 34.3  | 35.4          |
| Diabetes mellitus                  | 4     | 3             |
| Serum albumin level                | 2.34 ± 0.3 | 2.52 ± 0.4   |
| Chronic Kidney Disease             | 2     | 0             |
| Immunosuppressive Therapy          | 0     | 1             |
| Smoking                            | 24    | 11            |

Table 2: Wound Characteristics

| Characteristic                     | NPWT  | Control Group |
|------------------------------------|-------|---------------|
| Days until Wound Ready for Closure/Coverage | 13.2  | 22.3          |
| Wound Dimension (Cm)               |       |               |
| Length                             | 15.2  | 14.3          |
| Breadth                            | 7.4   | 8.3           |
| Depth (in Deepest zone)            | 2     | 2.1           |
| Method of Wound Closure            |       |               |
| Delayed Closure                    | 10    | 12            |
| Skin Graft                         | 35    | 31            |
| Flap (Free/Rotational)             | 5     | 2             |

Table 3: Distribution of Fractures by Grading of open Fractures

| Grading       | NPWT | Control Group |
|---------------|------|---------------|
| GRADE I       | 0    | 0             |
| GRADE II      | 5    | 6             |
| GRADE IIIA    | 9    | 10            |
| GRADE IIIB    | 29   | 22            |
| GRADE IIIC    | 7    | 7             |

Observations and results

9 (8.5%) fractures and 22 (20.9%) fractures were Grade IIIA 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 debridement’s 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. 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 15.2 cm 7.4 cm 2 cm. The average dimension of the wound in the group undergoing cleaning, debridement and dressing was 14.3 cm 8.3 cm 2.1 cm. 22 patients wounded in both groups underwent delayed closure while a total of 66 patients (35 in npwt and 31 in control group) needed skin grafting. Only 8 required a flap procedure for coverage (Table 2). 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 19 infections (18.05%) as opposed to only 5 (4.75%) in the group who received NPWT.
Table 4: Incidence of acute and deep infections in the NPWT and control groups

|                          | NPWT | Control group |
|--------------------------|------|---------------|
| Acute Wound Infection    | 0    | 3 (6.66%)     |
| Delayed deep Infection   | 5 (10%) | 16 (35.55%)  |
| Total                    | 5    | 19 (42.21%)   |

Fig 6: Incidence of acute and deep infections in the NPWT and control groups

Table 5: Distribution of positive culture in the two groups

|                | NPWT | Control |
|----------------|------|---------|
| Positive culture| 5 (10%) | 24 (53.33%) |
| Negative culture| 45 (90%) | 21 (46.6%) |

Fig 7: Distribution of positive culture in the two groups

Discussion
1. NPWT take average 13.2 days for wound closure or coverage using skin grafting or flap as compared to 22.3 days which will take in control group this signifies that VAC application increases rate of growth of granulation tissue as compared to normal Dressing of Wound
2. NPWT acute wound infection is 0 as compared to 3 patients in control Group as wound exposure in control group happens to be daily as compared to 7 day one time opening of VAC
3. NPWT Delayed Deep Infection is found in 5 (10%) patients as compared to 16 (35.55%) patients in control Group as superficial infection is less in NPWT which leads to less chances of deep infection as compared to control
4. NPWT shows 5 (10%) patient who is culture positive as compared to 24 (53.33%) Patients in control Group as wound is more frequently exposed to external environment in control group as compared to NPWT

Conclusion
1. NPWT increases rate of formation of granulation tissue and reduces the time of wound healing as it increases the blood flow towards the wound
2. Infection rate in NPWT is less as compared to open wound as it is less frequently exposed to external environment
3. Culture positive swabs are less in NPWT group as it is less exposed to environment and continuous suction of devitalised tissue leads to reduced chances of harbouring the organism in the wound and keeping it there
4. NPWT is more suitable for those patient having other blood disorder like coagulation disorder and hemoglobinopathy due to more loss of blood in daily dressing.

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