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Results of negative pressure wound therapy in compound grade 3 tibial fractures

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ABSTRACT

Background: Open fractures constitute major chunk of orthopaedic trauma in a busy tertiary hospital and involve lot of morbidity, efforts, cost and time. Negative pressure wound therapy (NPWT) is a relatively new treatment that has proven beneficial in various types of complex wounds. The purpose of our study is to see the utility of NPWT in compound type III tibial fractures and its impact on the outcome of the patients.
Methods: 30 patients were included in the study with a mean age of 40.27 years ranging from 13 years to 62 years. There were 26 male patients and 4 female patients with 22 right sided fractures and 8 left sided fractures. The patients were then distributed into VAC/NPWT (study) group and control group using table of random numbers. Each group had 15 patients each. Scoring was carried out at before the first debridement.
Results: In the study NPWT group it was estimated that 5 patients may need amputation or but of these only 1 (20%) patient went on to have amputation of the involved limb while the rest (80%) could be salvaged. In the control group, 1 patient was predicted to need amputation which indeed resulted in amputation. Of the 7 predicted to need flap cover in study group, 4 (57.1%) eventually needed flap cover while the 3 (42.9%) were covered with skin grafting. Contrary in the control group all the 8 patients predicted to need flap cover, all ended up having the same. In the control group, of the 6 patients who were prognosticated to needed skin grafting, 2 (33.3%) worsened and needed flap cover while in the rest 4 (66.7%) skin grafting sufficed.
Conclusions: NPWT resulted in healthy granulation of the wound. The study undertaken was a prospective randomised control trial. However, the main drawbacks were the sample size and the inability to have long term follow up. More studies with larger sample size and a long term follow up are necessary to substantiate the findings of the study.

Keywords: Compound fractures, NPWT, VAC

INTRODUCTION

Severe open extremity fractures remain a challenging injury for the orthopaedic surgeon to treat, frequently leading to complications, morbidity and even amputations. It is estimated that 4.5 million compound fractures occur in India each year.[1] These fractures involve significant morbidity due to loss of protective skin barrier with resultant high potential for contamination. The correct and timely management of these injuries can benefit the patients and lead to more favourable outcomes. Despite the many advances in the care of the patients with Gustilo Anderson (G/A) type III open fractures they remain at high risk for infection.[2] Type 1 has 0-2%, type 2 has 2-5%/ type 3 A has 5-10%, type 3 B has 10-50%, and type 3 C has 25-50% risk.[3-5]

The basic objectives in the management of open fractures are to prevent infection, reconstruct soft tissue defects and achieve bony union.[1,2] Current protocols for treating open fractures include early administration of antibiotics, immediate surgical debridement, skeletal stabilization, sterile dressing, systemic support and establishment of soft tissue coverage in a wound environment that is clean.

Early wound cover can prevent nosocomially acquired wound infection.[2,3]

Tibia is the most common bone to be involved in open fractures of diaphyseal region.[4] Negative Pressure Wound Therapy (NPWT) is a relatively new treatment that has proven beneficial in various types of complex wounds.[2] It is a technique of applying sub- atmospheric pressure to wound to remove the exudates and debris from wound. It is delivered through an integrated system of suction pump, a separate exudates collection chamber and a dressing set made up of foam. It optimises the use of vacuum to promote healing of wounds. Although NPWT application is simple, the effects provided to the compromised soft tissue are profound.

The purpose of our study is to study the utility of NPWT in compound type III tibial fractures and its impact on the outcome of the patients.

METHODS

Participants: 30 patients with Gustilo Anderson compound Grade III tibial fractures who presented to the hospital between March 2013 to June 2015.

Study design

This was a randomised control study conducted at Government Medical College and Hospital, Nagpur.

Selection criteria

The following were considered the inclusion and exclusion criteria for inclusion of patients in the study:

Inclusion criteria

Inclusion criteria were all the patients who presented to our hospital with compound Grade III B tibial fractures (Gustillo Anderson classification) were included in the study; patients willing to follow treatment protocols and follow up protocols.

Exclusion criteria

Exclusion criteria were patients with type I and II compound tibial fractures; open fractures which were closed after initial surgery and did not require any further treatment; patients in whom amputation was done before any attempt was done for salvage of the limb; patients who died during stay in ward; patients with proven vascular injury were excluded; patients with bleeding dyscrasias.

The patients were then distributed into VAC/NPWT (study) group and control group using table of random numbers. Each group had 15 patients each.

As a part of the working performa, the following details were noted from the patients and their attendants:

Demographic details, date and time of injury were noted.

Duration of time elapsed since the injury and presentation at the hospital.

All the patients underwent trauma assessment and appropriate emergency treatment according to the Acute Trauma Life Support (ATLS) protocol laid down by the American College of Surgeons. Once the patient was stabilised, evaluation of the orthopaedic injury was done. The affected limbs were inspected for the size and extent of soft tissue injury, the bony status and the amount of contamination. All the wounds were tentatively classified based on Gustilo Anderson classification of open fractures. Extensive and grossly contaminated wounds were lavaged with normal saline, hydrogen peroxide and betadine solution to remove all the accessible foreign bodies in the wound. At this stage, the wounds were then graded as per the wound score mentioned below:

Table 1: Wound score for compound fractures.

Score	Wound status
0	Clean wound
1	Skin or soft tissue defect
2	Bone, tendon, implant exposure (any 1)
3	Bone, tendon, implant exposure (any combination of 2 or more)
4	Associated or residual infection or contamination

All the patients were given IV antibiotics on admission. The antibiotics included inj. Cefeperazone 1gm (iv 12 hourly) and inj. Gentamicin 80 mg (iv 12 hourly). The wounds were covered with betadine guaze piece and dressing given. The limb was temporarily aligned and splinted.

The patients were then subjected to detailed neurovascular examination. Those with vascular injury were excluded from the study. After this, necessary X-rays of the affected part were taken. Routine blood investigations were done as per necessity and anaesthesia fitness was obtained. The patients were then subjected to surgery.

Initial debridement and fixation

The patients were subjected to thorough debridement of the wound under necessary anaesthesia. Irrigation of the

wound with solution of hydrogen peroxide, betadine and copious amounts of normal saline. Thorough surgical debridement. Adequate haemostasis was achieved.

Special consideration was given to the state of the bone and the neurovascular structures. In general, small pieces of bone that were free of any soft tissue attachment were excised. When a large fragment of bone had soft tissue attachment and was bleeding, it was preserved. Completely devascularised bone fragments were removed. The fracture edges were refreshed. Medullary canal was inspected and using a curette foreign bodies and haematoma was removed. The periosteum attached to the bone was preserved to maintain the viability of the bone and was washed with copious amount of normal saline. Attempt was made in all cases to preserve maximum possible length of the bone. The blood vessels and nerves which were exposed were carefully isolated. Any surrounding contaminated tissue was removed and the wound was washed. In all cases, attempt was made to cover these vital structures with surrounding soft tissues.

Tendons too were preserved when possible to allow for better function post operatively.

After, thorough debridement the wounds were stabilised with external fixator in configuration as deemed appropriate by the operating surgeon. At this stage the wound was definitively classified again as per Gustilo Anderson classification. This standard protocol was common for all the patients who were a part of this study. The further procedure depended on whether the patient belonged to the study group or the control group.

Control group

The patient had regular daily dressing changes until the wound was considered fit either for secondary closure or plastic and soft tissue cover. The wound was cleaned with hydrogen peroxide and normal saline and dressing to be done with povidone iodine (5%) and saline soaked gauze. In case of excessive exudation the frequency of dressing change was increased. The wound was evaluated every third day and graded as per wound score. Surgical debridement was done when necessary. Culture swab for microbiology was taken before soft tissue cover.

Study group

NPWT was applied to this group. The NPWT dressing was changed every third day or earlier in cases with excessive drain. The wound was evaluated at each dressing change and graded as above till the wound was taken up for closure/plastic surgery procedure. Wound culture was also taken at each dressing change and debridement done if necessary.

Procedure for application of VAC

NPWT system to be used: Kinetic Concepts Inc, San Antonio, TX., USA.

Wound preparation

Haemostasis was ensured. Exposed bone covered with Bactigrass dressing to prevent direct application of foam over the bone. The skin surrounding the wound was dried to ensure proper adhesion of the occlusive dressing.

Placement of foam

Open pore sterile polyurethane foam was used for dressing. The foam comes with pore size of 400 to 600 microns having hydrophobic open cell structure. Such sizes of pores are effective of transmitting mechanical forces across the wound and provide an even distribution of negative pressure over the entire wound bed to aid in wound healing. The foam was trimmed to appropriate size and geometry of each individual wound. In case of two contiguous wounds or cavities with communication, care was taken to cover both by individual pieces of foam. We, however, did not insert any foam in the cavity. After the application of negative pressure most of the cavities collapse and even seal completely. The removal of the inserted foam then requires either gently pulling out the foam or carefully dissecting out the foam from the cavity. In the first scenario, complete removal cannot be ensured and a small piece of foam is left behind, it cannot be detected as foam is radiolucent thus risking further complications. In the second case, the cavity is often reopened thus making the entire process futile. Simply involving the cavity within the negative pressure is often enough to cause it to collapse and seal off without any residual infection. Care was taken not to apply the foam directly over skin to avoid skin maceration.

Sealing with drapes

The wound was then sealed using double layer occlusive dressing covering the foam and at least 5 cm of the surrounding healthy tissue to ensure a airtight seal. The dressing was often cut into small pieces for the ease of application. Multiple layers were used in difficult areas. Whenever the wounds around a fixator were to be sealed, care was taken to include all the pin sites in the seal. For this the pin tracks were first dried and then covered with dry sterile guaze pieces. Adhesive occlusive dressing was then applied over this guaze pieces to ensure airtight seal.

Connecting tubes

A small hole was then cut into the adhesive dressing roughly in the centre. It was just large enough so that the central connector would fit over it. After placement of the connector, it was further covered with a layer of adhesive dressing to ensure that there was no leakage. The connecting tubes were then attached to the connector. The tubes are connected to a canister which is mounted on the side of the central processor. The canister is made of transparent plastic and is sterile. It comes in various sizes from 200 to 500 cc. It contains a material which converts the fluid exudates into jelly like substance which

ensures that the collected fluid won't spill in an inadvertent situation of breaking of canister. The tubes can be connected to each other by means of connectors which interlock. Y-connectors help to connect two different tubes to a single one which goes to the central processor. This enables to tackle two wounds at two anatomically different sites to be connected to a single NPWT machine.

All the procedure was done under strict aseptic conditions. The first application of the NPWT was done on the operating table itself after the surgery. Once the entire assembly is ensured the tubes are connected to the main processor.

Application of negative pressure

Uniform negative pressure was applied to the inner surface of the wound with the help of central pump. The pump was set at continuous mode and delivered -125 mmHg of pressure throughout the therapy. The pump allows for detection of leak in the system if any, pressure monitoring, any block in the connecting tube and sounds an alarm in case of interruption of therapy due to any reason.

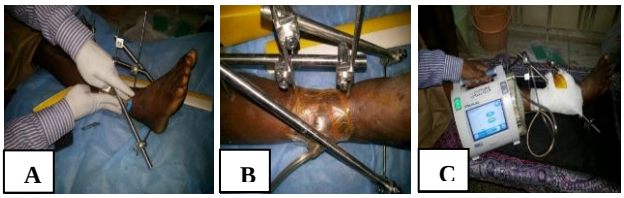

Figure 1: A and B= application of central connector and sealing of the foam with occlusive dressing. C= final picture after starting the pump and covering the dressing with pad and bandage.

After application, the dressings were changed every third to fifth day or earlier depending on the wound size and the amount of exudate. Debridement was done whenever deemed necessary. At each dressing, following parameters were evaluated:

1. Wound score
2. Infection of the wound
3. Infection following soft tissue cover.

The patients were then followed up till definitive wound cover was done.

Clinical end point or treatment failure

Definitive soft tissue cover of the wound was considered as the end point of the therapy.

The various methods included:

1. Secondary closure
2. Split skin grafting
3. Myocutaneous/transpostional/rotational/pedicle flaps

The two groups will be compared before final closure and the wounds will be scored and compared.

Failure of the wound score to improve by at least one point or in case of worsening of the wound score by the end of 15 days will be considered as treatment failure.

Necessity to ablate the limb before 15 days will be considered as the end point of the therapy. The patient will be considered as treatment failure.

Follow up protocol

The patients were followed up every month for first two months and then every 3 months. At each follow up serial x-rays were done. The patients were assessed for the following:

1. Development of infection
2. Graft or flap rejection or uptake
3. Graft or flap failure
4. Need for secondary intervention
5. Wound healing.

Statistical analysis

Continuous variables were presented as Mean± SD. Categorical variables were expressed in actual numbers and percentages. Pre and post wound scores were compared by performing paired test for normalized data. Changes in wound score between VAC and control group were compared by Wilcoxon sign rank test for non-normalized data. Time of presentation, time of surgery and time to closure were compared between VAC and control group by applying Wilcoxon rank sum test. Categorical variables were compared by performing Pearsons chi–square test. $P<0.05$ was considered as statistical significance. Statistical software STATA version 13.1 was used for data analysis.

RESULTS

30 patients were included in the study with a mean age of 40.27 years ranging from 13 years to 62 years. There were 26 male patients and 4 female patients with 22 right sided fractures and 8 left sided fractures. Thirty patients with Gustillo Anderson compound Type III B fractures who met the criteria for inclusion were included in this study. This was mainly because the type III A fractures were closed primarily while those with IIIC fractures had contraindication for the use of NPWT.

The average age of patients in the study group was 40.8 years while the average age in the control group was 39.73 years. With regards to distribution of fractures as per the anatomical location, there were 11 distal tibial fractures, 12 mid shaft fractures and proximal tibial fractures. There were 1 patient each with segmental and fractures of the malleolus. The average time needed for

the patient to be posted for surgery was 7.79 hours. It was 7.73 hours or the control group while it was 7.86 hours for the study group. Only 1 patient of the thirty was operated after a time lag of 7 days. This delay was due to the fact that the patient needed the time to arrange for the implants.

Table 2: Demographic profile of the patients in the study.

Parameter	Study group	Control group	P value
Age (mean)	40.8	39.73	
Sex ratio- M:F	14:1	12:3	
Type of fracture			
PROX. #	4	1	
Mid shaft #	6	6	
Distal #	4	7	
Segmental #	0	1	
Malleolar #	1	0	
Side			
Right	11	11	
Left	4	4	
Time to presentation (mean, hours)	27.66	21.1	0.2126, NS
Time to surgery (median, hours)	8	8	0.7697, NS

Table 3: Initial and final assessment of soft tissue procedure.

	NPWT		Control	
	Initial	**Final**	**Initial**	**Final**
Amputation	5	4 (80) Flap 1 (20) Amputation	1	1 (100)
Flap	7	4 (57.1) Flap 3 (42.9) STSG	8	8 (100)
STSG	3	3 (100)	6	2 (33.3) flap 4 (66.7) STSG

Table 4: Incidence of severity of infection.

Type of infection (%)	Study	Control
Superficial	6.7	20
Deep	6.7	13.3
Organ space	6.7	6.7

Thus the patients were taken up for surgery without a significant difference between the two groups.

The most common organism causing infection was *Staphylococcus aureus* which was responsible for infection in 5 out 9 patients. *E. coli* was responsible for infection in 3 patients while pseudomonas made up the last one.

DISCUSSION

During the past few years, the use of NPWT has increased substantially. This appears to be based on the marketing of the available technology and the favourable clinical experience.[5] There have been studies which have shown that use of NPWT leads to increased concentration of growth promoters and increased cellular proliferation at the site of application which may be the basis of its ability to fasten wound healing. Also, with its ability to promote healing of fractures as shown by Zhu et al by stimulating mesenchymal stem cell proliferation and osteogenic differentiation NPWT may play and stimulate healing of fractures itself.[6]

This study is a prospective randomised control study of 30 patients which aims to study the utility of NPWT in compound tibial fractures with respect to its impact on wound healing and soft tissue cover in a setting of a tertiary care centre. The observations of this study were subjected to comparison with the observations made by different authors.

Age and gender distribution

In this study, the average age of patients was found to be 39.96 years with 40.2 years in study group and 39.73 years in the control group. Most of the patients belonged to the age group of 21 to 40 years. There were 26 male

patients and 4 female patients which were evenly divided in the two groups. This distribution is comparable with that given in the literature.

The male to female ratio in the study and control group was 14:1 and 12:3 in this study.

Distribution as per the anatomic location

Most of the patients enrolled in the study had fractures in the mid shaft and distal shaft regions (83.33%). This is as compared to the 73% of fractures involving these regions in the study conducted by Blum et al.[7]

Wound score

The wound score was calculated as follows:

Table 5: Wound score for compound fractures.[8]

Score	Wound status
0	Clean wound
1	Skin or soft tissue defect
2	Bone, tendon, implant exposure (any 1)
3	Bone, tendon, implant exposure (any combination of 2 or more)
4	Associated or residual infection or contamination

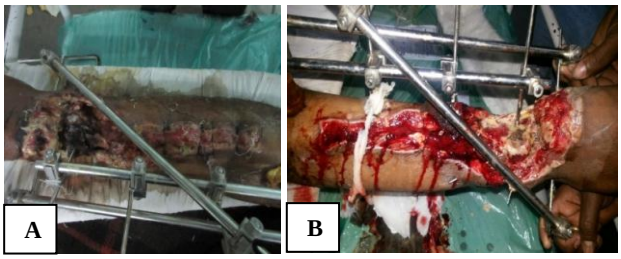

Figure 2: Wound status A=before and B=after debridement.

Average number debridement needed in our study was 2.07, whereas in the study of stannard it was 2.4, and the study of Dedmond and Barnett, three debridements on average were required.[9-11]

All the studies emphasize the fact that NPWT is not a substitution to surgery. NPWT cannot remove large necrotic and infected material present within the wound. Surgical debridement has to be done to remove the infected material to achieve a clean wound. NPWT maintains a clean environment by removing the exudates and keeping the wound area clear of moisture preventing accumulation of slough within the wound and promoting granulation. It is by this mechanism that NPWT decreases the need for further debridements. Indeed the need for debridement has shown to be decreased in various studies owing to this mechanism. To conclude, NPWT is only a bridge to achieving a clean wound state between initial debridement and final closure by promoting development of granulation and as such is not a replacement for debridement.

Infection

In our study the total infection rate was 60% of which 20% patients were in the study group while 40% were in the controls.

Complications

Temporary skin rash due to adhesive is the most commonly reported side effect, this can be easily avoided with proper preparation of the wound and skin, prior to application of NPWT.[12] Apart from this, the bleeding from wound bed remains a concern in an acute setting. This can be avoided by properly covering the vessels during debridement prior to NPWT application. Pain on removal of dressing is reported. We used to moisten the foam with normal saline prior to its removal which decreased the pain experienced by the patient. Serious complication like staphylococcal toxic shock syndrome have been rarely reported mainly in chronic settings.[13] In this study, there were no major side effects which were experienced by the patient.

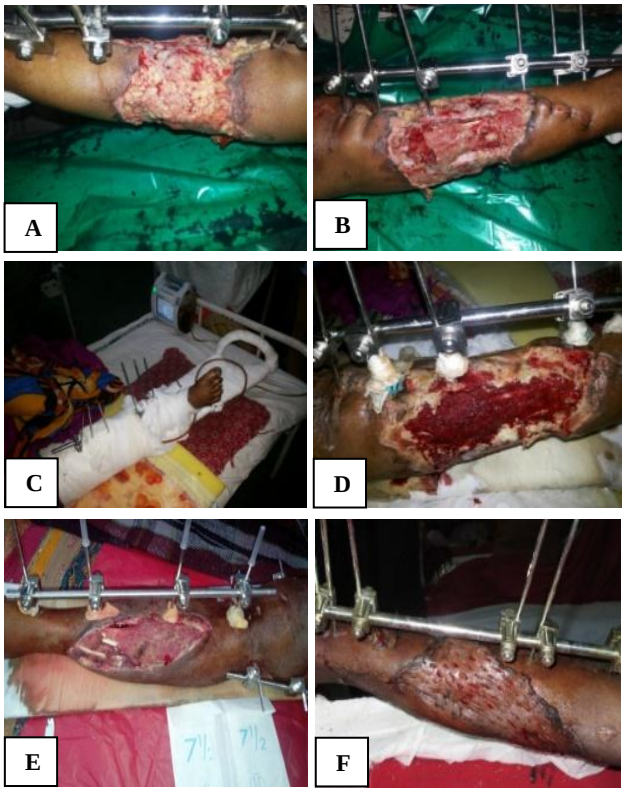

Figure 3: A and B= Wound after debridement and fixation. C= Application of NPWT to the wound. D= Wound after removal of NPWT covered in granulation. E= Wound post debridement and fixation and after successive NPWT application. F= Final closure of the wound with soft tissue cover.

Cost factors

Cost factors have been the major hindrance to the use of NPWT in many set ups. The cost effectiveness of NPWT is depended on the local health care practice and may not be applicable universally. The therapy would be cost effective only under the condition that it accelerates the healing of wound as compared to conventional methods.

The daily rental charges and the cost of disposables does seem to support the finding that NPWT is an expensive method of treatment. However when coupled with the fact that it decreases the hospital stay and downgrades the number and complexity of the required surgeries, NPWT does decrease the overall financial burden on the health care system.[14]

CONCLUSION

NPWT therapy can be regarded as a method that combines the benefit of both open and closed treatment and adheres to DeBakey's principles of being short, safe and simple. VAC is most useful in difficult cavity or highly exudative wounds. Deep infection in severe open fractures of tibia has always been the bone of contention of the orthopaedic surgeons. It vastly increases the morbidity associated with the fractures and the duration of hospitalisation. Use of NPWT has shown to decrease the amount of infection. Whether this is due to the closed environment created by NPWT preventing nosocomial infections or due to NPWT itself remains to be studied further. But NPWT undoubtedly has shown a lot of beneficial effects which can be directly attributed to the therapy itself. It has shown to facilitate rapid granulation of the tissue compared to conventional methods. The healing time has shown to be shortened considerably using NPWT.NPWT was very well tolerated by the patients across all age groups with no adverse effects thus ensuring proper adherence to treatment. It is a almost painless form of treatment.

Wound healing promoted by NPWT resulted in healthy granulation of the wound. This was achieved in shorter period of time. The soft tissue reconstruction procedure was often scaled down. Thus it can be stated that although NPWT may not be able to completely alleviate the need for soft tissue cover, it can definitely help to bring the procedure required down the rungs of the complexity ladder. This has helped to decrease the overall cost of the treatment.

To summarise, NPWT has proved to be viable adjuvant therapy in the management of compound tibial fractures. It has positively affected most of the aspects of the treatment

Limitation

However it has to be noted that it is not a replacement to surgical debridement and soft tissue cover. It is more of a bridge between the two enabling soft tissue cover at the earliest with little inconvenience to the patient. As such it is a well-deserved, although at present pragmatic addition to the wound healing armamentarium and the reconstructive ladder. The study undertaken was a prospective randomised control trial. Despite a number of studies which promote NPWT, there are a few prospective randomised studies evaluating the use of NPWT after severe compound fractures. Majority of them are retrospective studies which have made use of traditional controls as a comparison group. However, the main drawbacks were the sample size and the inability to have long term follow up. More studies with larger sample size and a long term follow up are necessary to substantiate the findings of the study.

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