Comparison between Negative Pressure Wound Therapy and Standard Wound Therapy for Open Musculoskeletal Injuries: A prospective study at a tertiary care Institute

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Abstract

BACKGROUND

Delay in wound healing leads to social and financial burden to the patients, with frequent hospital stay, visits and increase cost of treatment. Negative Pressure Wound Therapy is an alternative to the routine wound management. **Negative Pressure Wound Therapy** has evolved both as a mainstay and as an adjunct in wound management, especially in the last two decades.

MATERIALS & METHODS

This was a prospective study with a sample size of 60 patients with Gustilo Anderson type IIIA or IIIB open fractures, of whom 30 patients each were selected for Negative Pressure Wound Therapy(NPWT) or Vacuum Assisted Closure (VAC) therapy and standard saline wound therapy. RESULTS

Bacterial Culture Negativity was achieved faster with NPWT (average of 1.7 cycles) as compared to standard dressing(3.33 cycles) which was found to be statistically significant (with a p value of 0.000454). It was seen that the average wound contraction per cycle of NPWT was 7.74% [Mean = 7.739 +/- 3.334] as opposed to 2.2% with Standard Saline dressing [Mean = 2.238 +/- 1.15 which was statistically significant (p value of 0.000539).

Conclusion

Therefore, we can conclude that vacuum therapy provides not only safe temporary wound coverage but also conditioning of the soft tissues until definitive wound closure, along with other advantages like bacterial clearance and increased formation of granulation tissue attributed to vacuum therapy, which makes it an extremely attractive device in the field of wound healing.

Key Words: Negative Pressure Wound Therapy(NPWT), Vacuum Assisted Closure(VAC), Gustilo Anderson, Open fracture.

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I. Background

An open fracture is an injury where the fractured bone and/or fracture hematoma are exposed to the external environment via a traumatic violation of the soft tissue and skin.¹

Open Fractures can be classified by various systems. Most commonly the Gustilo Anderson System is used. Gustilo-Anderson type I open fractures is a low energy injury with wounds less than 1 cm with minimal soft tissue damage. Type II fractures are low to moderate energy injuries with wounds that are greater than 1 cm and less than 10 cm with moderate soft tissue and muscle damage. Type III fractures are high-velocity injuries have wound size greater than 10 cm. Type III injuries have highly contaminated wounds. Type III A injuries have severe crushing soft tissue damage, type III B have a significant loss of tissue coverage, and type III C have significant loss of tissue with an associated vascular injury.^{2,3}

Wound healing is a complex and dynamic process that includes an immediate sequence of cell migration leading to repair and closure. When wound fails to undergo this sequence of events, a chronic open wound without anatomical or functional integrity results.⁴

The importance of proper wound care in maximizing rates of limb salvage, and factors such as convenience to the patient and practitioner have evolved as valid variables that should be addressed when choosing a wound-care modality.

Current wound treatment options for these complex wounds include traditional dressings, advanced wound dressings (i.e., provide moisture balance, have antimicrobial properties), or advanced wound therapies (such as hyperbaric oxygen therapy and negative pressure wound therapy [NPWT]).⁵ However, these treatment options may fail if debris, infectious materials, fibrinous material, thick exudate, or devitalized tissue are present. Recently, NPWT has evolved to include the automated instillation of topical wound solutions with a user-specified dwell time (NPWTi-d) to provide an automated option for wound cleansing. A novel reticulated open-cell foam dressing with through holes provides an option to assist wound cleansing by removing thick wound exudate and infectious material when surgical debridement may not be possible or appropriate.^{6,7}

It has been established that open fractures need early bony stabilization and soft tissue reform.⁵ Unluckily, primary soft tissue procedures is not possible round the clock in our institution. Negative pressure wound therapy (NPWT) is a method to achieve wound closure or manage the wound bed for additional surgical intercessions.

VACUUM ASSISTED CLOSURE (VAC) THERAPY

Negative pressure wound therapy (NPWT), also called vacuum-assisted wound closure, refers to wound dressing systems that continuously or intermittently apply subatmospheric pressure to the surface of a wound.

Subatmospheric pressure has multiple beneficial effects on wound healing in animal models. However, clinical evidence of its superiority over conventional wound dressing techniques for all wound types has not been comprehensively proven. The available randomized trials have significant heterogeneity in the nature of wounds treated and in primary and secondary endpoints, making rigorous comparisons difficult and limiting the ability to generalize their results.

The optimal sub-atmospheric pressure for wound healing appears to be approximately 125 mm Hg utilizing an alternating pressure cycle of 5 minutes of suction followed by 2 minutes off suction.

Animal studies have demonstrated that this technique optimizes blood flow, decreases local tissue edema, and removes excessive fluid from the wound bed. These physiologic changes facilitate the removal of bacteria from the wound. Additionally, the cyclical application of sub-atmospheric pressure alters the cytoskeleton of the cells in the wound bed, triggering a cascade of intracellular signals that increases the rate of cell division and subsequent formation of granulation tissue. The combination of these mechanisms makes the VAC device an extremely versatile tool in the armamentarium of wound healing.

II. Materials & Methods

This prospective study was conducted to compare two methods of wound therapy by negative pressure wound therapy(NPWT) and standard wound therapy. This study was conducted at Deptt. of Orthopaedics, Calcutta National Medical College & Hospital, after obtaining clearance from the ethics committee of our Institution. Study population (sample size) comprised of sixty (60) consecutive patients (who satisfied the inclusion and exclusion criterion, and gave their informed written consent) above 12 years of age with open musculoskeletal injuries in extremities that required coverage procedures, admitted under Department of Orthopaedics in Calcutta National Medical College and Hospital, in the period between August 2017 to September 2019. These sixty patients were divided into two groups of thirty each on an alternate basis, on their admission at the IPD of the hospital.

Inclusion Criteria:

All patients with open musculoskeletal injuries Gustilo Anderson Types III A and B

Exclusion Criteria:

Patients with preexisting osteomyelitis in the wounds, neurovascular deficit in the injured limb, diabetics, malignancy, coagulation disorders and peripheral vascular disease. Patients with potentially life-threatening injuries that required emergency interventions were excluded from the study.

Procedure:

When a patient with an Open Musculoskeletal Injury came to our Hospital, either at the Out Patient Department (OPD) or at the Emergency, he/she was first resuscitated following the ATLS (Advanced trauma life support) protocol and was thereafter assessed for further evaluation as per the Gustilo Anderson System.

The wound was irrigated with copious amounts of Normal Saline and a preliminary dressing was done. Depending on the pre anaesthetic evaluation patients were prepared for surgery and appropriately anaesthetised for surgery at our Emergency OT.

Patients were scrubbed, painted and draped following recommended guidelines and routinely a thorough debridement was done along with saline irrigation (and Hydrogen Peroxide lavage if deemed necessary).Depending on the type of fracture dislocation, the fracture was fixed and then immobilized (as appropriate).

This was followed by appropriate post-operative dosage of analgesics and intravenous antibiotics. In our institution, we administered intravenous Cefuroxime (50mg/kg divided in 2 daily doses), intravenous Amikacin (500mg twice daily for adults) and intravenous Metronidazole (400mg thrice daily dosage for adult patients). This regimen of empirical antibiotic therapy was continued till the Staining and Culture Sensitivity reports came back from the laboratory. Post-operatively, the affected limb was elevated in bed, and the vital signs monitored regularly.

During debridement multiple samples were collected (of bone and soft tissue) and sent to the microbiology laboratory for Staining and Culture Sensitivity.

In patients selected under Standard Wound Therapy, repeat debridement was be done followed by Normal Saline Irrigation. Also routinely, samples for Staining and Culture were sent.

Wound dressing was continued till appearance of healthy granulation tissue. After which based on the size and type of wound it was decided whether to go for a secondary procedure or not.

Standard saline wound dressing

Each cycle of Standard saline wound dressing had been done at 3 day intervals.⁸

Following emergency debridement, wound lavage and stabilization as required the wound was left open or stay sutures were applied if applicable. The wound was sealed with sterile paraffin gauze dressing, further covered with Normal Saline soaked sterile gauze and then covered with sterile cotton and roller bandage.

The wound was again inspected within 48-72 hours of first debridement. Wound healing was defined, following wound inspection, as the presence of epithelial tissue covering the wound. These criteria had earlier been used by Griffiths et al. 9

Application of NPWT (VAC)

Each cycle of VAC (NPWT) had been of **5 day duration**.¹⁰

The VAC kit that we used uses medical grade open cell polyurethane ether foam (which is FDA approved for open wounds) as a dressing. The pore size is 1650 μ m (thought optimal for tissue growth). This foam is cut to fit and closely applied to the selected wounds. An evacuation tube with side ports, which communicate with the reticulated foam, is embedded in it. The aim of the reticulation being that the negative pressure will be applied equally to the entire wound bed. An adhesive drape is then applied over the area with an additional 3–5 cm border of intact skin to provide an intact seal.

The evacuation tube is connected to an adjustable vacuum pump and a 500 ml canister for collection of effluent. The pump can be adjusted in terms of both the timing (intermittent vs. continuous) and magnitude of the vacuum effect. We used an intermittent cycle (5 mins at 125mmHg and 2 mins off) setting for our subjects.

III. Results:

Out of sixty patients selected for the study, 40 were in the age group of 2nd to 4th decade. The 3rd decade accounted for 20 patients one third of the total, having Gustilo IIIA and IIIB injuries. Forty five patients were male (of whom 21 were selected for NPWT and rest were selected for standard therapy) and 15 were female (9 were selected for NPWT and rest were selected for standard therapy). Of the study sample, 24 out of 30 patients in the Saline Group had lower limb fractures and the rest had upper limb fractures. In the NPWT group 26 out of 30 patients had lower limb fracture and the rest had upper limb fractures. Among our study subjects in the NPWT Group 19 out of 30 subjects had GA Type III A fractures and rest had type III B fractures. In the Standard wound therapy group, 17 had GA Type III A fractures, while the rest had type III B fractures.

Bacterial Culture Negativity was achieved faster with NPWT (average of 1.7 cycles) as compared to standard dressing(3.33 cycles). This finding was found to be statistically significant with a p value of 0.000454 (Figure no.1).

It was seen that the average wound contraction per cycle of NPWT was 7.74% (Mean = 7.739 + 3.334) as opposed to 2.2% with Standard Saline dressing (Mean = 2.238 + 1.15). This finding has a p value of 0.000539 which is statistically significant (Table no.1)

On comparing cycle to cycle the wound contraction per cycle treated with NPWT versus Standard wound therapy (Table no. 2) stacked up as 8.91% vs 2.24%(First Cycle), 7.12% vs 2.15%(Second Cycle), 6.04% vs 2.21%(Third Cycle) and 5.34% vs 2.41%(Fourth Cycle), .

Average Number of cycles for NPWT dressing was 2.73 (Mean = 2.73 + -1.01). Average Number of cycles for Standard Dressing was 5.2 (Mean = 5.2 + -0.81).

Out of 30 patients in the NPWT group ,7 needed Secondary plastic surgical procedure for wound coverage. In the Standard wound therapy group ,13 out of 30 patients required Plastic Surgery later on.

Methicillin Resistant Staphylococcus aureus (MRSA) was the most common organism found in the Culture Sensitivity Reports.

IV. Discussion

It is a well-known fact that the fate of an open fracture depends a lot on the initial treatment administered to the wound.¹⁰ The use of Negative Pressure Wound Therapy (NPWT) or VAC (Vacuum Assisted Closure) for complex and large wounds has revolutionalised the management of open wounds over the past two decades.

Open fractures are at risk of developing complications; Wound Infection and nonunion are often the most common and can cause the most significant morbidity. NPWT dressings were first described in the medical literature for use with open fracture wounds. VAC 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. It was observed to promote wound healing, though NPWT or VAC therapy is not the answer for all wounds; however, it can make a significant difference in many casesPatient satisfaction in terms of time taken for wound closure, number of antibiotics used, and treatment related complications and outcome was better in the NPWT dressing group as compared to Standard wound therapy group.

Our study, though performed over a relatively small study sample and also with a short follow up period clearly demonstrates the superiority of NPWT over Standard Saline Wound Therapy when applied to wounds that satisfy the inclusion and exclusion criteria. Not only does the wound shrink faster in comparison to Standard Saline Wound Therapy, it also objectively reduces the bacterial load and thereby reduces the time to a secondary plastic surgical intervention. This has an unmediated relation to reducing patient morbidity and healthcare costs.

Therefore, we can recommend the use of NPWT as a bridging treatment in cases where definitive flap reconstruction/skin grafting is being delayed and also as a tool for closure of wounds that do not need any secondary surgical procedures. However, it is of significance that NPWT as a bridging therapy is time-limited and does not allow surgeons to delay surgery indefinitely.¹¹

V. Conclusion:

Our study showed a faster rate of wound contraction and Bacterial Culture Negativity with NPWT as compared to Standard Wound Therapy as well as a decreased need for secondary procedures (in the NPWT group). These findings were found to be statistically significant.

Therefore, we can conclude that vacuum therapy provides not only safe temporary wound coverage but also conditioning of the soft tissues until definitive wound closure. Amongst other advantages, bacterial clearance and increased formation of granulation tissue are attributed to vacuum therapy, which makes it an extremely attractive device in the field of wound healing

This study are based on a small number of cases and a short follow up period. The results might have been different if we had a larger and more diverse sample size .Also long term follow up is vital in a comparative study like ours as outcome can vary with time duration. Therefore, we would like to further continue the study in future to increase understanding of the therapeutic effects of NPWT therapy to give trauma surgeons stronger arguments to support its use in Open Musculoskeletal Injuries.

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| TABLES TABLE NO.1 | | | |
|----------------------|--------|------------|--|
| WOUND CARE TYPE | SALINE | NPWT (VAC) | |
| Mean | 2.238 | 7.739 | |
| SD | 1.15 | 3.334 | |
| Median | 2.01 | 7.49 | |

| TABLE NO.2 | | | |
|-------------------------|-----------------|--------------------|--|
| PHASE/CYCLE OF DRESSING | SALINE DRESSING | NPWT(VAC) DRESSING | |
| CYCLE 1 | 2.24 | 8.91 | |
| CYCLE 2 | 2.15 | 7.12 | |
| CYCLE 3 | 2.21 | 6.04 | |
| CYCLE 4 | 2.41 | 5.34 | |
| CYCLE 5 | 2.78 | | |
| CYCLE 6 | 2.90 | | |

FIGURES







NPWT (VAC) dressing

FIGURE NO.3



During debridement

FIGURE NO.4



After NPWT 1st cycle

FIGURE NO.5



After NPWT 2nd cycle

FIGURE NO.6



After NPWT 3RD CYCLE