ORIGINAL RESEARCH

Comparative study between Low Cost Modification Vs Standard Commercially Available method of Negative Pressure Wound Therapy/Vacuum Assisted Closure Therapy

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ABSTRACT
Introduction: Negative pressure wound therapy (NPWT) is a treatment modality in management of infected wound and compound injuries where primary closure is not possible. Conventional equipment's for NPWT are expensive, so we developed an affordable low cost alternative for our patients. **Aim** of our study was to evaluate the clinical efficacy and cost effectiveness of our system using resources which are easily available in most hospitals with conventional NPWT system. **Materials and Methods**: Commercially available Sponge foam which is normally available at hardware stores is autoclaved and placed over wound. We used Ryle's tube as connecting tube which is easily available and very cheap. Its perforated ends are kept over foam. Transparent adhesive film is used to provide air tight seal covering 2-3cm of surrounding skin Bedside suction machine system is used to create vacuum. **Results**: 46 patients were randomly allocated in both the group in which 29 were males while 17 were females. There was no significant difference in the rate of reduction of wound area as well as wound depth noted at 15 days in the Group A compared to the Group B. **Conclusion**: This study provides an alternative, easily reproducible and cost effective method to conventional NPWT and it's equally efficient in wound management.
Key words: NPWT, Sponge foam, wound healing

INTRODUCTION

Wound healing is a complex biological process influenced by several agents such as insulin-like growth factor (IGF) and recombinant human acidic fibroblast growth factor (rh-aFGF).[1] Wound healing consists of an orderly progression of events that re-establishes the integrity of the damaged tissue.

Acute and chronic wounds management constitute a significant workload and financial burden for health care organizations and also has a negative impact over the quality of life of patients.[2]Wound healing is a highly complex process, which starts with removal of dead and devitalized tissue, inflammatory changes with angiogenesis and finally deposition of granulation tissue, wound contraction and maturation.[3] Negative pressure wound therapy (NPWT) also known as Vacuum assisted wound closure (VAC) has emerged to be a promising technology over the years. First described by Fleischman et al in 1993, done in 15 patients with open fractures, negative pressure therapy or vacuum assisted closure proved to be effective in cleaning and conditioning of the wound.[4]

Negative pressure wound therapy is one of several methods enabling to obtain better treatment results in case of open infected wounds.[5]

The most substantial disadvantage of this procedure is its cost, which remains high and generally

unaffordable over prolonged use.[2] In the previous studies, we have looked at an alternative method of providing NPWT (Negative pressure wound therapy) using low-cost, universally available medical supplies called Gauze-SUCtion (GSUC) therapy and demonstrated therapeutically equal efficacy to commercialized product as the VAC (Vacuum assisted wound closure) .[6]

In the present study, we will apply the concept of Negative pressure wound therapy (NPWT) by using low cost, more easily available materials as compared to commercial Negative pressure wound therapy (NPWT) devices. Thereby, we will achieve similar results in low resource settings.[3,7] The purpose of this study is to show the clinical efficacy of low cost vacuum assisted closure (VAC) therapy compared to commercially available high cost negative pressure wound therapy and to determine the cost incurred with respect to equally healing rates, fewer dressing changes and material used in both groups.

METHODOLOGY

The present clinical study was carried out over a period of 18 months (Jan 2021-Aug 2022). Ethical approval was obtained from the Institutional Ethical Review Board (IERB) of Chirayu medical college and hospital, Bhopal, Madhya Pradesh. Informed Consent form contains the detail explanation of the study.

SAMPLE SIZE ESTIMATION

A total of 46 patient (23 in the study group and 23 in the control group) with skin wounds coming to Chirayu medical college and hospital, Bhopal (MP), during the period of January 2021 to August 2022 were included in the study. In the present study the sample size has been estimated to be 46 (23 in each arm) to get similar results with a relative precision of 95% confidence interval, 80% power and considering 10 mm^2/day as clinically significant difference in the rate of wound healing between the two groups.

Inclusion and exclusion criteria

Patients with chronic non- healing wounds or ulcers, postoperative hematoma in surgical wound, pressure sores or bed sores, chronic osteomyelitis, postoperative infection, diabetic ulcers, infected wounds, degloving injuries and skin avulsions, burn ulcers, dehisced surgical wounds with or without exposed bone, tendons and orthopaedic implants and wounds requiring grafting or flaps were considered in the study while patients with necrotic tissue with scar, exposed blood vessels, nerve, organs, severe pain, malignant wound, non-enteric and unexplored fistulas, coagulopathies, untreated osteomyelitis were excluded from the study.

STUDY DESIGN AND MEASUREMENTS

This study is designed as a randomized clinical study. Patients were randomly assigned to two groups (A = 23 and B = 23). Before starting the therapeutic procedure, all wounds were thoroughly washed with physiologic saline (0.9%). In **group A,** debridement of the wound was performed with cleaning of the surrounding area with 70% alcohol (spirit). Commercially available Sponge foam (pores size-300-400 micron) which is normally available at hardware stores was sterilized by autoclaving it twice and then was cut to fit the dimensions of wound bed. A Ryle's tube as connecting tube which is easily available and very cheap. Its perforated ends are kept over foam. An airtight dressing was given over the sponge and the Ryle's tube with the help of a transparent adhesive film with just a small opening for the emerging other end of the Ryle's tube, thus making it airtight. The other end of the tube was connected to the wall mounted centralized suction apparatus. Suction tube was connected to the central vacuum line and pressure was adjusted between -100-120 mmHg. We used to give intermittent negative pressure cycle of 15 minutes ON and 45 minutes OFF for 48 to 72 hours. After 48 to 72 hours dressing would be removed and wound washed thoroughly with normal saline and again NPWT (Negative pressure wound therapy) dressing to be re-applied. The same process was continued until a satisfactory healthy granulation wound bed was achieved for definitive procedure (skin graft or flap).

Group B received standard NPWT (Negative pressure wound therapy) dressing in which Polyurethane foam (pores size-400-600 micron) is used. In both groups, the wounds were covered with sterile cotton gauze and dressing completed.

Wounded surface was identified as the area without epithelium. Wound area was calculated by multiplying two largest perpendicular diameters measured in millimetres using a calliper. The condition of the wounds including wound depth; presence or absence (yes/no) of granulation tissue; presence or absence (yes/no) of blue edge; bleeding; pain; discharge; and other wound complications or healing factors were assessed and recorded pre-treatment and every 3 days after starting treatment. Once the wound is healthy, it can be taken up for plastic surgery cover depending on the patient's preference and larger wound size.

The end point of the study was complete wound closure. Rate of wound healing was calculated as the difference between the primary and final wound area in mm^2 divided by the healing time (in days) and reported as mm^2/day. A wound was considered fully healed when totally closed and epithelialized.

Rate of wound healing =

INITIAL AREA OF WOUND - AREA OF WOUND AT THE TIME OF EXAMINATION

The initial area measurement was taken on day 01, the on day 3 and day 7 and final area measurement on day 15. All 46 patients selected for this study complied for the 15 days duration of the study period. Various aspects of wound healing were studied after low cost NPWT and compared with standard NPWT, which included the following:

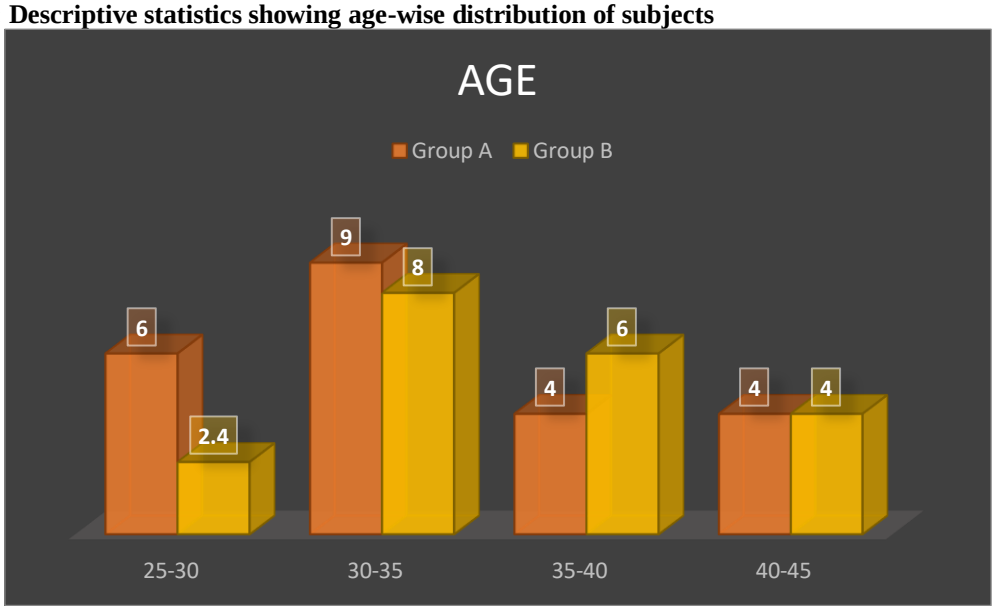
1. Rate of reduction of area of wounds
2. Rate of reduction in depth of wounds
3. Time taken for appearance of healthy granulation tissue
4. Time taken for formation of healing edge to the wounds
5. Local wound complications such as infection, slough formation, bleeding, pain etc.

All quantitative parameters such as age, sex, area of the wound, etc. were described in terms of mean & standard deviation. All qualitative parameters were summarized in terms of proportion with a confidence interval of 95%. Descriptive statistics of healing rate and the time to complete healing were analyzed and expressed in terms of Mean with Standard Deviation. Independent student t-test was used for the comparison of two groups.

RESULTS

A total of 46 patients were included and were randomly allocated to both the groups(23 each). Out of total participants 29 patients were male while 17 were females. In group A, 16 patients were males while 7 were females and in group B 13 were males and 10 were females. Age-wise distribution of the study participants was described in Graph 1

Graph 1: Descriptive statistics showing age-wise distribution of subjects



Type of wound included in the study was Diabetic ulcer, Traumatic ulcer, Pressure sores, Venous ulcer and Post-op infections. Most common wound type in both the study and control groups is Post- op infections wounds (30.44%, 26.08%) respectively. No significant difference is seen between the two groups.

Table 1 shows wound area and depth in two groups at initial and final assessment. There was no significant difference in the rate of reduction of wound area as well as wound depth noted at 15 days in the Group A compared to the Group B. Contracted wound area was more in the Group A (11.31±2.81) as compared to Group B (10.16±2.68) but it not statistically significant (p=.176). Rate of reduction of wound depth was faster in Group A(2.07 ± 0.96) as compared to Group B(1.94 ± 0.82) but it was not statistically significant (p=0.326).

Table 1: Comparison of wound area and depth in two groups at initial and final assessment

	Variables	Group A	Group B	p-value
AREA	**Initial area**	27.79±5.93	25.56±6.60	.107
	Final area	16.47±3.41	15.39±5.12	.236
	Contracted area	11.31±2.81	10.16±2.68	.176
	Percentage of area reduction	29.96 ± 2.77	28.53 ± 5.54	.282
DEPTH	**Initial depth**	4.28±1.26	4.47 ± 1.53	0.529
	Final depth	2.21 ± 0.76	2.53 ± 1.49	0.276
	Change in depth	2.07 ± 0.96	1.94 ± 0.82	0.326

There was no significant difference(p=.103) in the time taken to form healthy granulation tissue in the Group A (6.28 ± 1.26) compared to the Group B (6.12 ± 1.53). Time taken for appearance of healthy granulation tissue and formation of healing edge was faster in the Group A as compared to Group B. Also, there was no significant

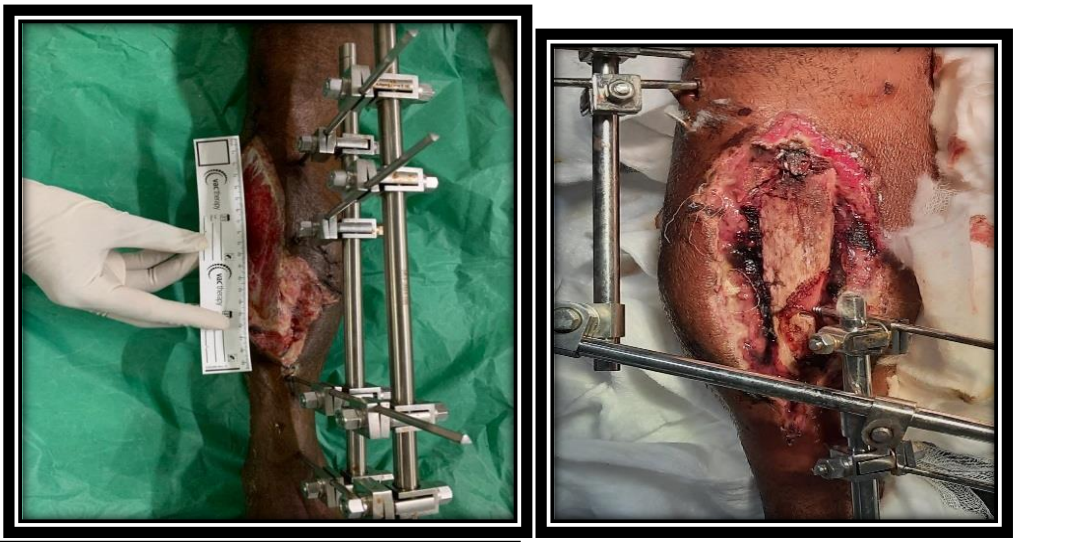
difference(p=.214) in the time taken to form healthy granulation tissue in the Group A (3.21 ± 0.76) compared to the Group B (3.01 ± 1.49).

The overall number of wound complications was lower in the Group A (30.44%) compared to the Group B (21.74%) as shown in Table 2.

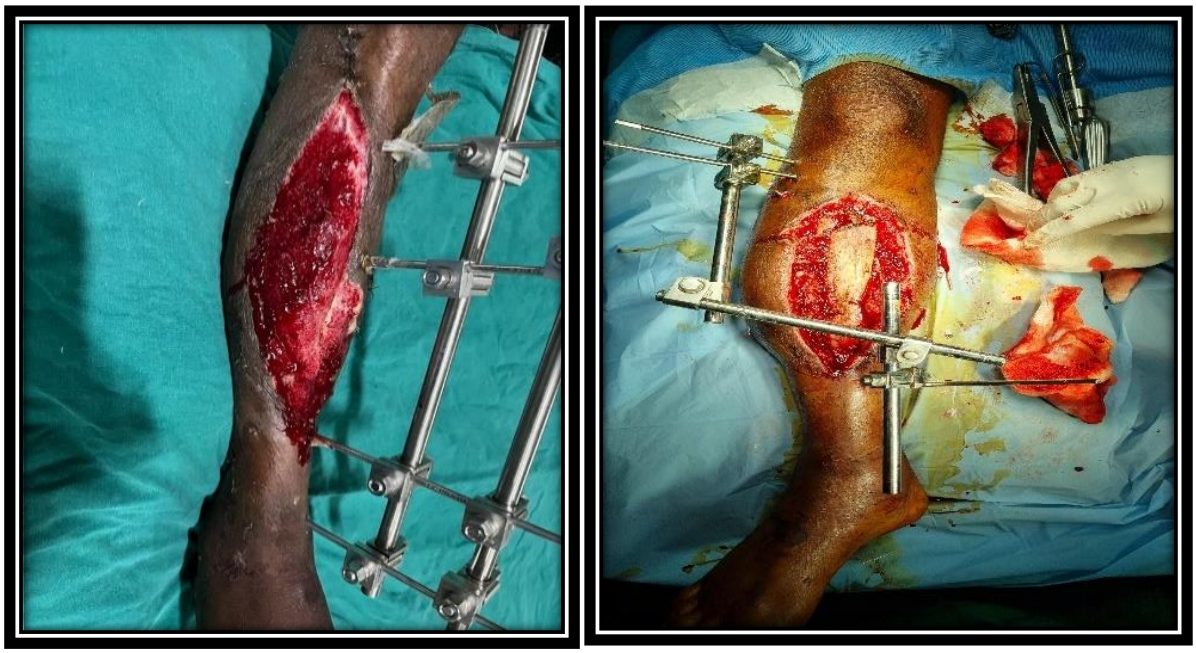
Table 2: Group wise distribution of Complications in two groups

Wounds	Group A		Group B	
	Frequency	Percentage	Frequency	Percentage
No complications	16	69.56	18	78.26
Complications	7	30.44	5	21.74
Infection	3	13.04	1	4.36
Slough	1	4.36	2	8.69
Pain	3	13.04	2	8.69
Total	23	100	23	100

COMPARISON OF CASE OF STANDARD VAC THERAPY AND LOW COST VAC THERAPY
STANDARD VAC THERAPYLOW COST VAC THERAPY
PRE-THERAPY



DURING TREATMENT



POST-THERAPY

DISCUSSION

Wound healing is a complex biologic process that involves a combination of chemotaxis, cell proliferation, angiogenesis and secretion of various cytokines and chemokines; which work in a coordinated manner that results in synthesis of extracellular matrix proteins and remodelling of tissues. Chronic skin wounds are more susceptible to bacterial contamination and more likely to develop unfavourable complications. Various studies have been conducted based on efforts and products to improve healing rates which may, in turn, reduce complication rates.[8-10]

Low cost Negative Pressure Wound Therapy technique was equally effective as standard Negative Pressure Wound Therapy. On comparing between all the 4 parameters it was found that there is no statistically significant between the two groups.

Since last few years, NPWT is developing as a new therapeutic strategy for treatment of infected acute and chronic wounds resistant to treatment by conventional methods.

Application of negative pressure in controlled manner helps the formation of granulation tissue on the wound bed but this therapy does not replace the surgical wound debridement, measures to improve blood circulation and treatment of infection by antibiotics as per pus culture sensitivity[11]**.** Hanasona *et al*. reported that the NPWT device is a useful tool in the fixation of skin grafts to microvascular free flaps and that its use does not compromise the free flap viability.[12]

Negative pressure therapy in theory reduces the local interstitial tissue oedema, increases micro perfusion of the wound, reduces bacterial colonies stimulates healthy granulation tissue growth in the wound bed and improves wound microenvironment. Negative pressure therapy results in accelerated wound closure. Acute or chronic wounds treated with NPWT show increased local IL-8 and VEGF concentrations, which may trigger the accumulation of neutrophils and angiogenesis, thereby accelerating neovascularisation. Some argue that NPWT confers no economic advantage compared to conventional dressing. There is a large range of opinions regarding the cost-effectiveness of NPWT. We experienced accelerated wound closure, increased wound bed vascularity, abundant growth of granulation tissue and defect size reduction with NPWT and with low cost NPWT, which is consistent with the experience of Campbell.[13]

Vacuum assisted therapy is more beneficial when compared to the conventional moist betadine dressings in terms of granulation tissue formation, clearance of the infection over the wound, decreasing the duration of hospital stay and cost effectiveness.

Results of our study are equal efficacy in low cost with this study. we have done an Alternative modification by using the concept of negative pressure wound therapy and have found highly satisfactory results in terms of granulation tissue formation, infection control, requirement of antibiotics, duration of hospital stay and cost effectiveness.

However, in the current health care climate with continually increasing emphasis on cost containment, it is also important to be mindful that sometimes these advancements can place undue pressure in foregoing lower cost options for perhaps more sophisticated, yet more costly products and services, even without good evidence for increased benefit.

Negative pressure wound therapy had no significant effect on the length of hospital stay compared with conventional wound dressings in subjects with closed incisions in orthopaedic trauma surgery. Yet, the

analysis of results must be done with attention due to the low sample size of some of the selected studies, five studies with less than 100 subjects as sample size, and the low number of studies found for the meta-analysis, recommending the necessity for additional studies to confirm these findings or perhaps to significantly impact confidence in the effect assessment, especially the wound dehiscence and the length of hospital stay with their low number of studies found for evaluation.

The efficacy and the many benefits of NPWT in wound management are well documented, yet current costs of utilizing commercialized products like the VAC can be prohibitive to universal access. An alternative method of providing NPWT using low cost NPWT technique using ryle's tube, foam and adhesive bandages. Given the ease and convenience of application from the use of virtually universally available supplies in any health care facilities, it can be used widely.

The per dressing cost was calculated from the sum of all its average component costs, which was determined to be Rs. 5000/-. Significant portion of that cost—was accounted by the daily rental cost of the portable suction unit. Per dressing cost of alternative technique was likewise calculated using sum of all its average component costs, which was determined to be Rs. 300/- and there is no requirement of portable suction unit which reduces its cost heavily.

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