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Original Research Paper

EFFICACY OF A SIMPLIFIED NEGATIVE PRESSURE WOUND DRESSING IN MANAGEMENT OF INFECTED WOUNDS

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ABSTRACT:

Background: Negative-pressure wound therapy (NPWT) or Vacuum assisted closure (VAC) is an established modality for management of infected wounds. However, it has a complex technology of real time pressure feedback system to provide intermittent suction which markedly increases its cost, thus limiting its routine use in low resource settings. The intermittent suction can also be provided by connecting a readily available portable suction machine to a timer switch. This unit works on the same principle as VAC and can serve as an effective simplified negative pressure wound dressing (SNPWD). **Methods:** Thisprospective observational studyinvolved24patients having highly exudative and infected wounds whoweremanagedwith low cost, indigenously developed SNPWD. The SNPWD consists of a portable suction machine connected to a timer switch and a pre sterilized dressing material consisting of a foam, adhesive material to cover the foam and connecting tube. The efficacy of this dressing was evaluated on basis of percentage reduction in wound surface area after the last SNPWD, the time taken and the number of dressings required for wound coverage by adequate healthy granulation tissue, decrease in amount of exudates after the last dressing and comparison of pre-SNPWD and post-SNPWD pus culture sensitivity reports. **Results:** The SNPWD was effective in improving the rate of wound healing. All the patients achieved healthy granulation tissue after application of SNPWD. The mean duration of SNPWD application was 16.5 days and mean number of dressings applied per patient was 5.3. There was a mean decrease of wound surface area by 27.2%. There was a 58% decrease in amount of exudates after SNPWD application. There were no significant adverse effects after SNPWD application. Also the cost per dressing of SNPWD was lesser than that of commercially available other NPWT options. **Conclusions:** The low-cost, indigenously developed SNPWD can achieve a comparable rate of wound healing to VAC and has an advantage that it is highly cost effective and the components are readily available which makes it a potential alternative to VAC in low resource settings. **Study design:** Prospective observational study.

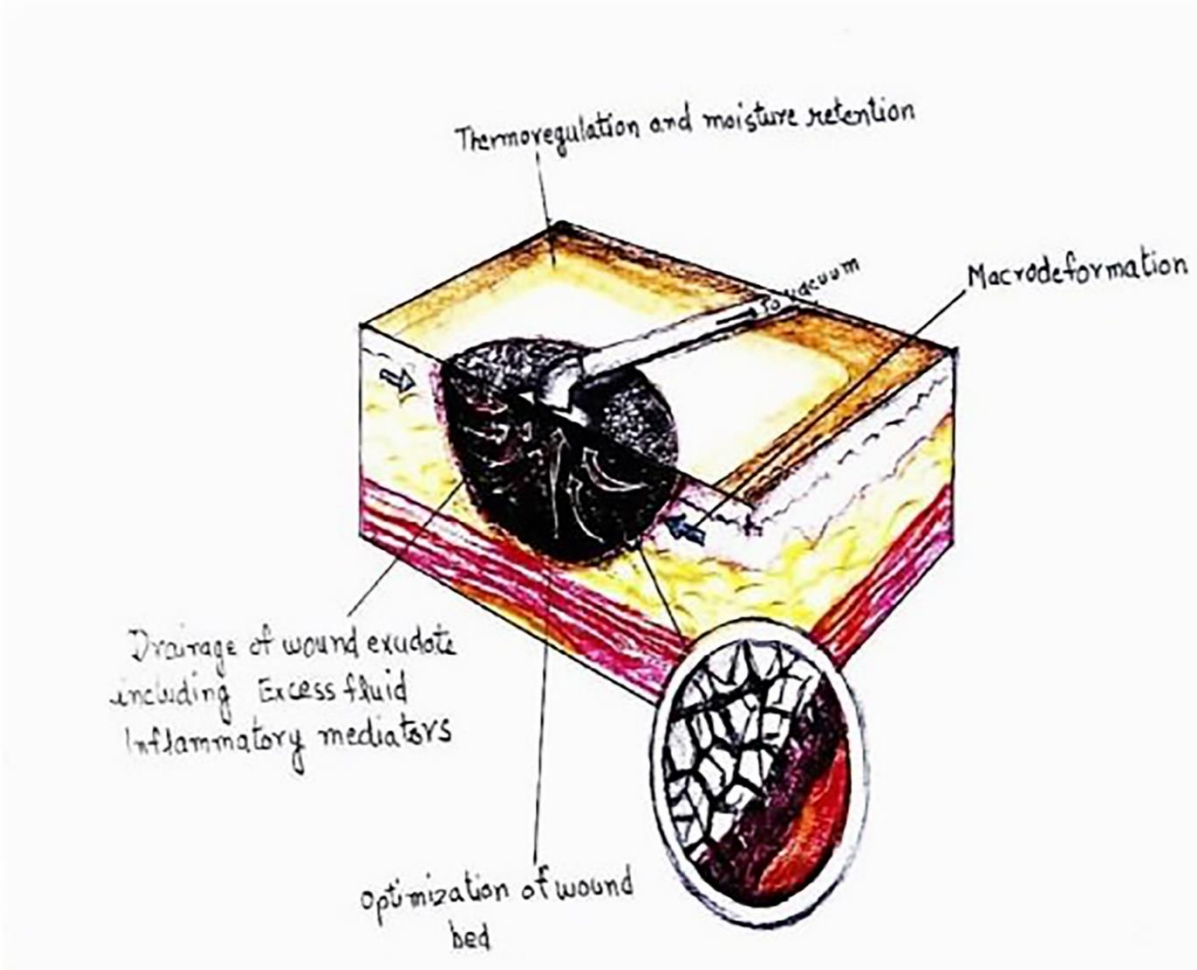
Key words: Vacuum assisted closure, simplified negative pressure wound dressing

INTRODUCTION:

Negative Pressure Wound Therapy (NPWT) or Vacuum Assisted Closure (VAC) is a relatively newer, adjuctive and non-invasive method to dress the highly exudative, chronic non-healing or infected wounds which are not amenable to primary surgical closure. These wounds lead to hazardous outcomes like prolonged hospitalization, amputation and sepsis, depending on various host and environment factors. Such wounds are associated with extensive soft tissue loss and require a reconstructive surgery, which cannot be immediately done due to presence of infection, necrotic material and large size of these wounds, thus they require topical dressings until surgical closure is possible. Conventional method for wound management involves frequent change of dressing and debridement until wound becomes healthy. However, it has been reported in studies by Caudle and Stern [1] that these dressings have a slower rate of skin coverage and take a longer duration of wound healing which prolongs the hospital stay of patients. Such wounds can be managed by NPWT which involves use of controlled intermittent sub atmospheric pressure sealed dressing connected to a suction machine to drain the exudates and remove infection load. The beneficial mechanisms of these dressings as described by Argenta LC et al [2]include reduction in amount of exudates, interstitial pressure and infection load over the

wound surface. It also causes reduction in cytokines, collagenases and elastase over the wound surface and increases fibroblast and endothelial cell proliferation causing wound contracture and angiogenesis which leads to early wound healing (figure 1).

Figure 1: Mechanism of Negative Pressure Wound Therapy



Some of the common indications of NPWT include open traumatic wounds, infected suture lines, radiation ulcers, degloving injuries, burns, bed sores and diabetic foot. There a lot of commercially available NPWT options in the market. Some of the common names include V.A.C.® GRANUFOAM™ (KCI, San Antonio, Texas), Versatile 1 Wound vacuum system (Bluesky Medical, La Costa Calif), PICO™ (Smith and Nephew, St. Petersburg, PL) and Cardinal Health™ NPWT. All these have common mechanism to provide intermittent suction to drain exudates and decrease infection load. The intermittent suction is preferred over continuous suction because there is more contraction of wound edges and more rapid formation of the granulation tissue when intermittent suction is used as compared to continuous suction. Leukocyte infiltration and tissue disorganization are also prominent with intermittent suction as described in studies by Malin Malmsjo et al [3]. These dressings use a complex technology to provide intermittent suction which involves using a real time pressure feedback system that adjusts the pump output compensating for wound distance, wound position, exudate characteristics and patient movement. The advanced technology to provide intermittent suction results in a very high cost of equipment of these VAC dressings, thus, limiting its routine use in low resource settings. In our study, a timer switch is used to convert a simple portable suction machine to a negative pressure wound dressing. Such simplified method presets the automatic intermittent supply to suction machine which in turn creates an intermittent vacuum at a set negative pressure [4]. This study is proposed to assess the effectiveness of such a low cost, indigenously developed and simplified negative pressure wound dressing (SNPWD) in management of wounds.

MATERIAL AND METHODS:

The study was conducted on 24 patients of all age groups having highly exudative wounds not amenable to primary surgical closure, e.g., traumatic wounds, open fractures, fasciotomy wounds, diabetic foot and pressure ulcers. Patients having wound malignancies, known allergy to adhesive materials, bleeding disorders and exposed blood vessels and nerves were excluded from the study. The materials used included (**figure 2**) :

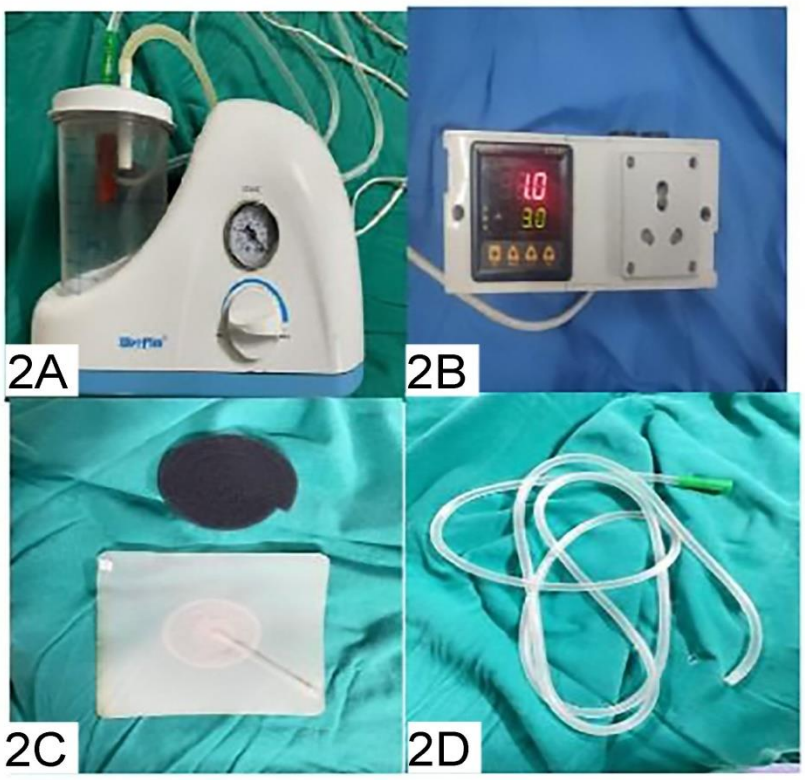


Figure 2: (a) Portable suction machine with attached canister
(b) Electric timer switch
(c) Foam dressing with adhesive material
(d) Adhesive material

(a) A portable suction machine having pre-attached canister adjusted to provide pressure between 100-120 mm hg.

(b) An electric timer switch placed between the main supply and suction machine to provide intermittent supply to suction machine. It can be set manually such that it keeps the suction on for a given time period (5 minutes) and then puts it on standby for the time set (3 minutes).

(c) Pre sterilized, biocompatible, hydrophobic polyurethane foam pore size of 400-600 microns [(5)] which allows maximum tissue regrowth and an even suction transfer across the foam.

(d) Pre sterilized packed tubes available in hospital which connect dressing material with portable suction machine.

The wound is carefully examined and initial granulation tissue amount, presence or absence of exudates, signs of inflammation and presence or absence of necrotic tissue documented. The wound surface area was measured by using an image measurement application in android play store in which largest measured wound dimension was used as a reference scale for image calibration purpose (**figure 3**).

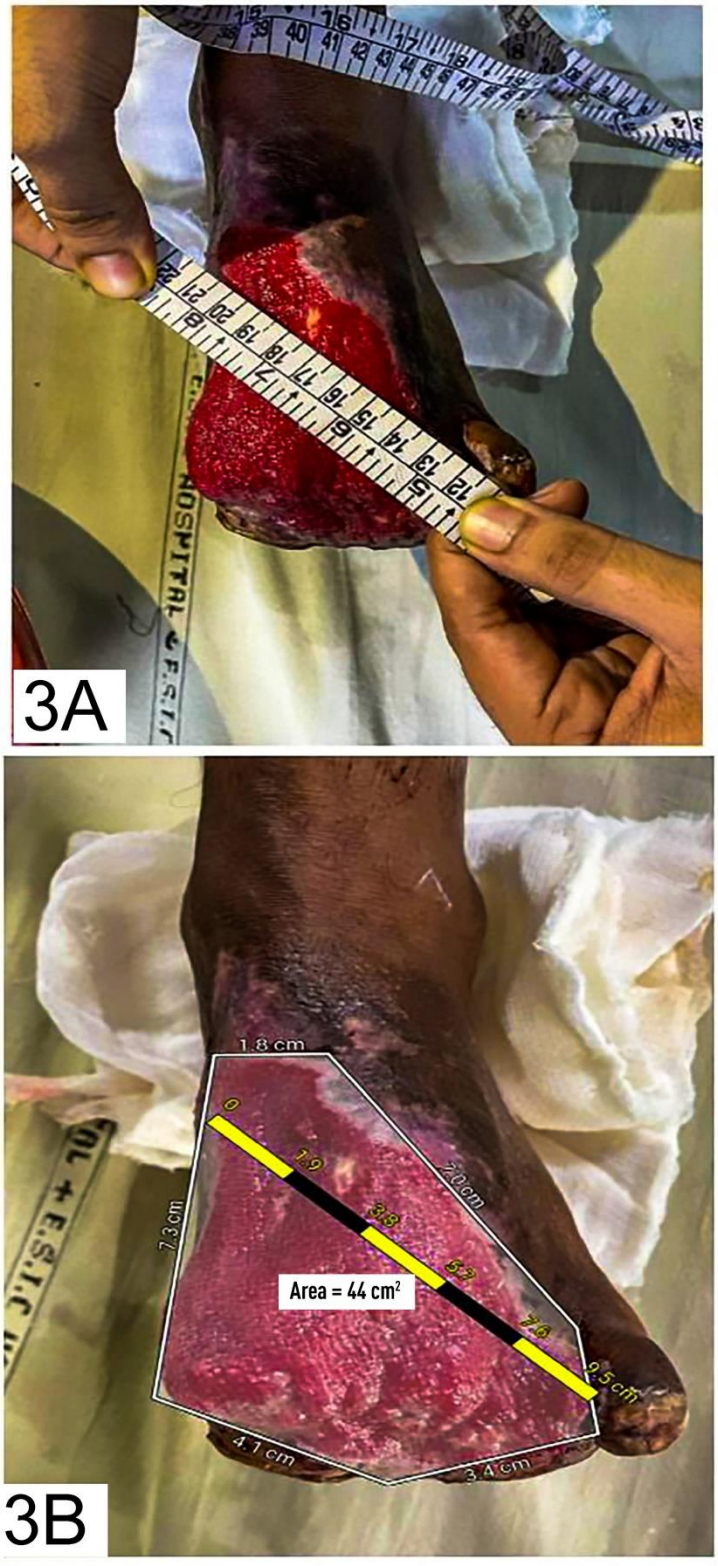


Figure 3: (a) Measurement of one wound dimension for image calibration
(b) Calibration of image for wound surface area measurement on mobile application

Application of SNPWD: After the debridement of wound to remove necrotic material, foam covered by adhesive material was placed to cover the wound surface. This dressing is connected to the suction machine which is connected to the mains supply through the timer switch.

- The pressure of suction machine is kept between 100-120 mm hg. [(2)]
- The electric timer is set to provide intermittent suction (cycles of 5 minutes on and 3 minutes off). [(4)]

These dressings are changed every 3rd day and continued till wound is healed or ready for definitive surgical closure (clean lesions without any infection and bright red granulation tissue coverage >85% of wound surface area.

RESULTS:

A total of 24 patients were treated by SNPWD between October 2019 and August 2021. All the patients were hospitalised as this was essentially an in-patient study. No patient was lost to follow up or withdrew from the study. Out of the 24 patients, 20 were males (83.3%) and only 4 were females (16.7%). The age of the subjects ranged from 17-80 years, with mean age being 41.58 years (**table 1**).

Table 1: Distribution of age and sex of study subjects

Socio-demographic characteristics	Frequency	Percentage
Age(years)		
Mean ± SD	41.58 ± 14.7	
Median(25th-75th percentile)	40(32-50.25)	
Range	17-80	
Gender		
Female	4	16.67%
Male	20	83.33%

Acute traumatic wounds (wounds that occurred immediately after trauma and were usually associated with underlying fractures) were present in 11 cases (46%), chronic wounds which were formed either due to prolonged hospital stay (e.g.: bed sores) or failure of previous wounds to heal were present in 6 cases while 7 cases had post-operative wounds. Most of the wounds were located at either of right or left knee followed by lower back (**table 2**).

Table 2:-Distribution of wound site and type of study subjects

Wound site and type	Frequency	Percentage
Wound site		
Left foot	2	8.33%
Left knee	3	12.50%
Left leg	1	4.17%
Left thigh	2	8.33%
Lower back	3	12.50%
Right ankle	1	4.17%
Right elbow	2	8.33%
Right foot	2	8.33%
Right forearm	1	4.17%
Right knee	5	20.83%
Right leg	2	8.33%
Wound type		
Acute traumatic	11	45.83%
Chronic	6	25.00%
Post-operative	7	29.17%

The amount of granulation tissue was observed by a single observer in terms of gross appearance of ulcer until it covered more than 85% of wound surface area. All the wounds were covered by healthy granulation tissue post SNPWD. The size of wound pre SNPWD ranged from 16 cm^2 to 138 cm^2, the mean size being 73.5 cm^2. Post SNPWD size of wound ranged from 13 cm^2 to 110 cm^2, the mean reduction being 20 cm^2 (27.2% decrease in wound surface area) **(table 3).**

TABLE 3: Amount of Exudate, Duration of SNPWD, Number of dressings applied and Wound Size Reduction after last SNPWD

Variable		Mean	Standard Deviation	Median	Range		P value
Amount of exudate after 1st SNPWD (in ml)		25.42	9.08	25	10-45		<0.0001
Amount of exudates after last SNPWD (in ml)		10.54	5.91	10	0-20		<0.0001
Decrease in amount of exudates (in ml)		14.88	10.08	15	0-35		-
Mean duration of SNPWD application (days)		16.5	4.81	16.5	8-27		-
Wound size before 1st SNPWD (cm^2)		73.54	31.5	71	16-138		<0.0001
Wound size after last SNPWD (cm^2)		53.46	25.17	47.5	13-110		<0.0001
Wound size reduction *(cm^2)*		20.08	9.49	22	0-36		-
Number of dressings applied per patient		5.33	1.7	5	3-9		-

The granulation tissue was observed by a single observer on every dressing change. The SNPWD was discontinued when healthy granulation tissue was found to cover more than 85% of wound surface area.

The pre SNPWD and post SNPWD condition of some of the wounds has been depicted in **figure 4 and figure 5**.

The duration of SNPWD application, that is, time required for the wound to be ready for definitive closure ranged from 8-27 days, with mean duration being 16.5 days. Also, the number of dressings required for wound healing ranged from 3-9, with mean being 5.3 per patient. The amount of exudates collected were measured in the canister of the suction machine. After the first dressing, the amount of exudates ranged between 10-45 ml, the mean amount being 25.4 ml. After the last dressing, the mean amount of exudates collected was 10.5 ml, that is, 58% decrease in amount of exudates post SNPWD **(table 3).** The swab for bacterial culture taken before applying first SNPWD was positive for Staphylococcus Aureus in 6 cases (25%), which was found to be the commonest pathogen followed by Pseudomonas in 4 cases (17%). 9 cases had a sterile report before first dressing itself. Post SNPWD, almost all the patients had a sterile culture

sensitivity report **(table 4).**

Table 4: Distribution of pus culture sensitivity report pre and post SNPWD

Culture	Frequency	Percentage
Pre SNPWD culture report of case		
No growth	9	37.50%
E coli	1	4.17%
Klebsiella	1	4.17%
MRSA	1	4.17%
Pseudomonas	4	16.67%
Staph aureus	6	25.00%
Streptococcus	2	8.33%
Post SNPWD culture report of case		
No growth	23	96%
Staph aureus	1	4%

After the final dressing, 3 patients (12.5%) recovered completely and did not require any surgical procedure. In the rest 21 patients healing by tertiary intention was carried out. 19 patients were subjected to SSG (79.2%) while 2 patients received flap coverage (8.3%) **(table 5).**

Table: 5. Distribution of final procedure done on study subjects

Final procedure	Frequency	Percentage
None	3	12.50%
Flap coverage	2	8.33%
SSG	19	79.17%
Total	24	100.00%

FIGURE 4 : Case of lacerated wound on right foot dorsum managed by SNPWD

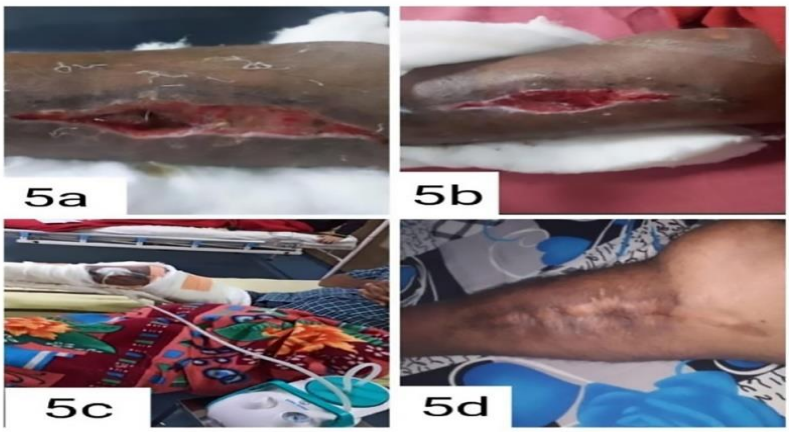
4a: Wound condition before SNPWD application

4b: Wound condition after SNPWD application

4c: SNPWD applied over the wound

4d: Wound condition after complete healing

FIGURE 5 : Case of compound fracture proximal tibia managed by SNPWD



5a: Wound condition before SNPWD application

5b: Wound condition after SNPWD application

5c: SNPWD applied over the wound

5d: Wound condition after complete healing

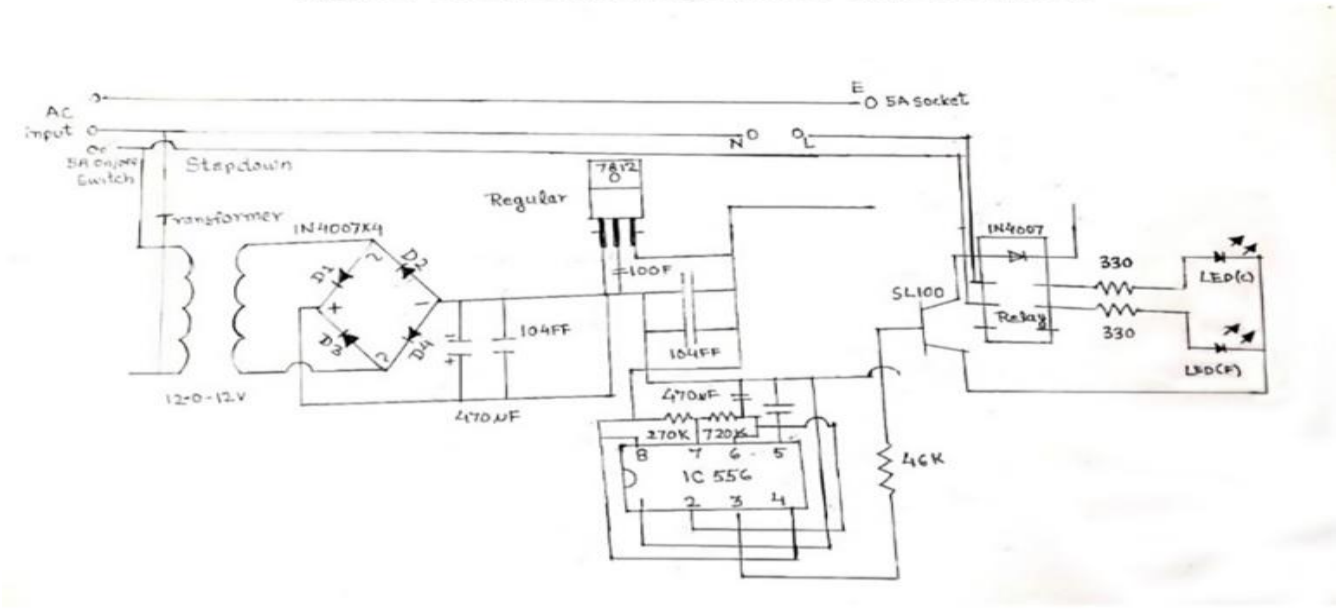
DISCUSSION:

The use of NPWT in developing countries like India is limited due to difficulties of terrain, equipment availability and high cost of material. In this study, different components of NPWT were assembled and integrated to be used as a simplified negative pressure wound dressing (SNPWD). The components of SNPWD include a negative pressure source, an electric timer switch and dressing materials.

a) The negative pressure source was a portable suction machine in which pressure gauge was adjusted to provide appropriate suction of 100-120 mm hg. The machine did not break down or overheat throughout the dressing period.

b) The second component was the electric timer switch with adjustable on and off timings. It was completely safe and did not pose any electric hazard to the patient. The working voltage of switch was around 12V. The circuit diagram of timer switch is shown (**figure 6**).

Figure 6: Circuit diagram of timer switch



The male preponderance in this study was also seen in studies of Surath Amarnath et al [4] and Stannard et al [7] which had 82% and 73% male population respectively. It can be attributed to the fact that most of the wounds managed by SNPWD were caused primarily by road traffic accidents which occurred when the patients were driving two wheelers and in Indian population most of the two-wheeler drivers are males.The most common site of wounds was right and left knee followed by ankle and lower back. Etiologically, most common type of wounds were acute traumatic wounds, followed by post-operative and chronic non healing wounds. The study of Atay et al [8] also had acute traumatic wounds as the most common type (66%). The reduction in wound surface area was comparable to studies done by Atay et al [8] and Daniel de Alcantara Jones et al [9] who achieved a mean reduction in wound surface area of 28.8% and 29% for pre-VAC wound size of 94.7 cm^2 and 95.65 cm^2 respectively, using commercially available NPWT options. The mean duration of SNPWD application, that is, the time taken for development of healthy granulation tissue ranged from 8-27 days, the mean duration being 16.5 days. Similar results were obtained in study of Kilic et al [10] who achieved 30% reduction in mean wound size after applying VAC to 17 patients for average 16 days. Demir et al [11] also demonstrated that mean duration of wound healing was 12.4 days and mean reduction in wound surface area after applying VAC to 50 cases was 23%. The decrease in amount of exudates was also reported in study of Ali Z. et al [12], in which there was complete cessation of amount of exudates in 60% patients after week 2 and reached to 96% till week 7. The increase in number of sterile culture reports post SNPWD may be due to the fact that wound debridement was being done after every dressing change and many patients were being given intravenous antibiotics during the course of SNPWD. Most of the wounds healed by tertiary healing and required either SSG or flap surgery for closure. This is comparable to study of Atay et al [8], in which only 18.75% of wounds closed by secondary healing whereas others required tertiary healing.

Cost analysis: The cost of suction machine and timer switch used to provide intermittent suction was ₹4,000 and ₹1,400 respectively. The per dressing cost of SNPWD was ₹600. In comparison, the cost per dressing of VAC is ₹7,000 while the machine costs approximately ₹2.5 lakh. Thus, not only SNPWD per dressing cost is 10 times lesser as compared to VAC dressing, but markedly lower cost of equipment makes it a potential alternative to VAC dressing in low resource settings.

The adverse effects of SNPWD were minor and rare. These included:

1) Pain at the dressing site, specially while removing the dressing was observed in some patients.
2) Skin maceration was seen in 2 patients, who were subjected to prolonged duration of SNPWDs.
3) Fever, documented at 101°F, occurred in 1 patient after the application of SNPWD. However, there were only 2 episodes which got relieved after giving suitable dose of antipyretic.

Also, a potential disadvantage of using SNPWD over VAC was that the lack of an automated pressure sensing system made it difficult to address the minor air leaks. This resulted in more frequent dressing changes in some patients.

CONCLUSION:

Our study showed that the results obtained with use of an indigenously made, simplified negative pressure wound dressing were comparable to that of commercially available NPWT options. There were no significant differences between SNPWD and commercially available NPWT options in terms of granulation tissue formation, reduction in wound surface area, duration of wound healing and reduction in quantity of exudates collected in canister, which are the key determinants of wound healing. All our patients responded well to SNPWD, and their wounds healed by secondary or tertiary intention. SNPWD has a good patient compliance, it is easier to handle and may be managed by patients at home itself which might reduce the need for hospital admission. This will help to reduce workload in already overburdened hospitals. Another advantage of using SNPWD is that per dressing cost is at least 10 times lesser than the commercially available VAC dressing. So, SNPWD is an affordable and safe alternative to VAC, is non inferior to it and highly useful in surgical units in low resource countries, where only a handful of patients can afford the highly expensive VAC dressings. The problem of high cost of NPWT is, thus, negated and whether or not to use NPWT depends solely on the fact that wound needs its benefits or not.

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