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Negative Pressure Wound Therapy with Instillation in the Management of Infected and/or Chronic Wounds in Indian Patients

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Abstract:-

- ***Background:***

Management of wounds is one of the most crucial aspects of surgical care. Wound management has come a long way in last 2-3 decades. During this period, Negative Pressure Wound Therapy (NPWT) has emerged as a boon for the surgeons. However, the management of infected and chronic wounds stills remains a challenge to the surgeons throughout the globe. To tackle these wounds, modifications were made in regular NPWT by adding intermittent automated instillation of topical wound irrigation solutions. This therapy is known as Negative Pressure Wound Therapy with Instillation (NPWTi). This method provided an additional dimension by reducing bioburden and biofilms present in these wounds, that may impair the processes of proper wound healing.

- ***Methods:***

A prospective analysis of 45 patients with infected and/or chronic wounds between December 2018 to June 2020 were included in this study. After surgical debridement, all patient were managed with NPWTi. Normal saline was used as instillation fluid in all cases with dwell time of 10mins, followed by 3 hours of NPWT at -125mmhg pressure. Data collection includes patient demographics, wound characteristic, number of debridements, number of dressing change, wound area reduction, time to wound closure, method of wound closure, complications and hospital stay.

- ***Results:***

Mean NPWTi dressing required were 2.45 dressings per patients and mean reduction in wound area was18.3%. Mean time for wound closure was 11.05 day. Average hospital stay for patients with infected/chronic wounds managed with NPWTi was 11.5 days Only 1 patient had wound related complication in post op period and none of them had dehiscence or wound recurrence in 3 month post op period.

- ***Conclusion:***

NPWTi with normal saline instillation has improved the management of infected and/or chronic wounds and has become the standard of care at our facility.

Keywords:- *Infected Wounds, Chronic Wounds, NPWTi.*

I. INTRODUCTION

Management of wounds is one of the most crucial aspect of surgical care. Better understanding of the physiology of wound healing, better surgical techniques and advancement in dressing materials have made management of wounds much easier, and has also improved the outcome of complex wounds. [1,2]

With the recent advancements in wound care, the incidence of the conditions that impairs wound healing, such as diabetes, smoking, high speed road traffic accidents and changes in life style has also increased.[2]

In the last 2 decades, Negative Pressure Wound Therapy (NPWT) has emerged as a boon for the surgeons, for the management of large complex wounds associated with extensive tissue loss or with exposed tendon or bone.[3-7.] NPWT facilitates wound healing by drawing wound edges together, removing exudates, reducing edema, promoting perfusion and granulation tissue formation.[8-10] Thus, NPWT helps in early wound closure, reduces the number of dressings required, shorter hospital stays and reduced overall morbidity.

Despite all the advancements the management of infected and chronic wounds stills remains a challenge to the surgeons throughout the globe. These wounds are difficult to tackle with regular NPWT. Several studies have shown that NPWT alone can lead to increase in bioburden. They were also found to be less effective in clearing thick exudates as well as biofilms.[11,12] Repeated debridements and multiple dressings for longer duration were the main modality to manage such wounds.

To manage these problems, modifications were made in regular NPWT by adding intermittent automated instillation of topical wound irrigation solutions. This therapy is known as Negative Pressure Wound Therapy with Instillation (NPWTi).

This method provided an additional dimension in the management of infected and chronic wound by reducing bioburden and biofilms present in wounds, by removing cellular debris, exudates and inflammatory molecules that may impair the processes of proper wound healing. [12-20]

In this study, we prospectively evaluate the efficacy of NPWTi in management of infected and/or chronic wounds in Indian subcontinent patients, in terms of wound closure, number of surgical procedures required till final wound closure, number of NPWTi dressing change required, reduction in wound size after NPWTi, total hospital stay for the management of wound and wound dehiscence or recurrence within three months after wound closure.

II. MATERIALS AND METHODS

This is a single center, prospective observational study from December 2018 to June 2020, to evaluate evaluate the efficacy of NPWTi using normal saline in management of infected and/or chronic wounds in Indian subcontinent patients. 45 patients were included in this study who met the inclusion & exclusion criteria.

- *Inclusion Criteria-*

All patients with infected and/or chronic wounds who underwent at least one operative debridement and were managed with negative-pressure wound therapy with instillation after debridement were included in this study.

- *Exclusion Criteria-*

Malignancy in wound, active bleeding in the wound, ischemic ulcers, fistulas, burn wounds, international patients and patients who were started on NPWTi but switched to another modality of treatment.

Assessment and data collection was done for following parameters: Wound etiology, location and size of the wound, depth of wound (bone exposed or not) and any discharge from the wound.

Size and area of the wound was measured by the mobile wound analyzer application (MoWa) as well as conventional method using ruler. MoWa is an application for smartphones and tablets that takes photos and uses software-based technologies to calculate wound area. Interface of Mowa app is shown in figure 1.

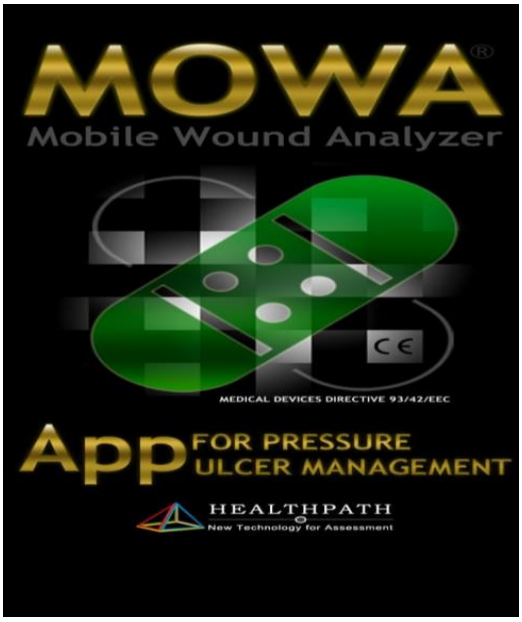

Fig 1 Mowa App Interface

After this initial evaluation all patients underwent surgical debridement of non-viable tissue and it was performed in a standard manner in all patients.

Negative-pressure wound therapy with instillation was applied either in operation theatre after the debridement if absolute haemostasis was secured or it was placed in the ward the next day after debridement.

The NPWTi device used was - V.A.C. Ulta with VeraFlo Instillation Therapy (Kinetic Concepts) shown in figure 2. The instillation fluid used for NPWTi was normal saline in all patients.

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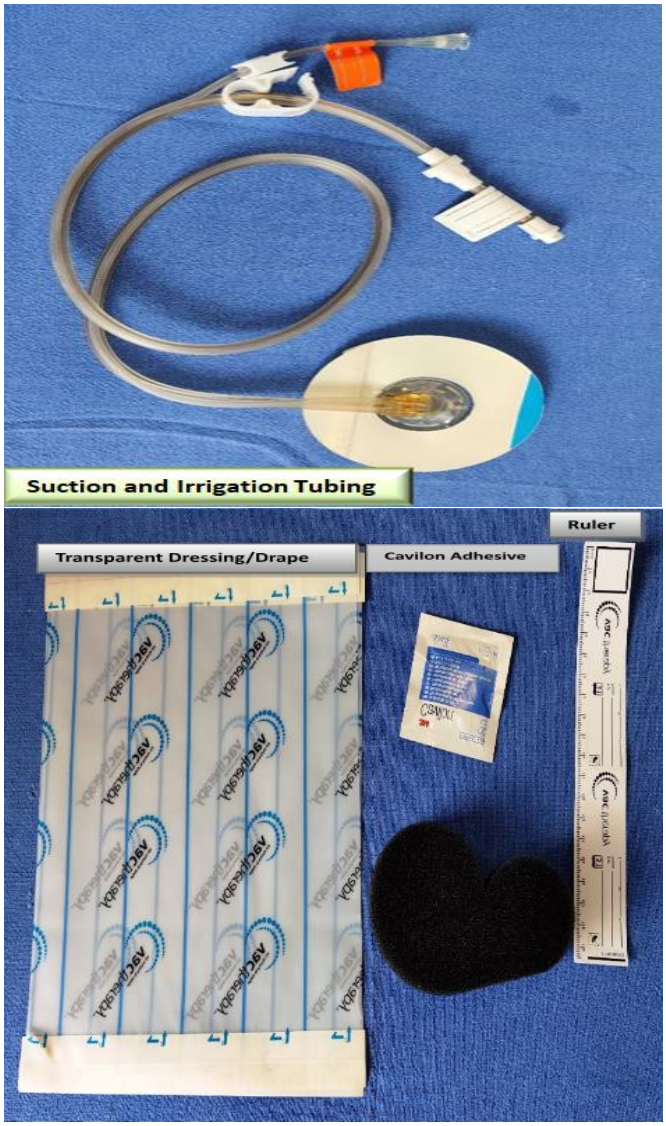

Fig 2 VAC ULTA Vera Flow

The application of the foam and drape to the wound surface was performed in a similar manner in all the patients. A 1-2 cm diameter round hole was cut into the drape, over which a Sensa TRAC (Therapeutic regulated accurate care) pad with tubing was applied. This tubing has two ends. One end of the tube was connected to a fluid collection canister attached to the VAC machine. (VAC Instill; KCI, San Antonio, TX) and second tube (installation tube) was connected to an intravenous bag containing normal saline.

NPWTi was programmed to a cycle through the following regimen for all patients

- *Instillation Fluid -Normal saline was used in all patients*
- *Instillation Fluid Volume - Volume of instillation fluid depended on the wound size. Fluid was installed into the wound till the foam is completely saturated (indicated by a darker color change) as shown in figure 3*
- *Dwell Time (soak time/hold time) - In our study dwell time was 10 minutes in all patients.*
- *Negative pressure - It was set to negative 125 mmHg in all patients.*

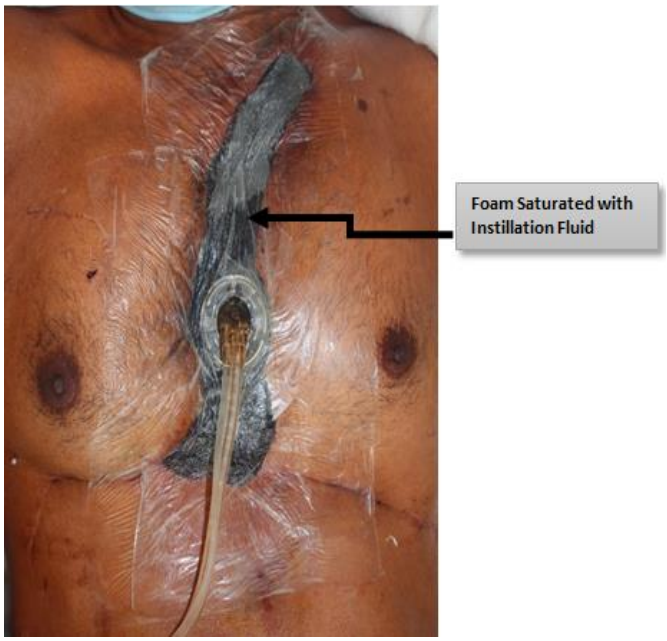

Fig 3 Foam Saturation on Instillation of Normal Saline

Duration of continuous negative pressure cycle - It was 3 hours in all the patients.

After 3 hours, cycle repeats automatically.

The VAC dressing was changed every 3rd to 5th day depending on the clinical condition of the wound at the time of application of NPWTi. It is also decided by the patient comforts. NPWTi therapy continued till the wound was ready for closure.

In addition to the NPWTi, all patients received parenteral antibiotics at the time of hospital admission on an empirical basis, and antibiotic therapy was adjusted according to the culture and sensibility results of the wound.

Once the wound is ready, closure of the wound was done either by ssecondary suturing or skin grafting or flap (Local/ free flap) depending on the condition of the wound.

Post closure, regular dressings were done and the patient was discharged once he/she was stable.

All patients were followed for 3 months after their discharge from the hospital for any breakdown or recurrence of wound

All the above-mentioned data was collected and collated. At the end of the study, this data was compiled and conclusions were drawn to know the efficacy of NPWTi in management of infected and/or chronic wounds in Indian patients.

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III. RESULTS

This study comprised of 45 patients who met the inclusion criteria. The mean age of the patients in this study was 48.40. Out of 45 patients, 28 (62 %) were male and 17 (38%) were female patients. 13 (29%) patients had no co morbidity. Remaining 32 (71%) patients had one or more comorbidities. More than 50% of the patients in our study were diabetic as shown in Table 1.

Table 1 List of Associated Co Morbidities

S. No	Co-Morbidity	Number of Patients
1	Diabetes	23 (51.1%)
2	Coronary Artery Disease (CAD)	15 (33.3%)
3	Hypertension	12 (26.6%)
4	Malignancy	2 (4.4%)
5	Chronic Kidney Disease (CKD)	2 (4.4%)
6	Other Systemic Disease	6 (13.2%)

Etiology and location wise distribution of wound in our study is shown in table 2 and 3. Out of 45 patients, 35 patients (77.8%) had infected wounds and 10 patients (22.2%) had chronic wounds.

Table 2 Wound Etiology

S. No	Etiology	Number of Patients	Percentage
1	Post infective wounds	12	26.7%
2	Post-operative wound dehiscence	10	22.2%
3	Post traumatic wounds	7	15.6%
4	Abscess	5	11.1%
5	Diabetic foot	5	11.1%
6	Chronic sinus	4	8.9%
7	Wounds with exposed implants	2	4.4%

Table 3 Anatomical Location of Wounds

S. No	Wound Location	Number of Patients	Percentage
1	Upper Limb	5	11.1%
2	Lower Limb	22	49%
3	Groin	1	2.2%
4	Gluteal Region	1	2.2%
5	Abdominal Wall	2	4.4%
6	Chest	12	26.7%
7	Back	2	4.4%

Only 2, out of 45 patients (4.5%) required an additional second debridement. One patient had progression of infection following application of NPWTi and he underwent additional debridement at the time of NPWTi dressing change. Second patient had haemorrhagic collection following wound cover with local flap. The collection was drained and the wound was debrided. After debridement, wound was again managed with NPWTi

In 29 out of 45 patients (64.5%), wound was ready for closure after 2 NPWTi dressing. Remaining 16 patients (35.5%) needed more dressing change. Mean NPWTi dressing required were 2.45 dressings per patients. Number of NPWTi dressing required is shown in figure 4.

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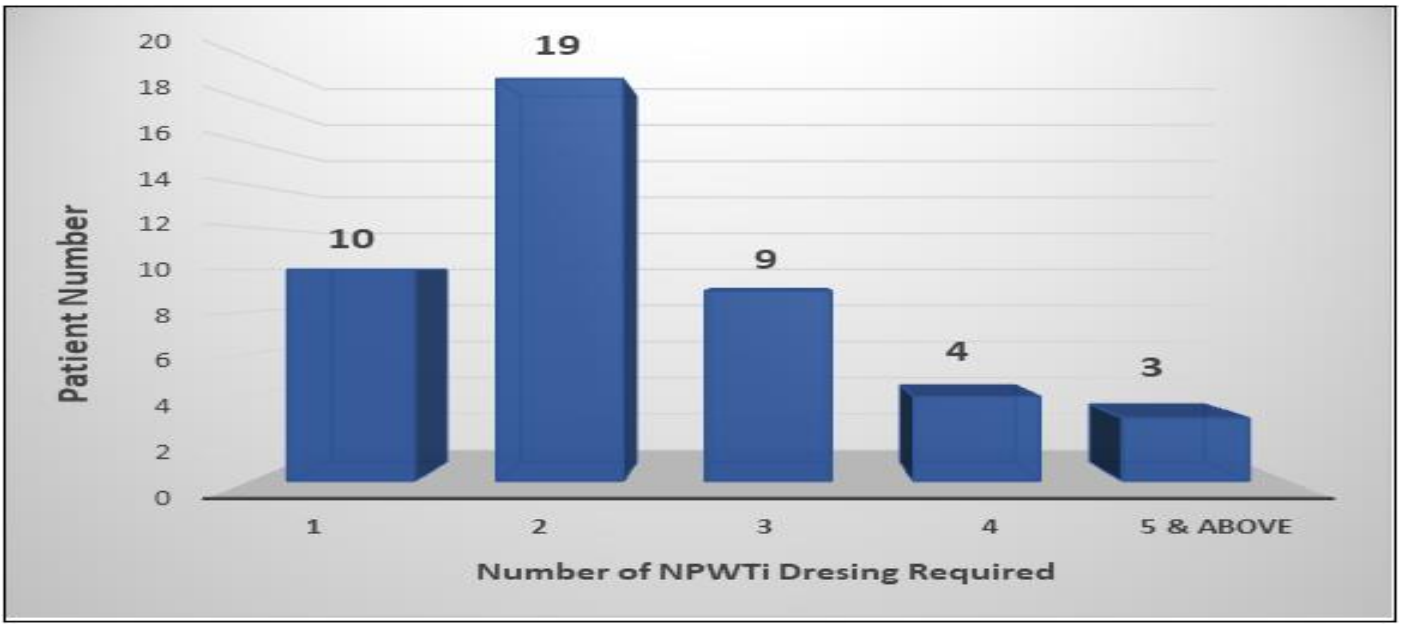

Fig 4 Number of NPWTi Dressing per Patient

The post debridement, wound area was calculated by MoWa app. Mowa app evaluate the dimension of wounds which are present over single surface/ 2D (two dimension like anterior surface of limb or posterior surface). In 39 patients, wound area was calculated using this app. In the remaining 6 patients, calculation of wound dimension was not feasible using this application. In these 6 patients, wound was either extending from anterior aspect of the limb to posterior aspect or they were present circumferentially around the limb.

Using Mowa application wound dimension was calculated in 39 patients. Mean area of the wound in 39 patients was 79.67 cm2 (Post debridement). Smallest wound in our study was 13.7cm^2 and largest was 320.9 cm^2. The mean reduction in wound size after NPWTi therapy was 18.3%. The mean reduction in wound size after each sitting of NPWTi dressings has been shown in figure 5.

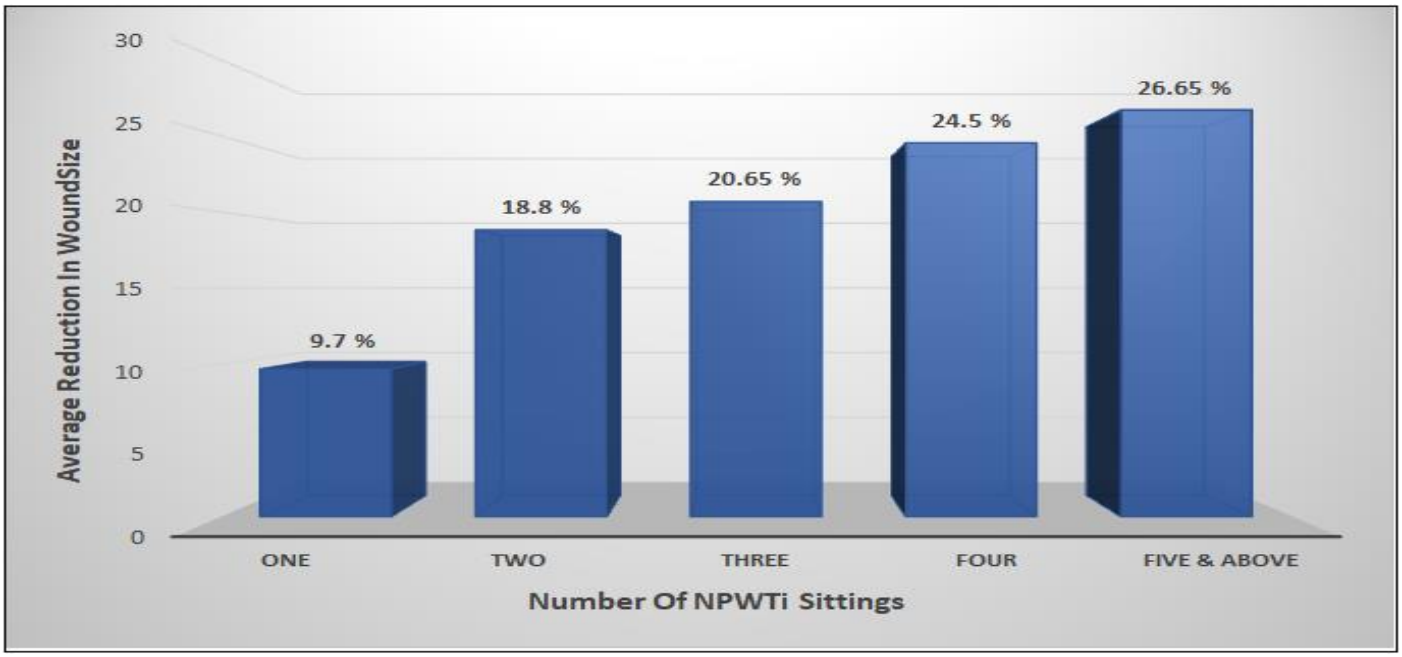

Fig 5 Mean Reduction in Wound Size after each NPWTi Sitting

Mean time for wound closure in our study was 11.05 +/- 5.9 days. Earliest wound was closed in 3 days after one NPWTi dressing maximum time was 28 days with eight NPWTi dressings (Figure 6). Mean closure time for infected and chronic wounds was 11.22 days and 10.4 days respectively.

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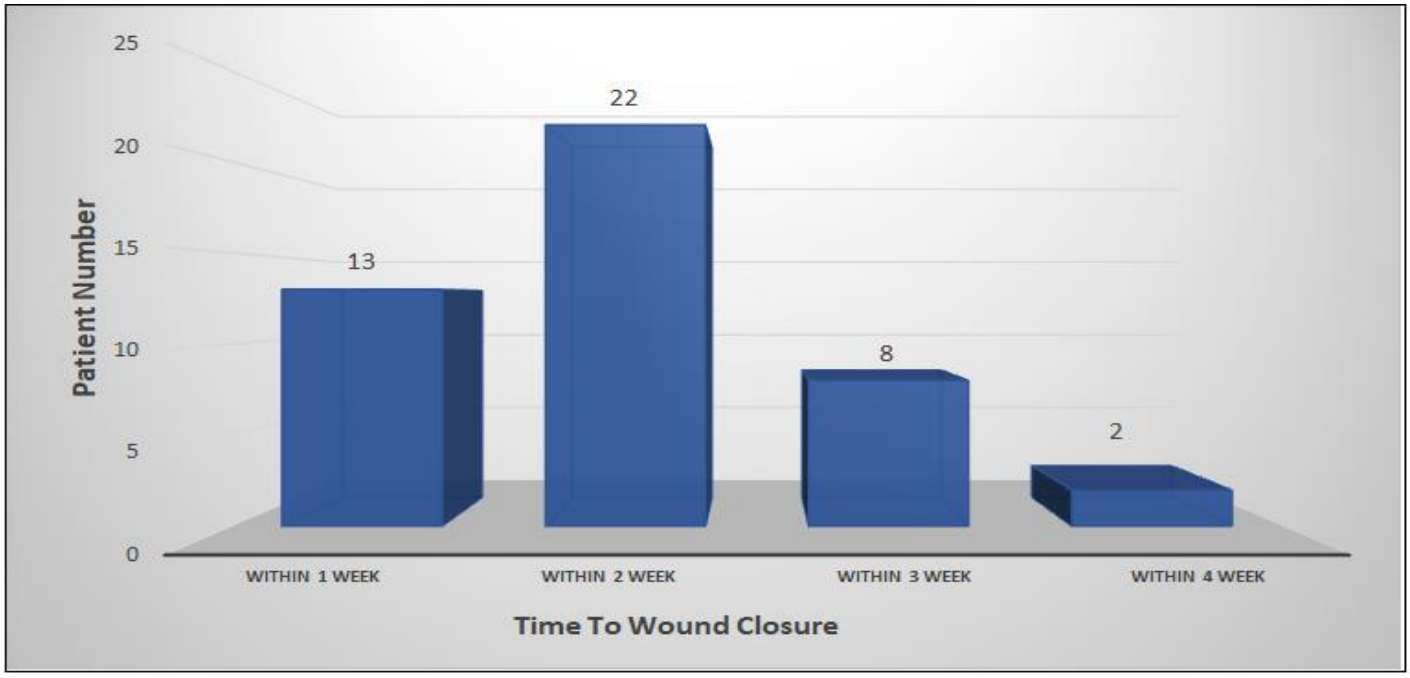

Fig 6 Time to Wound Closure

In 20 patients (44.5%), wound was closed by secondary suturing, 16 patients (35.5%) required skin grafting. In 2 patients (4.5%), wound was closed partially by secondary suturing and in remaining area skin graft was placed. Remaining 7 patients (15.5%) required flap cover. Out of these 7 patients, wound was resurfaced with free flap in 5 patients, local flap in 1 patient and pedicled flap in remaining 1 patient (Figure 7)

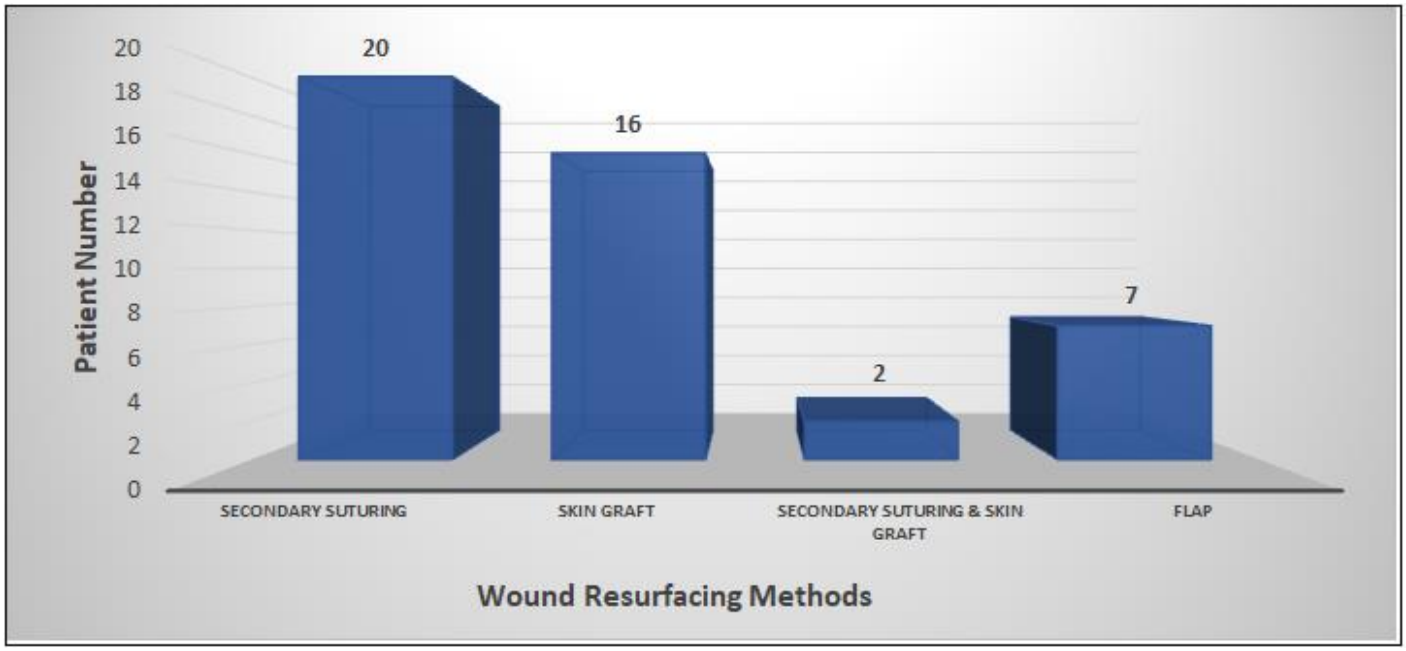

Fig 7 Wound Resurfacing

Only 1 patient (2.2%) out of 45 had wound related complication in the post-operative period. This patient had hematoma 3 days after secondary closure of the wound. Hematoma was evacuated and the wound was managed with NPWTi. After 2 sittings of NPWTi, the wound was covered with a skin graft.

Average hospital stay for patients with infected and chronic wounds managed with NPWTi was 11.5 days. All patients were followed up for a minimum period of 3 month following wound closure, during this period, none of them had dehiscence or wound recurrence.

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IV. DISCUSSION

Infected and/or chronic wounds are difficult to treat. For treating such wounds, the goal is to create an environment which promotes normal and timely healing. To achieve this goal, the first step is evaluation and optimization of the underlying disease/condition (such as diabetes, peripheral vascular disease, cardiovascular disease), the second step is wound debridement and the last step is the wound bed preparation for wound closure.[21,22]

NPWTi when combined with surgical debridement, restarts the granulation tissue formation in wounds that had failed to progress through the stages of healing with conventional treatment methods.[23]

In our study, 45 patients were enrolled. Out of 45 patients, 35 had infected wounds and 10 had chronic wounds. All patients underwent debridement prior to application of NPWTi.

In our study, mean debridements were 1.05 per patient. Only 2 patients out of 45 (4.45%) required additional debridement. It showed that NPWTi reduces the need for additional debridement, for wound preparation prior to closure. This reduced the additional cost of second surgery as well as exposure to anaesthesia. This may be because of its ability to prevent further progression of the infection, prevention of biofilm and to maintain a moist environment which is pre- requisite for wound healing.

Similar to our results, Gabriel et al. [16] in a retrospective analysis of 82 infected wounds also observed that mean debridement in NPWTi group was less (2.0 versus 4.4 in NPWT group), likewise Chowdhry S et al.[26] in a retrospective study of 30 patients treated for sternal wound complications reported mean debridements required in NPWTi group were 1.8 +/- 0.7 versus 3.1 +/- 1.0 in conventional dressing group (P = 0.0011).

Average number of NPWTi dressings required were 2.45 per patient in our study. With less dressing requirement, pain of dressing change is less in the patients managed with NPWTi compared with conventional dressing methods.

Burkhard et al.[24] reported that mean number of dressing changed required were 3.5 for the management of patients with infected orthopaedics implants managed with NPWTi. Likewise, Teot et al.[25] reported an average of 2.9 NPWTi dressing per patients in the management of wound with thick exudates.

It was reported in many studies that NPWTi reduces the size of the wound but none of these studies have specifically evaluated the percentage in wound size reduction by NPWTi. In our study, we have evaluated the percentage of wound size reduction using MoWa app. Post debridement mean area of the wound was 79.67 cm^2 and prior to closure mean area was reduced to 65.09cm^2. The mean reduction in wound size was 18.30 % using NPWTi. With the reduction in wound dimensions, need for flap or graft requirement is less and it also increases the chances of secondary suturing of the wound.

In our study, closure was either achieved with secondary suturing or/and skin grafting in majority of patients (84.5%). Only seven patients (15.5%) required complex reconstruction. 2 patients out of these 7, required a pedicle flap and in remaining 5, wound was resurfaced with microvascular free tissue transfer.

Similar results were shown by Brinkert et al.[20] in his case series of 131 patients. He reported that only 17.33% patients required complex reconstruction using flaps. In remaining 86.7% patient closure was either achieved with skin graft (57.76%) or suturing (24.83). Fluieraru et al.[19] reported similar results, 58.4% wounds (14 out of 24) were managed with skin graft, 8 with flaps and remaining 2 were closed primarily.

In our study, wound closure was achieved in all 45 patients. However, one patient had a collection at operated site 2 days after secondary suturing of the wound. All sutures were opened and collection was drained. Post drainage, wound was once again managed with NPWTi followed by skin grafting. Hence, wound closure rate in our study was 100%.

Various authors had reported good wound closure rate with NPWTi. Brinkert et al.[20] reported the wound closure rate of 98% in a case series evaluating the outcomes of 131 patients with infected. Fluieraru et al.[19] observed the wound closure rate of 96% in 24 patients with infected wounds managed with NPWTi. Chowdhry S et al.[26] reported 100% wound closure rate in management of sternal wound.

Biggest advantage of NPWTi in the management of infected and/or chronic wound is early wound closure as compared to NPWT as well as conventional gauze dressings. Time for complete healing of chronic wound by conventional dressings according to multiple randomized control trials and prospective studies range between 59 to 133 days.[27-29] In our study, mean closure time was 11.05 days. Early closure reduces the overall morbidity of patients, allows for early return to routine life and likewise cut down the cost of treatment.

In addition to effective management of infected and chronic wounds, NPWTi also helps in salvage of exposed or infected implants. The reported average rate of implant salvage without NPWTi is 65% in acute infection and 30% in chronic infection [30-34]. In our study, 2 patients had exposed orthopaedic implants with acute infections. In both we were able to salvage the orthopaedic implant using NPWTi with normal saline instillation.

With early wound closure, NPWTi cut down the hospital stay. In our study, mean hospital stay was 11.5 days. Shorter hospital stay cut down the cost of treatment.

In our study, all patients were followed for a minimum period of 3 month following the wound closure. None of them had a recurrence of wound or dehiscence.

V. CONCLUSION

NPWTi with normal saline instillation has improved the management of infected and/or chronic wounds and has become the standard of care at our facility. Outcomes from this prospective study showed a reduction in mean surgical debridements, mean time to wound closure and mean hospital stay. Furthermore, the reduced visits to the operative theatre for surgical debridements and shorter hospital stay also cut down the cost of treatment.

LIMITATIONS OF THIS STUDY

The study is a prospective observational study. No randomization has been done and also there is a no control group to which the results can be compared.

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