ASSESSMENT ON EFFICACY OF TOPICAL NEGATIVE PRESSURE DRESSINGS AGAINST CONVENTIONAL MOIST DRESSINGS

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ABSTRACT

BACKGROUND

A chronic wound is a wound that does not heal in an orderly set of stages and in a predictable amount of time. Wounds that do not heal within three months are often considered chronic. Recent studies have shown that application of a sub-atmospheric pressure in a controlled manner to the wound site has got an important role in assisting wound healing. The present study was conducted to assess the efficacy of topical negative pressure moist wound dressings as compared to conventional moist wound dressings in improving the healing process in chronic wounds.

The aim of this study was to compare the efficacy of topical negative pressure hydrocolloid moist dressing with that of a control group using conventional moist wound dressings in healing of chronic ulcers.

MATERIALS AND METHODS

This non-randomised controlled trial included 108 patients with chronic wounds, of varying aetiology, admitted in SVRRGGH, Tirupati for a period of one year. The whole sample population was divided into two equal and comparable groups of 54 patients, based on the willingness for undergoing topical negative pressure dressing. Those who were not willing were subjected to conventional moist wound dressings and formed the control group. Selection of patients was done by purposive sampling method. Care was taken so that both the groups had a comparable distribution of patients with regards to age as well as aetiology of the ulcer.

RESULTS

The mean rate of granulation tissue formation in both the groups were 81.01% (SD= 16.67) of the ulcer surface area for test and 63.96% (SD= 14.58) of ulcer surface area for control. The time to satisfactory healing was also compared and it was 12 days in the test group and 32 days in the control group. The change in the wound surface area was compared and it was 22% in the test group and 9% in the control group. The mean graft take-up in both the groups were 82.57% (SD= 13.78) of ulcer surface area for test and 68.18% (SD= 11.45) of ulcer surface area for control.

CONCLUSION

In our present study it was concluded that the rate of granulation tissue formation, overall graft survival and patient compliance was better in topical negative pressure dressing group as compared to conventional dressing group. It was also seen that the overall hospital stay and post-operative complications were less in the topical negative pressure dressing group.

KEY WORDS

Dressings, Moist, Negative, Pressure, Topical.

HOW TO CITE THIS ARTICLE: Keerthinmayee K, Vembuluru DR, Challapalli SR, et al. Assessment on efficacy of topical negative pressure dressings against conventional moist dressings. J. Evolution Med. Dent. Sci. 2018;7(26):3013-3016, DOI: 10.14260/jemds/2018/677

BACKGROUND

In this millennium where mankind has succeeded in deciphering the human genetic code, the issue of chronic wound management still remains an enigmatic challenge. Chronic wounds, especially non-healing types, are one of the most common surgical conditions a surgeon comes across.

'Financial or Other Competing Interest': None.
Submission 09-11-2017, Peer Review 08-06-2018,
Acceptance 14-06-2018, Published 25-06-2018.
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DOI: 10.14260/jemds/2018/677

A wound care revolution is currently in the making. Many techniques have been tried over the centuries to heal chronic leg ulcers. Recent studies have shown that application of a sub-atmospheric pressure in a controlled manner to the wound site has an important role in assisting wound healing. The present study was conducted to assess the efficacy of topical negative pressure moist wound dressings as compared to conventional moist wound dressings in improving the healing process in chronic wounds.[1,2,3,4]

A chronic wound is a wound that does not heal in an orderly set of stages and in a predictable amount of time. Wounds that do not heal within three months are often considered chronic.[5] These wounds cause patients severe emotional and physical stress and create a significant financial burden on patients and the whole healthcare system of the country.[6] The peculiarity of a chronic wound is that whatever management you give they refuse to heal, especially

the pressure ulcers or bed sores. The notion that wounds should be kept dry, although still held by a considerable number of clinicians, is steadily losing ground. We now know that wounds re-epithelialise much faster or develop granulation tissue faster when treated with dressings, which allow moist wound healing. A wound care revolution is currently in the making. Many techniques have been tried over the centuries to heal chronic leg ulcers. Although, wound dressing had been used for at least two millennia, there exists no ideal dressing.

Objectives

To compare the efficacy of topical negative pressure hydrocolloid moist dressing with that of a control group using conventional moist wound dressings in healing of chronic ulcers in terms of-

1. Number of days required for healing.
2. Number of ulcers unhealed in either group at the end of trial period.
3. Rate of granulation tissue formation as percentage of ulcer surface area.
4. Graft survival as percentage of ulcer surface area.
5. Period of hospital stay.

MATERIALS AND METHODS

This non-randomised controlled trial included 108 patients with chronic wounds of varying aetiology, admitted in SVRRGGH, Tirupati for a period of one year, satisfying all the inclusion criteria mentioned below after the clearance from the ethical committee was obtained. All chronic wounds where conventional dressings are indicated were included in the study.

The Main Inclusion Criteria were-

1. Patients with age between 18 - 75 years.
2. All types of chronic wounds irrespective of aetiology.
3. Wound size < 10% TBSA.
4. Patients giving consent for topical negative pressure dressings.

The Main Exclusion Criteria for the Study included-

1. Wounds with necrotic tissue.
2. Untreated underlying osteomyelitis.
3. Fistulas to organs or body cavities.
4. Exposed arteries or veins.
5. Malignancy within wounds.
6. Dry gangrene.

The whole sample population was divided into two equal and comparable groups of 54 patients, based on the willingness for undergoing topical negative pressure dressing. Those who were not willing were subjected to conventional moist wound dressings and formed the control group. Selection of patients was done by purposive sampling method. Care was taken so that both the groups had a comparable distribution of patients with regards to age as well as aetiology of the ulcer.

The science behind topical negative pressure dressings is to apply a sub-atmospheric pressure over a wound bed and maintain the negative pressure environment by means of a semi-permeable occlusive coverage. The fundamental principle behind topical negative pressure dressing is the application of sub-atmospheric pressures ranging from 25 to 200 mmHg at the wound bed. When negative pressure is applied over the wound bed, the oedema fluid is evacuated along with all growth inhibiting factors. This relieves the back-pressure effect on the healing tissues leading to improvement in local perfusion, local immunity, cellular waste disposal and tissue nutrition and oxygenation. Topical negative pressure application is believed to reduce microbial contamination by removal of accumulated interstitial fluid, improved local circulation and oxygenation and improved local immunity.[1,2,3] Topical negative pressure application has been proved to be effective in improving granulation tissue formation and maturation. Studies conducted by Morykwas and colleagues have shown that the mechanical stress that is applied on tissues by topical negative pressure has a stimulatory action on granulation tissue.

The topical negative pressure wound dressing is a combination of composite synthetic hydrocolloid sheet dressing with vacuum assisted wound closure systems.

The Technique involves Six Steps. These are-

1. The wound is thoroughly debrided, and devitalised tissue removed. A perforated drain tube is placed on top of the wound bed and the other end is brought out subcutaneously a little away from main wound.
2. The foam dressing is cut to size of the wound and applied over the drain tube.
3. The foam with the surrounding normal skin is covered with adhesive, semi-permeable, transparent membrane. A good air seal must be ensured around the wound.
4. Distal end of the drain tube is now connected to a device, which provides a negative pressure suction in the range of -25 to -200 mmHg. This can be achieved by wall suction apparatus, computerised devices or simple suction drain devices. Suction may be applied continuously or intermittently based on amount of wound discharge.
5. Once vacuum is applied, the foam must be seen collapsed into the wound bed.
6. The fluid from the wound is absorbed by the foam and is removed from the wound bed by suction.

The negative pressure has to be maintained for an average of 10 - 14 days for maximum benefit, as studies have proved. Once adequate granulation tissue is formed, the dressing should be removed, and definitive wound closure is achieved by partial or full thickness grafts, flaps or suturing.[7] Once adequate granulation tissue was formed, the dressing was removed and definitive wound closure achieved by skin grafts, flaps or suturing. At the end of ten days, the wounds in both the groups were inspected after removal of the dressings from the test group. The wounds were compared based on the following parameters. They are rate of granulation tissue formation as percentage of the ulcer surface area and quality of ulcer bed. Once these parameters were assessed, both the groups were subjected to split thickness skin grafting. Both groups were given the same systemic antibiotics during the postoperative period. The wounds were reassessed at the end of the fifth postoperative day and the following parameters were accounted for. They were skin graft take-up as a percentage of ulcer surface area, number of days of hospitalisation. The results obtained were

statistically evaluated and the main parameters which were analysed were- Rate of granulation tissue formation, graft survival, take-up and duration of hospital stay.

Statistical Analysis

Demographic data was calculated using Chi-square test. The mean rate of granulation tissue formation, graft survival and hospital stay were calculated and compared for both groups. The variables were compared using the Unpaired Student's t-test. A p-value of < 0.05 was considered significant. Epi Info version 7.2.0.1 dated 06/27/2016, a trademark of Centre of Disease Control and Prevention (CDC), Atlanta, USA was used for statistical analysis.

RESULTS

The mean rate of granulation tissue formation in both the groups were 81.01% (SD= 16.67) of the ulcer surface area for test and 63.96% (SD= 14.58) of ulcer surface area for control. The results analysed statistically showed highly significant difference in rate of granulation tissue formation ($p < 0.05$). The time for satisfactory healing was also compared and it was 12 days in the test group and 32 days in the control group. The change in the wound surface area was compared and it was 22% in the test group and 9% in the control group. The mean graft take-up in both the groups were 82.57% (SD=13.78) of ulcer surface area for test and 68.18% (SD=11.45) of ulcer surface area for control. Statistical analysis of the data revealed highly significant difference in graft take up ($p < 0.05$). The total days of hospital stay for the patients was also compared. The mean number of days of hospital stay was 31.59 days (SD= 10.9) for test and 54 days (SD= 15.03) for control. Statistical analysis of the data showed highly significant differences in the hospital stay in both groups with a p-value of < 0.05, which is significant.

	Control	Test
No. of Patients	**54**	**54**
Age - range	20 - 60	25 - 60
Age - Mean, SD	**47.35, 8.34**	**46.81, 10.12**
Male: Female	30:24 (55.5%:44.5%)	36:18 (66.7%:33.3%)
Ulcer size	10 - 80 cm^2	30 - 95 cm^2
Table 1		

Characteristics of patients in two groups.

	Control	Test
Traumatic	8 (14.8%)	7 (13%)
Trophic ulcer	13 (24.0%)	12 (22.2%)
Venous ulcer	7 (13%)	5 (9.3%)
Diabetes	18 (33.4%)	20 (37%)
Infection	8 (14.8%)	10 (18.5%)
Total	**54 (100%)**	**54 (100%)**
Table 2		

Aetiological distribution ($p > 0.05$).

Decrease in Wound Surface Area	Control	Test
Mean, SD	8.88, 5.82	33.77, 3.5
1 - 10%	34 (62%)	0
10 - 20%	20 (37%)	0
20 - 30%	0	08 (14.8%)
31 - 40%	0	46 (85.2%)
Total	**54(100%)**	**54 (100%)**
Table 3		

Decrease in wound surface area ($p < 0.0001$).

Percentage %	Control	Test
Mean, SD	**68.18%, 11.56%**	**82.57%, 13.87%**
> 90	6 (11.1%)	20 (37%)
80 - 90	6 (11.1%)	12 (22.2%)
70 - 80	5 (9.3%)	6 (11.1%)
60 - 70	8 (14.8%)	7 (13%)
50 - 60	22 (40.7%)	5 (9.3%)
40 - 50	7 (13%)	4 (7.4%)
Total	**54 (100%)**	**54 (100%)**
Table 4		

Distribution of patients based on graft uptake ($p < 0.0001$).

Days	Control	Test
Mean, SD	52, 15.17	31.59, 11.09
10 - 20 days	0	8 (14.8%)
20 - 30	4 (7.4%)	32 (59.3%)
30 - 40	4 (7.4%)	6 (11.1%)
40 - 50	24 (44.4%)	4 (7.4%)
50 - 60	12 (22.2%)	2 (3.7%)
60 - 70	4 (7.4%)	2 (3.7%)
> 70	6 (11.1%)	0
Total	**54 (100%)**	**54 (100%)**
Table 5		

Distribution of patients based on No. of days of hospital stay ($p < 0.0001$).

DISCUSSION

The concept of applying a sub-atmospheric environment on wounds to accelerate the healing process came into practice in 1993 and was first described by Fleischmann et al.[8] Argenta and Morykwas determined that intermittent negative pressure at 125 mmHg promoted wound healing by improving blood flow, granulation tissue growth rates and nutrient flow while reducing bacterial levels.[2,3]

The efficacy of Negative Pressure Wound Therapy (NPWT) was initially described by Morykwas et al and Morykwas Philbeck et al's pioneering work studied in 1,032 home healthcare patients with 1,170 wounds that failed to respond to previous interventions and were subsequently treated with NPWT and concluded NPWT to be efficacious and economical treatment modality.[2,3,4]

Soon after this study, a system promoting vacuum assisted closure was introduced to the United States market, specifically designed to avoid the problems described by Banwell. This system solved the previously mentioned problems by using a microprocessor-controlled vacuum unit. With the aid of this device, standardised levels of continuous or intermittent negative pressure from 25 to 200 mmHg could be provided.[9]

The cost issue of NPWT has been an ongoing debate since its introduction. According to a literature review regarding the cost effectiveness of negative pressure wound therapy (NPWT) by Othman published in 2012,[10] there is enough evidence that NPWT could be a useful source of cutting costs of chronic wound management for the National Health System (NHS) in the UK.

CONCLUSION

In our present study it was concluded that the rate of granulation tissue formation, overall graft survival and patient compliance was better in topical negative pressure dressing group as compared to conventional dressing group. It was also seen that the overall hospital stay, and postoperative complications were less in the topical negative pressure dressing group. Thus, topical negative pressure moist wound dressing can be considered as a superior option in the management of chronic wounds. But further studies with larger population will be needed in the future before topical negative pressure dressing can be added to the wide spectrum of treatment modalities available in the management of chronic wounds.

Vacuum assisted closure therapy has been around for no longer than 20 years and has facilitated the wound healing process to a large extent. This wound healing system has proven beneficial in a wide range of applications, predominantly in the management of chronic, open wounds as well as in acute and subacute wounds. Likewise, benefits have been seen in cases involving meshed skin grafts, diabetic ulcers and pressure sores. By reducing healing time and being cost-effective, NPWT dressing has made wound healing a more comfortable and cheaper process as well as improving the quality of life and morbidity of the patients requiring therapy.

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