

A Prospective Comparative Study of Negative Pressure Wound Therapy versus Conventional Moist Dressing in the Management of Diabetic Foot Ulcers

Dr. M.D.Thenmozhi.M.S.,M.Ch., Dr. S.Sivakumar. M.S.,M.Ch.

Assistant Professor Department of Plastic surgery. Government Mohan Kumaramangalam Medical College Hospital, Salem, Under the auspices of The TN Dr. MGR Medical University

Corresponding author: Dr. S.Sivakumar

Abstract: From the golden era of Joseph Lister, the concept of cleanliness of wound came into vogue and since then, there is ever increasing knowledge of wound care. Diabetic foot ranks first in decapitating the quality of patient's life. Dr. Catherine Le Gales- Camus, Assistant Director-General of WHO exclaims in grief, that "It is Unacceptable that so much disability and death are caused by leg amputations, when the solutions are clear and affordable". So, we compared negative pressure wound therapy with conventional moist dressing in our clinical day to day practice in a tertiary care centre and has conceived that the concept of Negative Pressure Wound Therapy (NPWT) is really a boon to the surgeon for early wound healing and also for improving the wound environment for early wound closure.

Key words: NPWT (Negative Pressure Wound Therapy), VAC- (Vaccum Assisted Closure, Diabetic foot).

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I. Introduction :

From the golden era of Joseph Lister, the concept of cleanliness of wound came into vogue and since then, there is ever increasing knowledge of wound care. Diabetic foot ranks first in decapitating the quality of patient's life. Dr. Catherine Le Gales- Camus, Assistant Director-General of WHO exclaims in grief, that "It is Unacceptable that so much disability and death are caused by leg amputations, when the solutions are clear and affordable". So, we compared negative pressure wound therapy with conventional moist dressing in our clinical day to day practice in a tertiary care centre

II. Aims and Objectives:

- (i) To compare the efficacy of negative pressure wound therapy against conventional moist dressing in Diabetic foot ulcerations in terms of early wound healing and preparation of wound bed for early wound closure.
- (ii) To compare the graded percentage decrease in ulcer size, periulcer edema and erythema and graded percentage increase in epithelialisation and granulation tissue.

III. Materials and Methods:

1. Study type - Interventional
2. Study design - Prospective Randomized comparative study
3. Study group - Over 2 years 50 patients suffering from grade 2 and grade 3 diabetic foot ulcers (according to University of Texas classification) admitted in surgical wards in GMK medical college hospital, Salem were considered as data source.

Patients who fulfilled the inclusive and exclusive criteria were enrolled in the study and randomized to enter the study. Out of fifty patients, 25 patients were randomized in to Group A as NPWT group and 25 patients were randomized into Group B as conventional moist dressing group. After routine wound debridement and slough excision, patients were randomized and included in the study.

4. Inclusion Criteria:

- (i) Age : 20 to 70 years
- (ii) Sex : Both Males & Females
- (iii) Both type I & type II Diabetic patients
- (iv) Grade 2 and Grade 3 foot ulcers –after debridement and slough excision.

5. Exclusion Criteria:

- (i) Grade 1, 4 & 5 foot ulcers
- (ii) Necrotic & sloughy ulcers

- (iii) Vascular occlusion
- (iv) Osteomyelitis in affected foot
- (v) Not willing to give consent

6. Study method instituted:

All 50 patients were admitted in surgical wards and were treated by a foot care team comprising of plastic surgeons, Diabetologist, Orthopaedic surgeon, Radiologist, Microbiologist and staff nurses. Initially clinical screening was done by history taking, clinical examination and laboratory investigations. For each group, assessment of foot ulcers were performed at the beginning of treatment and at each sitting. Initially, wound debridement was done and infection control was adopted as per culture sensitivity and institution policy. After slough excision cases were randomized into two study groups. Area of each wound was calculated at weekly intervals by multiplying longest vertical and horizontal dimensions of Diabetic foot ulcers. Bony involvement was excluded using X rays and orthopaedic surgeon’s opinion. Vascular occlusion was excluded using Duplex Doppler imaging and Radiologist expert opinion. Glycaemic management was carefully done by diabetologist daily care. Appropriate foot wear, offloading of ulcer and patient compliance were checked at each sitting. Both study groups were treated accordingly and concurrent treatment of associated hypoproteinaemia and anaemia were done. Both groups were treated until complete closure of wound or until the wound bed becomes fit for skin grafting. Statistical analysis of data were done using students T test (Paired samples T- test) and the results were tabulated.

7. Technique of dressing:

Group- A

The NPWT dressing is an amalgamation of composite synthetic hydrocolloid sheet dressing with vacuum assisted wound closure systems. All the patients included in Group-A were subjected to this technique.

- (i) Wound debrided and necrotic tissue removed. Foam made of polyurethane ether is cut to the exact size of the wound margin and placed within the wound and covered by semi permeable adhesive drape.
- (ii) One or more access ports are cut out of the adhesive tape over the summit of the foam, where suction tubes are placed.
- (iii) The suction tubes are connected to a disposable collection canister system and this machine creates a suction pressure of about 55mmHg to 175mmHg of negative pressure depending on size of the wound.
- (iv) Each sitting was maintained for 48hours with intermittent suction.
- (V) Procedure was repeated if needed.

Group- B:

Daily conventional dressing using normal saline.

8. Follow up:

Periodic ulcer survey was made once in 2 days up to three months.

IV. Results

Measurement of ulcer in square centimeters, measurement of granulation tissue in square centimeters, documentation of compliance and associated therapy were carried out and results tabulated. One patient withdrew from Group- A because of poor patient compliance.



Table I – Assessment of ulcer size:

Day	% of Decrease in ulcer size	
	Group- A	Group- B
1	Baseline	Baseline
7	18	15
14	32	20
21	74	50
28	82	65

P= 20.47 students T test

Table II – Assessment of peri -ulcer oedema and Erythema:

Day	% of Decrease in Peri- ulcer Oedema and Erythema	
	Group- A	Group- B
1	Baseline	Baseline
7	50	40
14	65	50
21	75	55
28	90	70

P= 0.3029 students T test

Table III – Time to lesion healing:

Mean healing time	
Group- A	Group- B
NPWT group	Conventional moist dressing group
28 ±10 days	40 ± 10days

In our study, based on above observation, it is well conceived that NPWT frames a superior concept over conventional moist dressing in view of decreased mean healing time, increased percentage of decrease in inflammatory signs, early wound contracture and early fitness of wound bed for skin grafting.

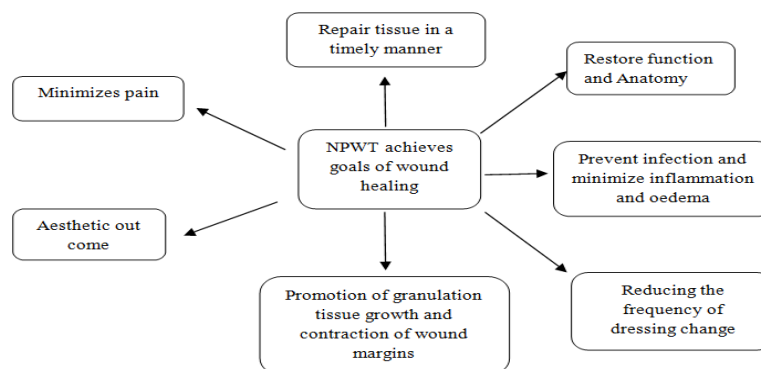
V. Discussion

Dr. Argert and Mark introduced the concept of applying sub atmospheric pressure to the wound bed to accelerate the formation of granulation tissue. After conceiving this negative pressure principle, NPWT otherwise called as micro deformation therapy oriented towards early wound healing as the primary end point and the reconstructive ladder helps in further management of the wound as per nature of the wound⁽¹⁾. NPWT promotes wound healing by primary and secondary mechanisms⁽⁴⁾.

Table IV – Mechanism of Action of NPWT

Primary mechanisms	Secondary mechanisms
1. Micro deformation	1. Promotion of angiogenesis
2. Macro deformation	2. Promotion of neurogenesis
3. Fluid removal	3. Bio-burden reduction
4. Alteration of wound environment	4. Modulation of inflammation

By above primary and secondary mechanisms, NPWT achieves the following goals of wound healing⁽³⁾



VI. Conclusion

So, there is no doubt that VAC therapy (NPWT) can definitely have a positive impact on patient's quality of life⁽²⁾ The only arising argument against VAC therapy is the cost factor, but considering early time to lesion healing and early return of patient to his occupation, cost effectiveness is also optimized. Still, future surgical practice needs to find out the ways of improvising more cost friendly VAC therapy tools⁽¹⁾ to improve the effectiveness in patient –surgeon compliance.

Conclusion

Negative pressure wound therapy is definitely superior than conventional moist dressing in views of

1. Decreased mean healing time.
2. Early wound contracture and early fitness of wound bed for skin grafting.
3. Early restoration of function and Anatomy of the affected limb.

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