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ORIGINAL ARTICLE

Different Modalities for the Management of Diabetic Foot Wounds: A Prospective Cohort Study

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Abstract

Background: **Between 5 and 10% of diabetics experience DFUs. It is a leading cause of lower extremity amputation. The medical community is paying close attention to DFUs (diabetic foot ulcers) which are a prevalent type of chronic or non-healing wound.**

The aim of the work: **is to assess the effectiveness of various management strategies for pathological diabetic foot lesions including conventional dressing, silver based and negative pressure wound therapy. Additionally, to compare clinical effectiveness of traditional versus commercialized modern wound dressing in a variety of pathological diabetic foot wound and their influence on its healing and clinical outcome.**

Patients and methods: **This prospective randomized clinical trial involved 60 patients who had either acute or chronic pathological diabetic foot wounds having surgical debridement for a diabetic foot infection, or needed a small conservative foot amputation.**

Results: **As regard outcome, Silver-based dressing had the best outcome with all cases had Primary healing of the ulcer, A. Conventional dressing using povidone-iodine group had 50% primary healing of ulcers, 40% had recurrent ulcers, 5% had Below knee amputation, 5% had Disarticulation of toes, in A. Following negative pressure wound therapy (NPWT), 55% of patients experienced primary ulcer healing, 25% had toe disarticulation, and 10% had unhealed ulcers, 5% had recurrent ulcers, 5% had below-knee amputation.**

Conclusion: **Silver-releasing dressings significantly affect the development and acceleration of granulation tissue. We suggest that silver-releasing dressings are more appropriate for deep, full-thickness wounds because they encourage the early closure of wounds and guarantee a better result.**

Keywords: Diabetic, Dressing, Wound

1. Introduction

Several persons with diabetes mellitus (DM) experience diabetic foot ulcers (DFUs). The prevalence of DFU varies from 1% in the West to up to 11% in communities in Africa. Up to 85% of non-traumatic amputation cases are caused by DFUs, making them the most frequent cause. Patients with DFU have a mortality rate that is approximately twice as high as those without DFU. The cost of care for patients with DFUs was discovered to be more than five times higher in the first year than it was for diabetics without foot ulcers. This is primarily caused by the lengthy hospital stays required for DFU patients.[1]

The recommended course of treatment for DFUs entails debridement, local wound care, infection management, and pressure off-loading. In recent years, a number of remedies have been promoted, including hyperbaric oxygen therapy, cultured skin substitutes, improved wound dressings, and growth factors.[2]

To further optimize the healing process and increase treatment effectiveness for diabetic foot patients, the clinical application of Nano-silver dressings can be taken into consideration. When compared with standard silver dressings, Nano-silver dressings have a bigger contact surface and a better antibacterial action. Additionally, it can be routinely cleaned to improve wound infection management and encourage wound healing.[3]

Although the majority of clinicians agree that negative pressure wound therapy (NPWT) (negative

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pressure wound therapy) is beneficial in encouraging wound healing, there are few high-quality clinical research proving this to be the case, and much more can be learned about the mechanisms of action. In the future, perhaps, we will have the information to help clinicians choose the best interface material, suction application waveform, and suction quantity for certain wounds. Additionally, more research into certain interface coatings and instillation therapy is required. We think that improvements in wound healing science, biofilm comprehension, and cell therapy will result in better treatment for our patients.[4]

This study's objective is to assess the effectiveness of various therapeutic strategies for pathological diabetic foot lesions. Moreover, to assess and evaluate the efficacy of the use of commercially available contemporary wound dressings in diverse pathological diabetic foot wounds versus the traditional type of dressing. And to evaluate the benefits and drawbacks of applying dressings to various types of diabetic feet pathological wounds, and their influence on its healing and clinical outcome.

2. Patients and methods

60 patients with acute and chronic pathological diabetic foot wounds, patients having surgical debridement of diabetic foot infection, and/or patients needing modest conservative foot amputation participated in this prospective, randomized clinical trial. The study was carried out in collaboration with the National Institute of Diabetes and Endocrinology (NIDE), Cairo, Egypt, in the Department of Vascular Surgery at Al-Hussein and Said-Galal University Hospitals, part of Al-Azhar University Hospitals - Cairo. The selected patients were randomly selected and distributed into 3 groups using a random number table produced by computerized Microsoft Excel for receiving either standard dressing, silver-based dressing, or NPWT.

3. Methodology

The following procedures were applied to all patients: taking a thorough history. Comprehensive clinical evaluation that includes a local and broad examination of the afflicted limb, its clinical status (i.e. ischemic or not), and the need for revascularization in selected cases. Local examination of the foot, the presence of foot deformities, ulceration, or wounds, including its onset, site, size, shape, edge, clean or infected, unilateral or bilateral, the distal pulse, foot movement, and foot sensation.

Wound dressing: The wounds were managed by either one of the following dressing: Conventional dressing using povidone-iodine: Polyvinylpyrrolidone (povidone, PVP) and elemental iodine combine chemically to form the stable compound known as povidone-iodine. Silver-based dressing: Nano-silver refers to three-dimensional silver nanoparticles having at least one dimension less than 100 nm. It is a brand-new antibacterial solution created with nanotechnology that possesses consistent physical and chemical traits. Negative pressure wound therapy (NPWT): Vacuum-assisted wound closure (VAWC), describes the use of wound dressing systems that periodically or continually supply subatmospheric pressure to the system, creating positive pressure on the wound's surface. NPWT has gained popularity as a management technique for a variety of acute and chronic wounds.

Preprocedure Assessment: thorough complete blood count (CBC), coagulation profile and renal and liver function. Using plain film radiography, the amount of foot infection is evaluated. Ankle/brachial pressure index measurement in conjunction with a Doppler ultrasound examination. For patients undergoing limb revascularization, It is possible to utilize computed tomography angiography (CTA) and/or duplex ultrasound evaluation.

Follow up: Follow-up was done every week in the first month, then 2 weeks in the second month, and then every month for a maximum 6 months' duration.

3.1. Inclusion criteria

The study will include all diabetic foot patients presented with Either acute or chronic wounds and Patients who undergo surgical debridement or conservative minor amputations because of osteomyelitis involving any of the toes or the metatarsal heads. Exclusion criteria: Patients with ongoing infections that initial surgical debridement could not successfully treat, renal failure patients, patients undergoing chemotherapy or radiation therapy, Charcot foot, and Patients with extensive hind foot or midfoot wounds associated with gross affection of the calcaneus or the tarsal bones.

3.2. Statistical analysis

With the aid of the IBM SPSS software package version 20.0, data were fed into the computer and evaluated. IBM Corp., Armonk, New York Number and percentage were used to describe qualitative data. The normality of the distribution was examined using the Kolmogorov-Smirnov test. Quantitative data were described using range (minimum and maximum), mean, and standard deviation,

Table 1. Distribution of the studied cases according to localization of lesion (n = 60).

Localization of lesion	No. (%)
Toes dorsal and plantar surface	18 (30.0)
Post-operative sole	17 (28.3)
Plantar metatarsal head	8 (13.3)
Mid foot and heal	8 (13.3)
Leg debridement	3 (5.0)
Heel debridement	6 (10.0)
Dorsum of foot	1 (1.7)
Dorsum debridement	5 (8.3)
Forefoot amputation	2 (3.3)

median and interquartile range (IQR) (IQR). At the 5% level, the significance of the results was determined. The tests used were: χ^2test: To compare two groups using categorical variables. Correction for $\chi^2$when more than 20% of the cells have an anticipated count below five using Fisher's Exact or Monte Carlo methods. *F*-test (ANOVA): To compare between more than two groups when comparing normally distributed quantitative variables. Kruskal-Wallis test: To compare between more than two examined groups for quantitative variables with aberrant distributions.

4. Results

Table 1.

As regard to localization of lesion 30% were at Toes dorsal and plantar surface, 28.3% at Postoperative sole, 13.3% at Plantar metatarsal head, Mid foot and heal, 10% at Heel debridement, 5% Leg debridement, 8.3% Dorsum debridement, 3.3% Forefoot amputation, 1.7% were Dorsum of foot Table 2.

Table 2. Relation between dressing type and different parameters.

	Dressing type			Test of Significance	*P*
	A. Silver-based dressing (*n* = 20) No. (%)	A. Negative pressure wound therapy (NPWT) (*n* = 20) No. (%)	A. Conventional dressing using povidone iodine (*n* = 20) No. (%)		
ALB (mg/l)					
Min. – Max.	3.90–4.20	4.30–4.50	4.0–4.50		
Mean ± SD.	3.99 ± 0.14	4.39 ± 0.08	4.30 ± 0.19	F = 40.944*	<0.001*
Median	3.90	4.40	4.40		
WBC (× 10^9/l)					
Min. – Max.	7678.0–8789.0	6578.0–24567.0	6578.0–14567.0		
Mean ± SD.	8069.55 ± 541.66	13389.35 ± 7798.98	9505.30 ± 3403.88	H = 2.649	0.266
Median	7687.0	11899.0	8238.0		
Wound duration (weeks)					
Min. – Max.	8.0–17.0	8.0–15.0	9.0–16.0		
Mean ± SD.	12.15 ± 3.42	11.75 ± 2.51	11.85 ± 2.28	F = 0.112	0.894
Median	12.0	12.0	11.50		
Wound size (cm^2)					
<5	18 (90.0)	6 (30.0)	4 (20.0)	χ^2 = 23.036*	<0.001*
>5	2 (10.0)	14 (70.0)	16 (80.0)		
Min. – Max.	1.90–5.60	2.40–7.60	2.30–7.80		
Mean ± SD.	3.45 ± 1.07	5.47 ± 1.44	5.99 ± 1.41	H = 25.452*	<0.001*
Median	3.20	5.60	6.50		
Local					
Toes dorsal and plantar surface	8 (40.0)	2 (10.0)	8 (40.0)	χ^2 = 5.714	0.057
Post-operative sole	4 (20.0)	10 (50.0)	3 (15.0)	χ^2 = 7.059*	0.029*
Plantar metatarsal head	5 (25.0)	3 (15.0)	0	χ^2 = 5.698	^{MC}P = 0.081
Mid foot and heal	5 (25.0)	3 (15.0)	0	χ^2 = 5.698	^{MC}P = 0.081
Leg debridement	2 (10.0)	0	1 (5.0)	χ^2 = 1.921	^{MC}P = 0.766
Heel debridement	0	3 (15.0)	3 (15.0)	χ^2 = 3.550	^{MC}P = 0.228
Dorsum of foot	0	0	1 (5.0)	χ^2 = 1.851	^{MC}P = 1.000
Dorsum debridement	1 (5.0)	2 (10.0)	2 (10.0)	χ^2 = 0.622	^{MC}P = 1.000
Forefoot amputation	0	0	2 (10.0)	χ^2 = 2.765	^{MC}P = 0.329
Side					
Unilateral	9 (45.0)	9 (45.0)	7 (35.0)	χ^2 = 0.549	0.760
Bilateral	11 (55.0)	11 (55.0)	13 (65.0)		
The distal pulse	17 (85.0)	12 (60.0)	9 (45.0)	χ^2 = 7.033*	0.030*
Clean or infected	0	11 (55.0)	10 (50.0)	χ^2 = 16.264*	<0.001*
Neuropathy	0	12 (60.0)	6 (30.0)	χ^2 = 17.143*	<0.001*
Vascular surgical treatment	0	3 (15.0)	1 (5.0)	χ^2 = 3.111	^{MC}P = 0.310

χ^2, Chi square test; F, F for One way ANOVA test; H, H for Kruskal Wallis test; MC, Monte Carlo; SD, Standard deviation.
P: *P* value for association between different categories.
*: Statistically significant at *P* less than or equal to 0.05.

Table 3. Relation between dressing type and different parameters.

	Dressing type			χ^2	^{MC}P
	A. Silver-based dressing ($n = 20$) No. (%)	A. Negative pressure wound therapy (NPWT) ($n = 20$) No. (%)	A. Conventional dressing using povidone iodine ($n = 20$) No. (%)		
Management					
Conservative management	20 (100.0)	14 (70.0)	20 (100.0)		
Lower extremity amputation (toes amputation)	0	5 (25.0)	0	10.559*	0.002*
Lower extremity amputation (forefoot amputation)	0	1 (5.0)	0		
Treatment modalities					
Sole debridement	2 (10.0)	9 (45.0)	3 (15.0)		
Daily wound care	13 (65.0)	0	0		
Dorsum debridement	5 (25.0)	2 (10.0)	7 (35.0)		
Heel debridement	0	3 (15.0)	1 (5.0)		
Minor LEA	0	5 (25.0)	0	55.406*	<0.001*
Fasciotomy	0	0	3 (15.0)		
Drainage of abscess with debridement	0	0	4 (20.0)		
Forefoot amputation	0	0	2 (10.0)		
Major LEA	0	1 (5.0)	0		
Outcome					
Recurrent ulcer	0	1 (5.0)	8 (40.0)		
Primary healing of ulcer	20 (100.0)	11 (55.0)	0		
Unhealed ulcer	0	2 (10.0)	10 (50.0)	54.457*	<0.001*
Below knee amputation	0	1 (5.0)	1 (5.0)		
Disarticulation of toes	0	5 (25.0)	1 (5.0)		

χ^2, Chi square test; MC, Monte Carlo.
P: *P* value for association between different categories.
*: Statistically significant at *P* less than or equal to 0.05.

As regard wound size was smaller in Silver-based dressing group with no infection or Neuropathy and higher number of distal pulse in comparison to other two groups Table 3.

As regard management all cases with A. Negative pressure wound therapy (NPWT) group 70% had Conservative management, 25% had Lower extremity amputation (toes amputation), 5% had Lower extremity amputation (forefoot amputation) with significant differences. Treatment modalities in A. Silver-based dressing was mainly Daily wound care in 65%, Dorsum debridement in 25%, Sole debridement in 10% in A. Conventional dressing using povidone iodine 35% had Dorsum debridement, 20% had Drainage of abscess with debridement, 15% had Fasciotomy, Sole debridement, 10% had Forefoot amputation, 5% had Heel debridement, in A. NPWT 45% had Sole debridement, 25% had Minor LEA, 15% had Heel debridement, 10% had Dorsum debridement, 5% had Major LEA with significant differences between three groups.

5. Discussion

DM is a chronic metabolic condition that poses a severe threat to people's health all over the world. Gangrene and foot ulcers are the primary clinical manifestations of diabetic foot ulcer which are significant chronic complications in people with DM and a significant cause of disability and death from DM Wang and colleagues.[5]

In the other hand a meta-analysis compare different types of dressing to diabetic foot ulcers found that Age, gender, sickness severity, and condition did not significantly differ between the study groups Zhang and colleagues.[6]

In line with our findings, when comparing the percentage of ulcer reduction caused by vacuum-assisted closure (VAC) with silver-releasing foam dressing, the area was measured in cm2 both at the start of therapy and during the final stages of care. The size of the ulcer decreased on average by 38.79% in the silver group and 26.56% in the VAC group Taliat and colleagues.[7]

It was discovered that the average treatment time for ordinary dressings was 25.5 days, whereas the average time for wound healing with VAC was only 10.09 days Gunal and colleagues.[8]

NPWT is equally safe and more effective than Advanced Moist Wound Therapy in the treatment of DFUs, and ulcer-related complications like infection, cellulitis, and osteomyelitis were not significantly different from each other Blume and colleagues.[9]

In comparison to a control group that received conventional dressing, the concentration of daptomycin in wounds treated with NPWT was investigated. The data revealed a significant rise in antibiotic concentration in the tissue following VAC therapy Lo Torto and colleagues.[10]

As regard outcome A. Silver-based dressing had the best outcome with all cases had Primary healing of ulcer, A. Conventional dressing using povidone-iodine group had 50% primary healing of ulcers, 40% had recurrent ulcers, 5% had Below knee amputation, 5% had Disarticulation of toes, in A. NPWT 55% had Primary healing of ulcer, 25% had Disarticulation of toes, 10% had Unhealed ulcer, 5% had Recurrent ulcer, 5% had Below knee amputation.

In our study, A. Silver-based dressing had best outcome with all cases had Primary healing of ulcer, A. Conventional dressing using povidone iodine group had 50% primary healing of ulcers, 40% had recurrent ulcers, 5% had Below knee amputation, 5% had Disarticulation of toes, in A. NPWT 55% had Primary healing of ulcer, 25% had Disarticulation of toes, 10% had Unhealed ulcer, 5% had Recurrent ulcer, 5% had Below knee amputation.

5.1. Conclusion

Our study's findings led us to the conclusion that silver dressings significantly affect the development and acceleration of granulation tissue. We suggest that silver-releasing dressings are more suitable for deep and full thickness wounds because they promote faster wound healing and better results. When negative pressure wound dressings are used instead of a typical dressing made of povidone iodine, the size of the wound is reduced more efficiently, and granulation tissue grows more quickly.

Disclosure

The authors have no financial interest to declare in relation to the content of this article.

Authorship

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Conflict of interest statement: The authors declared that there were no conflicts of interest.

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