Effectiveness of the use of Cutimed Sorbact versus standard dressing by nurses in diabetic foot ulcer

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Abstract: Diabetic foot is a serious complication of diabetes mellitus (DM) that may end up with leg amputation. The nurse has important roles in the care of diabetic foot. The aim of this study aim was to evaluate the effectiveness of the use of Cutimed Sorbact dressing on diabetic foot ulcer by nurses versus standard dressing. It was conducted at the diabetic center in Al-Noor Hospital at Makkah Al-Mukarmah, Saudi Arabia using a randomized clinical trial design on 60 patients with 2nd grade of diabetic foot ulcers, randomized into a study group (30) using Cutimed Sorbact® dressing and a control group (30) using standard dressing. The "University of Texas Wound Classification System Of Diabetic Foot Ulcers." was used to classify diabetic foot ulcer according to 3 grades of depth and another tool for wound characteristics. The fieldwork extended for 4 months, March to June 2011. The study followed all principles of Helsinki Declaration. The findings demonstrated better post-intervention glycemic (p<0.001) and cholesterol (p=0.01) control in the study group, with less edema (p=0.02), better pulse (p=0.001), cold extremities (p=0.003) and skin color (p=0.006). The wound in the study group showed lower wound grade (p <0.001) with more granulation tissue (p <0.001), decreased size (p <0.001) and exudates (p =0.006). Pain decreased in the study group but with no statistical significance (p =0.20). The study findings add to the evidence that Cutimed Sorbact is an effective dressing for diabetic foot wounds. Introducing the use of Cutimed Sorbact in the health care setting, with wider use in the early management of diabetic foot in primary care settings is recommended. Further studies are proposed to evaluate the cost-utility of the use of this dressing in primary care.
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1. Introduction

Diabetes mellitus (DM) is a medical problem with highly variable prevalence among different populations, and consistently increasing with aging.[1] The disease can affect individual's health through involvement of several body systems with complications as serious as losing vision, having leg amputation, renal failure, or coronary artery disease (CAD). According to the World Health Organization, the Kingdom of Saudi Arabia (KSA) has the second highest rate of DM in the Gulf Cooperation Council (GCC) after the United Arab Emirates. The number of diabetes patients in KSA is expected to grow by 283 percent by 2030 due to changes in lifestyle and diet leading to increasing levels of obesity.[2]

Diabetic patients have a lifetime risk as high as 25% for developing foot ulceration. Diabetic ulcers have 15 to 45 times higher risk of limb amputation than foot ulcers due to other causes. Every year more than a million diabetic patients require limb amputation worldwide. [3] It is estimated that by the year 2030, **Egypt** will have at least 8.6 million adults with diabetes. [4], Egypt also is in the world's top 10 in terms of the highest number of people with diabetes (3.9 million) in 2003 and this number is expected to increase to 7.8 million by 2025.[5]

Diabetic foot ulcer, a major cause of hospital admission in DM, is defined as a slow or non healing breakdown of epidermal and dermal tissue on the foot or below the knee. The majority of leg ulcers are associated with venous disease, peripheral arterial disease, mixed arterio-venous disease and DM. Ulcers in people with diabetes are mostly caused by peripheral vascular disease and loss of sensation because of peripheral neuropathy. [6]Diabetic foot ulcers are divided may be either neuropathic or neuro-ischemic. The neuropathic foot is warm and well-perfused with palpable pulses; sweating is diminished and the skin may be dry and prone to fissuring. The neuro-ischemic foot is cool and pulseless; skin is thin, shiny, without hair and there is atrophy of the subcutaneous tissue. Intermittent claudication and rest pain can be absent due to neuropathy. [7]

Regardless of etiology, foot ulcers cause considerable and prolonged distress for patients. Acute pain or continuous aching discomfort is usual and is exacerbated with infection and the production of a foul-smelling slough and copious exudates that promote general unhappiness and increasing social isolation, ultimately reducing quality of life. Other

issues for patients include restricted mobility, embarrassing dressings, and inability to continue working and socializing. The condition may last for longer than a year, and may be recurrent. [8]The ominous end-result may be gangrene and amputation. [9]

In individuals over the age of 45, diabetics were eight times more likely to have a lower-limb amputation than non-diabetics. Additionally, 1in 4 amputees may require an additional amputation on the opposite side of the body and/or re-amputation. [10]Diabetic foot amputation is associated with significant morbidity and mortality, along with immense social, psychological and financial consequences. The cost of treating foot ulcers is not simply the cost of a dressing multiplied by the frequency of dressing change, but also includes the nursing time, hospital stay, home health costs, and the risks and costs of complications. [11]

Cutimed Sorbact is a wound dressing without a chemically active agent; it promotes natural healing in unclean, colonised, and infected wounds by a unique mode of action. It works through a hydrophobic interaction between the microorganisms and the special coating of the dressing fibres. Two hydrophobic (water repellent) particles bind to each other with help from the surrounding water molecules that form a circle around the particles - like a jacket - and hold them together. The microorganisms bind to Cutimed Sorbact and are removed from the wound with every dressing change. As the interaction is impaired by fatty substances, Cutimed Sorbact should not be combined with creams or ointments. Moist wound condition is essential to ensure its efficiency.[12] The Sorbact adsorbs and inactivates a wide variety of pathogens, e.g. *Staphylococcus aureus* and *Pseudomonas aeruginosa*.[2] There are no side effects and no risks of cytotoxic or irrative reactions, or initiating or enhancing the development of resistant microorganisms.[13] The dressing is available as a wound contact layer (swab), absorbent pad, ribbon and round swab.[14]

Hospital care for patients with diabetic foot problems requires a multidisciplinary team that includes a diabetologist, a surgeon with relevant expertise, a diabetes nurse specialist, a podiatrist and a tissue viability nurse.[15] The role of diabetic care nurse involves assessment for dermatologic changes in the surrounding skin such as callus or musculoskeletal deformity, and documentation of ulcer characteristics such as location, shape, and size, and the presence of necrosis, exudates, and pain. It also involves evaluation for complications such as gangrene.[16] During dressing change, the nurse must minimize pain and trauma, empower the patient through education about wound bed preparation, coherent treatment plans, and the ability to practice prevention. Treatment plans that are developed without patient involvement will likely fail.[17,18] The nurse role also extends to educating patient about self-care at home including foot care,[19] avoidance of risk factors such as trauma, unsuitable footwear, and early detection of any abnormal changes,[20] and proper exercise and lifestyle. [21]

One of the most important roles of the nurse is to select a dressing that is appropriate for the needs of the wound, the patient, and the caregiver or clinical setting. No single wound dressing is suitable for all types of wounds and for all stages of wound healing. A patient's wounds must therefore be assessed at every dressing change to determine whether the dressing is still effective and whether another type of product should be selected. A thorough knowledge of the action, the indications and contraindications of all wound care products is therefore absolutely essential. Without this knowledge ineffective products may be selected which waste precious time and resources.[22]

Significance of the study

The diabetic foot ulcer is a significant and costly healthcare problem with great impact on the patient, family, and health care system. Inadequate or improper therapy could lead to life-threatening outcomes. Careful monitoring, patient education and education of the professionals caring for these ulcers are all imperative.

Aim of the study

This study aim is to evaluate the effectiveness of the use of Cutimed Sorbact dressing on diabetic foot ulcer by nurses versus standard dressing.

Hypothesis

The use of Cutimed Sorbact dressing by the nurse will improve diabetic foot ulcer healing and reduce the infection rates compared with the standard dressing.

2. Subjects and Methods

Research design and setting: The study used a randomized clinical trial design with two arms comparing two different dressing modalities for diabetic foot ulcer. It was conducted at the diabetic center in Al-Noor Hospital at Makkah Al-Mukarmah.

Participants: Sixty patients with 2nd grade of diabetic foot ulcers were enrolled to the study. The patients were randomized into two groups using sealed envelopes methods. Thirty patients in the study group had their dressing using Cutimed Sorbact®, and 30 patients in the control group had standard dressing. All enrolled subjects were medicated for glycemic control prior to entering the study.

Tools: The researchers used two different tools for assessment for patients' outcomes. The first tool is the "University of Texas Wound Classification System of Diabetic Foot Ulcers."[23] It was used to classify diabetic foot ulcer according to 3 grades (I to III) of the depth of the ulcer. Each of the three grades is further classified into 4 sub-grades (A to D) according to the presence of ischemia and/or infection. The second tool was for wound assessment, adopted from [24] and modified by the researcher. The tool includes a section for patient's demographic characteristics, past history, and risk factors. It has a second section for documenting wound dimensions (length x width), exudates amount (none, slight, moderate or heavy), level and consistency, ulcer tissue type (necrotic, epithelialization or closed), any signs of infection, and the presence of granulation tissue. This tool was content-validated by a panel of experts in nursing and medicine.

Pilot study: A pilot study was applied on five diabetic foot ulcer patients chosen randomly from the study setting to assess the tools for applicability, and clarity, and to test the feasibility of the study. Based on the pilot findings some item were omitted, others added or rephrased, and the final form was developed. These patients were not part of the study sample.

Maneuver: Official permission to conduct the study was obtained from the general manager of the diabetic center through a letter issued from the faculty of applied medical sciences after explaining the aim of the study and its maneuvers. Once approval was obtained, the recruitment and randomization process was started. Eligible patients were invited to participate after explaining to them the aim of the study and its procedures, and informing them about their rights. The fieldwork took a period of 4 months, March to June 2011. Data were collected 3 days a week from 8 a.m. to 1 p.m.

Firstly, the researchers started to classify the recruited patients using University of Texas Wound Classification System of Diabetic Foot Ulcers to determine the grade of ulcer for the inclusion criterion of 2nd grade ulcer. Then, eligible patients were randomized to study and control groups. Each patient was assessed using the two study tools for baseline data.

Study group: The researchers applied dressing by Cutimed Sorbact using a standard protocol: removal of soiled dressing; irrigation of the nail bed with sterile saline; and application of Cutimed Sorbact dressing on to the wound surface. Dressing was placed side by side to cover large wound areas or cut to size. The procedure took 20-30 minutes, and was done 3 days per week. Participants were seen for redressing and assessment until wound healing occurred. However, the endpoint for assessment of the effectiveness of the intervention was after a 3-month follow-up.

Control group: The wound was first cleansed with normal saline, followed by covering with povidone-soaked gauze. The procedure took from 20-30 minutes. The follow-up schedule was exactly similar to the study group.

The final assessment of the outcomes was done after three months using the same tools to evaluate the effectiveness of the dressing method. Blind assessment of the outcomes was done by nurses not involved in the study but trained in assessment of diabetic foot ulcer.

Ethical consideration: The study followed all principles of Helsinki Declaration. The research protocol approval was obtained before research implementation. The aim and procedures of the study as well as the benefits and any potential side effects were cleared to the participant. Each patient had to sign an informed consent before inclusion in the study sample. The researchers maintained privacy and confidentiality.

Statistical analysis:

Data entry and statistical analysis were done using SPSS 16.0 statistical software package. Qualitative categorical variables were compared using chi-square test. Whenever the expected values in one or more of the cells in a 2x2 tables was less than 5, Fisher exact test was used instead. In larger than 2x2 cross-tables, no test could be applied whenever the expected value in 10% or more of the cells was less than 5. Statistical significance was considered at p-value <0.05.

3. Results

The socio-demographic and health-related characteristics of the patients in the study and control group are quite similar as shown in Table 1. The majority of the two groups were males above 50 years age and having hypertension in addition to their diabetes. Only less than one-fourth of both groups were smokers. They are also similar in the independence in the activities of daily living (ADL), with the only exception that less patients in the study group were able to bath independently (p=0.02). They also had similar treatment of DM. The location of the wound was higher in the dorsal aspect of the foot in the study group, and more on the plantar surface in the control group.

Table 2 shows low percentages of glycemic and cholesterol control in both groups at the pre-intervention phase with no statistically significant differences between them. At the post-intervention assessment, higher percentages of patients in the

study group had glycemic (p<0.001) and cholesterol (p=0.01) control.

The comparison of inspection findings of the foot in the two groups (Table 3) demonstrated close similarity, with the only exception regarding wound moisture, which was higher in the control group (p=0.084). AT the post-intervention phase, statistically significant improvements were noticed among patients in the study group regarding their edema (p =0.02), pulse (p =0.001), cold extremities (p =0.003) and skin color (p =0.006).

Table 4 shows that the significantly more patients in the control group had fibrotic tissue at the pre-intervention phase (p <0.001). This was reversed at the post-intervention phase (p <0.001). The granulation tissue was similar in the two groups before the intervention, and significantly increased in the study group after the intervention (p <0.001). As for the wound grade, 85.7% of the patients in the study group moved to grade I compared to only 17.1% of those in the control group (p <0.001).

Concerning the wound assessment, Table 5 indicates that patients in the study group had larger and deeper wounds at the pre-intervention phase (p <0.001). At this phase, most patients in both groups had exudates, which were mostly scanty, but few of them had pain, with no differences of statistical significance. After the intervention, the wound size improved significantly in the study group compared with the control group (p <0.001), whereas the depth improved in both groups with no statistically significant difference. The exudates were also significantly less among them (p =0.006) and was scanty in all of them (p =0.03). As for pain, it was present in only 1 (2.9%) of the patients in the study group compared with 5 (14.3%) in the control group, but the difference did not reach statistical significance (p =0.20).

Table 1: Comparison of personal and medical history and activities of daily living (ADL) between the study and control groups before the intervention

	Group				X^2 Test	p-value
	Study (n=35)		Control (n=35)			
	No.	%	No.	%		
Age (years):						
<50	10	28.6	12	34.3		
50+	25	71.4	23	65.7	0.27	0.61
Gender:						
Male	25	71.4	23	65.7		
Female	10	28.6	12	34.3	0.27	0.61
Have:						
Hypertension	18	51.4	22	62.9	0.93	0.33
Asthma	0	0.0	1	2.9	Fisher	1.00
Renal failure	2	5.7	1	2.9	Fisher	1.00
Previous operations	17	48.6	14	40.0	0.52	0.47
Smoking	7	20.0	8	22.9	0.08	0.77
Able to:						
Exercise	15	42.9	19	54.3	0.92	0.34
Bath	24	68.6	32	91.4	5.71	0.02*
Dress	13	37.1	14	40.0	0.06	0.81
Eat	33	94.3	35	100.0	Fisher	0.49
Move around	20	57.1	27	77.1	3.17	0.07
Toilet	25	71.4	31	88.6	3.21	0.07
Totally independent in ADL	7	20.0	8	22.9	0.08	0.77
Treatment of DM:						
Oral	8	22.9	9	25.7		
Insulin	21	60.0	19	54.3	0.24	0.89
Both	6	17.1	7	20.0		
Wound location:						
Dorsal	23	65.7	15	42.9		
Planter	11	31.4	19	54.3	--	--
Both	1	2.9	1	2.9		

(*) Statistically significant at p<0.05 (--) Test result not valid

Table 2: Comparison of glycemic and cholesterol control between the study and control groups before and after the intervention

	Group				X^2 Test	p-value
	Study (n=35)		Control (n=35)			
	No.	%	No.	%		
Pre:						
Glycemic control (HbA1c<=7)	10	28.6	9	25.7	0.07	0.79
Controlled cholesterol	8	22.9	15	42.9	3.17	0.07
Post:						
Glycemic control (HbA1c<=7)	29	82.9	11	31.4	18.90	<0.001*
Controlled cholesterol	26	74.3	16	45.7	5.95	0.01*

(*) Statistically significant at p<0.05

Table 3: Comparison of foot inspection findings between the study and control groups before and after the intervention

Inspection	Group				X^2 Test	p-value
	Study (n=35)		Control (n=35)			
	No.	%	No.	%		
Pre:						
Edema	17	48.6	17	48.6	0.00	1.00
Unhealthy nails	24	68.6	24	68.6	0.00	1.00
Wound moisture	18	51.4	26	74.3	3.92	0.048*
Impaired pulse	19	54.3	25	71.4	2.20	0.14
Cold extremities	19	54.3	18	51.4	0.06	0.81
Inability to move	15	42.9	13	37.1	0.24	0.63
Abnormal skin color	26	74.3	30	85.7	1.43	0.23
Post:						
Edema	7	20.0	16	45.7	5.25	0.02*
Unhealthy nails	21	60.0	25	71.4	1.01	0.31
Wound moisture	20	57.1	25	71.4	1.56	0.21
Impaired pulse	7	20.0	21	60.0	11.67	0.001*
Cold extremities	8	22.9	20	57.1	8.57	0.003*
Inability to move	7	20.0	12	34.3	1.81	0.18
Abnormal skin color	17	48.6	28	80.0	7.53	0.006*

(*) Statistically significant at p<0.05

Table 4: Comparison of wound granulation and grade between the study and control groups before and after the intervention

	Group				X^2 Test	p-value
	Study (n=35)		Control (n=35)			
	No.	%	No.	%		
Fibrotic tissue present	1	2.9	13	37.1	12.86	<0.001*
Granulation tissue present	11	31.4	12	34.3	0.06	0.80
Texas wound grade:						
II-A	14	40.0	4	11.7		
II-B	2	5.7	7	20.0	--	--
II-C	0	0.0	5	14.3		
II-D	19	54.3	19	54.3		
Texas wound grade:						
I	0	0.0	0	0.0		
II	35	100.0	35	100.0	0.00	1.00
Fibrotic tissue present	33	94.3	12	34.3	27.44	<0.001*
Granulation tissue present	33	94.3	17	48.6	17.92	<0.001*
Texas wound grade:						
I-A	21	60.0	4	11.4		
I-B	2	5.7	1	2.9		
I-C	6	17.1	1	2.9		
I-D	1	2.9	0	0.0		
II-A	3	8.6	8	22.9	--	--
II-B	1	2.9	9	25.7		
II-C	0	0.0	4	11.4		
II-D	1	2.9	8	22.9		
Texas wound grade:						
I	30	85.7	6	17.1		
II	5	14.3	29	82.9	32.94	<0.001*

(*) Statistically significant at p<0.05 (--) Test result not valid

Table 5: Comparison of wound changes and pain between the study and control groups before and after the intervention

	Group				X^2 Test	p-value
	Study (n=35)		Control (n=35)			
	No.	%	No.	%		
Pre-intervention						
Wound size (cm2):						
<4	0	0	8	22.9		
4+	35	100	27	77.1	Fisher	0.005*
Wound depth:						
<3	0	0	19	54.3		
3+	35	100	16	45.7	17.54	<0.001*
Have exudates	30	85.7	28	80.0	0.40	0.53
Exudates type:						
Serous	6	20.0	9	32.1		
Sero-sanguinous	6	20.0	8	28.6		
Purulent	18	60.0	11	39.3	2.51	0.29
Exudates amount:						
Scant	22	73.3	20	71.4		
Heavy	8	26.7	8	28.6	0.03	0.87
Have pain	5	14.3	6	17.1	0.11	0.74
Post-intervention						
Wound size (cm2):						
<4	25	71.4	9	25.7		
4+	10	28.6	26	74.3	14.64	<0.001*
Wound depth:						
<3	29	82.9	25	71.4		
3+	6	17.1	10	28.6	1.30	0.25
Have exudates	24	68.6	33	94.3	7.65	0.006*
Exudates type:						
Serous	15	62.5	11	33.3		
Sero-sanguinous	7	29.2	14	42.4		
Purulent	2	8.3	8	24.2	--	--
Exudates amount:						
Scant	24	100.0	27	81.8		
Heavy	0	0.0	6	18.2	Fisher	0.03*
Have pain	1	2.9	5	14.3	Fisher	0.20

(*) Statistically significant at p<0.05 (--) Test result not valid

4. Discussion

This study was set to test the hypothesis that the use of Cutimed Sorbact dressing by the nurse will improve diabetic foot ulcer healing and reduce the infection rates compared with the standard dressing. The study findings showed significant improvements in the wound size and grade, with decreased exudates among patients in the study group, which lead to acceptance of the research hypothesis.

The two groups of the present study were similar in almost all socio-demographic characteristics, as well as in health-related variables such as the treatment of DM, wound location, as well as the control of glycemia and hypercholesterolemia. The only difference of statistical significance was that of independence in bathing, which was better in the control group. This means that if this difference would be a source of bias, this would work against the study hypothesis. The similarity of the two groups indicates the success of the randomization process, which would lead to more reliable results.

Moreover, the samples of patients in both groups of the present study have the characteristics typical of diabetic patients. Thus, they were mostly in the age 50 years or older as reported by (Seibel, 2010) [25] with a preponderance of men than women as in[26] Also, as in most diabetes patients, more than half of the present study participants were having hypertension as a concomitant disease, which is in congruence with (Akhter **et al., 2011 and NDIC 2011)** [27,28]. This similarity with typical diabetic patients would increase the external validity of our study, with more ability to generalize its findings to the diabetic population.

Concerning glycemic control, only approximately one-fourth of the patients in the current study were controlled. These rates of successful management of DM are in agreement with previous studies in developing countries[29-,31] but are lower than those reported in developed ones.[32-34] The low rate of glycemic control would certainly have a negative impact on the development and progress of

diabetic foot[35] Thus, the post-intervention results demonstrated significant improvement in diabetic control only in the study group patients, which indicates that the intervention was successful not only in improving the diabetic foot status but also the glycemic control.

The intervention used in the current study led to significant improvements in the condition of diabetic foot ulcers in the study group in comparison with the control. This has been demonstrated by both inspecting the foot status and the ulcer itself. Thus, the foot of the patients in the study group had significantly less edema, better pulse, more warmth, and less abnormal skin color. These signs indicate improvements in the circulation of the foot with positive consequences on the ulcer as mentioned before.[36-37]

The improved circulation was associated with improvements in the wound among patients in the study group after implementation of the intervention, but no such improvement was noticed in the control group. Thus, significant decreases in the wound dimensions were found in the study group, with some improvement in wound depth. These findings are in agreement with (Pirie et al. 2009)[36] who reported similar diabetic wound improvements using Cutimed Sorbact in non-healing wounds. The wounds of the patients in our study also had better signs of healing in terms of epithelialization and granulation tissue, findings that are in agreement with those of (Haycocks et al.2011).[38] who found more evidence of epithelialization at the wound margins after application of Cutimed Sorbact. The granulation tissue was observed in almost all patients in the study group of the current study, which is consistent with the study of[39] who reported that the Cutimed Sorbact dressing effectively managed devitalised tissue, resulting in 100% granulation tissue.

Additionally, the wounds of the patients in the study group had less exudates at the post-intervention assessment compared with the control group, indicating lower infection rates. This is an important property of the Cutimed Sorbact in reducing the amount of exudate and the signs of infection. This result is in congruence with the result of previous similar studies, which attributed the improvements to the efficacy of the product in the treatment of colonized and infected wounds, and in lowering the bacterial load through a binding action to common wound pathogens, including staphylococcus aureus, pseudomonas aeruginosa and Candida albicans**.** [40-42]

According to the present study findings, the pain sensation improved along with the improvement in the wound of the patients in the study group. However, the improvement was not of statistical significance. The lack of significance might be due to the small sample size for this variable which had a low prevalence before the intervention in both groups, not reaching one-fifth of the samples. This is a common finding in diabetic foot where the neurological changes lead to lowered sensation, which is in itself a risk factor for the development of diabetic foot.

The present study applied a standardized method for wound grading (Texas Wound Classification System of Diabetic Foot Ulcers) in addition to the use of blind assessment in order to avoid any bias in outcome ascertainment. According to this classification, the majority of the patients in the study group converted from grade II to grade I, compared with only a small minority of the control group. The findings confirm the effectiveness of the study intervention in the healing of diabetic wound. A similar success in wound grading was demonstrated by.[38]

Conclusion and Recommendations

The study findings add to the evidence that Cutimed Sorbact is an effective dressing for diabetic foot wounds with appealing properties leading to decrease of wound size, reduction of exudates and pain, and improvement of the clinical signs of infection thorough its universal antimicrobial action. The end result is increased amount of granulation tissue with improved wound healing.

This study recommends introducing the use of Cutimed Sorbact in the health care setting, with wider use in the early management of diabetic foot in primary care settings. This would be a part specialized diabetes mellitus clinics in all health centers with a diabetic foot care program to reduce the amputation rate through early detection and proper management. Further studies are proposed to evaluate the cost-utility of the use of this dressing in primary care.

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