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A Randomized Control Trial to Assess the Efficacy of Calcium Alginate Dressing Versus Conventional Gauze Dressing on Bacterial Load in Infected Diabetic Foot Ulcer

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Abstract

Diabetic foot ulcers are common and estimated to affect 15% of all diabetic individual during their lifetime. Infection is one of the major cause for non-healing of the ulcer in diabetes. Objectives of present study were to measure the effect of calcium alginate dressing on bacterial load in infected diabetic foot ulcer in comparison to conventional gauze dressing.

Present one year randomized controlled trial was conducted in Department of Surgery, KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belgaum on 60 patients with infected diabetic foot ulcer during period of January 2008 to December 2008. Patients were divided into two different groups by number randomization (Group 1 Calcium alginate and Group 2 conventional gauze). Bacterial load was determined per gram of tissue before first and after third dressing in both groups.

In the present study male preponderance was seen. The duration of DM was 6 to 10 years in majority of the patients. The mean bacterial load (X 10^5 CFU/gm tissue) before the first dressing in calcium alginate group was 513.3±122.4 while in conventional gauze group it was 516.7±117.7 and after the third dressing was 526.7±138.8 and 536.7±121.7 respectively. There was increase in bacterial load after the three dressings over the diabetic foot ulcer in both the groups. However this increase was not statistically significant (p=0.787).

Present study has shown that dressing with calcium alginate is ineffective in reducing bacterial load of infected diabetic foot ulcers.

Key Words: Bacterial load; Calcium alginate dressing; Conventional gauze dressing; Diabetic foot ulcer; Diabetes mellitus

Introduction

Diabetes mellitus is a metabolic disease characterized by hyperglycemia resulting from defects in insulin secretion, insulin action or both. The chronic hyperglycemia of diabetes is associated with long term damage, dysfunction and failure of various organs, especially the eyes, kidneys, nerves, heart and blood vessels.

The vast majority of cases of the diabetes fall into two broad categories: those having little or no endogenous insulin secretory capacity (IDDM or type 1 DM) and those who retain endogenous insulin secretory capacity but have a combination of resistance to insulin action and an inadequate compensatory insulin secretory response (NIDDM, or Type 2 DM).[1,2]

The worldwide prevalence of diabetes mellitus has risen dramatically over past two decades. Although the prevalence of both type 1 and type 2 diabetes mellitus is increasing, rise in type 2 diabetes mellitus is more rapid [2]. In 2000, the prevalence of diabetes mellitus was estimated to be 8.6% in people > 20 years of age. There is a considerable geographic variation in the incidence of both type 1 and type 2 diabetes mellitus. Scandinivia has the highest incidence of Type 1 diabetes mellitus (35/1,00,000 per year). The prevalence of type 2 diabetes mellitus is highest in certain Pacific islands, intermediate in India and US and relatively low in Russia and China. According to WHO statistics (2000) 31705000 people in India are affected with diabetes and the number is expected to grow upto 79445000 by 2030 [3].

Long term complications of diabetes include retinopathy with potential loss of vision, nephropathy leading to renal failure, peripheral neuropathy with risk of foot ulcers, amputations and Charcot joints, and autonomic neuropathy causing gastro intestinal, genitourinary and cardiovascular symptoms and sexual dysfunction.

Foot disorders such as ulceration, infection, and gangrene are the leading causes of hospitalization in patients with diabetes mellitus [4]. Neuropathy is often a predisposing factor to ulceration and amputation. Approximately 15 to 20 percent of the estimated 16 million persons in the United States with diabetes mellitus will be hospitalized with a foot complication at some time during the course of their disease. In India a study

has reported 5 to 9% incidence of active / healed diabetic ulcer and 1% incidence of amputation [5] .

The diabetic foot and its sequelae account for billions of rupees in direct medical expenditures, as well as lengthy hospital stays and periods of disability[6]. The most characteristic lesion of the diabetic foot is a mal perforans ulceration, which consequently is one of the major risk factors for amputation. Approximately 85% of all diabetes-related lower-extremity amputations are preceded by foot ulcers [7,8] .

A diabetic foot infection is most simply defined as any inframalleolar infection in a person with diabetes mellitus. These include paronychia, cellulitis, myositis, abscesses, necrotizing fascitis, septic arthritis, tendonitis, and osteomyelitis. The most common and classic lesion, however, is the infected diabetic "mal perforans" foot ulcer.[9] Wound infection is the deposition and multiplication of bacteria in tissue with colony count of more than 10^5 bacteria per gram of tissue with an associated host reaction.[10,11]

One of the major causes of non-healing of ulcer in diabetes is infection. It is caused by a variety of micro-organism. Most common are *Staphylococcus aureus* and *Pseudomonas aeroginosa* which invade the wound and multiply, producing harmful toxic substances, causing destruction of tissue and disturbance in wound healing.

Patients suffering from diabetic foot ulcers need special care. Infection of the diabetic ulcer can have serious consequences. The challenges in treating diabetic foot ulcers includes prolonged hospital stay, high morbidities, medical expenses and sometime leads to lower limb amputation. Dressing is one of the important part of the treatment of the diabetic ulcer. The types of wound dressing used in diabetic foot ulcer are traditional dressing (Gauze dressing) and Modern wound dressing (Occlusive / moist wound dressing like, alginate, amorphous hydrogels, hydrogel, hydrocolloid dressings, composite and transparent film dressings).

Treatment plan for diabetic foot includes surgical debridement of wound, improvement of circulation through surgery or therapy, special dressing and antibiotics. Numerous topical medication and gels are promoted for ulcer care and healing. Relatively few have proved to be more efficacious than saline wet to dry dressings. Topical antiseptic, such as povidine-iodine are usually considered to be toxic to healing wounds. Generally a warm moist environment that is protected from external contamination is most conducive to wound healing. This can be provided by commercially available special occlusive dressings like calcium alginate [9,10].

Alginic acid is a polymer of d-mannuronic acid. It was discovered in 1982, (D-mannuronate and L-galuranicocid) Scotland. Its formula bears a striking resemblance to that of cellulose. The main difference is that, the alcoholic group is replaced by the carboxyl group ($C_6H_{10}O_7$).

Alginates have been used in various forms for fifty years and yet they remain a poorly understood and probably underused dressing. It consists of naturally occurring polysaccharides, derived from the cell walls of brown seaweed. It is highly absorbent, biodegradable dressing, derived from cell wall of marine brown algae. They are manufactured as non woven, fibrous sheet or rope like packing. It can hold upto 20 times its weight in fluid. Calcium alginate accelerates wound healing by absorbing the exudates and keeping the wound surface in a moist environment. Bacteria on the wound surface moves into the dressing as wound exudates is absorbed. With high level of fluid absorption and bacteria retaining property calcium alginate provide a passive mechanism for reducing the bacterial load of the wounds [12,13,14] .

Randomized control trial studies have documented the faster healing rate of ulcers, decrease in ulcer size, amount of exudates and cost effectiveness by using calcium alginate dressing.[15,16]

Study on bacterial retaining ability of calcium alginate has documented 7 to 12% bacteria retaining ability in cases of *Staphylococcus aureus* and 30 to 40% retaining ability in case of *Pseudomonas aeruginosa.*[12]

Another study done by creating artificial infected wound has documented 37% bacteria retaining ability of calcium alginate in case of *Staphylococcus aureus* and 29% in case of *Pseudomonas aeroginosa* [13] .

Experimental studies[12,13,14] over bacteria retaining ability of calcium alginate dressing are available. But there are no adequate studies to evaluate the effect of calcium alginate on bacterial load, in infected, diabetic foot ulcer. In view of the above the present study is undertaken to measure its effect in comparison to conventional gauze dressing.

Objectives

The objective of the present study was to measure the effect of calcium alginate dressing on bacterial load in infected diabetic foot ulcer in comparison to conventional gauze dressing.

Methodology

The present randomized clinical trial was carried out our College and Hospital and Medical Research Centre, Belgaum for a period of one year (from January 2008 to December 2008) on 60 patients with diabetic foot ulcer. The sample size was calculated based on patient data at hospital for the last three consecutive years.

Selection Criteria

Inclusion criteria

Patients aged between 35 to 65 years with DM (HbA1c < 8.0), infected diabetic foot ulcer with bacterial count of more than 1 X 10^5 CFU per gm wound tissue with ulcer size less than 10 X 10 cms were included in the present study.

Exclusion criteria

Patients with immuncompromised state that is suffering from HIV or TB, on chronic steroid therapy, severely malnourished, evidence of underlying osteomyelitis, vasculopathy, cellulites and diabetic ketoacidosis were excluded from the present study.

Procedure

The study was approved by the Ethical and Research Committee of Jawaharlal Nehru Medical College, Belgaum. After finding the suitability as per inclusion and exclusion criteria patients were selected for the study and briefed about the nature of the study, the interventions used and written informed consent was obtained (Annexure–I). Further, descriptive data of the participants like name, age, sex, detailed history, were obtained by interviewing the participants and clinical examination and necessary investigations were recorded on predesigned and pretested proforma.

In all suitable enrollees, bacterial load was determined and infected diabetic foot was confirmed. After that they were divided into two different groups (Group 1 and Group 2) by number randomization. Both the groups were administered with similar sets of antibiotics till result of culture and antibiotic sensitivity. Later based on culture sensitivity, specific antibiotics were started. Calcium alginate dressing was done to every odd number enrollee (Group 1) and conventional gauze dressing to every even number enrollee (Group 2). Dressing was changed after every 24 hours for three days.

Tissue sample from the centre of the ulcer was taken before the first and after the third dressing in both the groups and sample was sent to Department of Microbiology laboratory in the transport medium immediately. The tissue was weighed and one gm of tissue was homogenized, serially diluted in 1:5 dilution in glucose broth, incubated and bacteria was sub cultured on to blood agar, chocolate agar and MacConkey agar under aerobic conditions using standard loop (4 mm internal diameter carrying 0.001 ml) and identified as per the standard protocol and the total viable bacterial count was determined.

Statistical Methods

At the end of the study mean bacterial load in the wound of the both groups was determined before the first and after the third dressing. Data was compared by using unpaired 't' test and a 'p' value of < 0.05 was considered significant.

Results

In the present study males preponderance was seen. (Group 1, males 83.3% and females 16.7%; Group 2, males 73.3% and females 26.7%). In Group 1 the male to female ratio was 5:1 and in group 2 it was 2.75:1 (Table 1). Majority (46.7% in group 1 and 43.3% in group 2) of the patients were aged between 56 to 65 years (Table 2). Duration of diabetes among the patients was ranged upto 20 years and majority of them had duration between six to ten years (40% in group 1 and 36.7% in group 2, Table 3).

In group 1 trauma was the most common (56.7%) cause for the onset of diabetic foot ulcer. In group 2, diabetic foot ulcers were commonly (50%) spontaneous in onset. Among 60 patients, diabetic foot ulcers were commonly (68.3%) located over the dorsal aspect of the foot. It was observed that peripheral neuropathy was the most common complication associated with diabetic foot ulcer in both the groups (33.3% in group 1 and 26.7% in group 2).

The mean bacterial load (X 10^5 CFU per gram of tissue) over the diabetic ulcer in group 1 before the first dressing was 513.3 ± 122.4. The bacterial load after the third dressing was 526.7 ± 138.8. There was increase in bacterial load over the diabetic ulcer after the third dressing. However this increase in bacterial load was statistically not significant (p=0.221). The mean bacterial load (X 10^5 CFU per gram of tissue) over the diabetic ulcer in group 2 before the first dressing was 516.7 ± 117.7. The bacterial load after the third dressing was 536.7 ± 121.7. There was increase in bacterial load over the ulcer after the third dressing. However this increase was statistically not significant (p=0.132) (Table 4).

It was observed that after the third dressing in group 1 there was no change in bacterial load in 63.3% of the patients. The bacterial load was increased 20% of the patients and decrease in 16.7%. In group 2 there was no change in bacterial load in 73.3% of the patients. The bacterial load was increased in 16.7% of the patients and decreased in 10% (Table 5).

After the third dressing in group 1 patients the net increase in mean bacterial load was 13.33 ± 93.71 X 10^5 CFU per gram of tissue. In group 2 the net increase in mean bacterial load was 20.00 ± 96.13 X 10^5 CFU per gram of tissue. However the mean increase of bacterial load in both the groups was statistically not significant (p=0.787).

Table 1: Distribution of the patients according to gender

Gender	Group 1		Group 2	
	Number	Percentage	Number	Percentage
Male	25	83.3%	22	73.3%
Female	05	16.7%	08	26.7%
Total	30	100%	30	100%

Table 2: Distribution of the patients according to Age

Age (Years)	Group 1		Group 2	
	Number	Percentage	Number	Percentage
35 – 45	6	20.0%	08	26.7%
46 – 55	10	33.3%	09	30.0%
56 – 65	14	46.7%	13	43.3%
Total	30	100%	30	100%

Table 3: Distribution of the patients according duration of diabetes mellitus

Duration (Years)	Group 1		Group 2	
	Number	Percentage	Number	Percentage
Upto 5	08	26.6%	07	23.3%
6 – 10	12	40.0%	11	36.7%
11 – 15	04	13.4%	08	26.7%
16 – 20	06	20.0%	04	13.3%
Total	30	100%	30	100%

Table 4: Mean bacterial load (X 105 CFU per gram of tissue) before the first and after the third dressing over the diabetic foot ulcer

Dressing	Group 1 (n=30)		Group 2 (n=30)		p value
	Mean	S.D.	Mean	S.D.	
Before first dressing	513.3	122.4	516.7	117.7	0.915
After third dressing	526.7	138.8	536.7	121.7	0.768
p value	0.221		0.132		

Table 5: Distribution of the patients according to the change in bacterial load after the third dressing

Bacterial load	Group 1 (n=30)		Group 2 (n=30)	
	Number	Percentage	Number	Percentage
Increase	06	20.0%	05	16.7%
Decrease	05	16.7%	03	10.0%
Unchanged	19	63.3%	22	73.3%

Discussion

The ulcer dressing is an important aspect of diabetic foot management. The basic function of any dressing is to protect the ulcer from mechanical trauma, to create a moist environment and prevent exposure to infections. The occlusive wound dressing reduces the bacterial load by absorption of the exudates and by preventing the bacterial contamination of the ulcer. This reduces the requirement for phagocytic and autolytic debridement and reduces the source for microbial growth.

In this study on comparing both the groups, increase in mean bacterial load (X 10^5 CFU per gram of tissue) after the third dressing with conventional gauze was 20.00 ± 96.13 as compared to increase in mean bacterial load (X 10^5 CFU per gram of tissue) 13.33 ± 93.71 with calcium alginate group. However this difference increase in mean bacterial load was statistically not significant (p=0.787).

An experimental study[12] has demonstrated the bacterial absorption and retaining ability of the calcium alginate over artificially created infected wound.

Another experimental study[13] has documented the bacterial retaining ability of calcium alginate dressing and supported its antibacterial property.

Another experimental study[7] has also supported the bacterial retaining property of calcium alginate dressings, and its passive mechanism for reducing the bacterial load over the wound and advocated for the in vivo study to explain the antibacterial effect of calcium alginate over wound in clinical surgical settings.

The difference in the results of previous experimental studies[12,13,14] and present study, may be due to moisture retaining property of calcium alginate itself, which promote the growth of bacteria in moist environment. To our knowledge this was the first randomized control trial which compared the effect of calcium alginate dressing on bacterial load in infected diabetic ulcer with conventional gauze dressing.

It must be emphasized that other previous studies[12,13,14] were over artificially created infected wound. However this present study was conducted over infected ulcer in patients with diabetes who have tissue hypoxia along with diminished phagocytic response of the neutrophils and macrophages, along with diminished neovascualrization, all of which greatly contribute to poor control of infection.

Also a recent randomized controlled trial[17] has concluded that the occlusive moist environment dressing (Calcium alginate) principle in the clinical surgical setting does not lead to quicker wound healing and it is not cost effective.

Conclusion

The present study has shown that dressing with calcium alginate is ineffective in reducing the bacterial load of the infected diabetic foot ulcers.

Further studies on larger population with longer duration of intervention may emphasize better interpretation of antibacterial property of calcium alginate dressing as compared to conventional gauze dressing.

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