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COMPARISON OF SAFETY AND EFFICACY OF CADEXOMER IODINE DRESSINGS AND CONTROLLED RELEASE IONIC SILVER DRESSINGS ON WOUND HEALING IN DIABETIC FOOT ULCER.

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ABSTRACT **Background:** Diabetic ulcers have an impact on patients' quality of life, morbidity, and mortality. The standard medical care includes cleaning and treating wounds with antiseptic. In chronic DFU, a silver stream solution containing silver ions has produced encouraging outcomes. **Aim:** The aim of the study was to compare the ability of controlled release ionic silver dressings and cadexomer iodine dressings to treat diabetic foot ulcers. **Patients and methods:** One ulcer dressing with controlled release ionic silver dressing or cadexomer iodine dressing was given to the two groups, 72 patients with cadexomer iodine dressings and 70 patients with controlled release ionic silver dressings (A and B). The dressings were changed every 48 hours. Ulcer size and healing were evaluated at 2 weeks and 8 weeks intervals respectively. **Results:** The difference in the mean of Group A and Group B was significant in considering the duration of diabetes, ulcer size, and HbA1C levels. ($p < 0.05$). When we consider the median levels of the variables above and below the median value, there was no significant difference on the basis of age, and gender ($p > 0.05$) whereas there is a statistically significant difference with respect to ulcer size and duration of treatment and HbA1C levels. ($p < 0.05$) **Conclusion:** In comparison to cadexomer iodine, the response rate with controlled release ionic silver dressings is much higher and the mean ulcer size is reduced by a significant amount.

KEYWORDS :

INTRODUCTION:

Diabetes is caused due to the inability of the body to produce or use insulin. In people with diabetes, the rate of wound healing is very slow and progresses more quickly. Therefore, a small injury on the foot can quickly develop an ulcer.

Foot ulcers become serious when left untreated. About 14-24 percent of people, with diabetes, tend to develop a foot ulcer and end up having a lower limb amputation. Hence it is important to catch the wounds early and monitor them closely.

Diabetic Foot Ulcer:

Foot ulcers are a common complication of diabetes, that cannot be managed by exercise, diet, and insulin treatment. A foot ulcer is usually defined as a break of the skin of the foot that involves the dermis and epidermis. Diabetic foot ulcer occurs in almost 15% of patients with diabetes and 6% of patients get hospitalized. Ulcers form due to a combination of factors such as lack of feeling in the foot, poor circulation, foot deformities, irritation such as friction or pressure, trauma, and duration of diabetes.

Grades Of Diabetic Foot Ulcer- Wagner Grading System -

Grade1: superficial diabetic ulcer

Grade2: ulcer extension

a) Involves ligament, tendon, joint capsule or fascia.
b) No abscess or osteomyelitis

Grade3: deep ulcers with abscess or osteomyelitis.

Grade 4: gangrene to the portion the forefoot

Grade 5: extension gangrene of the foot.

Epidemiology:

The global prevalence of diabetic foot ulcers was 6.3% which was higher in males than in females and higher in type 2 diabetes than in type1. Out of 62 million diabetics in India, 25% develop DFUs of which 50% become infected, requiring hospitalization while 20% need an amputation. Patients with history of DFU have a 40% higher 10-year death rate than those without.

Pathophysiology:

The pathophysiology of DFU is multifaceted. Neuropathy, abnormal foot mechanisms peripheral artery disease, poor wound healing contribute to diabetic foot ulcers. Approximately 50% of people with long-term type 1 and type 2 diabetes experience neuropathy. In addition to neuropathy, many diabetics have PAD, a macrovascular complication of diabetes. This leads to decreased tissue perfusion which then impairs wound healing.

Wound Care:

wound healing is a complex process, which involves highly regulated responses of specific cell types. Treating a diabetic foot infection requires proper wound care and antibiotic therapy. Adequate frequent debridement, offloading, moist wound care, treatment of infection, and revascularization of ischemic limb are the fundamentals of good clinical care.

By selecting the right topical regimen, wound healing can be accelerated. Assessment of wound, its classification and need for debridement have to be taken into consideration before proceeding with the appropriate selection of topical regime.

Wound Dressings:

These are mainly considered secondary to surgical and systemic care. The following are the ideal qualities of a wound dressing:

- sterile, easy to use, cost effective.
- Maintain a moist wound healing environment
- Absorb excess exudate
- Non adherent/ non-toxic/ non- allergic
- Not contaminate the wound with foreign particles.
- Allow gaseous exchange, control wound odor

- Provide thermal insulation and mechanical protection.

Clinical Presentations:
History:
- onset and progression of ulcer.
- Constitutional symptoms: fever

Physical Examination:
- Ulcer
- Neuropathic foot: warm, well perfused with palpable pulses, sweating is diminished, and the skin may be dry and prone to fissuring.
- Neuro -ischemic foot:
- Cool, pulseless foot, the skin is shiny, thin and without hair. There is also atrophy of the subcutaneous tissue and intermittent claudication and rest pain may be absent because of neuropathy.
- Infected.

Diagnosis:
Physical Examination:
Skin: general dermatologic assessment for skin quality, alopecia, atrophy, blanche, previous areas of scarring, condition of digital nails. Extremity: fissures, bullae, pre-ulcerative callus, interdigital maceration.

wound assessment including wound measurements length, width, depth, wound bed description, including exposed structures or probe to bone, presence of callus, exudate quality, odor, local or spreading signs of infection.

Lower extremity edema, pitting and non- pitting

Diagnostic Tests:
Serum laboratory values: WBC count, hemoglobin, hematocrit, prealbumin, transferrin, ESR, CRP.

Blood glucose, glycosylated (Hgb A1c)

MATERIALS AND METHODS:
It was a prospective randomized open label study. The study was carried out to compare the safety and efficacy of cadexomer iodine dressings and controlled release ionic silver dressings on wound healing in DFU. Patients of age 18 to 60 years were included in the study and patients with diabetic ulcers grade 1, 4, 5 of Wagner's classification, established gangrene, blackening of skin, absence of pedal pulses and allergies to particular drugs were excluded from the study. The ulcer size was measured by putting transparent plastic cover over the ulcer and markings were made along the margins and cover were placed on the graph paper and accessed periodically.

RESULTS AND DISCUSSION:
A total of 142 patients with diabetic foot ulcers were divided into two groups on the basis of the type of dressings. Group A comprised 72 patients with cadexomer iodine dressings and Group B comprising of 70 patients with controlled release ionic silver dressings. The mean, median, and standard deviation tests are used for calculations and the unpaired t-test is used for the calculations. The data is represented in the form of tables and graphs for easy understanding. The p-value is calculated from the t-test at a 95% significance level. The results with a p-value of < 0.05 are considered to have a statistically significant difference and at>0.05, there is no statistically significant difference.

Table1 Representing gender-wise distribution of patients.

Gender (%)	Cadexomer iodine group, n (%)	Silver group, n (%)	P
Male	44 (61.1)	40 (57.1)	>0.05
Female	28 (38.9)	30 (42.9)	>0.05

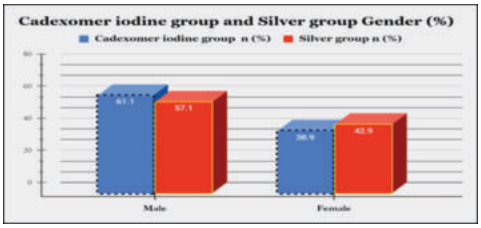


Fig 1 shows the gender-wise distribution of patients.

Table 2 represents the mean values of the characteristic features

Mean duration of diabetes (years) (median)	Cadexomer iodine group, n (%)	Ionic Silver group, n (%)	P
	14.9±3.7 (12.6)	15.2±3.1 (13.1)	<0.05
Mean HbA1c percentage (median)	9.7±2.4 (9.1)	9.5±2.6 (8.9)	< 0.05
Mean ulcer size (cm) (median)	11.1±2.3 (8.5)	10.9±2.2 (8.1)	<0.05

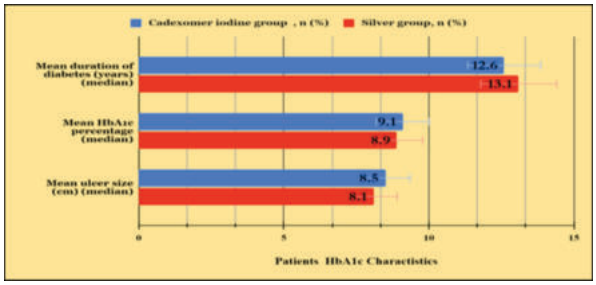
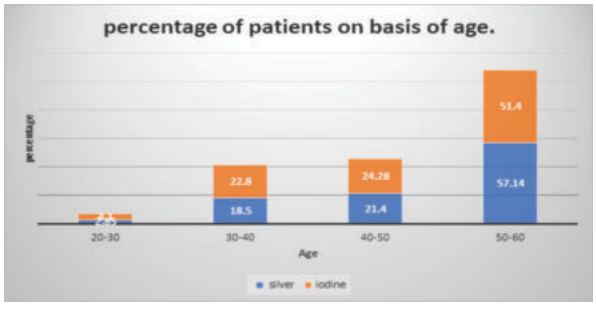


Fig 2 represents the mean value of the characteristic features.

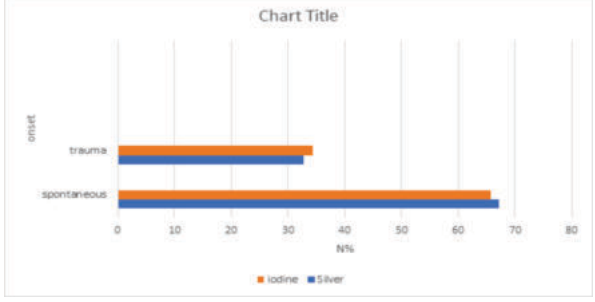
AGE	SILVER		IODINE		P VALUE
	N	%	N	%	
20-30	2	2.85	3	4.1	
30-40	13	18.5	16	22.8	
41-50	15	21.4	17	24.28	
51-60	40	57.14	36	51.4	
Mean+_S.d	48.825+_ 8.73		46.94+_9. 22		0.96

The result is not significant at P >0.05. Hence the data the difference is considered non-significant based on distribution of age.



Onset	Group silver		Group Iodine		P Value
	N	%	N	%	
Spontaneous	47	67.142	46	65.7	
Trauma	23	32.8	26	35.7	0.95

The calculated p-value is >0.05 Hence there is no statistically significant difference based on the onset of the ulcer.



Correlating variables			Significance P
Correlation with gender	Males	Females	P
Cadexomer iodine treatment group	31.4±7.7 days	29.3±6.9 days	>0.05 (IS)
Silver treatment group	33.9±8.1	32.5±6.1 days	>0.05 (IS)
Correlation with age	Below median age	Above median age	P
Cadexomer iodine treatment group	25.4±6.2 days	35.4±8.6 days	>0.05 (IS)

Silver treatment group	26.2±5.4	38.2±59.4	>0.05 (IS)
Correlation with the duration of the ulcer before treatment	Below median duration	Above median duration	P
Cadexomer iodine treatment group	20.3±4.8 days	38.3±9.3 days	<0.05 (S)
Silver treatment group	23.7±6.5	41.2±9.9	<0.05 (S)
Correlation with ulcer size with median size	Below median size	Above median size	P
Cadexomer iodine treatment group	27.2±5.1 days	35.8±7.3 days	<0.05 (S)
Silver treatment group	28.9±5	37.7±2.2 days	<0.05 (S)
Correlation with HbA1c	Below median (%)	Above median (%)	P
Cadexomer iodine treatment group	26.3±4.2 days	34.2±7.8 days	<0.05 (S)
Silver treatment group	25.9±6.1	37.9±9.1 days	<0.05 (S)

Summary:

In both the groups, the participation is higher in age 51 to 60 and lowest in the age 20-30 years age group as shown in table 1. The number of male participants is higher in Group A and Group B but there is no statistically significant difference. The difference in the mean of Group A and Group B was significant considering the duration of diabetes, ulcer size, and HbA1C levels. ($p < 0.05$). When we consider the median levels of the variables above and below the median value, there was no significant difference on the basis of age, and gender ($p>0.05$) whereas there is a statistically significant difference with respect to ulcer size and duration of treatment and HbA1C levels. ($p<0.05$).

CONCLUSION

A diabetic foot ulcer is not only a serious problem for the patient but is also a major health care concern in society. Cadexomer iodine is used in the treatment of ulcers for a long time but the controlled release ionic silver dressings are a relatively new compound and have not been as widely used as cadexomer iodine. Good results are seen in terms of duration and treatment of ulcers with the use of controlled release ionic silver dressings whereas the reduction in the size of ulcers is faster with the use of cadexomer iodine dressings. Therefore, controlled release ionic silver dressings can be used as a better option for the rapid and safe management of all patients with Diabetic Foot Ulcers.

Ethics And Consent:

Throughout the course of the study, the AHA/ ASA standards were upheld. All relevant and necessary information was acquired from health records, lab results, and patient interviews.

Conflict Of Interest: None.

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