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Comparison Of Efficacy Of Octenidine Wound Gel Versus Cadexomer-Iodine Dressing In Diabetic Foot Ulcers: A Randomized Controlled Trial

Dr. Adhithya Jeevan Balamurali[1] ,Prof. Dr. Vikram yogish [2] ,Dr. Eazhisai Chelvan R. A[3] ,Dr. Midhun Kumar J[4]

[1] SRM MEDICAL COLLEGE HOSPITAL AND RESEARCH CENTRE , GENERAL SURGERY, Kanchipuram,Tamilnadu, India
ORCHID ID – https://orcid.org/0009-0003-4976-196XAb8617@srmist.edu.in
[2] SRM MEDICAL COLLEGE HOSPITAL AND RESEARCH CENTRE , GENERAL SURGERY, Kanchipuram,Tamilnadu, India
ORCHID ID -https://orcid.org/0000-0002-7440-9787vikaramy@srmist.edu.in
[3] SRM MEDICAL COLLEGE HOSPITAL AND RESEARCH CENTRE , GENERAL SURGERY, Kanchipuram,Tamilnadu, India
ORCHID ID – https://orcid.org/0009-0008-7413-3320eazhisac@srmist.edu.in
[4] SRM MEDICAL COLLEGE HOSPITAL AND RESEARCH CENTRE , GENERAL SURGERY, Kanchipuram,Tamilnadu, India
ORCHID ID - https://orcid.org/0000-0003-4717-2267midhunkj@srmist.edu.in

ABSTRACT
Foot ulcers are a common and severe complication associated with diabetes mellitus, often contributing to substantial morbidity.[1]Globally, up to 6% of diabetic individuals are expected to develop foot ulcers, particularly those with long-standing disease, poor glycemic control, or neuropathy. Effective management involves both local and systemic approaches, with topical agents playing a critical role in wound healing.[2]

Keywords: Diabetic Foot Ulcer, Octenidine, Cadexomer-Iodine, Wound Healing, Randomized Trial

INTRODUCTION
Octenidine dihydrochloride is an antiseptic agent known for its antimicrobial action and low tissue toxicity. When formulated as a hydrogel, it helps maintain a moist wound environment conducive to healing. [3]Cadexomer-Iodine, a dressing that releases iodine slowly, has been widely used due to its ability to manage bacterial load and support granulation tissue formation. However, there is limited clinical evidence comparing these two agents directly.[4]
This study aims to fill that gap by comparing the effectiveness of Octenidine wound gel with Cadexomer-Iodine dressing in reducing ulcer area among patients with diabetic foot ulcers.[5]

MATERIALS AND METHODS
Study Design: Randomized Controlled Trial .
Study Setting: The study was undertaken at SRM Medical College Hospital and Research Centre.
Duration: The trial spanned one year, including three months of recruitment and two weeks of intervention.
Participants: Adults aged 35 and older with diagnosed Type 2 diabetes and Wagner Grade 1 ulcers over 4 cm in size and of at least 4 weeks duration were included. Patients with osteomyelitis or peripheral vascular disease were excluded.

Figure 1: Superficial Diabetic Foot Ulcer

Randomization and Blinding: Eligible participants were randomly assigned to one of two groups using a computer-generated sequence and sealed envelopes to maintain allocation concealment.

Intervention: Group A received daily Octenidine gel dressings, and Group B received Cadexomer-Iodine dressings. All other aspects of wound care were standardized.

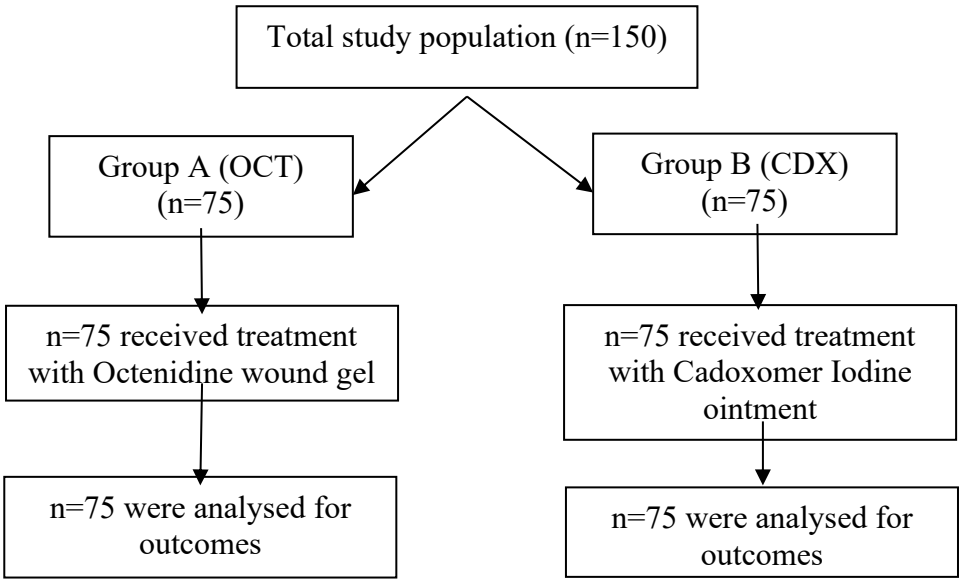


Figure 2: Study population

Outcome Measures: The primary endpoint was the percentage change in ulcer area over 14 days. Secondary outcomes included infection control, pain during dressing changes, and patient satisfaction.

Data Collection: Ulcer area was measured at baseline and Day 14 using PictZar software. Infection signs, pain scores, and dressing costs were also documented.

Statistical Analysis: Data were analyzed using SPSS version 25. Continuous data were assessed using t-tests, and categorical data using chi-square tests. A significance level of $p < 0.05$ was used.

Ethics: The study received approval from the Institutional Ethics Committee. Written informed consent was obtained from all participants.

RESULTS

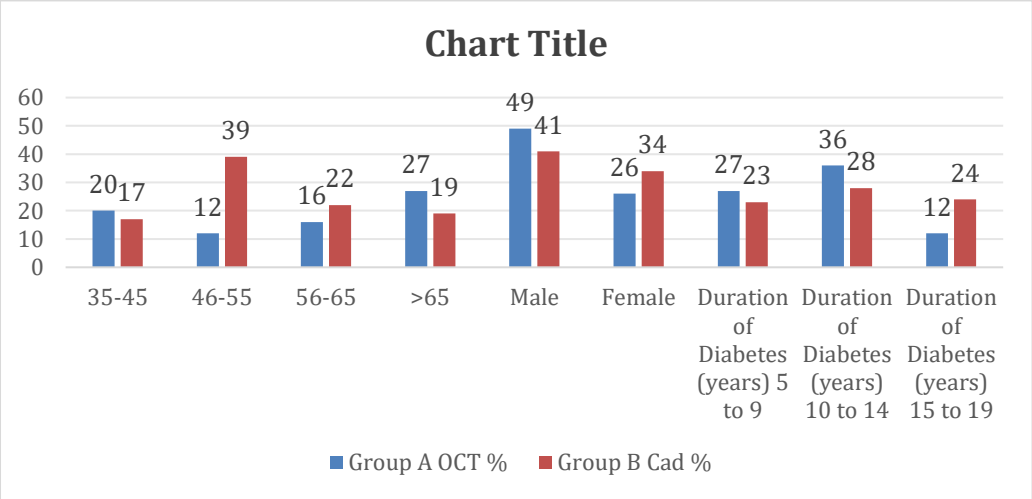
Demographics:

The study included 150 participants, equally divided into two groups. The average age was slightly higher in the Octenidine group. Gender and diabetes duration were similar between groups.

Table 1: Demographic Characteristics of Patients in Group A (OCTENIDINE) and Group B (Cadexomer-Iodine)

Demographic data	Group A OCT %	Group B CDX %	P
Age (years)			
35-45	20 (26.7)	17 (22.7)	0.0025
46-55	12 (16)	39 (52)	
56-65	16 (21.3)	22 (29.3)	
>65	27 (36)	19 (25.3)	
Gender			
Male	49 (65.3)	41 (54.7)	0.2433
Female	26 (34.7)	34 (45.3)	
Duration of Diabetes (years)			
5 to 9	27 (36)	23 (30)	0.0699
10 to 14	36 (48)	28 (37)	
15 to 19	12 (16)	24 (32)	

Figure 3 : Graph 1: Demographic Characteristics of Patients in Group A (OCTENIDINE) and Group B (Cadexomer-Iodine)



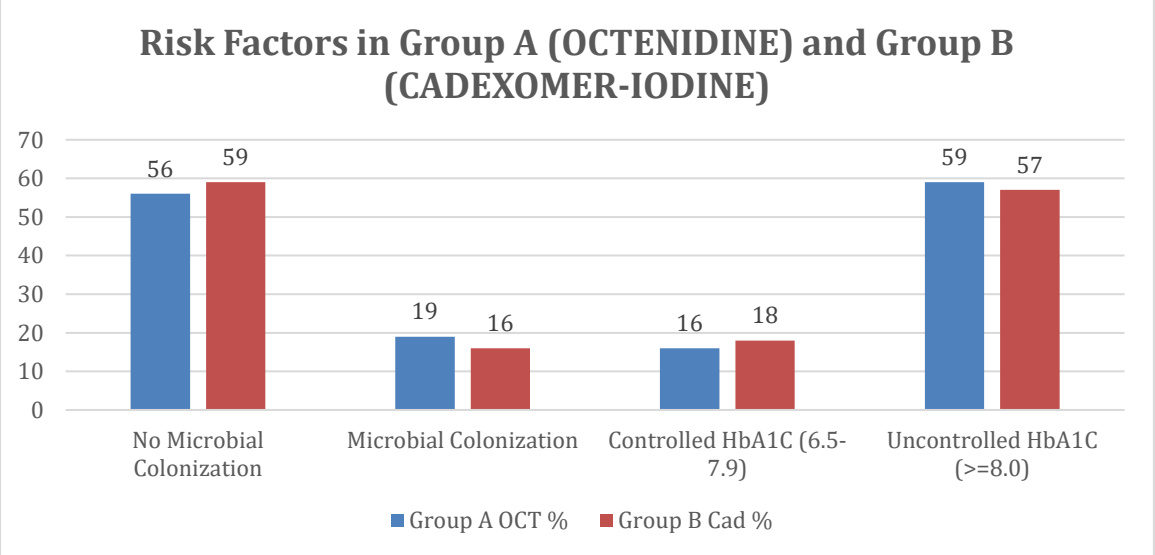
Risk Factors: There were no statistically significant differences in microbial colonization or HbA1C levels between the two groups.

Table 2: Risk Factors in Group A (OCTENIDINE) and Group B (Cadexomer-Iodine)

Risk Factor	Group A OCT %	Group B CDX %	P

Microbial Colonization			
No	56 (74.7)	59 (78.7)	0.55
Yes	19 (25.3)	16 (21.3)	
HbA1C			
Controlled (6.5-7.9)	16 (21.3)	18 (24)	0.72
Uncontrolled (>=8.0)	59 (78.7)	57 (76)	

Figure 4: Graph 2: Risk Factors in Group A (OCTENIDINE) and Group B (Cadexomer-Iodine)

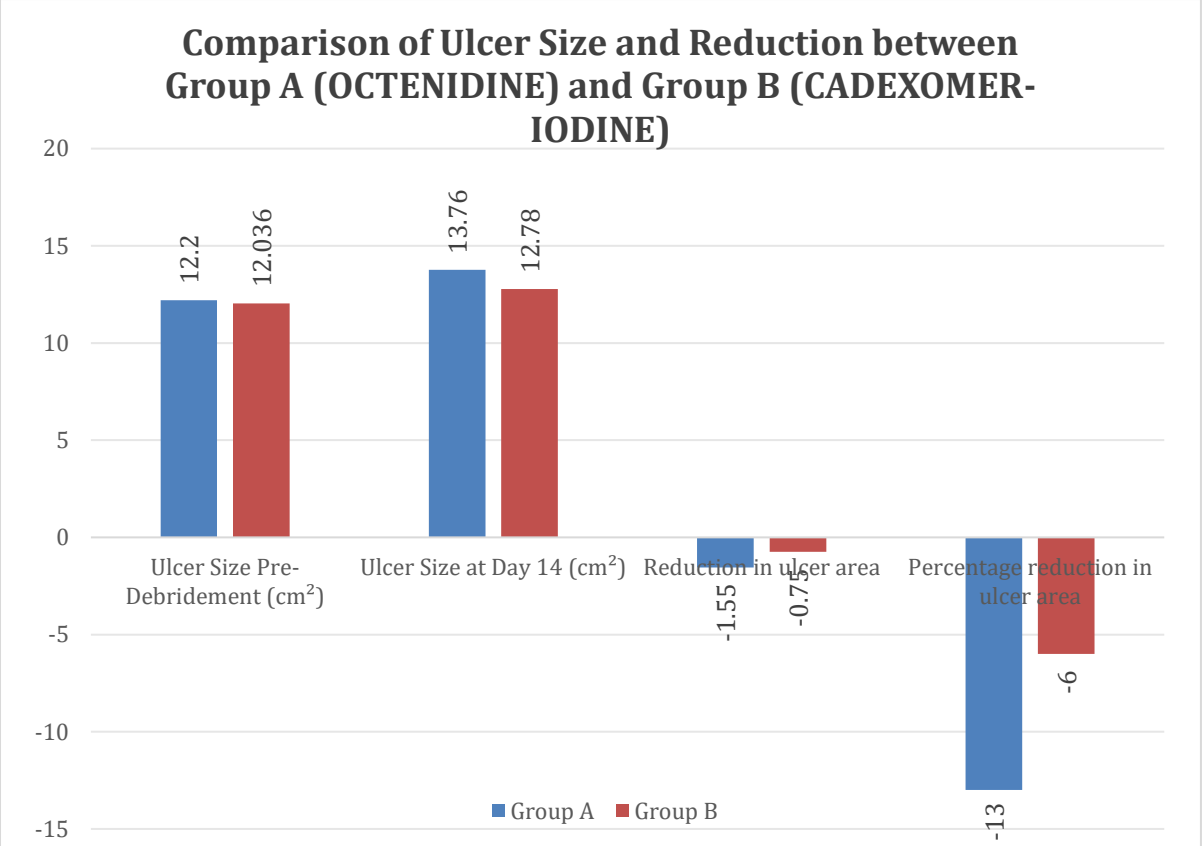


Ulcer Area Reduction:
At the end of the study, the Octenidine group showed a significantly higher mean reduction in ulcer area compared to the Cadexomer-Iodine group (-1.55 ± 0.36 cm² vs. -0.75 ± 0.64 cm², $p < 0.001$). The percentage reduction also favored the Octenidine group (-13% ± 8% vs. -6% ± 14%, $p < 0.001$).

Table 3: Comparison of Ulcer Size and Reduction between Group A (OCTENIDINE) and Group B (Cadexomer-Iodine)

Parameter	Group A (OCT)	Group B (CDX)	P
Ulcer Size Pre-Debridement (cm²)	12.20 ± 4.35	12.036 ± 4.58	0.8
Ulcer Size at Day 14 (cm²)	13.76 ± 3.98	12.78 ± 3.94	0.15
Reduction in ulcer area	(-1.55) ± 0.36	(-0.75) ± 0.64	<0.001
Percentage reduction in ulcer area	(-13%) ± 8%	(-6%) ± 14%	<0.001

Figure 5: Graph 3: Comparison of Ulcer Size and Reduction between Group A (OCTENIDINE) and Group B (Cadexomer-Iodine)



DISCUSSION

This study found that Octenidine wound gel resulted in significantly greater reduction in ulcer area compared to Cadexomer-Iodine over a 14-day period. These findings support previous evidence of Octenidine's efficacy in managing chronic wounds. The antiseptic's ability to disrupt biofilms and maintain a moist wound environment may account for the observed improvements.

Limitations include the short treatment duration and the focus on only Grade 1 ulcers. Future studies should evaluate longer-term outcomes and include higher-grade ulcers.

CONCLUSION

Octenidine wound gel appears more effective than Cadexomer-Iodine in reducing ulcer size over two weeks in patients with diabetic foot ulcers. These results suggest potential for Octenidine to be a preferred option in DFU wound management protocols, pending further investigation.

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CONFLICT OF INTEREST

None declared.

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