CADEXOMER VERSUS POVIDONE IODINE DRESSING IN CHRONIC LEG ULCERS- A PROSPECTIVE STUDY.

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Abstract

Background:

In the present scenario the entire healthcare system has been overburdened with chronic wounds be it monetary wise or manpower requirements like nurses, doctors, etc. A chronic wound is being treated by many topical drugs which are prevailing in the market. So we considered this study i.e. "the effect of cadexomer and providone iodine on chronic leg ulcers".

Objective:

The main and primary objective of this study was to compare the outcome of both, Cadexomer and povidone-iodine, about their effect on the treatment of leg ulcers.

Methods:

With 30 patients in each group, 30 patients with chronic wounds participated in this prospective study. As part of the statistical analysis, Pearson's Correlation Coefficient and the Student's Paired T-Test are used.

Results:

Patients who received cadexomer iodine ointment had a significantly ($p<0.05$) greater rate of wound healing, as well as a significantly lower level of bacterial overload and promotion of the creation of granulation tissue.

Conclusion:

The effect of cadexomer as a vector in combination with providone iodine ointment resulted in a higher rate of biofilm, slough, and debris reduction and a better rate of granulation tissue formation promotion, both of which increased the rate at which a wound heals and lowered the cost of managing chronic wounds.

Recommendation:

It is recommended that the efficacy of the ointments (cadexomer and providone iodine) be researched for proper healing of ulcers and wounds in diabetic leg ulcers because a significant number of diabetic patients experience leg ulcers because, in this study, it was discovered that over 60 people suffered with the risk of leg ulcers.

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1. INTRODUCTION

There is a reduction in patients' quality of life and burden on the health care system with

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an increase in lower extremity amputation and mortality with an increase in chronic non-healing wounds [1, 2]. Among chronic wounds, diabetic foot ulcers (DFUS), venous leg ulcers (VLUS), and pressure ulcers (PUs) are common. In a developing country like India these account for high morbidity and also cause a drain on already limited healthcare resources [3]. There are various modalities of treatment for treating chronic wounds but there is no single line of effective therapy for chronic wounds. Therefore, new means and modalities are continuously explored [4].

Elemental iodine is physically bounded to cadexomer iodine which is a modified starch. There is the release of iodine in the wound which absorbs wound exudate in a controlled manner. The amount of iodine released is proportional to the amount of exudate that has been absorbed. Iodine's brown color is an indicator of the need to change the dressing when the color of the dressing has changed from brown to yellow/grey (normally after 2-3 days, depending on the amount of exudate in the wound), the absorption capacity of the cadexomer has been used up and all the iodine has been released [5, 6].

Povidone iodine, is a loose complex of iodine and a carrier base, polyvinyl-pyrrolidone. Providone iodine is bactericidal and active against Gram-negative and Gram-positive bacteria, fungi, protozoa, and some viruses. The antimicrobial action on the molecules of the membrane and cytoplasm of the infective agent is done by iodination and oxidation of free iodine [7].

2. MATERIAL AND METHODS

This study was a prospective study carried out on 60 patients admitted to IGIMS, in the department of general surgery, Patna who underwent treatment for chronic leg ulcers. The patients were recruited from July 2021 to August 2022. The subjects were randomized into two groups of 30 patients each a) the cadexomer iodine dressing group and b) the povidone-iodine dressing group. The wound dressings were changed every day for six weeks of follow-up period or till complete healing. International standards or university, standards are written ethical approval has been collected and preserved.

2.1. ***Inclusion criteria***

- All patients presenting with chronic leg ulcer (>3 months)

2.2. ***Exclusion criteria***

- Patients with renal failure (serum creatinine > 3.0 mg/dL)
- Poor nutritional status (serum albumin < 3.0 g/dL or total protein <6.5 g/d)
- History of uncontrolled thyroid disorder.
- Biopsy-proven malignant ulcer

2.3. ***Statistical Analysis***

Using SPSS 22.0 and GraphPad Prism 7.50 as statistical software, descriptive and inferential statistics were performed using Student's paired t-test and Pearson's Correlation Coefficient, with a threshold of significance of $p < 0.05$.

3. RESULTS

Cadexomer iodine ointment and providone iodine ointment in the management of chronic wound has a very good role and is safe and effective, but cadexomer as a vector in iodine ointment proves to be comparatively more effective, better compliance, and less time consuming, leading to better outcomes and reduction in health care costs. Various studies show the efficacy and effectiveness of cadexomer iodine in the treatment of chronic ulcers [8]. There hasn't been much research comparing the effects of cadexomer and betadine iodine ointment in terms of the percentage of wound healing, the encouragement of granulation tissue formation, and the quantity of soakage or frequency of dressing changes. Compared to betadine iodine ointment, cadexomer iodine considerably ($P < 0.01$) increased the average or mean change in the size of the ulcers. Dexomer iodine ointment provides a greater rate of healing, according to our study.

The mean wound size at baseline in group A patients after the first sitting, second sitting, and third sittings were 186.45+ 57.42 cm2 which decreased significantly to 176.35 + 57.36 cm2 by 1st sitting, 166.75+ 57.62 cm2 by 2nd sitting and 155.85+ 57.36 cm2 by third sitting. At baseline, first sitting, second sitting and third sitting in group B patients were 188.43+ 75.41 cm2 which decreased significantly to 183.35 + 75.36 cm2 by 1st sitting, 177.75+ 75.62 cm2 by 2nd sitting, and 171.65+ 76.32 cm2 by third sitting. There was a significant difference in wound area during the follow-up period as per the ANOVA test ($p < 0.05$). According to the chi-square test, the granulation tissue significantly improved from the first sitting to the third ($p < 0.05$). According to the chi-square test, there were significantly more patients in group A than in group B who displayed improvement in granulation tissue in each sitting ($p < 0.05$). (Figure 1).

At baseline, group A patient experienced a total of 19 patients has mild discharges and 11 with moderate discharges. At the first, second, and third sittings, all patients experienced a moderate discharge. According to the chi-square test, the discharge significantly improved from the initial assessment to the third sitting ($p < 0.05$). At baseline, the first sitting, and the second sitting, 20 and 10 patients in group B, respectively, experienced mild and moderate discharge. In the third sitting, 45 patients had light discharge, 9 patients had substantial discharge, and 6 patients had no discharge. According to the chi-square test, the discharge significantly improved from the initial assessment to the third sitting ($p < 0.05$).

4. DISCUSSION:

The microbicidal property of iodine appears to include the suppression of essential bacterial cellular functions and structures, as well as the oxidation of nucleotides, fatty/ amino acids, and cytosolic enzymes involved in the respiratory chain, causing them to become denatured and deactivated [7]. In the group treated with cadexomer iodine as opposed to the group treated with normal care from one to eight weeks, it was found that the presence of exudates, debris, biofilm, erythema, discomfort, and edema was significantly on the lower side. Cadexomer iodine ointment had similar benefits in reducing pain and erythema as well as slough, debris, and biofilms, which in turn led to an increase in the production of granulation tissue and wound healing [8–10]. In 93 patients with venous ulcers, Skog et al. showed the efficiency of cadexomer iodine; after 6 weeks of treatment, there was a 34% reduction in wound size compared to conventional treatment modalities [11].

Additionally, a meta-analysis has demonstrated the effectiveness of Cadexomer Iodine Ointment in managing chronic wounds by removing obstacles to recovery. To prepare the wound bed for subsequent lines of treatment and maintenance, it might be utilized [12]. To handle various forms of chronic wounds, numerous more studies have also been examined [3, 4, 12]. In terms of de-sloughing, promoting granulation tissue, and shrinking the size of the wound, it was discovered that using cadexomer as a vector with iodine ointment produced effective results [13]. This study had a limited sample size, and there is limited literature and research available on this topic of comparing the outcome of cadexomer iodine and providone iodine ointments for wound management. Thus more such studies and research are required to determine the efficacy and efficiency of cadexomer iodine ointment.

5. CONCLUSION

In comparison to Povidone Iodine Ointment, Cadexomer Iodine Ointment was found to be more effective at managing chronic wounds as the prolonged release of iodine provides broad-spectrum antibacterial action, while the unique cadexomer matrix provides de-sloughing action which eliminates the hurdle to healing. For doctors and surgeons treating patients with infected wounds or ulcers, cadexomer iodine stands out as another capable, dependable, and effective therapeutic choice with these potential advantages. Both cadexomer iodine and povidone-iodine ointments are secure and effective for treating wounds or ulcers, thereby enhancing patient well-being

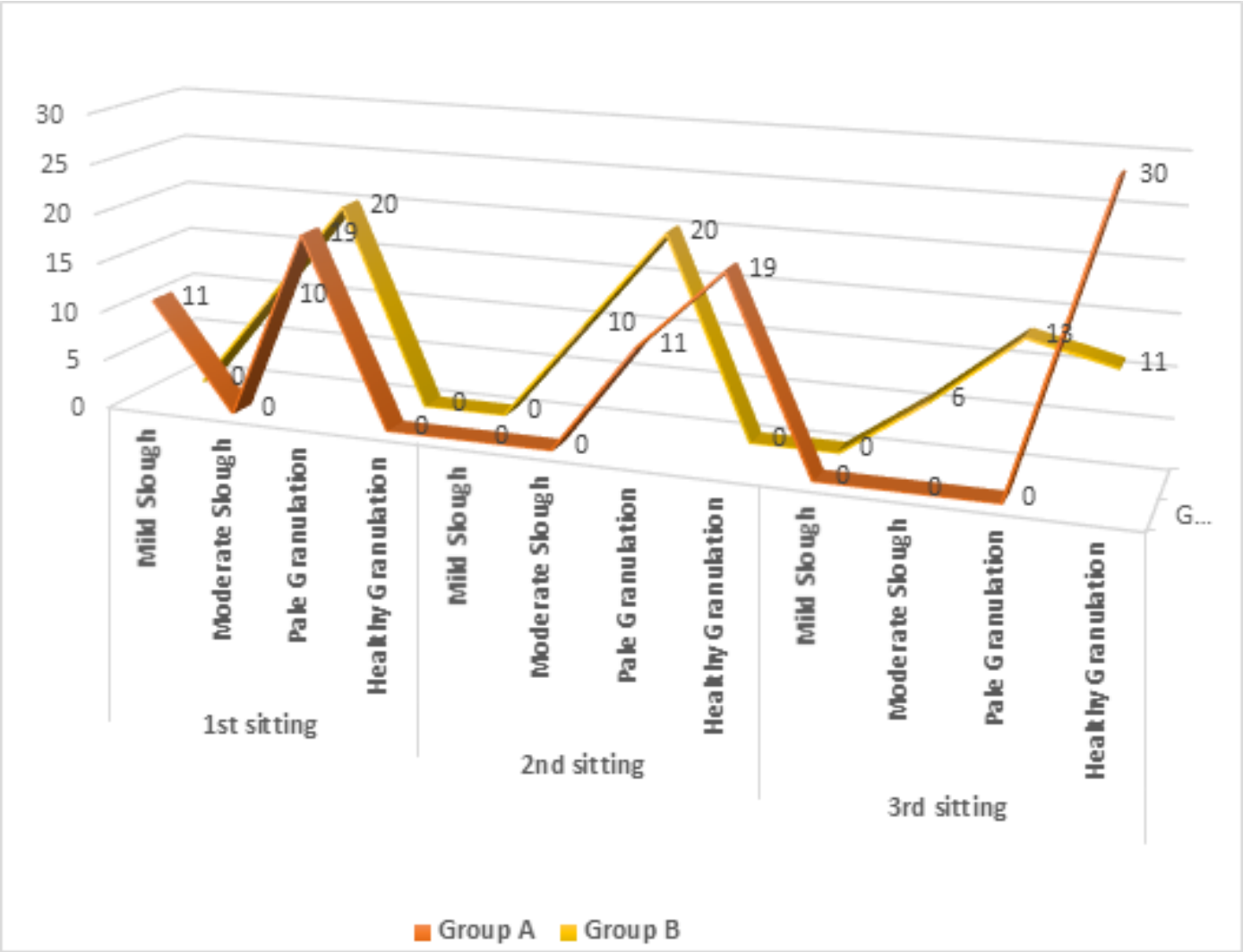

Figure 1: Comparing granulation tissue during first, second and third sitting between the groups

and reducing medical costs.

6. STUDY LIMITATION:

The results of cadexomer iodine and povidone-iodine ointments for managing wounds were compared in this study, however, there is little literature and research on the subject.

To evaluate the effectiveness and efficiency of cadexomer iodine ointment and its comparison with conventional topical formulations for wound care management, we advise conducting an additional study with bigger sample numbers.

7. ACKNOWLEDGMENTS:

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8. LISTS OF ABBREVIATIONS:

DFUS : diabetic foot ulcers
VLUS: venous leg ulcers
PUs: pressure ulcers

9. CONFLICT OF INTEREST:

The authors state that they have no conflicts of interest.

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