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# Povidone Iodine Ointment vs Cadexomer Iodine Ointment in Management of the Chronic Wound: A Study Protocol

Shubham Gupta <sup>a\*#</sup>, Raju Kamalrao Shinde <sup>a†</sup> and Sangita Shinde <sup>b¥</sup>

 <sup>a</sup> Department of Surgery, Jawaharlal Nehru Medical College, Datta Meghe Institute of Medical Sciences, Sawangi (M), Wardha, Maharashtra, India.
<sup>b</sup> Department of Pharmacology, Jawaharlal Nehru Medical College, Datta Meghe Institute of Medical Sciences, Sawangi (M), Wardha, Maharashtra, India.

## Authors' contributions

This work was carried out in collaboration among all authors. All authors read and approved the final manuscript.

## Article Information

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Study Protocol

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# ABSTRACT

**Introduction:** Chronic wound and its care has always been a health burden for patient, health care professionals and the entire health care system. There have been certain topical preparations available in market today for application in chronic wound management. In our study, we are comparing effects of cadexomer and povidone iodine ointment in context of reduction in bacterial overload, slough reduction, facilitations of granulation tissue formation, reduction in size of the wound and ultimately in percentage of wound healing and its cost of management.

Aim: Comparison of outcome of Povidone Iodine Ointment and Cadexomer iodine Ointment in management of the wound.

Methodology: This cross section observational study has been conducted among 40 patients

<sup>#</sup> Junior Resident;

<sup>&</sup>lt;sup>†</sup> Professor;

<sup>\*</sup>Professor and Head;

<sup>\*</sup>Corresponding author: E-mail: sg2638@gmail.com;

diagnosed as chronic wound with 20 patients in each group. Student's paired t-test and Pearson's Correlation Coefficient is being used as statistical analysis.

**Results:** The percentage of patient treated with cadexomer iodine ointment shows significantly (p<0.05) higher rate of wound healing along with significant reduction in bacterial overload and promotion of granulation tissue formation.

**Conclusion:** Cadexomer as a vector with iodine ointment shows higher rate of reduction of biofilm, slough and debris with better rate of promotion of granulation tissue formation, thus leading to increased and effective rate of healing of wound as well as cost effective management of chronic wounds.

Keywords: Cadexomer; betadine; iodine ointment; chronic wound; biofilm; wound healing.

## 1. INTRODUCTION

Wound care has been a major health concern which has affected many individuals with different types of wounds and has consumed vast resources. Chronic wounds have shown to represent a significant burden to patients, health care professionals and the entire health care system.[1] Wound care has been a major common consideration in the day to day caring of patients with chronic wounds.

3% of people over 60 years of age are estimated to be affected with the chronic wounds [2]. Estimating the prevalence of wound is challenging as there is no clear pre- established consensus of chronicity or any exact distinction between acute and chronic wounds [3]. A commonly used definition- any wound that fails "to proceed through an orderly and timely process to produce anatomic and functional integrity within 3 weeks duration" is termed as chronic wound [4]. Thus due to absence of authentic and reliable studies related to chronic wound, it has been made difficult to determine the prevalence of chronic wound in general population and has hindered the improvement efforts.

Currently, there are several factors that contribute to stalled wound. However, increased bio-burden and biofilm formation is a major concern which delays healing of chronic wounds. It has been observed that biofilms complicates about >90% of chronic wounds that are difficult to treat [5]. Diabetic foot ulcers (DFUs), venous leg ulcers (VLUs), and pressure ulcers (PUs) are commonly found wounds, among chronic wounds. High morbidity has been recorded especially in developing countries which has caused drain on limited health resources [6].

In chronic wound treatment, infection control has been identified as a basic requirement. Many

changes have been done in the art of science on how the wounds should be managed in past two decades. To achieve positive outcome in wound healing, there have been great aggrandizement in the field of wound technology, research and development of standards of care based on research and clinical testaments or evidences. However, there is a lack of reliable evidences and studies which endorse or suggests routine use of systemic antibiotics for chronic wounds treatment [7]. In current literatures, there is an affiance to the use of topical preparations for chronic wounds [8]. Among several topical products available, iodine-based preparations promote wound healing by release of free iodine when they come in contact with wound exudates, thus are known to acts as an antiseptic and to control the rate of infection [9]. Though many studies have revealed the effects of povidoneiodine in reduction of bacterial load in chronic wounds but still there is a lack of corroboration that povidone iodine ointment has positive or negative effect on wound healing when there is no infection. On the other hand, in the chronic wound environment cadexomer iodine has proven commendatory impact on wound healing [10]. A complex is formed between iodine and polymer synthetic carrier povidone in povidone iodine, which itself has no microbicidal activity [11]. In an aqueous medium, from the povidone iodine complex, free iodine is released and an equilibrium is established, germicidal activity proceeds with release of more free iodine from the povidone iodine reservoir [12,13]. The microbicidal activity of iodine involves the hindrance in important bacterial cellular mechanisms and structures by oxidizing nucleotides, amino acids or fatty acids in bacterial cell membranes, along with cytosolic enzymes which are involved in the respiratory chain which causes them to get deactivated and become denatured [14]. In contrast, Cadexomer is a starch polymer bead which is hydrophilic in and contains 0.9% w/w nature iodine.

Pharmacodynamic study shows that when it comes in contact with wound exudates, free iodine (an antiseptic) is released from cadexomer iodine, which decreases the bacterial count [15]. It also absorbs fluid (as much as 6 mL/g of cadexomer iodine), promotes desloughing and removes pus and debris [16]. Also, to facilitate the healing of chronic skin ulcers, cadexomer iodine maintains moist а environment [6].

Keeping this context we proposed a study to compare the outcome of Povidone lodine Ointment and Cadexomer lodine Ointment on chronic wounds.

## 1.1 Aim

Comparison of outcome of Povidone lodine Ointment and Cadexomer iodine Ointment in management of the wound.

## **1.2 Objectives**

- 1. To study the different demographic feature of the ulcer patients.
- 2. Study the causes / etiological factors for non healing ulcers.
- 3. To study the outcome of povidone iodine.
- 4. To study the outcome of cadexomer iodine.
- 5. To compare the outcome of vectors used with iodine.

# 2. MATERIALS AND METHODS

# 2.1 Study Type

Cross Sectional Observational Type of Study.

## 2.2 Study Design

A prospective study will be conducted in the Acharya Vinoba Bhave rural Hospital (AVBRH), a tertiary care teaching hospital situated in the rural area of Wardha District. The selected hospital, AVBRH, is a 1280 bedded teaching hospital providing healthcare to the rural people of central India.

## 2.3 Sample Size

Forty patients being diagnosed to be having chronic wound in Department of General Surgery, Acharya Vinoba Bhave Rural Hospital (AVBRH) were enrolled for the study- 20 in each group [6].

#### 2.3.1 Assessment of wound size

Calculated by placing acetate sheet over the wound and tracing the wound border with permanent pen. Area of the wound is calculated by counting the complete and half or more than half squares within the wound border taking it as  $1 \text{ cm}^2$  [17].

## 2.4 Statistical Analysis

Descriptive and inferential statistics using Student's paired t-test and Pearson's Correlation Coefficient will be done using SPSS 22.0 version and Graphpad prism 7.50 versions as a statistical software and p< 0.05 is considered as level of significance.

## 2.5 Inclusion Criteria

The following definitions will be adopted for the purpose of the study:

- 1. Patients of age group between 18 and 65 years.
- 2. Patients of both sexes (male and female).
- 3. Patients with Venous Leg Ulcer, Diabetic Foot Ulcer and Pressure Ulcers with adequate arterial blood supply assessed by Color Doppler.
- 4. All the patients with acute or chronic wounds measuring more than 25sq centimeters.

## 2.6 Exclusion Criteria

- 1. Patients on immunosuppression, corticosteroid, anti- cancer drugs.
- 2. Patients with Severe malnutrition(serum albumin <3.0 g/dl or total protein <6.5g/dl)
- 3. Patients with renal dysfunction(serum creatinine >3.0 mg/dl)
- 4. Patients with hepatic dysfunction.
- 5. Patients with thyroid dysfunction.

# 3. EXPECTED RESULTS

Our study revealed that cadexomer iodine ointment and betadine iodine ointment both are safe and effective in management of wound but cadexomer as a vector in iodine ointment proves to be comparatively more effective, better compliance, less time consuming leading to better outcome and reduction in health care costs in management of the chronic ulcers and wound.

## 4. DISCUSSION

Many studies are available on the therapeutic benefits of cadexomer iodine in the treatment of chronic wounds [10]. However, limited studies have been conducted comparing outcomes of both cadexomer and betadine iodine ointment in context to percentage of wound healing, promotion of granulation tissue formation and amount of soakage or frequency of change of dressings.

The average or mean change in size of the ulcers was significantly (P<0.01) higher of cadexomer iodine in comparison with betadine iodine ointment. Thus, our study revealed that cadexomer iodine ointment has higher rate of healing [18].

According to the scores of total wound evaluation, presence of exudates, debris, biofilm, erythema, pain and edema were found to be on lower side in group treated with cadexomer iodine as compared to group treated with standard care from 1 to 8 weeks. Similar effects were noted with cadexomer iodine ointment in pain and erythema reduction as well as reduction in slough, debris and biofilms leading increased granulation tissue formation and wound healing.<sup>[16;19; 20]</sup> Skog et al. demonstrated the effectiveness of cadexomer iodine over 93 patients with venous ulcers, in which after 6 weeks of treatment, there was 34% reduction in wound size as compared with other treatment modalities [21]. A meta-analysis also have shown that Cadexomer lodine Ointment is effective for chronic wound management since it removes the barriers which are hurdles in healing process. Thus, it can be used for preparation of wound bed for further line of treatment and management [22]. Various other studies have also been reviewed in view of management of different types of chronic wounds [23,24,25,26]. and it was found that cadexomer as a vector with iodine ointment have shown effective results in management of chronic wound with respect to de-sloughing, granulation tissue promotion and size reduction of the wound.

## **5. CONCLUSION**

The Cadexomer lodine Ointment was found to be better in management of chronic wound in terms of anti-microbial action, de-sloughing agent and facilitating wound healing as compared to Povidone lodine Ointment.

## CONSENT

As per international standard or university standard, patients' written consent has been collected and preserved by the author(s).

#### ETHICAL APPROVAL

As per international standard or university standard written ethical approval has been collected and preserved by the author(s).

## **COMPETING INTERESTS**

Authors have declared that no competing interests exist.

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