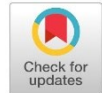


ORIGINAL ARTICLE

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A comparison of the effects of contemporary dressings and 1% Povidone Iodine on the healing of diabetic ulceration: A Quasy Experiment

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Abstract

Background: Diabetes ulcers are a consequence of diabetes mellitus (DM). Modern dressing techniques are essential for the treatment of diabetic ulcers, which are lesions that necessitate specific attention and control. The researchers set out to find out how a diabetic ulcer wound healing score changed after using a contemporary dressing.

Aims: Analyse the effectiveness of dressing and povidone iodine 1% on diabetic foot ulcer healing.

Design and Methods: Quasi experiment, pre-test and post-test of experiment group using modern dressing and control group using iodine. Total sampling technique was used in this study with a total of 84 patients. Data analysis was performed with a parametric test, namely paired t-test, and independent t-test.

Results: Both groups originally exhibited comparable wound diameters. On the 30th day, there was a decrease in wound size score (MD-CI) due to modern dressing. The drop was -1.94 with a 95% confidence interval of -4.37 to 0.14. The p-value was 0.043 and the r-squared value was -0.121. On the 60th day, the MD-CI treatment resulted in a reduction in wound size of -5.14 (95% confidence interval: -11.50 to -1.34; p=0.013; r²= -0.416).

Conclusion: At first, contemporary dressing therapy achieved a marginal reduction in lesion size. However, lesion size decreased substantially in diabetic foot ulcers after day 60. It is possible to suggest this intervention as a therapeutic approach for diabetic foot ulcers.

Keywords: modern dressing; povidone iodine 1%; wound care; wound healing

1 | INTRODUCTION

Although all forms of diabetes mellitus (DM) can cause hyperglycemia, there are a number of subtypes that differ in the disease's etiology, clinical manifestations, and treatment (Sapra & Bhandari, 2022). An increasingly common complication of diabetes is diabetic foot ulcers (DFUs), which are a major cause of the disease (Izadi et al., 2019). Commonly acknowledged as major contributors to the onset of diabetic foot ulcers, diabetic neuropathy, and peripheral vascular dysfunction account for most cases (Marks et al., 2009). Diabetic foot ulcers, or DFUs for short, are among the most serious consequences that can arise from diabetes (Akkus & Sert, 2022). An estimated 19% to 34% of people with diabetes will develop diabetic foot ulcers

(DFUs) at some point in their lives. A large percentage of diabetics experience a return of diabetic foot ulcers (DFUs) between one and five years after the first ulcer has healed, according to the available data. This recurring phenomena affects between forty-five and sixty-five percent of diabetic patients (Armstrong et al., 2017). 6.3% of the global population and 5.5% of the Asian population have DFUs (Zhang et al., 2017). Evidence from several studies (Crocker et al., 2021), indicates that patients with DFUs are at a higher risk of complications such as infection, necrosis, recurrence, and potential amputation. According to (Ministry of Health RI, 2018), almost 15% of Indonesians will get diabetic ulceration. Out of those, 30% will require amputation, and 14.8% will pass away within a year after their amputation. Infection is a known cause in the nearly 50% five-

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year mortality rate of patients with diabetic foot ulcers (Mohammadi et al., 2022). Hospitalization for DFUs is most common among diabetic patients; 20% of these cases end in amputation (Lim et al., 2021), and 25% pose a risk of amputation (Fedorko et al., 2016). Additionally, a meta-analysis found that patients with gangrenous DFU had a much higher probability of needing an amputation (Ahmed et al., 2019). The increasing morbidity of DFU patients highlights the critical need for wound care services, and wound nurses in particular, to enhance their competency. In addition, a meta-analysis found that patients with gangrenous DFU had a much higher chance of needing an amputation (Burhan & Sebayang, 2022).

Moisture is essential for the Modern dressing technique. The primary purpose of the wet key is to optimize the fibrinolysis process, minimize the risk of infection, promote the generation of active cells, and stimulate angiogenesis (Seidel et al., 2020). This concept of moisture management is implemented through the practice of closed wound care. Closed wound care creates a moist environment in the wound, which can accelerate the wound healing process by 2-3 times compared to open wound care (Akin et al., 2022).

The physiological stages of the wound healing process can be divided into three phases. The first phase, known as the inflammatory phase, lasts until the fifth day (Burhan & Arofiati, 2021). During this phase, blood vessels contract and platelets aggregate, leading to a homeostasis reaction (Jeong et al., 2010). The second phase is the proliferation phase, which is characterized by the presence of platelets. The second phase is known as the proliferation phase (Burhan et al., 2022). It starts around the 5th day after the inflammatory phase and lasts for up to 3 weeks. During this phase, there is an increase in the production of matrix, angiogenesis, and epithelialization (Burhan et al., 2023). The final phase is the maturation or remodeling phase, which lasts from 21 days to 1 year. This phase is characterized by an increase in wound tension (Bagheri Miyab et al., 2020).

Regarding the recovery process of DFUs, no significant effects were noted, and not all participants believed that modern dressings could

be beneficial. The purpose of this study was to evaluate and compare the effectiveness of modern dressing therapy with povidone iodine wound care in the treatment of diabetic foot ulcers (DFU).

1 THE STUDY

2 I METHODOLOGY

The Health Research Ethics Commission of Harapan Bangsa University approved this randomized controlled trial (RCT) on January 2023, with registration number B. LPPM-UHB/112/01/2023.

Study Design & Participants

Individuals classified as adults who have been diagnosed with diabetes and subsequently develop foot ulcers throughout the time frame spanning from February 1, 2023, to April 2, 2023. Intervention and control groups (N=42) were randomly assigned. A triple-blind randomized controlled trial in Indonesia involved 84 individuals with diabetic foot ulcer lesions. The study recruited patients from Rumah Sakit Banjarnegara. This study included individuals of both genders who were undergoing treatment for diabetic foot ulcers. The study's inclusion criteria were established using the Wagner scale, which encompassed individuals with a current blood sugar level ranging from 120 to 180 mg/dl, a HbA1c level between 4.5 and 7%, a lesion length surpassing 5 cm, and the presence of infection. This investigation includes immunodeficiency illnesses as examples of exclusion criteria.

Sample Size

The researchers utilised the G-Power software to determine the appropriate sample size for the study, with a specific emphasis on the variable pertaining to the healing process of diabetic foot ulcer ulcers [2]. The final sample size for each group was calculated to be 42, based on several critical values (alpha level = 0.05), statistical power = 95%, and M1 (mean of group 1) = 42.12, M2 (mean of group 2) = 28.12, SD1 (standard deviation of group 1) = 18.13, SD2 (standard deviation of group 2) = 14.45. This resulted in a total sample size of 84 (Figure 1).

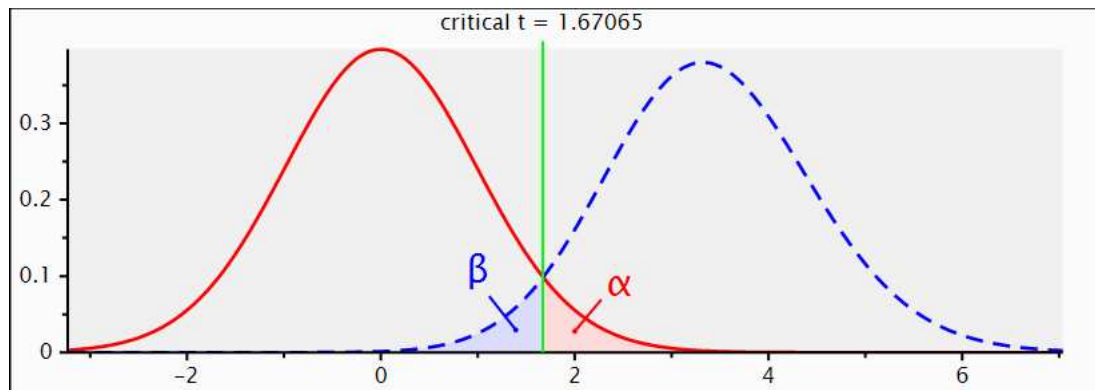


Figure 1. Mean difference between two independent means (two groups)

Sampling

The study registration was completed, resulting in the acquisition of a distinct registration number and the receipt of a referral. Subsequently, the researchers proceeded to enter the specified room and formally acquainted themselves with patients suffering from diabetic foot ulcers (DFU). Following this, the wound was evaluated by the researcher using the Bates Jensen Assessment Wound scale, the inclusion criteria were examined, and a thorough elucidation of the study's objectives and methodologies was given during the wound care session. Qualified individuals of both genders who expressed their willingness to participate provided a written consent form.

Researchers acquired demographic data through the analysis of medical records. In a random assignment approach, the participants were assigned to either the ozone therapy or placebo groups in a 1:1 ratio. This randomization was achieved using block randomization with block sizes of 4 and 6, facilitated by the Random Allocation Software (RAS). Envelopes were created and, after that, filled with capsules based on the number of samples. Each envelope was assigned a number ranging from 1 to 84. The allocation of interventions was established by sequentially opening the envelopes corresponding to the order of participant enrolment in the trial. A person who was not involved in the sampling procedure prepared allocation envelopes. All researchers, participants, and outcome evaluators in this study were maintained in a state of blinding.

Intervention

Throughout the wound care procedure, the group with diabetic foot ulcers (DFU) were provided with contemporary main dressings and secondary dressings for a duration of 60 days, with dressing replacements occurring every three days. The control group received wound care treatment with povidone iodine 1% for a duration of 60 days. The dressings were changed every three days on patients with diabetic foot ulcers (DFU). Each group was provided with instructions on DFU wound care, personal hygiene, and food. As per the global criteria established by the International Working Group on the Diabetic Foot (IWGDF), the participants were provided with a document that included a table displaying the days of the week. Patients were provided with a telephone number to contact in the event of any inquiries or apprehensions.

Data Collection Tool

Researchers evaluated individual appropriateness by utilizing demographic factors and the BWAT scale, which quantifies wounds [23]. This study incorporated demographic variables such as age, educational attainment, occupational status, sufficient household income, duration of diabetes, and treatment protocol for diabetic foot ulcers (DFU). quantity of stitches utilized, blood sugar levels, Hb1AC values. The data collection for wound size utilized the Bates-Jasen score assessment sheet to forecast and assess the average wound healing score. This score incorporates various evaluations

such as wound area, wound stage, wound edges, GOA or undermining, skin color surrounding the wound, edema, granulation, epithelialization, as well as the type and quantity of exudate.

Data analysis

The gathered data underwent analysis utilising the Jamovi programme (Jamovi, 2023), and its normality was assessed through the application of the Kolmogorov-Smirnov test. The results were examined by the researchers using an intention-to-treat (ITT) methodology. The current study aimed to examine the effects of infection and ischemia on the wound healing process. An independent t-test and Mann-Whitney U test were used to evaluate wound size, toe-brachial index, transcutaneous oxygen tension, and infection rates in the two experimental groups.

3 | RESULTS

Participant recruitment was conducted in February and April 2023. In a study involving 84 people with diabetic foot ulcers, we randomly divided the 84 people into two groups, each consisting of 42 participants. One people in the modern dressing group refused to continue participation and were excluded from the trial, while 2 others refused due to comorbidities. Eighty-four men and women with diabetic foot ulcers remained for study after two placebo group participants were eliminated due to systemic diseases (Figure 1).

The age distribution of participants in the ozone group was 54.11 (13.45), while in the placebo group it was 52.13 (11.01) ($P = 0.622$). In the dressing group, the average (standard deviation) increase in body mass index (BMI) was 27.67 (5.56), while in the placebo group, it was 26.90 (5.12) ($P = 0.415$). Most dressing (60%) and placebo (55%) group participants were housekeepers (0.766). More than 35.1 high school of participants in the dressing and placebo categories were university 40.9% ($p = 0.341$). In the dressing and placebo groups, the duration of diabetes history was predominantly within three years of diabetes diagnosis ($p=0.347$).

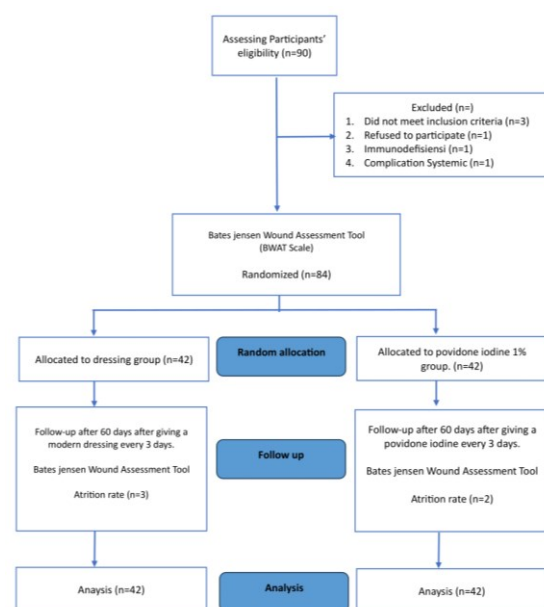


Figure 2. Flowchart of the study (CONSORT)

Table 1. Comparison of diabetic foot ulcer characteristics baseline between ozone and placebo groups.

Variable	Dressing group (n=42) Mean±SD and n (%)	Povidone Iodine 1% group (n=42) Mean±SD and n (%)	P-value
Age (Years) 53.12±12.26	54.11±13.45	52.13±11.07	*0.622
Body mass index (kg/m ²) 27.28±5.34	27,67±5.56	26.90 ±5.12	*0.415
Gender			
Male	20 (50.8)	18 (48.12)	**0.535
Female	22 (52.2)	24 (51.88)	
Level Education			
Junior high school	14 (33.7)	11 (24.8)	**0.539
High school	16 (35.1)	10 (34,3)	
University	12 (31.2)	16 (40,9)	
Occupation			
Housekeeper	18 (60.0)	20 (55.0)	**0.766

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Employed Worker	14 (25.3)	14 (36.7)	
Duration of diabetes			
Three years	34 (77.4)	26 (61.9)	**0.347
Four years	6 (14.1)	4 (13.7)	
>Five years	2 (8.5)	12 (24.4)	
Long-term diabetic foot ulcer			
1 years	13 (21.8)	9 (24.5)	**0.436
2 years	15 (37.8)	26 (65.1)	
>3 years	14 (40.4)	7 (10.4)	
Glicemic (mg/dl) 153.52±43.78	154.14±41.69	152.91±45.88	*0.568
HbA1c (mmol/L) 10.84±4.3	11.56±2.17	10.13±6.43	*0.136
Wagner scale			
Superficial ulcer	18 (61.2)	16 (37.27)	
Deep ulcer	7 (10.6)	12 (34.11)	**0.313
Absessed deep ulcer	10 (7.0)	8 (15.74)	
Limited Gangrene	7 (14.1)	6 (12.88)	
Wound Size (Cm) Baseline 25.61±12.14	32.8±16.11	18.14±8.17	*0.142

Primary data source 2023; Mean±Standard deviation; *Independent t-test, **Chi-square (χ^2)

The average length of treatment for diabetic foot ulcers was determined to be two years, with frequent recurrence of lesions in both the dressing and placebo groups ($p=0.436$). The average glycemic level, as shown by the mean (standard deviation), was found to be 154.14. Specifically, in the ozone group, the mean glycemic level was 189.6 (with a standard deviation of 41.69), while in the placebo group, it was 152.91 (with a standard deviation of 45.88). A p-value of 0.568 was obtained from the statistical analysis, indicating that there was no statistically significant difference seen between the two groups. The mean (standard

deviation) of glycated haemoglobin (HbA1c) was 11.56 (2.17), in the dressing group, and 10.13 (76.43) in the placebo group ($p=0.136$). According to the Wagner scale, the majority of diabetic foot ulcer severity was attributed to superficial ulcer. The mean percentage of superficial ulcers in the dressing group was 41.2%, while in the placebo group it was 37.27% ($p = 0.131$). Meanwhile, the wound size of baseline dressing group was 32.8 (16.11) and placebo was 18.14 (8.17) with a value of ($p=0.142$). Thus, we report all respondents' dermatographic data were homogeneous.

Table 2. Comparison of mean scores of wound healing size, and placebo groups

Variable	Dressing group (n=42) Mean±SD	Povidone Iodine 1% group (n=42) Mean±SD	Mean difference (95% Confidence Interval)	P-value	r^2/r_{rb}
Day 30 treatment	20.24±9.72	21.52±11.33	-1.94 (-4.37 to 0.14)	0.043*	-0.121*
Day 60 treatment	12.15±7.14	18.11±10.54	-5.14 (-11.50 to -1.34)	0.013*	-0.416*

Primary data source 2023; After controlling for the 30-day and 50-day score, the adjusted mean difference was independent t-test*, Mann–Whitney U**, effect size (r^2), and rank biserial correlation (r_{rb}).

The average (standard deviation) wound size score in the dressing group showed a non-significant drop from 32.8.6 (16.11) before therapy to 20.24 (9.72) at 30 days. However, a significant decrease of 12,15 (7.14) was observed at 60 days after dressing therapy. Furthermore, the average (standard deviation) wound size score in the povidone iodine group rose from 18.14 (8.17) to 21.52 (11.33) after

30 days, and then reduced to 18.11 (10.54) after 60 days. The study revealed a 60-day adjusted mean difference (AMD) of -5.14 (95% confidence range [CI]: -11.50 to -1.34, $P = 0.013$), indicating a moderate effect size with $r^2 = -0.416$. The results of this study demonstrated a statistically significant reduction in the size of diabetic foot ulcers after 60 days in the group using contemporary dressings, as

compared to the group using povidone iodine 1%. Consequently, the group that received the modern dressing intervention exhibited a more rapid rate of wound healing, as indicated in table 2.

4 | DISCUSSION

Consistent with a systematic review of wound healing (L. Zhang et al., 2019), the accelerated wound size reduction and wound repair of DFU with confidence intervals from 46.18 to 86.08 indicate positive aspects of the DFU healing process. Furthermore, there are no known examples of negative consequences associated with dressing application. Planimetric evaluation showed that the application of dressings every three days gave the tissues a chance to expand, leading to a considerable reduction in the surface area of the lesion (Lindholm & Searle, 2016). In addition, we found that dressing can reduce the intensity of pain during DFU wound care because the stable moisture during dressing changes does not stick to the surface which can create damaging new blood vessels of pain (Jiang et al., 2023). In addition, randomised controlled studies examining the effect of dressing showed a reduction in the surface area of lesions that had increased epithelialisation (Everett & Mathioudakis, 2018). The International Wound Bed Preparation Advisory Board (IWBPAB) introduced the idea of wound bed preparation to facilitate the transition of the wound bed from necrotic tissue and infection to a healthy state characterized by epithelialization. This remark aligns with the idea proposed (Gould et al., 2015), namely focusing on TIME management. Tissue management, including the assessment of the wound bed before to selecting the appropriate form of debridement (autolytic debridement and conservative sharp wound debridement), is referred to as Tissue Management (T) (Burhan et al., 2022). Infection inflammation control refers to the management of germ growth in a wound. Refers to moist balance management, which involves the management of moisture in wounds. The objective of this care is to facilitate wound healing by selecting an appropriate dressing, absorbing the discharge from the wound, and safeguarding the surrounding skin. Examples of materials include hydrogel, hydrocolloid, foam, alginate (Verdolino et al., 2021). Epithelialization advancement

management, also known as wound edge management, involves considering the wound margins to ensure optimal epithelialization process (Rousselle et al., 2019).

Observations of wound assessment in diabetic ulcer patients who underwent modern dressing wound treatment revealed a reduction in wound severity scores. Furthermore, it also demonstrates diminished necrotic tissue, decreased wound area, and the presence of granulation tissue. Modern dressings are suggested and regarded beneficial in accelerating the healing process of wounds in patients with diabetic ulcers. Additionally, the use of moist dressings can lower the risk of further injury to the lesion.

5 | STRENGTHS AND LIMITATIONS OF THE STUDY

This study employed quasi-experiments as the selected research methodology, which, by its research design, lacks statistical power. Allocation concealment was recognized as a significant methodological advantage for identifying the risk of bias. Caution should be exercised when interpreting the findings of this study due to several limitations. Consistent with prior research, this study gathered self-reported variations among enumerators in evaluating the extent of lesions or perceptual data among individuals with prior expertise in treating diabetic foot ulcers.

6 | IMPLICATION FOR THE PROFESSION AND/OR PATIENT CARE.

Implications for the profession and/or wound care: The results of this study contribute very important information for wound nurses, especially in the selection of primary and secondary dressing techniques as treatments. The findings will benefit wound care professionals, healthcare providers, researchers and academics who provide diabetic foot ulcer.

7 | CONCLUSIONS

Initially, the impact of topical ozone therapy on the reduction of wound size was not perceptible. However, the extended application of this therapeutic intervention has demonstrated significant efficacy in improving peripheral microcirculation, diminishing wound size, and

managing infection while healing diabetic foot ulcers. Future investigations should evaluate the impact of topical ozone on the maturation of biological and hematological systems.

AUTHOR CONTRIBUTIONS

Made substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data: Indra Ariani; Involved in drafting the manuscript or revising it critically for important intellectual content: Dimas Putra Harsya and Asmat Burhan; Gave final approval of the version to be published. Each author must participate sufficiently in the work to take public responsibility for the appropriate portion of the content: Indra Ariana; Agree to take responsibility for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work can be appropriately investigated and resolved: Dimas Putra Harsya and Asmat Burhan.

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None

CONFLICT OF INTEREST STATEMENT

The authors declare that they have no competing interests.

DATA AVAILABILITY

The datasets produced or examined in the present investigation can be obtained from the corresponding author upon a reasonable request.

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