ORIGINAL RESEARCH PAPER
Volume - 15 | Issue - 04 | April - 2026 | PRINT ISSN No. 2277 - 8179 | DOI : 10.36106/ijsr
INTERNATIONAL JOURNAL OF SCIENTIFIC RESEARCH

SAFETY AND EFFICACY OF TOPICAL DIPEROXOCHLORIC ACID VERSUS CONVENTIONAL POVIDONE-IODINE FOR CHRONIC NON-HEALING ULCERS

General Surgery

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ABSTRACT

Background: Chronic non-healing wounds place an immense clinical and financial strain on global healthcare systems [1]. While povidone-iodine (Betadine) remains a popular antiseptic choice, its prolonged application can induce cellular toxicity that hampers tissue repair [3]. This study evaluated the clinical safety and wound-healing efficacy of a Diperoxochloric acid (DPCA) topical solution compared to standard Betadine dressings.**Methods:** A randomized controlled trial was conducted involving 100 participants suffering from chronic leg ulcers. Individuals were allocated equally to receive either DPCA or Betadine (50 per arm). Early area reduction (Day 7), Percentage Area Reduction (PAR) at Day 30, overall healing at Day 180, closure duration, and adverse events were tracked.**Results:** By Day 7, wounds treated with DPCA decreased in size significantly more than those in the control group (1.9 cm^2 vs. 0.8 cm^2, $p = 0.041$). At the four-week mark, the DPCA cohort reached a 32.3% PAR, vastly outperforming Betadine's 15.4% reduction ($p < 0.0001$). Ultimately, 76.0% of DPCA-treated ulcers closed entirely by 180 days, compared to 60.0% in the control arm ($p = 0.014$). DPCA also shortened the median closure time to 42 days (versus 56 days for Betadine, $p < 0.01$) and demonstrated a superior safety profile.**Conclusion:** DPCA is a highly effective, well-tolerated alternative to povidone-iodine. It accelerates wound contraction and increases definitive closure rates without the toxic side effects associated with traditional antiseptics [4].

KEYWORDS

INTRODUCTION

The global prevalence of chronic non-healing ulcers poses a relentless challenge for medical professionals [1]. Typically defined as a tissue defect that fails to progress toward anatomical closure within four to six weeks, these ulcers are sustained by complex local and systemic barriers, including poor tissue perfusion, exaggerated protease activity, and an arrested inflammatory phase [1].

Bacterial biofilms are central drivers of wound chronicity [2]. These robust microbial communities resist host immune clearance and heavily blunt the efficacy of standard antimicrobial therapies [2]. Povidone-iodine (Betadine) is frequently utilized to manage this bioburden due to its broad-spectrum properties and cost-effectiveness. However, recent studies suggest that prolonged iodine exposure may lead to damages delicate microcapillary networks and suppresses fibroblast proliferation, inadvertently delaying re-epithelialization [3]. Such limitations have spurred the search for alternative topical agents capable of eradicating infection while actively supporting cellular repair. Diperoxochloric acid (DPCA) represents a novel class of oxidizing solutions [4]. By generating targeted reactive oxygen species (ROS), DPCA quickly dismantles mature biofilms without exerting toxic effects on viable host tissues [5]. This randomized controlled trial was initiated to directly compare the therapeutic efficacy and safety of DPCA against standard Betadine dressings in a cohort of patients with chronic non-healing leg wounds.

Materials and Methodology

Study Design

A hospital-based, randomized controlled trial was executed within the General Surgery Department at GSVM Medical College and LLR Hospital (Kanpur) from 2024 to 2026.

Participants

The trial enrolled 100 eligible participants who provided written informed consent.

Inclusion criteria: Adults aged 18 to 75 years diagnosed with chronic non-healing lower extremity wounds (such as diabetic, pressure, or venous ulcers) persisting for ≥ 3 weeks. Eligible patients had a wound area of ≤ 15 cm^2, random blood sugar (RBS) levels under 250 mg/dL, and HbA1c below 9%.

Exclusion criteria: Individuals exhibiting severe clinical infection (defined by copious purulence or a total leukocyte count > 20,000) or active cellulitis were excluded.

Randomization and Intervention

To eliminate selection bias, patients were assigned in a 1:1 ratio into two parallel arms (50 individuals per group). The experimental group received Diperoxochloric Acid (DPCA/Woxheal), an agent that targets fibroblast proliferation via selective ROS generation [4]. A conventional dressing protocol using povidone-iodine was applied to the control cohort.

Sample Size Calculation

To compare independent means, we employed a standard power analysis formula to establish the necessary sample size. Relying on preliminary data, a pooled standard deviation for wound size reduction of 4 cm^2 and a minimum expected clinical difference of 2 cm^2 were estimated. This calculation established a target of roughly 63 patients per arm. Balancing statistical power with logistical constraints, a final sample size of 100 participants was selected.

Statistical Analysis

Clinical data were processed using SPSS version 21. Continuous metrics were analyzed via independent t-tests or Mann-Whitney U tests, whereas categorical outcomes were assessed using Chi-square or Fisher's exact tests. Multivariable logistic regression and Receiver Operating Characteristic (ROC) curve analysis were also applied to identify independent predictors of healing. A p-value < 0.05 determined statistical significance.

RESULTS

Baseline Demographics and Clinical Profile

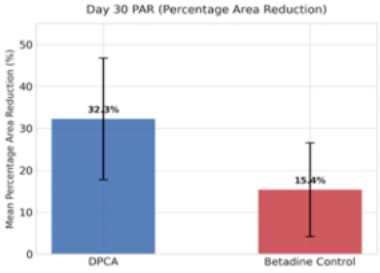
The mean age of participants was 44.7 ± 13.4 years, with a slight majority being male (54.0%). Initial wound dimensions were virtually identical across both groups (DPCA: 24.1 ± 11.5 cm^2; Betadine: 23.4 ± 11.2 cm^2), confirming robust geometric homogeneity prior to treatment ($p = 0.81$). It was noted that elevated baseline HbA1c levels directly correlated with larger ulcer areas ($p = 0.012$). Geographic location had no measurable impact on healing velocity ($p = 0.45$).

Efficacy and Healing Trajectories

DPCA consistently outperformed Betadine across every measured time interval.

Days 1–7: DPCA facilitated a significantly larger initial reduction in ulcer area (1.9 cm^2 vs. 0.8 cm^2, p = 0.041).

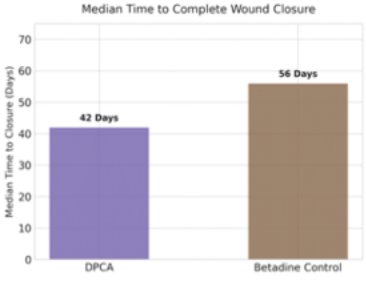
Day 30: The experimental cohort recorded a mean Percentage Area Reduction (PAR) of 32.3%, more than double the 15.4% observed in the control group ($p < 0.0001$). Notably, 42.0% of DPCA patients surpassed the critical 50% PAR threshold, compared to a mere 16.0% of Betadine patients.



Days 60 and 90: At Day 60, cumulative geometric reduction hit 61.0% for DPCA and only 30.7% for Betadine ($p < 0.001$). By Day 90, complete closure occurred in 38.0% of the DPCA arm versus 12.0% of the control group ($p < 0.01$).

Day 180: Over the six-month observation window, 76.0% of the DPCA-treated ulcers closed completely. The Betadine group lagged at 60.0% (p = 0.014).

Furthermore, DPCA accelerated the median healing timeline to 42 days, reducing the median closure time by two weeks compared to Betadine (56 days) ($p < 0.01$).



Predictors of Delayed Healing

Multivariable logistic regression identified four distinct variables that independently predicted delayed healing (defined as an open ulcer at Day 180): initial wound area > 25 cm^2 (OR 4.82, p = 0.002), active tobacco use (OR 3.95, p = 0.011), HbA1c > 8.0% (OR 3.44, p = 0.024), and placement in the Betadine treatment arm (OR 2.85, p = 0.035). Furthermore, ROC curve analysis confirmed that achieving a PAR of ≥ 50% by Day 30 serves as a powerful diagnostic predictor for successful closure at Day 180 (AUC = 0.915, Sensitivity 72.4%, Specificity 88.6%).

Safety Profile

DPCA proved to be exceptionally well-tolerated. Only a single patient (2.0%) noted transient local itching. Conversely, the Betadine group suffered from higher frequencies of localized erythema (8.0%), paradoxical ulcer expansion (4.0%), and localized gangrenous changes (2.0%).

DISCUSSION

Successfully managing chronic ulcers requires interventions that balance antimicrobial power with cellular preservation [2]. Our findings clearly indicate that Diperoxochloric acid (DPCA) achieves this balance far better than traditional povidone-iodine.

During the first week, DPCA initiated a more aggressive reduction in wound dimensions. This early shrinkage reflects efficient bioburden eradication without the collateral cellular damage commonly seen with harsh antiseptics [5]. In vitro models corroborate this, demonstrating that oxidative solutions effectively penetrate biofilms without inhibiting local fibroblast activity [5,8].

The clinical divergence became undeniable at the four-week mark. The DPCA group achieved an impressive 32.3% PAR, vastly eclipsing the control group. Because achieving a 50% reduction within the first month is a widely accepted prognostic indicator for ultimate closure, the fact that nearly half of the DPCA patients met this benchmark highlights the solution's ability to shift stagnant wounds back into a proliferative state. These outcomes align with recent literature identifying oxidative regimens as superior drivers of granulation tissue in infected neuropathic and venous ulcers [6,7].

By the end of the six-month study, DPCA had secured definitive closure in 76.0% of cases. The clinical stalling observed in the Betadine arm (60.0% closure) underscores the iatrogenic risks of prolonged iodine application [3]. Continuous exposure to such agents frequently paralyzes keratinocyte migration and suppresses angiogenesis, effectively halting the proliferative phase [3]. DPCA avoids this trap entirely. By safely generating ROS, it disrupts biofilms and maintains host cell viability, paving a much faster, safer pathway to re-epithelialization [4,8].

CONCLUSION

Topical Diperoxochloric acid (DPCA) provides a robust, safe, and highly effective therapeutic alternative to conventional Betadine dressings for chronic non-healing ulcers. Patients managed with DPCA benefited from rapid early wound contraction, exceptional four-week area reduction, and a much higher likelihood of permanent closure at six months. By avoiding the cytotoxic complications inherent to sustained iodine use, DPCA represents a substantial advancement in routine surgical wound care.

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