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A Comparative study of Effectiveness between Topical Diperoxochloric acid versus Normal Saline dressings in Management of Diabetic Foot Ulcers

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KEYWORDS

Diabetic foot ulcer, Wound healing, Diperoxochloric acid, Normal saline, Granulation tissue, Randomized controlled trial

ABSTRACT:

Background: Diabetic foot ulcers (DFU) are a common and severe complication of diabetes, often leading to prolonged morbidity and risk of amputation. Effective wound care strategies, including topical agents, are essential to promote healing and prevent complications.

Objectives: To compare the effectiveness of topical Diperoxochloric acid and normal saline dressings in managing DFU; and to evaluate the specific efficacy of Diperoxochloric acid in promoting ulcer healing.

Methods: This was a single centre, hospital based, prospective, randomized controlled trail conducted in the Department of General Surgery, JSS Medical College, Karnataka, India for a duration of 18 months.

Results: Baseline characteristics including age, gender, comorbidities, BMI, smoking status, haemoglobin, HbA1C, and wound culture results were statistically comparable between the topical Diperoxochloric acid dressings (TDCA) and normal saline dressings (NS) groups (N = 71 in each group). Ulcer size reduction was significantly greater in the TDCA group, with a mean surface area of 3.8 cm^2 at Week 2 compared to 4.9 cm^2 in the NS group ($p = 0.001$), and the percentage reduction in ulcer surface area was markedly higher in the TDCA group (40.4%) than in the NS group (11.2%; $p = 0.002$). Granulation tissue formation was significantly more frequent in the TDCA group, observed in 73.2% by Week 2 versus 40.8% in the NS group ($p < 0.001$), indicating faster wound healing progression. The mean BWAT score decreased significantly in the TDCA group to 26.6 by Week 2 compared to 33.5 in the NS group ($p < 0.001$), reflecting superior wound improvement. Additionally, adverse events were lower in the TDCA group (23.9%) than in the NS group (47.9%; $p = 0.005$), with notably fewer wound infections (1.4% vs. 14.1%; $p = 0.008$).

Conclusion: Topical Diperoxochloric acid was found to be significantly more effective than normal saline in enhancing wound healing in DFU. It offers superior outcomes in terms of ulcer size reduction, granulation tissue formation, and infection control.

Introduction

Diabetes mellitus is one of the most pressing global health challenges of the 21st century. Its prevalence continues to rise dramatically, largely due to changes in lifestyle patterns, increasing physical inactivity, and the global obesity epidemic. According to the International Diabetes Federation, approximately 8.3% of the global population is affected by diabetes.(1, 2) In India alone,

Journal of Chemical Health Risks

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there are an estimated 77 million people living with diabetes, and this number is steadily growing.(3) Foot ulcers are among the most common and serious complications encountered in diabetic patients. The lifetime risk of a diabetic individual developing a foot ulcer is around 25%, and the risk of ulcer recurrence within three years after healing is as high as 50%.(4, 5) As the severity of diabetic foot ulcers (DFUs) increases, so too does the risk of lower-limb amputation. Major amputation rates in diabetics are 5–10 times higher than in non-diabetics.(6, 7) Notably, DFUs account for approximately 80% of all non-traumatic lower-limb amputations in India each year.(5, 8) One of the critical challenges in managing diabetic foot infections is the blunted pain perception due to peripheral neuropathy. Consequently, diabetic patients may not recognize the presence or severity of an infection until substantial tissue damage has occurred. In addition, an immunocompromised state inherent to diabetes often leads to rapid infection progression, with serious complications such as cellulitis, abscesses, and osteomyelitis if not promptly treated.(9)

Effective management of DFUs involves several strategies, including glycaemic control, infection management, debridement, pressure offloading, and wound care.(10) Among these, wound dressings play an integral role. Various types of wound dressings have been developed for DFUs, including moist dressings, antimicrobial dressings, and topical agents.(11) However, none have shown universal effectiveness in accelerating wound healing.(12) Consequently, research continues into more effective topical treatments. One promising topical agent is Diperoxochloric acid, a bifunctional antibacterial molecule. Diperoxochloric acid has shown dual action — it possesses potent antimicrobial properties while simultaneously stimulating fibroblast proliferation, a critical step in wound healing. Studies have demonstrated that Diperoxochloric acid can disinfect the wound base, reducing the microbial load to nearly zero within two hours, and promote fibroblast activity in Medical Research Council cell strain 5 (MRC-5) fibroblast cell lines.(13) Diperoxochloric acid ($HClO_5$) is an extremely powerful oxidizing agent. Its mechanism of action involves the release of highly reactive oxygen species (peroxyl radicals and chlorine radicals), which initiate oxidative reactions leading to microbial death. When Diperoxochloric acid comes into contact with biological tissues, it transfers oxygen atoms to microbial components, leading to the destruction of pathogens. Moreover, the stimulation of fibroblast proliferation contributes to granulation tissue formation and subsequent wound closure.(14) Recent case reports have highlighted the successful use of Diperoxochloric acid in treating infected diabetic foot ulcers complicated by osteomyelitis, indicating its potential as an effective adjunct in DFU management.(15) Given the high morbidity, mortality, and economic burden associated with DFUs, there is an urgent need for novel, effective, and affordable treatments. In this context, the present study aims to compare the effectiveness of topical Diperoxochloric acid against conventional normal saline dressings in the management of DFU, with the goal of improving patient outcomes and reducing the burden of diabetic complications.

Materials and Methods

This was a single centre, hospital-based, prospective, randomized controlled trail conducted in the outpatient department and/or inpatient wards of the Department of General Surgery, JSS Medical College, Mysuru, Karnataka, India for a duration of 18 months. The study was approved by the Institutional Human Ethics Committee (IHEC). The participants (and their attenders) were given the Participant Information Sheet (PIS) in their native language, and its contents were verbally explained to ensure their understanding and satisfaction. Enrolment into the study proceeded upon receipt of written informed consent. Patients >18 years of age, of both gender, with a diagnosis/past history of diabetes, presenting with diabetic foot infections for the first time, with DFUs of Grade 1 and 2 of Wagner's classification were included. However, patients with X-rays showing features of osteomyelitis; DFUs of Grade 3, 4, or 5 of Wagner's classification; doppler showing gross atherosclerotic arterial changes and venous abnormalities including varicosities of lower limbs; and septicaemia were excluded.

The sample size was calculated to detect a difference in mean ulcer–surface area reduction between topical Diperoxochloric acid (μ_1=3.5 cm²; σ_1=1.75 cm²) and normal saline dressings (μ_2=2.75 cm²; σ_2=1.4 cm²), with equal allocation. Using the standard formula for two

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independent means with two-sided α=0.05 ($Z_{1-\alpha/2}$=1.96) and 80% power (β=0.20; $Z_{1-\beta}$=0.84), the assumed mean difference was 0.75 cm². The resulting sample size was 71 participants per group (total N=142). We used nonprobability sampling technique – purposive sampling/complete enumeration to enrol patients. Following initial assessment, wound debridement was carried out under strict aseptic precautions. After visually inspecting the wound, a wound swab was collected and sent for routine culture and sensitivity analysis. A meticulous wound cleansing protocol was followed, involving a thorough wash with povidone-iodine (betadine) and hydrogen peroxide solutions. Debridement was performed until fresh bleeding from the wound bed was achieved, ensuring removal of all necrotic and slough tissue. Following debridement, participants were randomized into two groups (using a computer-generated random number sequence; allocation concealment was maintained through the use of sealed, opaque, sequentially numbered envelopes prepared by an independent third party): the control group, which received conventional normal saline dressings (Group NS), and the intervention group, which received topical Diperoxochloric Acid dressings (Group TDCA). In the intervention group, the wound bed was sprayed with Diperoxochloric acid and dressed every alternate day, whereas in the control group, normal saline dressings were applied according to standard wound care protocols. No local antiseptics were applied in either group to maintain consistency across treatments. Wound dimensions, including surface area and depth, were documented at baseline and on the 7th (Week 1) and 15th days (Week 2) of treatment. Surface area was measured by tracing the wound margins onto transparent plastic sheets, which were subsequently transferred onto graph paper for accurate area calculation. Wound assessments were performed by a blinded observer to eliminate assessment bias. Parameters such as size reduction, depth, granulation tissue formation, and the presence of pus were systematically recorded at each time point. Antibiotic therapy was administered to all participants according to the results of the wound culture and sensitivity tests. Throughout the study, adverse effects such as pain, rash, or signs of local irritation were carefully monitored. Patients exhibiting adverse reactions were withdrawn from the study and managed appropriately. The primary outcome was the percentage of reduction in ulcer surface area, calculated using the formula: Percentage of change = [(pretreatment surface area – final surface area)/pretreatment surface area] x 100. Granulation tissue development and ulcer readiness for grafting were additionally assessed by the treating consultant at each follow-up point. The interventions continued for a duration of two weeks, after which final assessments were performed and recorded for analysis.

Statistical analysis: The data obtained was manually entered into Microsoft Excel, coded, and recoded. The analysis was done using Statistical Package for Social Sciences (SPSS) v27. All the categorical variables were summarised using frequencies/numbers and percentages. Continuous variables were summarized using mean (standard deviation) and/or median (interquartile range) (based on the results of data normality, tested using Kolmogorov–Smirnov test and the Shapiro–Wilk test). To test for association and baseline comparison of study groups, Chi square test or Fisher exact test (for categorical variables) and independent 't' test (for continuous variables) was used. The before and after treatment comparison was done based on repeated measures analysis of variance (ANOVA) test. Statistical significance was considered at p value less than 0.05.

Results

Of 154 patients screened, 12 were excluded (7 ineligible, 5 declined), and 142 were randomized 1:1 to TDCA (n=71) or normal saline (n=71). All participants received their allocated intervention with no deviations or withdrawals, and no losses to follow-up occurred. The final analysis included all 142 patients (71 per group), with evaluations at baseline (day 0), week 1, and week 2. Baseline characteristics were comparable between groups. Mean age was 51.5 (11.6) years in TDCA vs 49.5 (11.1) in NS (p=0.483); males comprised 57.7% vs 60.6% (p=0.711); BMI 24.7 (1.8) vs 25.0 (2.2) kg/m² (p=0.587). Comorbidities were similar: hypertension 21.1% vs 15.5% (p=0.393), chronic kidney disease 12.7% vs 12.7% (p=1.000), coronary artery disease 14.1% vs 14.1% (p=1.000). Glycaemic control and labs were alike—HbA1c 9.7 (1.5)% vs 10.3 (1.4)% (p=0.103), haemoglobin 10.2 (1.6) vs 10.2 (1.8) g/dL (p=0.999); culture positivity was ~50% in both (50.7% vs 49.3%, p=0.860).

Journal of Chemical Health Risks

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JCHR (2025) 15(5), 1595-1604 | ISSN:2251-6727

At baseline, ulcer size was similar between groups (TDCA 6.8±1.9 vs NS 6.7±2.3 cm²; p=0.561). By week 1, TDCA showed a greater reduction (4.8±1.5 vs 6.5±2.4 cm²; p=0.001), sustained at week 2 (3.8±1.2 vs 4.9±1.3 cm²; p=0.001), corresponding to a larger overall percentage shrinkage with TDCA (40.4%±21.9% vs 11.2%±47.5%; p=0.002). Granulation tissue appeared earlier and more frequently in the TDCA arm (week 1: 53.5% vs 29.6%; week 2: 73.2% vs 40.8%; both p<0.001). Wound quality, assessed by the Bates-Jensen score, improved more by week 2 with TDCA (26.6±5.7 vs 33.5±8.8; p<0.001), while within-group time effects were significant for both arms on repeated-measures ANOVA (p<0.001). Overall, TDCA produced faster and greater ulcer improvement over two weeks than normal saline.

Adverse events were less frequent with TDCA than normal saline (any event: 23.9% [17/71] vs 47.9% [34/71]; p=0.005). Notably, wound infection occurred far less often in the TDCA group (1.4% vs 14.1%; p=0.008). Other events—pain at the wound site (12.7% vs 19.7%; p=0.260), skin irritation/rash (5.6% vs 9.9%; p=0.343), peri-wound maceration (4.2% vs 7.0%; p=0.464), and allergic reaction (0% vs 1.4%; p=1.000)—were infrequent and did not differ significantly.

Discussion

The present study aimed to evaluate the comparative effectiveness of topical Diperoxochloric acid and normal saline dressings in patients with diabetic foot ulcers. The baseline characteristics of the two groups demonstrated homogeneity, indicating the appropriateness of randomization and strengthening the internal validity of the study outcomes. The mean age of participants was 51.5 years (SD = 11.6) in the TDCA group and 49.5 years (SD = 11.1) in the NS group, with no statistically significant difference. Age is an important variable as delayed wound healing in diabetic patients can often be exacerbated by advancing age due to compromised vascular integrity and reduced immune response.(16) The comparability of age distribution between groups suggests that the observed differences in ulcer healing were unlikely to be influenced by age-related factors. Gender distribution was also statistically comparable, with males comprising 57.7% of the TDCA group and 60.6% of the NS group. Since some studies have reported gender-related differences in peripheral vascular disease and foot ulcer healing,(17) maintaining a balanced distribution minimizes this as a confounder. Comorbidities, which can significantly influence wound healing and infection susceptibility,(18) were present in 49.3% of TDCA patients and 40.8% of NS patients, again reflecting comparable baseline health status. Specific comorbid conditions such as hypertension, chronic kidney disease, and coronary artery disease showed no statistically significant intergroup differences, thereby ruling out differential comorbidity burden as a potential confounder in interpreting treatment outcomes.

Body mass index, an important determinant of metabolic health and wound healing dynamics,(19, 20) was similar in both groups—24.7 kg/m² in the TDCA group and 25.0 kg/m² in the NS group (p = 0.587). Obesity has been linked with delayed ulcer healing due to impaired angiogenesis and local tissue hypoxia,(21) and the comparable BMI values in this study further support the validity of outcome differences being attributed to the intervention rather than baseline nutritional status. Smoking, a known risk factor for peripheral arterial disease and poor ulcer healing,(22) was reported in 42.3% of the TDCA group and 39.4% of the NS group (p = 0.729), suggesting no significant variation in vascular risk profiles between the cohorts.

The haemoglobin levels were equivalent in both groups (mean = 10.2 g/dL), with no significant difference. Ferris & Harding (2019) noted that anaemia is associated with tissue hypoxia and poor wound healing,(23) and the observed parity suggests that oxygen delivery to wound tissues was unlikely to be a confounding factor. Similarly, the mean HbA1C, which reflects long-term glycaemic control, was 9.7% in the TDCA group and 10.3% in the NS group, and although slightly lower in the former, the difference was not statistically significant. Armstrong et al. (2017) noted that poor glycaemic control is a major predictor of delayed wound healing in diabetes,(24) and the relatively high but comparable values in both groups reaffirm the relevance of the treatment effect as the primary contributor to differences in wound outcomes. Wound culture positivity, an indicator of baseline infection burden, was nearly equal in both groups—50.7% in the TDCA group and 49.3% in the NS group. As infection can delay granulation and epithelialization,(25) this comparability confirms that

Journal of Chemical Health Risks

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JCHR (2025) 15(5), 1595-1604 | ISSN:2251-6727

both groups started with similar microbial challenges, ensuring that observed healing differences were not confounded by infection status.

The most crucial clinical variable in the study was the change in ulcer size. At baseline, ulcer surface areas were comparable (6.8 cm^2 in TDCA vs. 6.7 cm^2 in NS). However, a significant difference emerged by Week 1, with the TDCA group demonstrating a reduction to 4.8 cm^2 compared to 6.5 cm^2 in the NS group. This trend continued into Week 2, with the TDCA group showing a further reduction to 3.8 cm^2, while the NS group averaged 4.9 cm^2. Repeated measures ANOVA confirmed a significant interaction effect over time, validating the progressive and superior reduction in ulcer size within the TDCA group. The percentage reduction in ulcer surface area over two weeks further highlighted this effect, with TDCA achieving a mean reduction of 40.4% (SD = 21.9) versus only 11.2% (SD = 47.5) in the NS group. These findings are consistent with prior evidence suggesting that topical diperoxochloric acid promotes wound healing through multiple mechanisms, including broad-spectrum antimicrobial activity, reduction of oxidative stress, and stimulation of local tissue regeneration.(13) The rapid reduction in wound size observed with TDCA may be explained by its role in modulating the inflammatory response and promoting early granulation tissue formation. Diperoxochloric acid has been shown to enhance fibroblast proliferation and angiogenesis, which are critical for wound closure. In contrast, normal saline, while effective as a moist wound healing agent, lacks intrinsic antimicrobial or pro-regenerative properties.(26)

In the present study, at baseline, neither group exhibited granulation tissue, indicating that all participants began the study at a similar phase of wound healing. By Week 1, granulation tissue formation was observed in over half of the participants in the TDCA group (53.5%) compared to less than one-third in the NS group (29.6%), with this difference being statistically significant. This effect was even more pronounced by Week 2, with 73.2% of participants in the TDCA group developing granulation tissue compared to 40.8% in the NS group. The marked difference in granulation tissue development highlights the role of topical diperoxochloric acid in promoting the proliferative phase of wound healing. This may be attributed to the agent's ability to facilitate fibroblast activity, enhance neovascularization, and maintain an optimal moist wound environment while exerting antimicrobial action, as documented in previous clinical studies on oxidative antiseptics in chronic wound care.(13) Further evidence supporting improved wound healing in the TDCA group was derived from the Bates-Jensen Wound Assessment Tool scores. At baseline, the BWAT scores were comparable between the two groups, with the TDCA group averaging 46.3 (SD = 7.6) and the NS group averaging 43.9 (SD = 6.8), a difference that was not statistically significant. Although both groups showed some improvement by Week 1, the difference in scores remained statistically non-significant. However, by Week 2, the TDCA group demonstrated a significantly lower mean BWAT score of 26.6 (SD = 5.7) compared to 33.5 (SD = 8.8) in the NS group ($p < 0.001$), indicating a more substantial improvement in wound status. The BWAT is a validated composite measure that assesses multiple domains of wound healing, including tissue type, exudate, and surrounding skin condition.(27) The significant reduction in BWAT score in the TDCA group reinforces the clinical impression of accelerated and more effective wound repair.

Importantly, the safety profile of DCA dressings was also favourable. Adverse events occurred in only 23.9% of participants in the TDCA group compared to 47.9% in the NS group, a statistically significant difference. Among specific adverse events, pain at the wound site was reported by 12.7% of DCA-treated participants versus 19.7% in the NS group, while skin irritation or rash occurred in 5.6% versus 9.9% of participants, respectively. Peri-wound maceration was noted in 4.2% of DCA participants and 7.0% of NS participants. Although these individual adverse events did not reach statistical significance, the overall lower rate of complications in the TDCA group suggests better local tissue compatibility. Most notably, wound infection—a critical complication in DFU management—occurred in only 1.4% of participants in the TDCA group compared to 14.1% in the NS group, a difference that was statistically significant. This outcome aligns with the known broad-spectrum antimicrobial properties of TDCA, which has been shown to effectively reduce microbial load and prevent secondary infections. No allergic reactions were observed in the TDCA group, further supporting its favourable tolerability.

Journal of Chemical Health Risks

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The present study has several limitations that should be considered when interpreting the findings. Being a single-centre trial conducted at a tertiary care institution, the generalizability of the results to broader populations, including primary care or rural settings, may be limited. Although randomization was employed, the nonprobability purposive sampling technique could introduce selection bias. The relatively short follow-up period of two weeks may not fully capture long-term wound healing trajectories, recurrence rates, or delayed complications such as reinfection or graft failure. Additionally, while the study controlled for many baseline variables, unmeasured confounders such as nutritional status, patient compliance with offloading, and glycaemic control during the intervention period may have influenced outcomes. The subjective nature of some outcome measures, despite the use of standardized tools like the BWAT, may introduce observer bias, although efforts were made to blind outcome assessors.

Conclusion

In conclusion, the present study demonstrates that topical Diperoxochloric acid is significantly more effective than normal saline dressings in promoting wound healing in patients with diabetic foot ulcers. The use of Diperoxochloric acid resulted in greater ulcer size reduction, accelerated granulation tissue formation, improved wound assessment scores, and a lower incidence of wound infections and adverse events. These findings suggest that Diperoxochloric acid is a safe and efficacious alternative to conventional dressings in the management of diabetic foot ulcers, with the potential to enhance clinical outcomes and reduce complication rates.

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Journal of Chemical Health Risks

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Journal of Chemical Health Risks

www.jchr.org

JCHR (2025) 15(5), 1595-1604 | ISSN:2251-6727

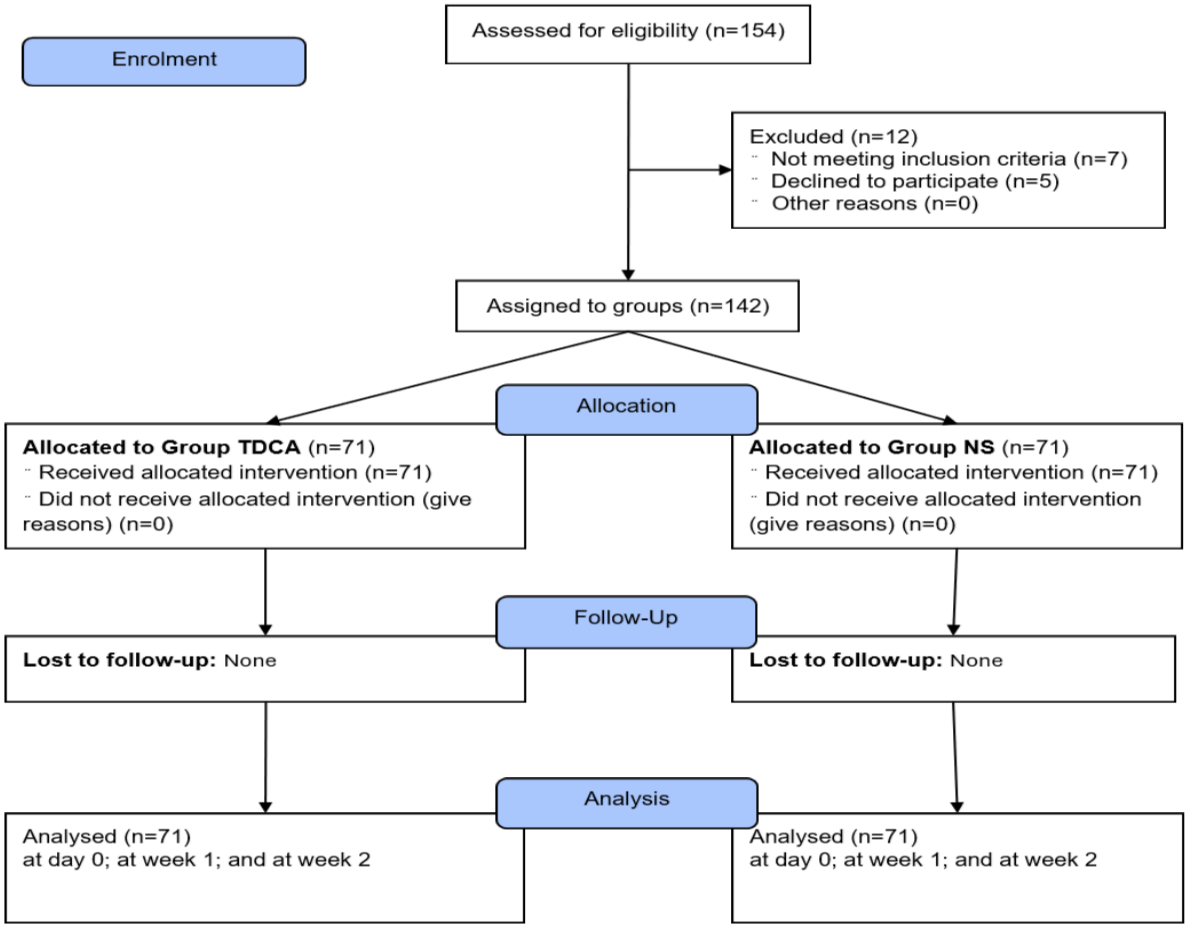

Figure 1: CONSORT flow diagram

Table 1: Baseline characteristics of the study groups

		Group TDCA N = 71	Group NS N = 71	P value
		n (%)	n (%)	
Age (in years), Mean (SD)		51.5 (11.6)	49.5 (11.1)	0.483
Age (in years)	≤50	32 (45.1)	34 (47.9)	0.794
	>50	39 (54.9)	37 (52.1)	
Gender	Female	30 (42.3)	28 (39.4)	0.711
	Male	41 (57.7)	43 (60.6)	
Comorbidities	Present	35 (49.3)	29 (40.8)	0.336
	Absent	36 (50.7)	42 (59.2)	
Hypertension	Present	15 (21.1)	11 (15.5)	0.393
	Absent	56 (78.9)	60 (84.5)	
Chronic kidney disease	Present	9 (12.7)	9 (12.7)	1.000
	Absent	62 (87.3)	62 (87.3)	
Coronary artery disease	Present	10 (14.1)	10 (14.1)	1.000
	Absent	61 (85.9)	61 (85.9)	

Journal of Chemical Health Risks

www.jchr.org

JCHR (2025) 15(5), 1595-1604 | ISSN:2251-6727

BMI (in kg/m2), Mean (SD)		24.7 (1.8)	25.0 (2.2)	0.587
Smoking	Present	30 (42.3)	28 (39.4)	0.729
	Absent	41 (57.7)	43 (60.6)	
Haemoglobin (in g/dl), Mean (SD)		10.2 (1.6)	10.2 (1.8)	0.999
HbA1C (in %), Mean (SD)		9.7 (1.5)	10.3 (1.4)	0.103
Culture	Positive	36 (50.7)	35 (49.3)	0.860
	Negative/no growth	35 (49.3)	36 (50.7)	
*Statistically significant at p<0.05 SD, Standard deviation				

Table 2: Comparison of study groups by ulcer size, change (reduction) in ulcer surface area, granulation and Bates-Jensen Wound Assessment Tool

		Group TDCA N = 71	**Group NS N = 71**	**P value**
		Mean (SD)	**Mean (SD)**	
Ulcer size (in cm^2)	Day 0	6.8 (1.9)	6.7 (2.3)	0.561
	Week 1	4.8 (1.5)	6.5 (2.4)	0.001*
	Week 2	3.8 (1.2)	4.9 (1.3)	0.001*
	RM-ANOVA	<0.001*	<0.001*	
Change (reduction) in ulcer surface area (in %)		40.4 (21.9)	11.2 (47.5)	0.002*
Granulation	Day 0	0 (0.0)	0 (0.0)	1.000
	Week 1	38 (53.5)	21 (29.6)	<0.001*
	Week 2	52 (73.2)	29 (40.8)	<0.001*
Bates-Jensen Wound Assessment Tool	Day 0	46.3 (7.6)	43.9 (6.8)	0.202
	Week 1	34.8 (9.0)	38.5 (7.5)	0.089
	Week 2	26.6 (5.7)	33.5 (8.8)	<0.001*
	RM-ANOVA	<0.001*	<0.001*	
*Statistically significant at p<0.05 RM-ANOVA, Repeated measures analysis of variance				

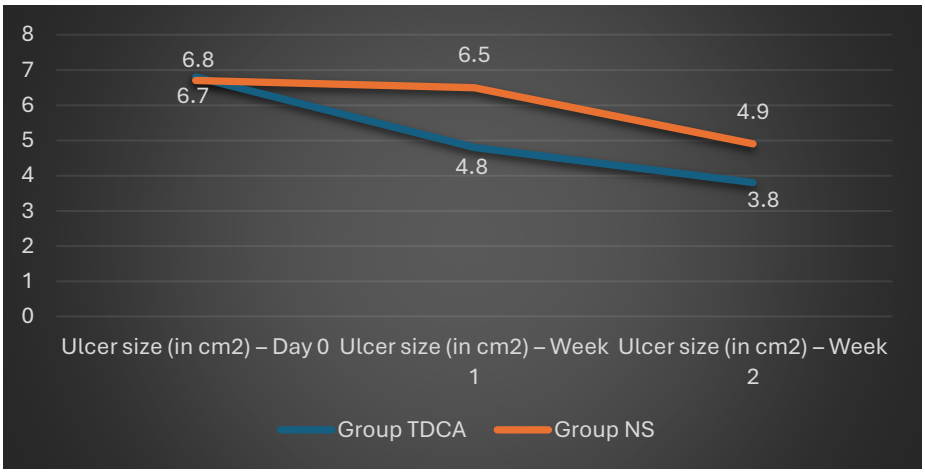

Figure 2: Comparison of study groups, by ulcer size

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Table 3: Comparison of study groups by adverse events

	Group TDCA N = 71	**Group NS N = 71**	**P value**
	n (%)	**n (%)**	
Pain at wound site	9 (12.7)	14 (19.7)	0.260
Skin irritation/rash	4 (5.6)	7 (9.9)	0.343
Peri wound maceration	3 (4.2)	5 (7.0)	0.464
Wound infection	1 (1.4)	10 (14.1)	0.008*
Allergic reaction	0 (0.0)	1 (1.4)	1.000
Total	17 (23.9)	34 (47.9)	0.005*
*Statistically significant at $p<0.05$			