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Efficacy of Trichloroacetic Acid Versus Cryotherapy in Patients with Xanthelasma Palpebrarum: A Randomized Controlled Trial

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ABSTRACT

Xanthelasma palpebrarum is a common benign eyelid lesion with multiple treatment options. **Objectives:** To compare the efficacy and safety of 100% trichloroacetic acid (TCA) versus cryotherapy in its management. **Methods:** A randomized controlled trial was conducted at the Department of Dermatology, Nishtar Hospital, Multan, from November 2024 to April 2025. Sixty patients with untreated bilateral xanthelasma palpebrarum were enrolled using non-probability consecutive sampling and randomly assigned using a computer-generated simple randomization technique (1:1) to receive either 100% trichloroacetic acid or cryotherapy. Treatment efficacy and adverse effects were evaluated at six weeks using standardized clinical criteria. Data were analyzed using SPSS version 26. A confidence level of 95% was used for all statistical analyses. Results were considered statistically significant at a p-value≤0.05. **Results:** A total of 60 patients (30 patients in each group) with xanthelasma palpebrarum were enrolled, with a mean age of 40.10 ± 7.40 years and a mean disease duration of 11.18 ± 2.94 months. Females comprised 60.0% of the sample, and 63.3% were aged 36–55 years. Excellent treatment response was observed in 53.3% of patients treated with 100% TCA and 20.0% with cryotherapy (p=0.023). Hyperpigmentation (p=0.020) and scarring (p=0.010) were significantly higher in the TCA group. Age, gender, and lesion location showed no significant association with efficacy or adverse effects. **Conclusions:** TCA offers superior clinical efficacy compared to cryotherapy but with a higher risk of adverse cosmetic effects, underscoring the need for individualized treatment planning in xanthelasma management.

INTRODUCTION

Xanthelasma palpebrarum (XP) is the most commonly encountered type of cutaneous xanthoma, marked by yellowish plaques over the medial aspects of the eyelids [1]. These lesions are typically bilateral, symmetrical, and localized to the upper eyelids, although they may also involve the lower eyelids in some cases. XP is a benign condition with no malignant potential, but it frequently prompts patients to seek medical attention due to its prominent cosmetic impact, particularly when lesions are large or disfiguring [2]. The reported prevalence of XP ranges from 0.3% to 4.4%, with a higher incidence observed among middle-aged women [3, 4]. While XP has traditionally been associated with hyperlipidemia, recent studies suggest that up to 34.5–58% of patients may have normal lipid profiles, though isolated low HDL or altered lipoprotein metabolism may still be present [5, 6]. Other contributing factors include hypothyroidism, diabetes mellitus, and familial dyslipidemia. The underlying pathology involves dermal infiltration by cholesterol-laden macrophages (foam cells), which are influenced by both systemic metabolic dysfunction and local factors such as trauma or friction [7]. Several therapeutic options are

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available for the treatment of XP, including surgical excision, electrosurgery, laser ablation, radiofrequency, cryotherapy, and chemical cauterization using trichloroacetic acid (TCA). However, there is no consensus on the most effective first-line treatment [8]. Surgical excision offers low recurrence rates but is invasive and may result in scarring or ectropion, especially in periorbital lesions. Laser therapies require specialized equipment and carry a risk of pigmentary changes and prolonged erythema. Consequently, there is a growing preference for minimally invasive, cost-effective outpatient procedures such as TCA cautery and cryotherapy [9]. TCA induces epidermal and superficial dermal coagulation, resulting in protein denaturation and lesion resolution. Its use in concentrations ranging from 50% to 100% has demonstrated clearance rates between 61% and 100% depending on lesion size and number of sessions. However, treatment-related complications such as hypopigmentation, erythema, and recurrence have also been reported, especially with lower concentrations [10, 11]. In one study using 95% TCA, complete lesion resolution was achieved in 33% of patients, while others required multiple sessions [10]. Another trial using 100% TCA reported lesion clearance in 95% of cases, suggesting improved efficacy with higher concentrations [12]. In contrast, cryotherapy causes tissue necrosis via rapid freezing and thawing, but has historically been underutilized due to concerns over periorbital edema. More recent studies using very short freeze times have reported promising results with minimal complications and excellent patient tolerability [13]. Despite the availability of both TCA and cryotherapy, direct comparative data assessing their efficacy remain sparse. Previous studies have either focused on single-arm interventions or lacked standardized outcome assessment.

Despite the availability of multiple treatment modalities for xanthelasma palpebrarum, there is no clear consensus regarding the most effective and cosmetically acceptable first-line therapy. Although both 100% trichloroacetic acid (TCA) and cryotherapy are widely used due to their accessibility and cost-effectiveness, direct randomized comparisons between these two modalities remain limited. Most previous studies have been single-arm or split-face designs with small sample sizes and inconsistent outcome measures. Therefore, robust comparative data evaluating both efficacy and safety profiles are needed to guide evidence-based clinical decision-making. This study aimed to compare the efficacy, safety, and tolerability of 100% TCA versus cryotherapy in xanthelasma palpebrarum, with the hypothesis that 100% TCA would yield superior lesion clearance with acceptable side effects.

METHODS

This randomized controlled trial (RCT No. NCT06839638) was carried out at the Department of Dermatology, Nishtar Hospital, Multan, from November 2024 to April 2025. Ethical approval was obtained from the Institutional Ethical Review Board of Nishtar Medical University, Multan (Reference No. 21456/NMU). A non-probability consecutive sampling technique was used to enroll eligible patients presenting with xanthelasma palpebrarum. The sample size was calculated using OpenEpi software, assuming a treatment success rate of 61% for 100% TCA and 18% for cryotherapy. With a two-sided significance level of 0.01, power of 80%, and equal group allocation (1:1), the sample size was determined to be 30 participants per group, yielding a total of 60 participants [10, 14]. Patients aged 20 to 55 years of either gender with clinically diagnosed bilateral xanthelasma palpebrarum (0.5–3.0 cm), no prior treatment history, and currently receiving anti-lipidemic therapy for systemic control of disease were included. Only those who provided informed consent and agreed to follow-up were enrolled. Patients with hypersensitivity to trichloroacetic acid or cryotherapy, active periorbital skin conditions, bleeding disorders, or a history of keloid formation were excluded. After obtaining informed consent, participants were assigned to one of two treatment groups using a computer-generated simple randomization technique in a 1:1 allocation ratio. Baseline demographic and clinical characteristics, including age, gender, duration of xanthelasma, and area of lesion, were documented before initiating treatment. Participants in Group A received 100% trichloroacetic acid (TCA), while those in Group B underwent cryotherapy with liquid nitrogen. Both treatment procedures were performed by a qualified dermatologist under standardized clinical conditions. In Group A, TCA 100% was applied directly to the lesion using a fine-tipped wooden applicator after cleaning the skin with normal saline with a rotatory motion from the periphery toward the center. The acid was applied until a uniform white frosting appeared over the lesion surface, indicating adequate protein coagulation. To protect the surrounding healthy skin, white soft paraffin was applied around the lesion margins to prevent accidental spillage of the acid. In Group B, cryotherapy was administered using one freeze-thaw cycle of liquid nitrogen until a narrow halo of white ice formed around the lesion. Patients were instructed to keep the area clean and to report any signs of blistering or infection. All patients were prescribed topical fusidic acid 2% to be applied twice daily over the treated area for one week following the procedure. Participants in both groups were followed up at six weeks after the intervention. At the follow-up visit, the primary outcome, which includes treatment efficacy and secondary outcomes, included the frequency of adverse

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effects (edema, erythema, pigmentary changes, scarring) were assessed using standardized clinical examination. Efficacy was graded based on percentage reduction in lesion: mild (<50%), moderate (50–75%), or excellent (>75%) response [12]. Side effects, including edema, erythema, hypopigmentation, hyperpigmentation, and scarring, were evaluated and recorded. All assessments were performed by a blinded evaluator to reduce observer bias. Data were collected using a predesigned, structured data collection form developed specifically for this study. The data were analyzed using IBM SPSS Statistics version 26.0. Continuous variables were expressed as mean ± standard deviation and compared between the treatment groups using the Independent Samples t-test. Categorical variables were presented as frequencies and percentages. The association between categorical variables and treatment groups was analyzed using the Pearson Chi-square test. A confidence level of 95% was used for all statistical analyses. Results were considered statistically significant at a p-value ≤ 0.050 (Figure 1).

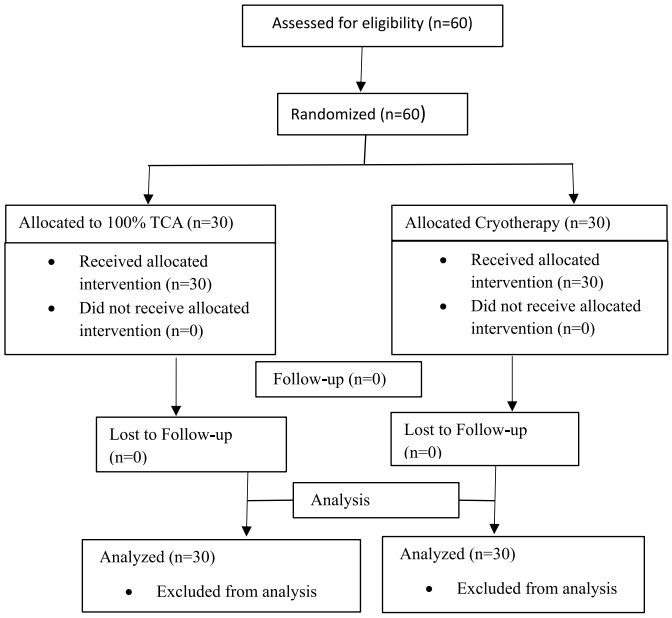

Figure 1: CONSORT Flow Diagram

RESULTS

The mean age of participants was 40.10 ± 7.40 years, while the average duration of xanthelasma was 11.18 ± 2.94 months. There was no statistically significant difference in baseline characteristics between the two treatment groups. The mean age in the TCA group was 41.17 ± 7.80 years, compared to 39.03 ± 6.95 years in the cryotherapy group (p=0.268). The average duration of xanthelasma was 10.80 ± 3.18 months in Group A and 11.57 ± 2.69 months in Group B (p=0.317). The age distribution (p=0.176), gender composition (p=0.598), and lesion location (p=0.941) were also comparable across both groups. Baseline lesion size (mean ± SD) was 1.73 ± 0.86 cm in the TCA group and 1.83 ± 0.89 cm in the cryotherapy group, with no statistically significant difference (p=0.660) (Table 1).

Table 1: Baseline Demographic and Clinical Characteristics of Patients

Variables	Group A (TCA 100%) n = 30	Group B (Cryotherapy) n = 30	p-Value
Age (years) (Mean ± SD)	41.17 ± 7.80	39.03 ± 6.95	0.268
Age Group			
20–35 years	8 (26.7%)	13 (43.3%)	0.176
36–55 years	22 (73.3%)	17 (56.7%)	
Gender			
Male	13 (43.3%)	11 (36.7%)	0.598
Female	17 (56.7%)	19 (63.3%)	
Area of Lesion			
Upper Eyelid	17 (56.7%)	16 (53.3%)	0.941
Lower Eyelid	5 (16.7%)	6 (20.0%)	
Both Upper and Lower Eyelid	8 (26.7%)	8 (26.7%)	
Duration of Xanthelasma (months) (Mean ± SD)	10.80 ± 3.18	11.57 ± 2.69	0.317
Baseline lesion size (cm) (mean ± SD)	1.73 ± 0.86	1.83 ± 0.89	0.660

Chi-square test was used for dichotomous variables, and the Independent Samples t-test was applied for continuous variables. A p-value < 0.050 was considered statistically significant

At 6 weeks post-treatment, mean lesion size reduced to 0.47 ± 0.40 cm in the TCA group compared to 0.77 ± 0.45 cm in the cryotherapy group, with a statistically significant difference favoring TCA (p=0.010). Post-intervention, treatment response differed significantly between groups (χ^2=7.52, df=2, p=0.023). In Group A (TCA), 53.3% achieved excellent response compared to 20.0% in Group B (Cryotherapy). Conversely, moderate responses were more common in Group B (43.3% vs. 30.0%), while mild responses were also higher in Group B (36.7% vs. 16.7%). This indicates that the statistical difference was driven primarily by a relative shift in Group B from excellent responses toward moderate and mild outcomes (Figure 2).

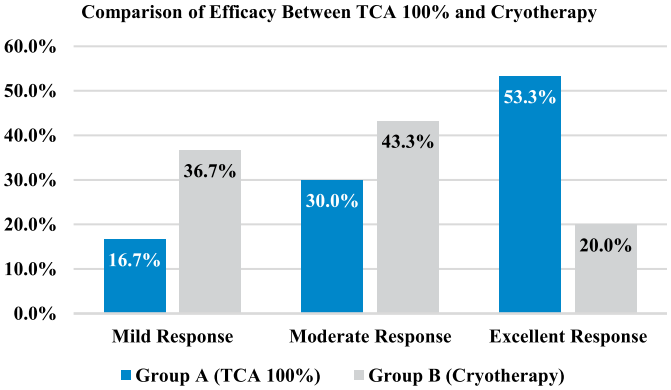

Figure 2: Comparison of Efficacy Between TCA 100% and Cryotherapy in Patients with Xanthelasma Palpebrarum (N=60)

In Group A, edema was reported in 5 (16.7%), erythema in 7

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(23.3%), hypopigmentation in 5 (16.7%), hyperpigmentation in 9 (30.0%), and scarring in 6 (20.0%) patients. In contrast, Group B (Cryotherapy) showed edema in 3 (10.0%), erythema in 4 (13.3%), hypopigmentation in 3 (10.0%), hyperpigmentation in 2 (6.7%), and no cases of scarring. Statistically significant differences were observed for hyperpigmentation (p = 0.020) and scarring (p=0.010), indicating a higher frequency of these adverse events in the TCA-treated group (Table 2).

Table 2: Comparison of Treatment-Related Side Effects Between TCA 100% and Cryotherapy in Patients with Xanthelasma Palpebrarum (N=60)

Variables	Group A (TCA 100%) n = 30	Group B (Cryotherapy) n = 30	p-Value
Edema	5 (16.7%)	3 (10.0%)	0.448
Erythema	7 (23.3%)	4 (13.3%)	0.317
Hypopigmentation	5 (16.7%)	3 (10.0%)	0.448
Hyperpigmentation	9 (30.0%)	2 (6.7%)	0.020*
Scarring	6 (20.0%)	0 (0.0%)	0.010*

The Pearson Chi-square test was applied to assess statistical significance. A p-value <0.050 was considered statistically significant

DISCUSSION

This randomized comparative study evaluated the efficacy and safety of 100% trichloroacetic acid (TCA) versus cryotherapy in the treatment of xanthelasma palpebrarum (XP). The two treatment groups in this randomized trial were comparable at baseline, with no significant differences in age, gender distribution, lesion location, or lesion duration. The mean age of participants was 40.10 ± 7.40 years, with Group A (TCA 100%) averaging 41.17 ± 7.80 years and Group B (Cryotherapy) 39.03 ± 6.95 years (p = 0.268), which aligns with previous studies that report XP most frequently affects individuals between 40 and 60 years of age [12, 15]. Gender distribution in our study showed a female predominance (60% overall), with 56.7% females in Group A and 63.3% in Group B (p=0.598), which is consistent with earlier studies reporting a higher prevalence of XP in women [4, 14]. Lesions most frequently involved the upper eyelids in both groups, also mirroring typical patterns noted in literature (upper lids are more often affected than lower lids) [16]. These similarities in baseline characteristics between groups ensure that any differences in outcomes can be attributed to the treatment effects rather than confounding demographic factors. Moreover, the study's patient profile (middle-aged adults with bilateral xanthelasma) is representative of the general xanthelasma population, enhancing the relevance of the findings. Each group's mean lesion duration was around 11 months, indicating that most patients had relatively recent plaques; this is somewhat shorter than in some series, possibly reflecting earlier cosmetic concern and treatment seeking in our cohort [17]. Our findings demonstrate that high-strength TCA is significantly more efficacious than cryotherapy for xanthelasma palpebrarum. After a single treatment session and follow-up evaluation, the TCA group showed a markedly higher rate of substantial lesion reduction: 53.3% of patients achieved an "excellent" response (>75% reduction in lesion size) with TCA, compared to only 20.0% with cryotherapy (with the majority of cryotherapy patients having only mild-moderate improvement). This difference was statistically significant (p=0.023), confirming the superior efficacy of TCA in lesion clearance. These results closely parallel those of Tahir *et al.*, who reported complete resolution of lesions in 75% of sites treated with a single session of 100% TCA, versus only 17.5% complete clearance with cryotherapy (p<0.001) [14]. Notably, this superiority of TCA is also reflected in other comparative studies: for example, a systematic review by Malekzadeh et al. noted that one trial found 100% TCA to be more effective than cryosurgery for xanthelasma resolution [18]. Similarly, Faysal and Rehman compared 100% TCA to another chemical cautery (silver nitrate) and observed 95% of patients achieving ≥75% lesion clearing with TCA, against only 20% with the alternative agent after one treatment [12]. This further underscores the potent efficacy of concentrated TCA, even relative to other destructive modalities. Güngör *et al.* reported that application of TCA (70% concentration) produced similar efficacy to erbium: YAG laser ablation when each was applied to separate lesions in the same patients [19]. This suggests that chemical peeling at sufficient strength can achieve lesion clearance comparable to laser ablation, at least for superficial to moderately thick plaques. Taken together, the evidence positions 100% TCA as one of the most effective single-session treatments for xanthelasma, often outperforming cryotherapy and matching the efficacy of more resource-intensive options in appropriate lesions. Our trial's efficacy data are in line with this consensus. It should be noted that cryotherapy can still gradually reduce xanthelasma with repeat sessions, but its initial impact is clearly less pronounced, as also reflected in Tahir *et al.*'s study, where 80% of cryotherapy-treated lesions needed a second session for full clearance. Although 100% trichloroacetic acid (TCA) demonstrated superior efficacy in lesion clearance, it was associated with a significantly higher frequency of pigmentary alterations and scarring. In the present study, post-treatment hyperpigmentation occurred in 30.0% of TCA-treated patients versus 6.7% of cryotherapy cases (p=0.020). This high incidence represents a potential limitation to the cosmetic use of TCA, particularly in patients with darker skin phototypes, where pigmentary alteration may be more

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pronounced and persistent. The absence of scarring in the cryotherapy group, compared with 20.0% incidence in the TCA group (p=0.010), indicates a statistically significant safety advantage of cryotherapy. Clinically, this finding reinforces cryotherapy's safer cosmetic profile, particularly in periorbital regions where scarring is highly undesirable. These findings are consistent with those reported by Tahir *et al.*, where hyperpigmentation was noted in 37.5% and scarring in 30% of lesions treated with 100% TCA, compared to 10% and 0%, respectively, with cryotherapy [14]. These results align with the known mechanism of TCA, a caustic agent that induces coagulative necrosis extending variably into the dermis, increasing the risk of post-inflammatory pigmentary changes and fibrosis [18]. In our study, minor transient side effects such as erythema and edema were observed in both groups (TCA: 23.3% erythema, 16.7% edema; cryotherapy: 13.3% and 10.0%, respectively), but these were not statistically significant. Previous studies support this trend. Arora *et al.* reported post-treatment hyperpigmentation in 25% and hypopigmentation in 10% of patients treated with 50% TCA [17]. Similarly, Sapra *et al.* found lower rates (hyperpigmentation 7.8%, hypopigmentation 2.6%) with TCA 80%, potentially due to more conservative application in lighter phototypes [11]. Nassief also compared 30% and 70% TCA and observed a clear concentration-dependent increase in both efficacy and adverse effects, with 70% TCA providing greater lesion clearance but a higher incidence of transient pigmentary changes [20]. In contrast, Labandeira *et al.* demonstrated that brief, low-pressure liquid nitrogen cryotherapy caused minimal pigmentary disturbance, reinforcing its favorable safety profile [13]. Thus, while TCA remains effective, its use warrants caution, particularly in patients with darker skin tones or cosmetic sensitivity. Cryotherapy may be preferred when minimizing pigmentation risk is paramount. This study provides comparative clinical evidence on the efficacy and safety of 100% trichloroacetic acid versus cryotherapy in the treatment of xanthelasma palpebrarum. Its strengths include a randomized design, balanced group characteristics, and objective outcome assessment. However, limitations include the single-center setting, short-term follow-up, and absence of lipid profile analysis or quality-of-life evaluation. The study's scope did not extend to long-term recurrence tracking or patient satisfaction. Future multicenter trials with extended follow-up, dermoscopic documentation, and correlation with systemic lipid parameters are recommended to better guide individualized treatment selection and assess the durability of lesion clearance across diverse patient subgroups.

This study has certain limitations, including its single-center design, relatively small sample size, and short-term follow-up period, which precludes assessment of long-term recurrence and sustained cosmetic outcomes. Additionally, patient satisfaction scores and objective lipid profile correlations were not evaluated. Future multicenter randomized trials with larger cohorts, longer follow-up durations, and inclusion of quality-of-life assessments are recommended to better determine long-term efficacy, recurrence rates, and optimal patient selection for each treatment modality.

CONCLUSIONS

The findings of this randomized trial indicate that 100% trichloroacetic acid provides superior lesion clearance compared to cryotherapy in the management of xanthelasma palpebrarum, albeit with a higher incidence of adverse cosmetic outcomes. However, its use is associated with a greater frequency of adverse effects, particularly pigmentary changes and scarring. The findings emphasize the importance of balancing efficacy with cosmetic outcomes when selecting a therapeutic approach. Clinical decision-making should be individualized, taking into account patient expectations, skin type, and tolerance for potential treatment-related complications.

Authors' Contribution

Conceptualization: SI, MIJ
Methodology: AB[1], ST
Formal analysis: RT, AB[2]
Writing and Drafting: RT, AB[2], ST, SI, MIJ
Review and Editing: RT, AB[2], ST, SI, MIJ, AB[1]

All authors approved the final manuscript and take responsibility for the integrity of the work

Conflicts of Interest

All the authors declare no conflict of interest.

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