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A Comparative Study of Intralesional Cryotherapy Versus Intralesional Steroid in the Treatment of Keloid

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ABSTRACT

Background: Keloids are benign fibro-proliferative dermal tumours defined by excessive collagen deposition that extends beyond the confines of the original wound. They are characterised by an aggressive, non-regressing growth pattern and high recurrence rates following treatment, posing significant therapeutic challenges in dermatological practice.

Objectives: To compare the therapeutic efficacy of intralesional steroid (ILS) and intralesional cryotherapy (ILC) in the treatment of keloid scars, and to document the adverse effect profiles of both modalities.

Materials and Methods: A prospective, randomised, open-label comparative study was conducted at the Department of Dermatology, Venereology and Leprosy, SRM Medical College Hospital and Research Centre, from March 2016 to August 2017. Of 102 enrolled patients, 89 completed the study (Group A – ILS, n=45; Group B – ILC, n=44). Injections were administered at three-weekly intervals for a maximum of 15 weeks. Scar height was assessed using the double scale method. Statistical analysis employed IBM SPSS v23.0; significance was set at $p \leq 0.05$.

Results: Males constituted 55.1% of participants; the dominant age group was 21–30 years (42.7%). The chest was the most common site (51.7%). Complete flattening was achieved in 73.3% (Group A) versus 61.4% (Group B) at week 15 ($p=0.231$). Keloids of ≤1 year duration responded equally (100% in both groups), whilst those of >1 to ≤4 years showed statistically superior response to ILS (94.1% vs 62.5%, $p=0.028$). Hypopigmentation was significantly more frequent in Group A (26.6% vs 9.1%, $p=0.028$); blistering and necrosis occurred exclusively in Group B.

Conclusion: Intralesional steroid demonstrates superior efficacy in keloids of intermediate chronicity, while intralesional cryotherapy carries fewer overall adverse effects. Keloid chronicity should guide modality selection in clinical practice.

Keywords: *Keloid; Intralesional cryotherapy; Triamcinolone acetonide; Fibro-proliferative scar; Scar management; Randomised comparative study.*

INTRODUCTION

Keloids are pathological fibro-proliferative tumours arising in the dermis at sites of cutaneous trauma, defined by uncontrolled fibroblast proliferation, excessive extracellular matrix deposition, and lateral invasion into adjacent normal skin beyond the boundaries of the original wound hallmark that distinguishes them from hypertrophic scars [1]. Unlike hypertrophic scars, keloids lack the capacity for spontaneous involution, exhibit a relentless growth trajectory, and carry a high propensity for recurrence following surgical intervention [2].

Keloids occur in 5–15% of cutaneous wounds and are observed exclusively in humans [3]. Epidemiological data demonstrate a 15-fold higher incidence in deeply pigmented skin types, with Chinese and Afro-Caribbean individuals disproportionately affected [4]. The aetiopathogenesis is multifactorial, encompassing genetic predisposition (autosomal dominant inheritance patterns with incomplete penetrance, HLA-B14, HLA-DR5 associations), hormonal influences, altered immunological responses, and local biomechanical factors [5]. At the molecular level, dysregulated transforming growth factor-beta (TGF-β) signalling drives aberrant fibroblast activity and collagen overproduction; TGF-β1 and TGF-β2 promote fibrogenesis, whereas TGF-β3 exerts a protective role [6]. Elevated platelet-derived growth factor (PDGF) receptor expression on keloid fibroblasts further amplifies the proliferative cascade [7].

The clinical morbidity of keloids extends beyond cosmetic disfigurement; patients frequently experience pruritus, pain, and significant psychological distress. Management is challenging, with no universally efficacious treatment. The therapeutic armamentarium includes intralesional pharmacotherapy, cryotherapy, pressure therapy, laser modalities, and combination approaches [2].

Intralesional triamcinolone acetonide (ILS) has long been the cornerstone of keloid management, reducing fibroblast proliferation, inhibiting collagen and glycosaminoglycan synthesis, and suppressing inflammatory mediator release. Intralesional cryotherapy (ILC), introduced in the 1990s by Weshahy, achieves focal scar destruction through cryogenic injury to keloidal fibroblasts via intracellular ice crystal formation, osmolarity shifts, and apoptosis, with minimal collateral epidermal damage [9,10]. Despite their clinical ubiquity, head-to-head comparative data on ILS versus ILC in a prospective randomised setting, particularly in a South Asian population, remain limited. This study was therefore designed to provide robust comparative evidence on the efficacy and safety of these two modalities.

AIM AND OBJECTIVES

(i) To compare the effectiveness of intralesional cryotherapy versus intralesional steroid in the treatment of keloid scars.
(ii) To document and compare the adverse effect profiles of the two therapeutic modalities.

MATERIALS AND METHODS

Study Design and Setting

This was a prospective, randomised, open-label comparative clinical study conducted at the outpatient department of Dermatology, Venereology and Leprosy, SRM Medical College Hospital and Research Centre, Kattankulathur, Tamil Nadu, from March 2016 to August 2017. Institutional ethics committee approval was obtained prior to commencement, and written informed consent was secured from all participants. The study was conducted in accordance with the ethical principles of the Declaration of Helsinki.

Study Population

A total of 102 patients aged 10–60 years with clinically diagnosed keloid scars were enrolled and randomised 1:1 by simple randomisation into Group A (ILS, n=51) and Group B (ILC, n=51). Thirteen patients were lost to follow-up; 89 participants (Group A: n=45; Group B: n=44) completed the study and were included in the final analysis.

Inclusion criteria: Patients of either sex, aged 10–60 years, with clinically diagnosed keloid at any accessible site (excluding face and neck).

Exclusion criteria: Keloids of the face or neck; pregnancy or lactation; significant cardiac, hepatic, or renal disease; immunocompromised status; treatment for keloids within the preceding three months; known hypersensitivity to study medications.

Treatment Protocols

Group A – Intralesional Triamcinolone Acetonide (ILS): Triamcinolone acetonide 40 mg/ml was injected intralesionally using a 27-gauge needle attached to an insulin syringe (~0.2 ml per site) via a sequential multiple-puncture technique, causing blanching confined strictly to the lesion margin.

Group B – Intralesional Cryotherapy (ILC): Liquid nitrogen was delivered intralesionally via a scalp vein set connected to a cryogun until minimal blanching was visible within the scar parenchyma, with careful avoidance of spread to surrounding normal skin [8,11].

In both groups, injections were administered at three-weekly intervals until complete scar flattening was achieved or for a maximum of 15 weeks (five sessions).

Clinical Assessment

Treatment response was evaluated at each visit (weeks 0, 3, 6, 9, 12, 15) by measuring scar height using the double scale method on an ordinal scale: 0 = complete flattening (0 mm); 1 = >0–2 mm; 2 = >2–3 mm; 3 = >3–4 mm; 4 = >4–5 mm; 5

= >5 mm. Serial standardised photographs were obtained at each time point. Adverse effects, hypopigmentation, atrophy, telangiectasia, blistering, necrosis, and post-injection pain were systematically recorded.

Statistical Analysis

Data were analysed with IBM SPSS Statistics v23.0. Categorical variables are expressed as frequencies and percentages; continuous variables as mean ± SD. Inter-group comparisons used the unpaired Student's t-test for continuous data and the Chi-square or Fisher's exact test (when expected cell counts <5) for categorical data. A p-value ≤0.05 was considered statistically significant.

RESULTS

Baseline Demographic and Clinical Characteristics

Of 102 enrolled patients, 89 completed the 15-week study (Group A: n=45; Group B: n=44). Baseline characteristics were comparable between groups with no statistically significant differences (Table 1). Males constituted 55.1% of the cohort (Group A: 57.8%; Group B: 52.3%). The 21–30 year age group was most prevalent overall (42.7%), with males predominantly presenting in this decade and females most frequently in the 31–40 year range. A positive family history was elicited in 7.9% of patients. The majority (60.7%) were asymptomatic; pruritus was reported by 25.8%, pain by 9.0%, and combined pruritus-pain by 4.5%.

Table 1. Baseline Demographic and Clinical Characteristics of Study Participants

Variable	Group A (ILS)n=45	Group B (ILC)n=44	TotalN=89	p-value
Male, n (%)	26 (57.8%)	23 (52.3%)	49 (55.1%)	0.602
Female, n (%)	19 (42.2%)	21 (47.7%)	40 (44.9%)	
Mean Age ± SD (years)	32.9 ± 10.4	30.3 ± 9.7	31.6 ± 10.1	0.213
Dominant age group 21–30 yrs	20 (44.4%)	18 (40.9%)	38 (42.7%)	0.718
Duration ≤1 year	15 (33.3%)	16 (36.4%)	31 (34.8%)	0.753
Duration >1 to ≤4 years	17 (37.8%)	16 (36.4%)	33 (37.1%)	0.890
Duration ≥5 years	13 (28.9%)	12 (27.3%)	25 (28.1%)	0.861
Positive family history	4 (8.9%)	3 (6.8%)	7 (7.9%)	0.716
Asymptomatic	29 (64.4%)	25 (56.8%)	54 (60.7%)	0.444

ILS = Intralesional Steroid; ILC = Intralesional Cryotherapy; SD = Standard Deviation. Chi-square test or unpaired t-test applied; p≤0.05 considered significant.

Site of Involvement and Aetiology

The chest was the predominant site (51.7%), followed by the shoulder (16.9%), arm and forearm (9.0% each), breast (4.5%), leg (4.5%), back (3.4%), and hand (1.1%). These findings are broadly concordant with the distribution reported by Ramakrishnan et al. [19], who documented presternal predominance in 34% of a South Indian cohort of 1000 patients. Spontaneous onset accounted for the majority of cases (66.3%), followed by trauma (18.0%), acne (10.1%), surgery (2.2%), chickenpox (2.2%), and tattooing (1.1%). No significant inter-group differences were observed in site distribution or aetiology (Table 2).

Table 2. Distribution of Keloid Site and Aetiology in Both Groups

Characteristic	Group A (ILS)n=45	Group B (ILC)n=44	Total N=89	p-value
Site: Chest	22 (48.9%)	24 (54.5%)	46 (51.7%)	0.588
Shoulder	5 (11.1%)	10 (22.7%)	15 (16.9%)	0.125
Arm	5 (11.1%)	3 (6.8%)	8 (9.0%)	0.489
Forearm	4 (8.9%)	4 (9.1%)	8 (9.0%)	0.972
Others (breast/back/leg/hand)	9 (20.0%)	3 (6.8%)	12 (13.5%)	0.053
Etiology: Spontaneous	27 (60.0%)	32 (72.7%)	59 (66.3%)	0.193
Trauma	9 (20.0%)	7 (15.9%)	16 (18.0%)	0.601

Acne	6 (13.3%)	3 (6.8%)	9 (10.1%)	0.303
Surgery / Chickenpox / Tattoo	3 (6.7%)	2 (4.5%)	5 (5.6%)	0.642

Serial Scar Height Reduction

Mean baseline scar height scores were equivalent between Group A (2.78 ± 0.74) and Group B (2.80 ± 0.73) (p=0.910). Progressive height reduction was observed in both groups at every time point. At week 15, mean scores were 0.44 ± 0.83 (Group A) and 0.61 ± 0.87 (Group B) (p=0.351). The trajectory of reduction was consistently more pronounced in Group A throughout, though no individual time point reached statistical significance (Table 3).

Table 3. Serial Scar Height Reduction: Mean Scores and Inter-group Comparison

TimePoint	Group AMean (SD)	95% CI(A)	Group BMean (SD)	95% CI(B)	Mean Diff(A–B)	p-value
Week 0	2.78 (0.74)	2.56–3.00	2.80 (0.73)	2.57–3.02	−0.02	0.910
Week 3	2.42 (0.64)	2.23–2.61	2.40 (0.63)	2.21–2.59	+0.02	0.856
Week 6	1.91 (0.62)	1.73–2.10	2.02 (0.64)	1.83–2.22	−0.11	0.403
Week 9	1.38 (0.80)	1.14–1.62	1.50 (0.82)	1.25–1.75	−0.12	0.479
Week 12	0.79 (0.91)	0.52–1.06	0.89 (0.86)	0.63–1.14	−0.10	0.603
Week 15	0.44 (0.83)	0.19–0.69	0.61 (0.87)	0.35–0.87	−0.17	0.351

CI = Confidence Interval; SD = Standard Deviation. Scar height score: 0 = flush with skin; 1 = ≤2 mm; 2 = >2–3 mm; 3 = >3–4 mm; 4 = >4–5 mm; 5 = >5 mm.

Complete Flattening: Overall and Subgroup Analysis

At week 9, complete flattening was achieved in 13.3% (Group A) and 11.4% (Group B). By week 15, complete flattening was attained in 73.3% (n=33) and 61.4% (n=27) of Group A and Group B patients respectively; this overall difference was not statistically significant (p=0.231).

Duration-stratified subgroup analysis revealed pivotal differential findings (Table 4). For keloids of ≤1 year duration, 100% complete flattening was achieved in both groups at week 15 (p=1.000), confirming equivalent efficacy of both modalities in early-stage disease. For keloids of >1 to ≤4 years duration, Group A demonstrated a statistically significant superiority over Group B (94.1% vs 62.5%; p=0.028), indicating that the sustained anti-fibrotic mechanisms of ILS confer an advantage over ILC in more established lesions. Keloids of ≥5 years duration showed minimal response in both groups (Group A: 15.4%; Group B: 8.3%; p=0.618), underscoring the inverse relationship between lesion chronicity and treatment responsiveness.

Table 4. Complete Flattening Stratified by Keloid Duration and Assessment Time Point

Duration	Gp AWk 9	Gp BWk 9	Gp AWk 12	Gp BWk 12	Gp AWk 15	Gp BWk 15	p-value(Wk 15)
Overall	6 (13.3%)	5 (11.4%)	22 (48.9%)	18 (40.9%)	33 (73.3%)	27 (61.4%)	0.231
≤1 year	6 (40.0%)	4 (25.0%)	12 (80.0%)	12 (75.0%)	15 (100%)	16 (100%)	1.000
>1 to ≤4 years	0 (0%)	1 (6.3%)	9 (52.9%)	6 (37.5%)	16 (94.1%)	10 (62.5%)	0.028*
≥5 years	0 (0%)	0 (0%)	1 (7.7%)	0 (0%)	2 (15.4%)	1 (8.3%)	0.618

*Statistically significant (p≤0.05). Gp = Group; Wk = Week.

By age, the 21–30 year cohort showed the most favourable response at week 15 (Group A: 42.2%; Group B: 34.0%). Forearm and leg keloids in Group A achieved 100% complete flattening; shoulder (80%) and chest (77.3%) also showed high response rates. In Group B, shoulder (70%) and arm (66.6%) were most responsive. Breast keloids showed the least favourable response to ILC (0%), while Group A achieved 25% flattening at this site.

Adverse Effects

A total of 25 patients (28.1%) experienced at least one adverse event: 19 (42.2%) in Group A and 6 (13.6%) in Group B (p=0.002). Hypopigmentation was the most prevalent adverse effect overall, occurring significantly more frequently in Group A (26.6% vs 9.1%; p=0.028). Post-injection pain (8.9%) and telangiectasia (4.4%) were exclusive to Group A. Blistering and skin necrosis were each observed in one Group B patient (2.3% each) and were absent from Group A. The complete adverse event profile is presented in Table 5.

Table 5. Comparative Adverse Effect Profile of Intralesional Steroid Versus Intralesional Cryotherapy

Adverse Effect	Group A (ILS)n=45	Group B (ILC)n=44	Total	p-value
Hypopigmentation	12 (26.6%)	4 (9.1%)	16 (18.0%)	0.028*
Post-injection pain	4 (8.9%)	0 (0%)	4 (4.5%)	0.041*
Telangiectasia	2 (4.4%)	0 (0%)	2 (2.2%)	0.241
Cutaneous atrophy	1 (2.2%)	0 (0%)	1 (1.1%)	0.318
Blister formation	0 (0%)	1 (2.3%)	1 (1.1%)	0.318
Skin necrosis	0 (0%)	1 (2.3%)	1 (1.1%)	0.318
Total adverse events	**19 (42.2%)**	**6 (13.6%)**	**25 (28.1%)**	**0.002***

*Statistically significant (p≤0.05). ILS = Intralesional Steroid; ILC = Intralesional Cryotherapy.

DISCUSSION

This prospective randomised comparative study evaluated ILS against ILC in keloid management over a 15-week protocol. The demographic profile/male preponderance (55.1%) and dominant representation of the 21–30 year age group (42.7%)is consistent with the established epidemiological literature [4,5]. The chest as the leading site (51.7%) reflects the recognised predilection of keloids for areas of high skin tension and aligns with data from Ramakrishnan et al. [19], who identified the presternal region as the most commonly affected site in a large South Indian cohort. The preponderance of spontaneous onset (66.3%) is consistent with the recognised occurrence of keloids following trivial, often unidentified trauma or folliculitis in susceptible individuals [1].

The 7.9% family history positivity rate is higher than the 3.2% reported by Cosman et al. [20] in a surgical cohort, though still a minority finding, corroborating the view that whilst genetic predisposition is a recognised risk factor, it is not the primary determinant in the majority of presenting patients [5].

The 73.3% complete flattening rate achieved with ILS at 15 weeks is broadly consistent with the 85% response documented by Layton et al. [13] in acne keloids treated with intralesional triamcinolone, with the modest discrepancy attributable to differences in keloid subtype, site, and chronicity between the two study populations. The observation that meaningful flattening commenced at week 9 in Group A aligns with the findings of Manuskiatti and Fitzpatrick [15], who noted significant scar reduction by the eighth week of intralesional corticosteroid treatment. These consistent findings across multiple centres validate the use of ILS as a reliable, reproducible modality. The partial response observed in Group A patients who failed to achieve complete flattening (26.6%) was predominantly attributable to prolonged lesion chronicity (≥5 years) and older age at presentation, parameters similarly associated with reduced steroid responsiveness in the study by Darougheh et al. [16].

The 61.4% complete flattening rate for ILC at week 15 is concordant with the 73% complete response reported by Rusciani et al. [17] for intralesional cryotherapy, most of which occurred in lesions of less than two years duration an observation that parallels our subgroup findings. Van Leeuwen et al. [18] documented 63% scar reduction with ILC at 12 months, a figure broadly similar to our 15-week outcome and lending further support to the comparability of our results to the published evidence base. Har-Shai et al. [8] demonstrated an average of 51.4% scar reduction after a single ILC session; the incrementally superior rate in our cohort likely reflects the benefit of multiple treatment sessions administered at three-weekly intervals.

The most clinically consequential finding of this study is the duration-dependent differential efficacy. Keloids of ≤1 year achieved universal complete flattening with both modalities (100%), emphasising that early treatment initiation yields optimal outcomes irrespective of the chosen modality [3]. Conversely, in keloids of >1 to ≤4 years duration, ILS demonstrated a statistically significant advantage (94.1% vs 62.5%; p=0.028). This is mechanistically plausible: the progressive consolidation of keloid collagen architecture over time likely renders the fibrous matrix less susceptible to cryogenic destruction, whereas ILS continues to exert sustained molecular inhibition of fibroblast activity and TGF-β/collagen signalling [6,7,12]. The near-complete refractoriness of keloids persisting for ≥5 years to both monotherapies

(Group A: 15.4%; Group B: 8.3%) reinforces the need for multimodal approaches incorporating surgical excision, adjuvant radiotherapy, or targeted agents in longstanding disease.

The adverse effect profiles of the two modalities carry significant clinical implications. The significantly higher overall adverse event burden in Group A (42.2% vs 13.6%; p=0.002) is primarily attributable to hypopigmentation (26.6%), which is particularly relevant in the context of darker skin phototypes the very population at greatest keloid risk [4]. This complication reflects the documented melanocytotoxic and vasoconstrictive sequelae of repeated intralesional corticosteroid injection [13,14,15]. Blistering and skin necrosis, though uncommon (2.3% each), occurred exclusively in Group B and are consistent with the cryogenic mechanism of action requiring precise delivery technique to avoid collateral epidermal damage [11,12]. These findings suggest that whilst ILC offers a more favourable aggregate safety profile, its unique complications necessitate careful patient counselling, adequate operator training, and meticulous technique.

The principal limitation of this study is the absence of post-treatment follow-up, precluding evaluation of recurrence rates a critical outcome parameter in keloid research. The open-label design introduces the potential for performance bias, mitigated to a degree by the objective scar height measurement methodology. Future studies should incorporate blinded outcome assessment, patient-reported outcomes, quality-of-life instruments, and extended follow-up of at least 12–24 months to capture recurrence data.

CONCLUSION

Intralesional triamcinolone acetonide (ILS) achieves a numerically superior complete flattening rate at 15 weeks (73.3% vs 61.4%) compared to intralesional cryotherapy (ILC), though the overall inter-group difference does not reach statistical significance. The critical finding is that keloids of >1 to ≤4 years duration exhibit a statistically significant preferential response to ILS (94.1% vs 62.5%; p=0.028), establishing lesion chronicity as a key determinant of modality selection. Both treatments achieve equivalent complete resolution in keloids of ≤1 year duration, affirming the imperative of early intervention. Intralesional cryotherapy confers a significantly lower overall adverse event burden, though exclusive complications of blistering and necrosis necessitate technical precision and patient counselling. The substantially higher rate of hypopigmentation with ILS warrants particular consideration in darker-skinned individuals. Prospective studies incorporating long-term follow-up, recurrence data, and patient-reported outcomes are needed to consolidate the evidence base for optimal keloid treatment algorithms.

DECLARATIONS

CONFLICT OF INTEREST

The authors declare no conflict of interest.

FUNDING

No external funding was received for this study.

ETHICAL APPROVAL

The study protocol was approved by the Institutional Ethics Committee, SRM University, Kattankulathur. Written informed consent was obtained from all participants. The study was conducted in accordance with the ethical principles of the Declaration of Helsinki.

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