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Freeze and Flatten Beyond Steroids Using Cryotherapy in the Treatment of Keloids

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ABSTRACT

Introduction: Keloids are benign fibroproliferative scars characterized by excessive collagen deposition, frequently associated with pain, pruritus, cosmetic disfigurement, and high recurrence rates. Intralesional triamcinolone acetonide (TAC) remains the standard treatment, while cryotherapy has been proposed as an adjunct to enhance therapeutic outcomes.

Objective: To evaluate the efficacy and safety of intralesional TAC alone versus cryotherapy combined with intralesional TAC in patients with keloids.

Methods: Fifty patients were randomly allotted to two groups (25 each): Group 1 received monthly intralesional TAC injections, while Group 2 received cryotherapy followed by intralesional TAC. Treatment outcomes were assessed using the Vancouver Scar Scale (VSS), scar height, vascularity, pigmentation, pliability, pain, and pruritus.

Results: Both groups demonstrated significant improvement in all clinical parameters throughout follow-up. Mean VSS scores decreased from 9.76 ± 0.83 to 0.28 ± 0.61 in the TAC group and from 10.08 ± 1.22 to 0.16 ± 0.47 in the combination group. Complete resolution of pain and pruritus was achieved in all patients by four weeks. Although combination therapy showed a trend toward earlier improvement in selected scar characteristics, overall efficacy was comparable between groups. The pattern of complications differed, but adverse events were infrequent.

Conclusion: Intralesional TAC alone remains an effective, simple, and well-tolerated treatment for keloids, while adjunctive cryotherapy may be considered in selected patients based on lesion characteristics and individual risk profiles.

Keywords: keloids, intralesional TAC, cryosurgery, pruritus

INTRODUCTION

Keloids, characterized by aberrant fibroproliferative activity, excessive deposition of extracellular matrix (ECM), and progressive extension beyond the original wound boundaries, represent a pathological form

of scar formation unique to human skin. [1] These lesions are frequently disfiguring and are associated with significant impairment in quality of life. [2–4]

The mechanisms underlying exuberant scar formation remain incompletely understood, with no single dominant pathogenic pathway identified. Experimental studies implicate multiple transcription factors, growth factors, cytokines, ECM components, and regulatory mediators in dysregulated wound healing, disrupting the normal phases of hemostasis, inflammation, proliferation, reepithelialisation, and remodeling. Aberrant immune cell–fibroblast crosstalk may lead to excessive scarring through impaired remodeling and/or prolonged inflammation. [5,6]

The aetiology of keloids is multifactorial, reflecting the convergence of genetic susceptibility, inflammatory signalling, mechanical stress, tissue hypoxia, delayed-type hypersensitivity reactions, and metabolic dysregulation. [7] Familial clustering has been documented, with inheritance patterns consistent with autosomal dominant transmission exhibiting incomplete penetrance and variable phenotypic expression. [8–10] These factors collectively contribute to individual variability in disease susceptibility, severity, and treatment response.

Intralesional corticosteroids, particularly triamcinolone acetonide (TAC), remain the most widely employed first-line therapy for keloid management. Corticosteroids exert their therapeutic effect through suppression of inflammatory pathways, inhibition of fibroblast proliferation, reduction of collagen and glycosaminoglycan synthesis, and enhancement of collagen degradation, thereby limiting excessive ECM accumulation. [11] TAC may be used as monotherapy for mature lesions or as an adjunct to surgical or laser-based interventions. Clinical response rates range from 50% to 100%, although recurrence remains a major limitation, with approximately one-third of lesions recurring within one year and up to half recurring within five years following treatment. [12]

Cryotherapy induces tissue destruction through repeated freeze–thaw cycles, causing cellular injury and microvascular compromise. Conventional surface cryotherapy may result in epidermal damage, prompting the development of intralesional cryotherapy, which delivers targeted freezing directly within the lesion using specialized probes. [13,14] A systematic review of eight studies demonstrated that intralesional cryotherapy effectively reduces keloid volume, pain, and pruritus; however, persistent hypopigmentation remains a concern, particularly in individuals with Fitzpatrick skin types IV–VI, and reported recurrence rates range from 0% to 24%. [15]

Multiple comparative studies indicate that combining cryotherapy with intralesional steroids improves volumetric regression and accelerates clinical response compared with either modality alone. [16–18] Collectively, these studies indicate that although intralesional corticosteroids remain the cornerstone of keloid therapy, adjunctive cryotherapy may enhance lesion regression, accelerate therapeutic response, and potentially reduce recurrence in selected clinical settings. [19]

Therefore, the present study was undertaken to evaluate the clinical efficacy, safety profile, and therapeutic outcomes of intralesional steroid therapy with and without adjunctive cryotherapy in keloid management, with the objective of generating locally relevant evidence to refine evidence-based treatment strategies and improve long-term patient outcomes.

MATERIALS & METHODS

This was a retrospective comparative study conducted on 50 patients attending the Outpatient Department of Dermatology, Sapthagiri Hospital, Sapthagiri Institute of Medical Sciences and Research Centre (SIMSRC). The study was carried out from May 2025 to May 2026.

Patients aged more than 18 years, those with 1-5 keloids and willing to participate in the study were included in the study. Pregnant and lactating women, those unsuitable for the treatment modalities used in the study, and those unlikely to adhere to the treatment schedule regularly were excluded from the study
After obtaining approval and clearance from the Institutional Ethics Committee, patients fulfilling the inclusion criteria were enrolled in the study after obtaining written informed consent. A detailed clinical history, complete cutaneous and systemic examination, and basic laboratory investigations were performed prior to initiation of therapy. The findings were recorded in a structured proforma. Patients were randomly allocated into two treatment groups.

Group 1 – Intralesional Triamcinolone Acetonide

Patients received intralesional injections of triamcinolone acetonide at a concentration of 40 mg/mL using an insulin syringe. The lesion was cleaned with antiseptic solution prior to injection. Treatment was administered at four-week intervals for a total duration of 16 weeks.

Group 2 – Cryotherapy with Intralesional Triamcinolone Acetonide

At each session, cryotherapy was administered using liquid nitrogen under strict aseptic precautions until a freeze halo of approximately 1 mm appeared, typically achieved within 10–20 seconds. Following the second thaw, intralesional triamcinolone acetonide at a concentration of 40 mg/mL was injected. The volume administered was calculated as 0.1 mL per cm^2 of lesion area, not exceeding 1 mL per lesion. Treatment was repeated once monthly for a maximum of four sessions or until complete flattening of the lesion, whichever occurred earlier.

Outcome Assessment

Each patient was evaluated at baseline and at monthly follow-up visits. Objective assessment was performed using the Vancouver Scar Scale (VSS), and subjective assessment included evaluation of pain and pruritus. Keloid height was measured using calipers, pliability was assessed by palpation, vascularity by visual inspection, and pigmentation was scored relative to surrounding skin.

Table 1: Pain and pruritus graded on a three-point scale:

Score	Pain or pruritus
0	None
1	Mild
2	Moderate
3	Severe

Statistical Analysis

Data were collected and entered into Microsoft Excel. Statistical analysis was performed using the Statistical Package for the Social Sciences (SPSS), version 20. Descriptive and inferential statistics were applied. Baseline demographic and clinical variables were summarized using mean and standard deviation or median and interquartile range for continuous variables, and frequencies with percentages for categorical variables. Normality testing was performed to determine appropriate parametric or non-parametric statistical tests. A p-value of less than 0.05 was considered statistically significant.

RESULT

Table 2: Demographic distribution by treatment group

	Group 1 N (%)	Group 2 N (%)	Total N (%)	p-value
Age Category (years)				
18-20	4 (16.0)	2 (8.0)	6 (12.0)	0.479
21–40	12 (48.0)	13 (52.0)	25 (50.0)	
41–60	8 (32.0)	6 (24.0)	14 (28.0)	
>60	1 (4.0)	4 (16.0)	5 (10.0)	
Sex				
Female	14 (56.0)	9 (36.0)	23 (46.0)	0.156
Male	11 (44.0)	16 (64.0)	27 (54.0)	
Site of lesion				
Abdomen	2 (8.0)	4 (16.0)	6 (12.0)	0.734
Arm	5 (20.0)	5 (20.0)	10 (20.0)	
Back	0 (0.0)	1 (4.0)	1 (2.0)	
Chest	10 (40.0)	12 (48.0)	22 (44.0)	
Earlobe	2 (8.0)	0 (0.0)	2 (4.0)	
Knee	1 (4.0)	0 (0.0)	1 (2.0)	
Neck	1 (4.0)	1 (4.0)	2 (4.0)	
Shoulder	4 (16.0)	2 (8.0)	6 (12.0)	
Duration of disease				
≤12	7 (28.0)	6 (24.0)	13 (26.0)	0.88
13–24	3 (12.0)	7 (28.0)	10 (20.0)	
25–36	8 (32.0)	5 (20.0)	13 (26.0)	
>36	7 (28.0)	7 (28.0)	14 (28.0)	

Most of patients in both treatment groups belonged to the 21–40 years category, accounting for 48% in Group 1 and 52% in Group 2, contributing to half of the total study population (50%). The 41–60 years group formed the next largest proportion, with 32% in Group 1 and 24% in Group 2. The study population showed a slight male predominance overall (54%), with males constituting 44% of Group 1 and 64% of Group 2. The chest was the most common site of keloid occurrence in both groups, observed in 40% of Group 1 and 48% of Group 2, making up 44% of the total cases. The arm was the second most frequent site (20% in both groups). Other sites such as abdomen and shoulder showed moderate representation, while sites like earlobe, knee, back, and neck were less common. The highest proportion was seen in patients with duration greater than 36 months (28% in each group). However, none of the above parameters were statistically significant. (Table 2)

Table 3. Keloid characteristics by treatment Group

	Group 1 N (%)	Group 2 N (%)	Total N (%)	P value
Preceding factors				

Spontaneous	1 (4.0)	0 (0.0)	1 (2.0)	**0.546**
Acneiform eruption	8 (32.0)	9 (36.0)	17 (34.0)	
Piercing	2 (8.0)	0 (0.0)	2 (4.0)	
Trauma	14 (56.0)	16 (64.0)	30 (60.0)	
Number of keloids				
1	7 (28.0)	5 (20.0)	12 (24.0)	**0.540**
2	7 (28.0)	7 (28.0)	14 (28.0)	
3	9 (36.0)	9 (36.0)	18 (36.0)	
≥4	2 (8.0)	4 (16.0)	6 (12.0)	
Number of treatment sessions				
≤3	2 (8.0)	3 (12.0)	5 (10.0)	**1**
4	23 (92.0)	22 (88.0)	45 (90.0)	
Complications				
None	22 (88.0)	21 (84.0)	43 (86.0)	**0.026**
Type 1	3 (12.0)	0 (0.0)	3 (6.0)	
Type 2	0 (0.0)	4 (16.0)	4 (8.0)	

Trauma emerged as the most common preceding factor for keloid formation in both groups, observed in 56% of Group 1 and 64% of Group 2. Most patients presented with multiple keloids, with the highest proportion having three lesions (36% in both groups). Patients with one or two keloids were also common, while those with four or more lesions were relatively fewer, though slightly higher in Group 2 (16%) than Group 1 (8%). Most patients in both groups required four treatment sessions (92% in Group 1 and 88% in Group 2). Most patients in both groups did not experience complications (88% in Group 1 and 84% in Group 2). However, the type of complications differed between groups: Group 1 reported only Type 1 complications (12%), while Group 2 showed only Type 2 complications (16%). However, none of the above parameters were statistically significant. (Table 3)

Table 4: Vascularity Score During Follow-up by Treatment Group

Time Point	Category	Group 1 N (%)	Group 2 N (%)	Total N (%)	Test	p-value
Baseline	Score 2	8 (32.0)	11 (44.0)	19 (38.0)	$\chi^2 = 0.764$	0.382
	Score 3	17 (68.0)	14 (56.0)	31 (62.0)		
4 weeks	Score 1	8 (32.0)	11 (44.0)	19 (38.0)	$\chi^2 = 0.764$	0.382
	Score 2	17 (68.0)	14 (56.0)	31 (62.0)		
8 weeks	Score 0	8 (33.3)	11 (47.8)	19 (40.4)	$\chi^2 = 1.024$	0.312
	Score 1	16 (66.7)	12 (52.2)	28 (59.6)		
12 weeks	Score 0	23 (100)	22 (100)	45 (100)	—	—
16 weeks	Score 0	23 (100)	22 (100)	45 (100)	—	—

At baseline, a higher proportion of patients in both groups exhibited increased vascularity, with 68% in Group 1 and 56% in Group 2 having severe vascularity, while the remaining patients had moderate vascularity. By 4 weeks, there was a clear shift toward improvement, with 32% of Group 1 and 44% of

Group 2 already achieving mild vascularity (Score 1). At 8 weeks, further improvement was evident as 33.3% of Group 1 and 47.8% of Group 2 achieved complete resolution (Score 0), while the remaining patients had only mild vascularity. By 12 and 16 weeks, 100% of patients in both groups achieved Score 0. Statistical analysis at earlier time points showed no significant difference, and later comparisons were not possible due to uniform outcomes. (Table 4)

Table 5: Pigmentation Score During Follow-up by Treatment Group

Time Point	Category	Group 1 N (%)	Group 2 N (%)	Total N (%)	Test
Baseline	1	17 (68.0)	12 (48.0)	29 (58.0)	$\chi^2 = 2.053$
	2	8 (32.0)	13 (52.0)	21 (42.0)	
4 weeks	0	13 (52.0)	6 (24.0)	19 (38.0)	$\chi^2 = 4.169$
	1	8 (32.0)	13 (52.0)	21 (42.0)	
	2	4 (16.0)	6 (24.0)	10 (20.0)	
8 weeks	0	14 (58.3)	10 (43.5)	24 (51.1)	$\chi^2 = 1.039$
	1	7 (29.2)	9 (39.1)	16 (34.0)	
	2	3 (12.5)	4 (17.4)	7 (14.9)	
12 weeks	0	16 (69.6)	16 (72.7)	32 (71.1)	
	1	5 (21.7)	4 (18.2)	9 (20.0)	
	2	2 (8.7)	2 (9.1)	4 (8.9)	
16 weeks	0	18 (78.3)	19 (86.4)	37 (82.2)	
	1	3 (13.0)	2 (9.1)	5 (11.1)	
	2	2 (8.7)	1 (4.5)	3 (6.7)	

At baseline, 68% of patients in Group 1 had lower pigmentation scores (Score 1) compared to 48% in Group 2, while higher pigmentation (Score 2) was more common in Group 2 (52% vs 32%). By 4 weeks, improvement was observed, with 52% of Group 1 achieving normal pigmentation (Score 0) compared to only 24% in Group 2**.** At 8 weeks, 58.3% of Group 1 and 43.5% of Group 2 achieved Score 0, maintaining the trend of better early improvement in Group 1. By 12 weeks, both groups showed comparable improvement, with around 70% of patients in each group achieving normal pigmentation. At 16 weeks, complete or near-complete pigmentation normalization was seen in 78.3% of Group 1 and 86.4% of Group

2. The differences were not statistically significant. (Table 5)

Table 6: Pliability Score During Follow-up by Treatment Group

Time Point	Category	Group 1 N (%)	Group 2 N (%)	Total N (%)	Test	p-value
Baseline	3	15 (60.0)	15 (60.0)	30 (60.0)	$\chi^2 = 0.000$	1.000
	4	10 (40.0)	10 (40.0)	20 (40.0)		
4 weeks	2	15 (60.0)	15 (60.0)	30 (60.0)	$\chi^2 = 0.000$	1.000
	3	10 (40.0)	10 (40.0)	20 (40.0)		
8 weeks	1	14 (58.3)	13 (56.5)	27 (57.4)	$\chi^2 = 0.016$	0.900
	2	10 (41.7)	10 (43.5)	20 (42.6)		

12 weeks	0	13 (56.5)	12 (54.5)	25 (55.6)	$\chi^2 = 0.018$	0.894

At baseline, both groups had identical distributions, with 60% of patients having Score 3 (moderate stiffness) and 40% having Score 4 (severe stiffness). By 4 weeks, improvement was seen in both groups, with 60% shifting to Score 2 and 40% to Score 3. At 8 weeks, further improvement occurred, with approximately 57–58% of patients in both groups achieving Score 1, while the remaining had Score 2. By 12 weeks, more than half of patients (56.5% in Group 1 and 54.5% in Group 2) achieved normal pliability (Score 0). Thus, both groups showed parallel and nearly identical improvement trajectories, with no meaningful proportional difference at any stage, indicating equal efficacy in improving scar pliability. (Table 6)

Table 7. Height Score During Follow-up by Treatment Group

Time Point	Category	Group 1 N (%)	Group 2 N (%)	Total N (%)	Test	p-value
Baseline	2	16 (64.0)	10 (40.0)	26 (52.0)	$\chi^2 = 2.885$	0.089
	3	9 (36.0)	15 (60.0)	24 (48.0)		
4 weeks	1	16 (64.0)	10 (40.0)	26 (52.0)	$\chi^2 = 2.885$	0.089
	2	9 (36.0)	15 (60.0)	24 (48.0)		
8 weeks	0	15 (62.5)	9 (39.1)	24 (51.1)	$\chi^2 = 2.567$	0.109
	1	9 (37.5)	14 (60.9)	23 (48.9)		
12 weeks	0	23 (100)	22 (100)	45 (100)	—	—
16 weeks	0	23 (100)	22 (100)	45 (100)	—	—

At baseline, 36% of Group 1 and 60% of Group 2 had more elevated scars (Score 3). By 4 weeks, the distribution mirrored baseline improvement, with 64% of Group 1 improving to Score 1 compared to only 40% in Group 2. At 8 weeks, 62.5% of Group 1 achieved complete flattening (Score 0) compared to 39.1% in Group 2. However, by 12 and 16 weeks, 100% of patients in both groups achieved Score 0. Thus, Group 1 demonstrated faster early reduction in scar height, but both groups reached identical final outcomes. (Table 7)

Table 8. Pain Score During Follow-up by Treatment Group

Time Point	Pain score	Group 1 N (%)	Group 2 N (%)	Total N (%)	Test	p-value
Baseline	0	16 (64.0)	14 (56.0)	30 (60.0)	$\chi^2 = 0.333$	0.564
	1	9 (36.0)	11 (44.0)	20 (40.0)		
4 weeks	0	25 (100)	25 (100)	50 (100)	—	—
8 weeks	0	24 (100)	23 (100)	47 (100)	—	—
12 weeks	0	23 (100)	22 (100)	45 (100)	—	—
16 weeks	0	23 (100)	22 (100)	45 (100)	—	—

At baseline, 64% of Group 1 and 56% of Group 2 reported no pain, while the remaining patients had mild

pain. By 4 weeks, 100% of patients in both groups reported complete absence of pain, and this persisted throughout all subsequent follow-ups. This demonstrates that both treatment modalities resulted in rapid and complete relief of pain within the first month, with no difference between groups. (Table 8)

Table 9. Pruritus During Follow-up by Treatment Group

Time Point	Pruritus score	Group 1 N (%)	Group 2 N (%)	Total N (%)	Test	p-value
Baseline	0	10 (40.0)	11 (44.0)	21 (42.0)	$\chi^2 = 0.082$	0.774
	1	15 (60.0)	14 (56.0)	29 (58.0)		
4 weeks	0	25 (100)	25 (100)	50 (100)	—	—
8 weeks	0	24 (100)	23 (100)	47 (100)	—	—
12 weeks	0	23 (100)	22 (100)	45 (100)	—	—
16 weeks	0	23 (100)	22 (100)	45 (100)	—	—

At baseline, pruritus was present in a majority of patients, affecting 60% of Group 1 and 56% of Group 2, indicating similar symptom severity. By 4 weeks, all patients (100%) in both groups reported complete absence of pruritus, and this improvement was sustained throughout the study period. (Table 9)

Table 10: Comparison of Total Vancouver Scar Scale (VSS) Scores Between Treatment Groups

Time Point	Group 1 (n=25) Mean ± SD	Group 2 (n=25) Mean ± SD	Mann–Whitney	p-value
Baseline	9.76 ± 0.83	10.08 ± 1.22	268.0	0.373
4 weeks	6.08 ± 0.81	6.56 ± 1.45	260.0	0.291
8 weeks	2.88 ± 0.97	3.04 ± 1.77	292.5	0.698
12 weeks	0.76 ± 0.60	0.72 ± 0.94	346.5	0.480
16 weeks	0.28 ± 0.61	0.16 ± 0.47	338.0	0.447

At baseline, mean VSS scores were slightly higher in Group 2, indicating marginally more severe scars. Over time, both groups showed a progressive and steep decline in VSS scores. By 4 weeks, scores reduced by approximately 35–40% in both groups, and by 8 weeks, there was a reduction of nearly 70% from baseline values. At 12 and 16 weeks, scores approached near zero in both groups, indicating almost complete resolution of scar severity. The proportional reduction in VSS scores was similar in both groups at all time points, indicating comparable overall efficacy. (Table 10)



Figure 1: Group 1 – Intralesional Steroids at baseline and 16 weeks

Figure 2: Group 2- Intralesional Steroid with Cryotherapy at baseline and 16weeks



DISCUSSION

Keloids are often associated with symptoms such as pain, pruritus, and cosmetic disfigurement. Despite the availability of multiple therapeutic modalities, an optimal treatment strategy remains elusive due to high recurrence rates and variable responses. Among the various treatment options, intralesional corticosteroids, particularly triamcinolone acetonide, have long been considered the mainstay of therapy due to their anti-inflammatory, vasoconstrictive, and collagen synthesis-inhibiting properties. Cryotherapy, on the other hand, acts by inducing vascular damage, cellular necrosis, and subsequent scar remodeling, and has been increasingly used either as a standalone modality or in combination with intralesional steroids to enhance therapeutic outcomes. The rationale behind combining cryotherapy with intralesional triamcinolone lies in its potential to improve drug penetration, accelerate lesion softening, and achieve faster reduction in scar volume.

In this context, the present study was undertaken to compare the efficacy of intralesional triamcinolone acetonide alone versus cryotherapy combined with intralesional triamcinolone acetonide in the management of keloids, using objective assessment tools such as the Vancouver Scar Scale and caliper measurements, along with evaluation of symptomatic parameters like pain and pruritus.

Majority of patients (48% and 52%) belonged to the 21–40 years age group in the Intralesional Triamcinolone Acetonide group and the Cryotherapy with Intralesional Triamcinolone Acetonide group

respectively, with a slight male predominance overall (54%; 44% vs 64%), and no statistically significant difference in age or sex distribution, indicating good baseline comparability between the groups. Comparable demographic trends have been reported in several studies. Cohen AJ et al. [17] noted a female predominance while Anjana G et al,[20] noted a male predominance highlighting the variability in gender distribution.

Similarly, Krishna PS et al. [21] demonstrated a predominantly young adult population with comparable age and gender distribution across treatment groups, which aligns with the baseline similarity observed in our study. In contrast, Jannati P et al. [22] reported a younger cohort (mean age 24.25 years) with nearly equal gender distribution (47.5% males vs 52.5% females), indicating that demographic patterns may vary depending on population characteristics. Overall, the findings across studies suggest that keloids predominantly affect young adults, with variable gender distribution, and that most clinical trials, including ours, maintain comparable baseline demographics between treatment groups to ensure reliable assessment of therapeutic efficacy.

In our study, the chest was the most common site of keloids in both the Intralesional Triamcinolone group (40%) and the Combination therapy group (48%), followed by the arm (20% in both groups). Most patients had long-standing disease (>36 months: 28% in both groups), and trauma was the most common etiological factor (56% vs 64%), followed by acneiform eruptions (~34%). Similar patterns of anatomical distribution and etiology have been reported in previous studies. Cohen AJ et al. [17] observed that the ear (28.6–28.8%) and chest (25– 27%) were the most common sites, with surgery and ear piercing being the leading etiological factors, which aligns with our findings of site predominance and trauma-related causes. Krishna PS et al. [21] reported trunk involvement in 43.33% of cases, followed by head and neck (23.33%), with spontaneous etiology being most common (56.66%), again supporting that trunk/chest regions are frequently involved. Jannati P et al. [22] reported the chest as the most common site (35%, p = 0.034), with burns (31.25%) as the leading cause and a significant proportion of patients presenting with itching (40%) and moderate VSS involvement, which is comparable to our study where symptomatic presentation and moderate disease severity were common.

With respect to disease chronicity and symptom profile, Barara M et al [23]. reported keloid duration ranging from 1–15 years with variable thickness (0.2–1.6 cm), and patients commonly presenting with cosmetic concerns (58%), pruritus (36%), and pain (6%), which parallels the chronic and symptomatic nature observed in our study. Similarly, Gamit HH et al. [18] reported spontaneous keloids (43%) as the most common, followed by infection and trauma, with itching present in 55% and pain in 8% of patients, again reflecting comparable etiological and symptomatic patterns.

In our study, the majority of patients in both the Intralesional Triamcinolone group and the Combination therapy group presented with multiple keloids, most commonly three lesions (36% in both groups), and required four treatment sessions (92% vs 88%), with no statistically significant difference indicating comparable disease burden and treatment exposure. Similar observations have been reported in previous studies. Cohen AJ et al. [17] treated 178 keloids across 109 patients, demonstrating a high lesion burden per patient, which is consistent with our findings of multiple lesions being common. Krishna PS et al. [21] also reported a mean of approximately three keloids per patient, further supporting the trend of multiple lesion involvement in keloid patients.

With respect to treatment exposure, Anjana G et al [20] reported up to five treatment sittings with progressive improvement, while Jwa SJ et al [24] observed a higher mean of 6.26 treatment sessions, indicating that repeated interventions are often necessary for optimal outcomes. In contrast, Jannati P et

al. [22] reported a shorter treatment duration of approximately 6 weeks for combination therapy, though outcomes were still achieved through structured sessions. Furthermore, Ahsan MQ et al. [19] showed comparable lesion burden and treatment follow-up across groups with multiple visits up to 12 weeks, aligning with our study design. Overall, these findings suggest that keloids commonly present with multiple lesions and require repeated treatment sessions over time, and that our study design is consistent with existing literature in terms of disease burden and therapeutic exposure.

In our study, most patients in both the Intralesional Triamcinolone group (88%) and the Combination therapy group (84%) did not develop complications; however, a statistically significant difference was observed in the type of complications, with Type 1 complications occurring only in Group 1 (12%) and Type 2 complications only in Group 2 (16%) ($p = 0.026$), suggesting differing safety profiles between the two modalities.

Comparable safety patterns have been reported in the literature. Cohen AJ et al. [17] did not report significant complications, indicating overall safety of both modalities. However, several studies have highlighted a higher side-effect burden with combination therapies. Anjana G et al [20] reported erythema (28%), edema (24%), skin atrophy (24%), and post-inflammatory hyperpigmentation (28%) in the combination group, emphasizing steroid-related adverse effects such as atrophy.

Similarly, Krishna PS et al. [21] reported procedural pain (63.3%), pigmentary changes, and ulceration in the cryotherapy with steroid group, while Jannati P et al. [22] observed pain in 100% of patients and telangiectasia in 20%, indicating a higher incidence of treatment-related discomfort with combination therapy. Overall, while most studies including ours, demonstrate that both modalities are generally safe, combination therapy may be associated with a higher incidence of local adverse effects, although these are typically mild and manageable, and must be weighed against potential therapeutic benefits.

In our study, all components of the Vancouver Scar Scale showed progressive and significant improvement in both the Intralesional Triamcinolone group and the Combination therapy group. Severe baseline involvement, such as vascularity Score 3 (68% vs 56%) and height Score 3 (36% vs 60%), reduced steadily over time, with complete or near-complete resolution achieved by 12–16 weeks, where 100% normalization of vascularity and height was observed. Early trends indicated slightly faster vascularity reduction in the combination group, whereas height reduction occurred earlier in the steroid-alone group. Pigmentation showed earlier improvement in Group 1 (Score 0 at 4 weeks: 52% vs 24%), but better final normalization in Group 2 (86.4% vs 78.3%), while pliability improved similarly in both groups, with approximately 55% achieving Score 0 by 12 weeks. These findings suggest comparable overall efficacy of both modalities, with minor temporal variations in response.

Comparable improvements in scar characteristics have been consistently reported in the literature. Jwa SJ et al [24] demonstrated significant improvement across all VSS components, with vascularity reducing from 2 to 1.1, pigmentation from 1.9 to 1.6, pliability from 3.8 to 1.3, and height from 2.4 to 1, supporting the effectiveness of combination therapy in improving scar quality. Furthermore, Gamit HH et al [18] observed faster improvement in vascularity, pliability, and thickness in the cryotherapy with steroid group ($p < 0.05$), while Ahsan MQ et al. [19] reported significant reduction in lesion size in both groups (from 8.17 cm to 3.57 cm vs 7.50 cm to 4.75 cm), again supporting improvement in scar height.

Overall, the findings across studies consistently demonstrate that both intralesional steroids and combination therapy lead to significant improvement in vascularity, pigmentation, pliability, and height of keloids. While some studies suggest a trend toward faster or greater improvement with combination

therapy, our study demonstrates that both modalities achieve comparable and near-complete resolution of VSS parameters over time.

In our study, pain and pruritus were present at baseline in both the Intralesional Triamcinolone group (pain 36%, pruritus 60%) and the Combination therapy group (pain 44%, pruritus 56%), but both symptoms resolved completely (100%) by 4 weeks and remained absent throughout follow-up, demonstrating rapid and equivalent symptomatic relief with both modalities. Comparable findings have been reported in the literature. Jwa SJ et al. [24] reported early improvement in symptoms such as pain and itching, often after the first treatment session, reinforcing the rapid onset of symptomatic relief observed in our study. In contrast, Jannati P et al. [22] reported improvement in itching (present in 40% at baseline), but also noted pain as a frequent treatment-related adverse effect, indicating that while symptomatic relief is achieved, procedural discomfort may influence patient experience.

Notably, Bijlard E et al. [3] reported that cryotherapy alone did not significantly improve symptoms such as pain and itching, whereas alternative modalities like excision with brachytherapy showed significant improvement, highlighting the limited efficacy of cryotherapy as a standalone modality. Overall, the findings across studies suggest that both intralesional steroids and combination therapy provide effective and rapid symptomatic relief, with combination therapy not demonstrating clear superiority, while cryotherapy alone may be less effective in symptom control.

In our study, mean VSS scores reduced markedly in both the Intralesional Triamcinolone group (from 9.76 ± 0.83 to 0.28 ± 0.61) and the Combination therapy group (from 10.08 ± 1.22 to 0.16 ± 0.47), representing over 90% improvement, while ΔVSS reached 9.48 ± 1.19 and 9.92 ± 1.15 respectively at 16 weeks, with no statistically significant difference, indicating comparable and near complete efficacy of both treatment modalities.

Anjana G et al. [20] in their study note that the cryotherapy with intralesional steroid group demonstrated superior efficacy, with 100% of patients achieving >75% improvement on GPA scoring compared to 60% in the comparator group, and >90% lesion reduction seen in 72% vs 32%, with statistically significant differences across most sittings, suggesting better outcomes with combination therapy compared to our study where both groups showed comparable efficacy without significant difference. In the study done by Jwa SJ et al., [24] the mean VSS score reduced from 10.1 at baseline to 5.0 after treatment, reflecting approximately 50% improvement, and 78.3% of recurrent lesions responded to additional therapy, indicating good efficacy of combination therapy, though the magnitude of improvement was comparatively lower than the near-complete resolution observed in our study. In the study done by Barara M et al [23] , 76.67% of patients achieved good to excellent response (≥50% flattening), with average flattening reaching 58.13% after 6 sessions, demonstrating moderate efficacy of cryotherapy alone, which is lower compared to the near-complete resolution observed in our study using intralesional steroids with or without cryotherapy.

LIMITATIONS

This study has several limitations. The small sample size (n=50), single-center design, and 16-week follow-up may limit the generalizability of the findings and preclude assessment of long-term keloid recurrence. Limited reporting of randomization and blinding may have introduced observer bias, particularly for subjective outcomes such as pain, pruritus, and Vancouver Scar Scale (VSS) scores. Although objective measures were used, some VSS components remain subjective. The absence of advanced imaging or histopathological assessment, inclusion of keloids from different anatomical sites

and etiologies, and lack of patient-reported outcomes (e.g., satisfaction and quality of life) further limit the interpretation of the results.

RECOMMENDATIONS

Future studies should include larger, multicenter cohorts with longer follow-up to improve generalizability and evaluate long-term recurrence. Robust randomization and blinding, along with stratification by keloid characteristics (e.g., size, site, duration, and etiology), would strengthen the evidence. Incorporating objective assessment tools, patient-reported outcomes, and comparisons with other treatment modalities or combination therapies would provide a more comprehensive evaluation. Further research should also determine optimal dosing schedules, treatment frequency, and cost-effectiveness to guide clinical practice.

CONCLUSION

This study demonstrates that both intralesional triamcinolone acetonide alone and in combination with cryotherapy are effective for keloid management, producing significant improvements in scar characteristics, pain, and pruritus over 16 weeks. Although combination therapy showed a trend toward earlier improvement in some parameters, overall efficacy, including reduction in Vancouver Scar Scale scores, was comparable between the two groups. However, the pattern of complications differed significantly, suggesting differences in safety profiles. Overall, intralesional triamcinolone alone remains an effective and simpler treatment option, while the choice of therapy should be individualized based on patient characteristics, lesion features, and potential risk of complications.

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