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Original Article

Comparison of Cryotherapy Plus Triamcinolone Versus 5-Fluorouracil Plus Triamcinolone for Keloid Treatment

Misha Saghir[1*], Saeed Ahmad[1]

[1]Department of Dermatology, Aziz Fatimah Medical and Dental College, Faisalabad.

Abstract

Background Keloids are a common fibroproliferative disorder resulting from abnormal wound healing and can cause significant cosmetic concerns, itching, pain, and psychological distress. Despite the availability of multiple treatment options, recurrence remains a major challenge, and no single therapy has been established as the gold standard. Therefore, identifying more effective treatment combinations is essential for improving patient outcomes.

Objective To compare the efficacy of cryotherapy combined with intralesional triamcinolone acetonide (TA) versus intralesional 5-fluorouracil (5-FU) combined with TA for the treatment of keloids.

Methods 122 patients with keloids were equally divided into two groups. Group A received cryotherapy followed by intralesional triamcinolone acetonide, while Group B received intralesional 5-fluorouracil combined with triamcinolone acetonide. Treatments were administered at 4-week intervals for six sessions. Efficacy was assessed at 24 weeks based on a ≥50% reduction in scar height measured using a caliper.

Results Overall efficacy was significantly higher in Group B (91.8%) compared to Group A (70.5%) (*P*= .003). A greater response was observed in older patients, higher BMI categories, and in nodular, flat, mid-sternal, and leg lesions.

Conclusion Intralesional 5-FU combined with TA is more effective than cryotherapy with TA for keloid management, particularly in resistant or long-standing lesions. Larger randomized trials with extended follow-up are recommended to assess long-term outcomes and recurrence.

Keywords Keloid; Cryotherapy; Triamcinolone acetonide; 5-Fluorouracil; Intralesional injection.

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Introduction

Severe, raised, fibrous lesions that spread beyond the boundaries of the initial incision are known as keloid lesions, and they develop as a consequence of improper wound healing.[1,2] Pain, pruritus, and cosmetic disfigurement associated with keloids may significantly impair patients' quality of life.[1] Factors such as their placement on the body, the size of the lesion, the degree of elevation, the pigmentation, and any pain they may cause greatly affect clinical appearance.[3,4]

Even though keloids are a frequent skin issue, no single method has been definitively shown to cure them. The high risk of recurrence after treatment is one of the primary obstacles in their management. Keloid development is more common in some parts of the body, including the ears, front chest, shoulders, upper back, and upper limbs.[5,6] Furthermore, the anatomical site and the treatment method both have a role in determining the

Address for correspondence
Dr. Misha Saghir, PGR,
Department of Dermatology,
Aziz Fatimah Medical & Dental College, Faisalabad.
Email: mish_blog@yahoo.com

likelihood of recurrence.[7,8] Several treatment approaches for keloid management have been proposed over the years, but no single approach has emerged as the gold standard.[6,8] The results of monotherapy have been mixed and have only been shown in the short term. The primary treatment modality remains intralesional corticosteroid injection, most often triamcinolone acetonide. Because of its antimitotic properties, it prevents keratinocytes and fibroblasts from proliferating.

It also increases collagenase activity, which makes collagen breakdown easier, and it decreases plasma protease inhibitor levels, both of which contribute to fibroblast degeneration.[9] In keloid lesions, the primary mode of action of cryotherapy is by forming intracellular ice crystals resulting in direct tissue hypoxia.[10] This disrupts endothelial cell junctions and results in vascular thrombosis, microthrombi, vascular stasis, and tissue necrosis and sloughing. Combined therapies such as cryotherapy and intralesional corticosteroids, among others, have proven effective in comparison to single agents in terms of cure rate, response and recurrence.[11]

Triamcinolone acetonide (TA) and cryotherapy were shown to have a 75% effectiveness rate in a research,[12] while another study reported the efficacy of TA in combination with 5-fluorouracil (FU) as 93%.[13] Keloids are common and can be difficult to treat skin lesions. Keloids do not have a gold standard treatment, and although a variety of treatments are available, they are highly recurrent. The aim of this study is to compare the effect of cryotherapy and triamcinolone acetonide (TA) versus 5-fluorouracil (5-FU) and TA in the treatment of keloids. This study aimed to improve the management of this chronic condition by comparing the outcomes of the two treatment regimens, which may help identify a more readily available but effective treatment.

Methods

This non-randomized controlled trial was conducted at the Department of Dermatology, Aziz Fatimah Hospital, Faisalabad, Pakistan, from June to November 2025 after approval from the Institutional Ethical Review Committee (IERC) (Ref. No. IEC/356-25 dated 05.05.2025). Using a 5% significance level and an 80% power, the sample size was determined using the World Health Organization's sample size calculator for comparison of two proportions. Group B was expected to achieve 93.3%[13] effectiveness, whereas group A was projected to achieve 75%.[12] A total of 122 patients were included in the sample, including 61 individuals from each group. It was done using a non-probability consecutive sampling method.

Patients of either gender, aged 20-60 years, clinically diagnosed with keloids measuring not more than 10 cm in the largest diameter were included. Pregnant or lactating females, patients who have received any form of scar treatment within the last six months, individuals with deranged liver function tests, serum creatinine levels exceeding 1.2 mg/dL, known cases of chronic kidney disease, and those with a white blood cell count below 4,000 or above 11,000 cells/µL were excluded from the study.

Body weight and height were measured after obtaining ethical approval, and informed consent was taken from each participant. Eligible patients were enrolled according to the inclusion criteria. A detailed history was obtained from each patient, particularly regarding the duration of the lesion and the nature of the initial injury that led to keloid formation. Body weight was measured using a calibrated digital weighing scale with patients in light clothing and without footwear, recorded to the nearest 0.1 kg. Height was measured using a wall-mounted stadiometer with patients standing erect without footwear, recorded to the nearest 0.1 cm. BMI was then calculated as weight (kg) divided by height squared (m^2). Patients were categorized as underweight (<18.5 kg/m^2), normal weight (18.5-24.9 kg/m^2), overweight (25-29.9 kg/m^2), and obese (≥30 kg/m^2). The patients were then divided into two

groups. Group A received a combination of cryotherapy and intralesional triamcinolone acetonide (TA). Cryotherapy was performed by applying a liquid nitrogen spray twice for 10 seconds directly onto the keloid surface. After an interval of 15-30 minutes, intralesional TA (Triamhexal) at a concentration of 40 mg/mL was administered using a 27-gauge insulin syringe at a dose of 0.2 mL/cm² injected intradermally into the lesion. Group B was treated with a combination of intralesional 5-fluorouracil and TA. Each patient was receiving an injection consisting of 0.9 mL of 5-fluorouracil (50 mg/mL) mixed with 0.1 mL of TA (40 mg/mL) in a 9:1 ratio. The injection was administered intralesionally at 1 cm intervals, delivering 0.1 mL at each site.

Treatments in both groups were repeated at four-week intervals for six sessions. Efficacy was assessed at 24 weeks, after completion of all six sessions. Treatment was considered effective if there was a ≥ 50% reduction in the initial scar height compared to baseline. Scar height measurements were obtained using a calibrated vernier caliper at baseline and during follow-up assessments. The data sheet was completed with all clinical and treatment details and outcome variables.

The statistical analysis was conducted using SPSS 25.0. Mean±standard deviation was used to show continuous variables such as age, weight, height, body mass index, duration of illness, time from original injury, length, and area of the scar. Qualitative variables such as gender, treatment effectiveness, keloid site, and lesion shape were presented as frequencies and percentages. Independent sample t test was applied to compare quantitative variables among two groups such as mean age, weight, height, BMI, duration of illness and duration of injury. To compare the two therapy groups' effectiveness, a chi-square test was used. Age, sex, BMI, illness duration, injury time, scar location, form, size, and area are all effect modifiers that were controlled for by stratification. To ascertain their impact, a post-stratification Chi-square test was used. Statistical significance is defined as a p-value below .05.

Result

The research had 122 participants, including 61 from each of the two groups, all of whom had keloids identified clinically. Group A participants had an average age of 38.85±11.84 years, whereas Group B participants had an average age of 40.38±12.37 years. In the end, there were 50.8% men and 49.2% women. On the whole, the two groups were similar when it came to clinical and demographic factors from the outset. Nonetheless, there was a notable disparity in both the mean BMI (*P*=.047) and the BMI categories (*P*=.026). Results showed that Group B's therapy was more effective than Group A's at 24 weeks (*P*=.003).

The demographic information of the patients in the two therapy groups is shown in **Table 1**. Both Group

Table 1 Baseline demographic and clinical characteristics of patients by treatment group.

Category	*Group A*	*Group B*	*Total*	*P-value*
Gender				.717
Male	32 (52.5%)	30 (49.2%)	62 (50.8%)	
Female	29 (47.5%)	31 (50.8%)	60 (49.2%)	
Age Mean±SD	38.85±11.84	40.38±12.37	-	.488
Age groups				.647
20-29	17 (27.9%)	16 (26.2%)	33 (27.0%)	
30-39	13 (21.3%)	11 (18.0%)	24 (19.7%)	
40-49	19 (31.1%)	16 (26.2%)	35 (28.7%)	
50-60	12 (19.7%)	18 (29.5%)	30 (24.6%)	
Weight Mean±SD	70.33±12.39	73.89±10.81	-	.094
Height Mean±SD	1.71±0.12	1.68±0.11	-	.221
BMI Mean±SD	24.54±5.65	26.46±4.92	-	.047
BMI group				.026
Underweight	9 (14.8%)	1 (1.6%)	10 (8.2%)	
Normal Weight	26 (42.6%)	26 (42.6%)	52 (42.6%)	
Overweight	16 (26.2%)	15 (24.6%)	31 (25.4%)	
Obese	10 (16.4%)	19 (31.1%)	29 (23.8%)	

Table 2 Keloid characteristics and duration of illness in patients by treatment group.

Category	*Group A*	*Group B*	*Total*	*P-value*
Site of Keloid				.556
Shoulder	8 (13.1%)	9 (14.8%)	17 (13.9%)	
Ear Lobe	12 (19.7%)	12 (19.7%)	24 (19.7%)	
Arm	12 (19.7%)	9 (14.8%)	21 (17.2%)	
Mid Sternum	8 (13.1%)	13 (21.3%)	21 (17.2%)	
Legs	13 (21.3%)	7 (11.5%)	20 (16.4%)	
Others	8 (13.1%)	11 (18.0%)	19 (15.6%)	
Shape of Keloid				.597
Nodular	20 (32.8%)	19 (31.1%)	39 (32.0%)	
Bulky	17 (27.9%)	22 (36.1%)	39 (32.0%)	
Flat	24 (39.3%)	20 (32.8%)	44 (36.1%)	
Duration of Illness (months)				.107
1-6	3 (4.9%)	11 (18.0%)	14 (11.5%)	
7-12	12 (19.7%)	12 (19.7%)	24 (19.7%)	
13-4	21 (34.4%)	21 (34.4%)	42 (34.4%)	
>24	25 (41.0%)	17 (27.9%)	42 (34.4%)	
Duration of Illness				.009
Mean±SD	21.61 ± 9.77	16.84±10.02	-	
Duration of Initial Injury (months)				.879
1-3	9 (14.8%)	12 (19.7%)	21 (17.2%)	
4-6	9 (14.8%)	10 (16.4%)	19 (15.6%)	
7-12	11 (18.0%)	10 (16.4%)	21 (17.2%)	
>12	32 (52.5%)	29 (47.5%)	61 (50.0%)	
Duration of Injury				.434
Mean±SD	12.43±7.30	11.39±7.24	-	

A and Group B had similar gender distributions (*P*=.717). Both groups had comparable means of age (*P*=.488), and there was no statistically significant difference between the age groups (*P*=.647). There was no statistically significant difference (*P*=.094 for weight and *P*=.221 for height) across the categories. Nonetheless, Group B had a noticeably higher mean BMI than Group A (26.46±4.92 vs. 24.54±5.65; *P*=.047). Group B had a greater percentage of obese patients (31.1% vs. 16.4% in Group A) and this difference was statistically significant (*P*=.026) when compared to other BMI categories.

Table 2 summarizes the keloid characteristics and duration of illness in both groups. The distribution of keloid sites was comparable between the groups (*P*=.556), with the ear lobe being the most frequent site (19.7%). The shape of keloids (nodular, bulky, and flat) did not differ significantly (*P*=.597). Although the categorical distribution of illness duration was not statistically significant (*P*=.107), the mean duration of illness was significantly longer in Group A compared to Group B (21.61±9.77 vs. 16.84±10.02 months; *P*=.009). The duration of initial injury, both categorical and mean values, was comparable between the two groups (*P*=.879 and *P*=.434, respectively).

Scar size and area were compared at baseline and after 24 weeks of therapy. There was no statistically significant difference between the two groups at baseline in terms of scar area (*P*=.407) or scar size (*P*=.814). Group B had a considerably smaller mean scar size at 24 weeks compared to Group A (2.67±1.478 vs. 3.52±2.219; *P*=.013). However, after 24 weeks, neither group showed a statistically significant difference (*P*=.181) in scar area change **(Table 3)**.

The results of the therapy for the two groups are shown in **Table 4**. Group B included 56 patients who demonstrated effectiveness (91.8%), whereas Group A had 43 individuals (70.5%). The combination of triamcinolone acetonide and 5-fluorouracil seems to be more effective than cryotherapy combined with TA (*P*=.003), according to this answer.

Treatment effectiveness broken down by demographic variables is shown in **Table 5**.

Table 3 Scar Size and area at baseline and after 24 weeks.

Outcome/ Group	*Mean*	*Std. Deviation*	*P-value*
Scar Size at Baseline			
Group A	5.72	2.339	.814
Group B	5.61	2.723	
Area Baseline			
Group A	7.17	3.031	.407
Group B	7.75	4.527	
Scar Size 24weeks			
Group A	3.52	2.219	.013
Group B	2.67	1.478	
Area 24weeks			
Group A	4.30	2.474	.181
Group B	3.67	2.698	

Table 4 Comparison of Efficacy in both groups.

Out-come	*Group A*	*Group B*	*Total*	*P-value*
Yes	43 (70.5%)	56 (91.8%)	99 (81.1%)	
No	18 (29.5%)	5 (8.2%)	23 (18.9%)	.003
Total	61 (100%)	61 (100%)	122 (100%)	

Table 5 Treatment efficacy stratified by demographics.

Category	*Group A*	*Group B*	*p-value*
Gender			
Male	25/32 (78.1%)	29/30 (96.7%)	.030
Female	18/29 (62.1%)	27/31 (87.1%)	.025
Age group (years)			
20–29	12/17 (70.6%)	14/16 (87.5%)	.235
30–39	12/13 (92.3%)	10/11 (90.9%)	.902
40–49	12/19 (63.2%)	15/16 (93.8%)	.032
≥50	7/12 (58.3%)	17/18 (94.4%)	.015
BMI group			
Underweight	7/9 (77.8%)	1/1 (100%)	.598
Normal weight	18/26 (69.2%)	24/26 (92.3%)	.035
Overweight	10/16 (62.5%)	13/15 (86.7%)	.124
Obese	8/10 (80.0%)	18/19 (94.7%)	.215

Group B's effectiveness was noticeably higher than Group A's (*P*=.030 for males and *P*=.025 for women). In the age ranges of 40-49 years (*P*=.032) and ≥50 years (*P*=.015), Group B benefited from the substantial differences in effectiveness that were seen when stratified by age. Group B's normal-weight patients showed statistically significant differences (*P*=.035) when compared to other BMI categories. Treatment effectiveness according to keloid and illness features is shown in **Table 6**. Patients with lesions in the middle of the sternum (*P*=.027) and the legs (*P*=.032) favoured Group B. Group B showed significantly better treatment response for nodular (*P*=.017) and flat keloids (*P*=.030) lesion shapes. Patients in Group B had a greater reaction when their injuries had lasted longer than 12 months, according to a statistically significant difference (*P*=.005).

Discussion

Keloids represent a challenging fibroproliferative disorder characterized by excessive collagen deposition and aberrant wound healing. Various treatment modalities have been explored; however, no single therapy has demonstrated universal efficacy.[14,15] This study evaluated the effectiveness of two methods for treating keloids: cryotherapy and intralesional triamcinolone acetonide (TA), and 5-fluorouracil (5-FU) and TA. When comparing cryotherapy with TA to a combination of 5-FU and TA, our results revealed that the latter was more effective in reducing scar height by 50% or more.

Their anti-inflammatory, vasoconstrictive, and anti-proliferative actions on fibroblasts make intralesional corticosteroids the gold standard for keloid therapy. Triamcinolone acetonide reduces collagen synthesis and glycosaminoglycan production while enhancing collagen degradation.[16] However Bernabe *et al*; stated that monotherapy with TA has been associated with recurrence rates ranging from 33% to 50%, prompting the need for combination therapies.[17]

In the present study, Group A received cryotherapy followed by intralesional TA. Cryotherapy induces vascular damage, cellular necrosis, and subsequent

Table 6 treatment efficacy stratified by keloid and illness characteristics.

Variable/ Category	*Group A*	*Group B*	*p-value*
Site of keloid			
Shoulder	5/8 (62.5%)	8/9 (88.9%)	.200
Mid Sternum	4/8 (50.0%)	12/13 (92.3%)	.027
Legs	7/13 (53.8%)	7/7 (100%)	.032
Ear Lobe	11/12 (91.7%)	11/12 (91.7%)	1.000
Arm	10/12 (83.3%)	8/9 (88.9%)	.719
Others	6/8 (75.0%)	10/11 (90.9%)	.348
Shape of keloid			
Nodular	11/20 (55.0%)	17/19 (89.5%)	.017
Bulky	13/17 (76.5%)	19/22 (86.4%)	.425
Flat	19/24 (79.2%)	20/20 (100%)	.030
Illness duration			
1–6 months	3/3 (100%)	8/11 (72.7%)	.308
7–12 months	8/12 (66.7%)	12/12 (100%)	.028
13–24 months	14/21 (66.7%)	20/21 (95.2%)	.018
>24 months	18/25 (72.0%)	16/17 (94.1%)	.073
Injury duration			
1–3 months	6/9 (66.7%)	10/12 (83.3%)	.375
4–6 months	7/9 (77.8%)	9/10 (90.0%)	.466
7–12 months	8/11 (72.7%)	9/10 (90.0%)	.314
>12 months	22/32 (68.8%)	28/29 (96.6%)	.005

collagen remodeling. Previous studies have demonstrated that cryotherapy combined with TA improves outcomes compared to TA alone. Li *et al*. reported significant flattening of keloids with combination therapy, particularly in smaller lesions.[17] However, cryotherapy may lead to hypopigmentation and delayed wound healing, particularly in darker skinned patients, restricting its use.[9] In our study while a large number of patients in Group A showed improvement, the response rate was not as good as Group B, which is consistent with what has been reported by Muneuchi *et al*. who reported moderate but not the best responses with the use of the cryotherapy-based combinations.

In our study, Group B was treated with intralesional 5-FU and TA. 5-Fluorouracil is an anti-metabolite that inhibits thymidylate synthase, leading to decreased fibroblast proliferation and collagen synthesis.[18] 5-FU and TA have demonstrated synergistic effects, with corticosteroids reducing the inflammatory response, and 5-FU acting directly on the fibroblasts.[19] The combination of 5-FU and TA led to a marked improvement in scar height and erythema, when compared to steroid-only treatment. Likewise, Davison *et al*. found the 5-FU and TA combination to be more effective, with lower recurrence and improved cosmetic outcomes.[20]

On the other hand, cryotherapy in conjunction with intralesional corticosteroids has been reported as successful. Tahir *et al*. found cryotherapy combined with TA had a 75% success rate (similar to our success rate of 70.5% in Group A).[12] Cryotherapy causes vascular stasis and cell death by crystal formation within cells, which results in keloid shrinkage. Similarly, Cohen *et al*. reported better results with cryotherapy and corticosteroid treatment than with corticosteroid treatment alone.[9] However, although cryotherapy is effective, cryotherapy may lead to pigmentary changes and induce pain after treatment, especially in dark-skinned individuals, who are prevalent in our society.

Subgroup analysis in our study demonstrated TA + 5-FU had significantly superior results in patients aged ≥40 years, in nodular and flat keloids. We also found that TA + 5-FU was significantly effective in mid sternum and leg sites. This is significant as keloids in high-tension areas, such as sternum, are difficult to treat. Ekstein *et al*. found location of the keloid to be a strong predictor of response and recurrence.[8] Based on our findings, TA + 5-FU may be particularly beneficial for these high-risk sites.

Our results indicate that patients with injury duration 7-24 months had significantly higher efficacy in TA+5-FU. Further, patients with duration of injury over 12 months had significantly better response in Group B (P=.005). These results indicate that the anti-proliferative effect of 5-FU might have a better effect in mature fibroproliferative tissues than tissue destructive treatments. Liu *et al*. found that progressive keloid lesions have increased fibroblast activity and collagen synthesis, which may account for the superior efficacy of pharmacologic modulation of this activity.[3]

While cryotherapy remains a popular and readily available treatment option, its action is primarily destructive. Nishi and Rajashekar found combination therapies are more effective than cryotherapy alone, but recurrence rates are still significant.[10] Savant *et al*. similarly stressed the importance of combination approaches to achieve the lowest recurrence rate and best long-term outcome.[11]

Our results are consistent with recent studies, which indicates that pharmacologic combinations, targeting different pathways of disease, are the most effective. Qi *et al*. noted that keloids are fibro-inflammatory as well as hypertrophic scars.[7] Cao *et al* further proposed that keloids may represent a spectrum of auto-inflammatory fibrotic disorders, underscoring the importance of targeted anti-proliferative therapy.[2] This study has several limitations. First, the study was non-randomized and conducted at a single center, which may limit generalizability. Second, the follow-up duration was relatively short and recurrence rates could not be adequately assessed.

Third, patient-reported outcomes such as pain, itching, and cosmetic satisfaction were not evaluated. Future multicenter randomized controlled trials with longer follow-up periods are recommended.

Conclusion

This study demonstrated that both treatment modalities were effective in reducing keloid size. But intralesional injection of 5-fluorouracil (5-FU) and triamcinolone acetonide (TA) was more effective than cryotherapy with TA. More patients in the 5-FU + TA group showed a ≥50% reduction in scar height, especially older patients, obese individuals and keloids with nodular or flat type of lesion. This combination was also more effective in mid-sternal and lower limb keloids. These findings suggest that 5-FU + TA may be a more effective treatment option. More large randomised trials with extended duration are needed to assess recurrence and safety.

Declaration of patient consent Authors certify that they have obtained all appropriate patient consent.

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Conflict of interest No conflict of interest.

Author's contribution

MS: Substantial contribution to study design, acquisition of data and manuscript writing.

SA: Substantial contribution to concept, study design, critical review of the manuscript.

Every author has given final approval of the manuscript version to be published and agreed to be accountable for all aspects of the work.

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