Section: Dermatology

Original Research Article

THERAPEUTIC EVALUATION OF VARIOUS MODALITIES IN KELOID

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ABSTRACT

Background: Keloids are benign fibroproliferative scars resulting from abnormal wound healing characterized by excessive collagen deposition beyond the boundaries of the original injury. They are associated with cosmetic disfigurement, pruritus, pain, and a high rate of recurrence, making their management challenging. The aim is to evaluate and compare the efficacy and adverse effects of various treatment modalities used in the management of keloids.

Materials and Methods: This open-label, prospective, randomized controlled trial was conducted in the Department of Dermatology, Ananya College of Medicine & Research kalol, Gandhinagar ,Gujarat India, from July 2024 to June 2025. One hundred patients with keloids were randomly allocated into five groups (20 patients each): Group 1—Cryotherapy alone; Group 2—Cryotherapy with intralesional triamcinolone acetonide (40 mg/ml); Group 3—Cryotherapy with intralesional 5-fluorouracil (50 mg/ml); Group 4—Cryotherapy with a combination of triamcinolone acetonide and 5-fluorouracil; and Group 5—Cryotherapy with intralesional triamcinolone acetonide (20 mg/ml) and silicone gel sheets. Treatment response was assessed using the Patient and Observer Scar Assessment Scale (POSAS).

Results: The majority of patients were aged 21–30 years (45%), and the chest was the most commonly affected site (42%). The greatest reduction in POSAS scores was observed in Group 5 (29.95) followed by Group 4 (29.40). Excellent or good responses were achieved in 90% of patients in Groups 4 and 5, compared with 40% in Group 1. Recurrence was highest with cryotherapy alone (75%), whereas no recurrence was observed in Groups 2 and 5. Adverse effects were generally mild and manageable.

Conclusion: Combination therapies, particularly cryotherapy with intralesional triamcinolone acetonide and silicone gel sheets or cryotherapy with triamcinolone acetonide and 5-fluorouracil, demonstrated superior efficacy, lower recurrence rates, and better scar improvement compared with cryotherapy alone.

Keywords: Keloid, Cryotherapy, Triamcinolone Acetonide, 5-Fluorouracil, Silicone Gel Sheet, POSAS, Scar Assessment, Recurrence, Combination Therapy, Dermatology.

INTRODUCTION

Keloids are benign fibroproliferative disorders characterized by excessive deposition of collagen and extracellular matrix components beyond the boundaries of the original wound. Unlike hypertrophic scars, keloids continue to grow progressively and rarely regress spontaneously. They represent an abnormal wound-healing response resulting from dysregulated inflammation, fibroblast proliferation, and collagen synthesis. Although keloids are not malignant, they often cause significant cosmetic disfigurement, pain, pruritus, restricted movement, and psychological

distress, thereby adversely affecting the quality of life of affected individuals.[1]

The incidence of keloids varies considerably among different populations, with a higher prevalence reported in individuals with darker skin pigmentation, particularly those of African, Asian, and Hispanic descent. Genetic predisposition plays a substantial role in keloid formation, and a positive family history is frequently observed. Keloids commonly develop following skin injuries such as surgical incisions, burns, trauma, acne, ear piercing, vaccination scars, and inflammatory dermatoses. Certain anatomical locations, including the chest, shoulders, upper back, neck, and earlobes, are particularly susceptible to keloid development due to increased skin tension and local mechanical forces.[2,3]

The pathogenesis of keloid formation is complex and multifactorial. Current evidence suggests that prolonged inflammation, excessive fibroblast activity, increased expression of growth factors such as transforming growth factor-beta (TGF-β), and abnormal collagen metabolism contribute significantly to the development of these lesions. Keloid fibroblasts exhibit increased proliferative capacity and produce excessive amounts of type I and type III collagen, leading to the formation of dense fibrous tissue that extends beyond the original wound margins.[4,5]

Despite extensive research, the management of keloids remains a therapeutic challenge because of their high recurrence rates and unpredictable response to treatment. Numerous treatment modalities have been employed, including intralesional corticosteroid injections, surgical excision, cryotherapy, pressure therapy, silicone gel sheeting, laser therapy, radiotherapy, and newer pharmacological agents such as 5-fluorouracil, bleomycin, and interferons. However, no single treatment has been universally accepted as the gold standard due to variable efficacy and the risk of recurrence.[6,7]

Intralesional corticosteroids remain one of the most commonly used first-line therapies because of their ability to suppress inflammation, inhibit fibroblast proliferation, and reduce collagen synthesis. Cryotherapy has shown effectiveness, particularly in smaller lesions, by inducing tissue necrosis and reducing scar volume. Surgical excision alone is associated with high recurrence rates, but when combined with adjuvant therapies such as corticosteroid injections or radiotherapy, improved outcomes have been reported.[8,9]

Given the wide range of available therapeutic options and the lack of consensus regarding optimal management, comparative evaluation of different treatment modalities is essential. Understanding the efficacy, safety profile, recurrence rate, and patient satisfaction associated with various therapies can help clinicians formulate individualized treatment strategies. Therefore, the present study was undertaken to evaluate and compare the therapeutic outcomes of different treatment modalities used in the management of keloids and to assess their associated adverse effects.[10]

The present study was undertaken to evaluate the therapeutic effectiveness of various treatment modalities used in the management of keloids and to compare their clinical outcomes. The study aimed to assess the efficacy of cryotherapy alone, cryotherapy combined with intralesional triamcinolone, cryotherapy combined with intralesional 5-fluorouracil, cryotherapy combined with a mixture of triamcinolone and 5-fluorouracil, and the combination of cryotherapy, intralesional triamcinolone, and silicone gel sheets. In addition, the study sought to identify and compare the adverse effects associated with each treatment modality, thereby determining their relative safety, tolerability, and overall usefulness in achieving optimal keloid management.

MATERIALS AND METHODS

Study Design: An open-label, prospective, randomized controlled trial with a five-arm comparative interventional design.

Study Population: Patients aged 18–60 years diagnosed with keloids attending the Outpatient Department of Dermatology, Ananya college of Medicine and Research

Sample Size: A total of 120 patients were enrolled based on sample size calculation (98% confidence interval, 1% margin of error, SD 0.7). Twenty patients were lost to follow-up, and the remaining 100 patients were randomly allocated into five treatment groups, with 20 patients in each group.

Study Duration: July 2024 to June 2025.

Study Place: Department of Dermatology, Ananya college of medicine and Research, kalol, Gandhinagar, Gujarat, India.
India.

Inclusion Criteria

1. Patients aged 18–60 years with clinically diagnosed keloids.
2. Keloids measuring 1–10 cm in greatest dimension and of ≤5 years duration.
3. Patients willing to provide written informed consent for treatment, photography, and follow-up.

Exclusion Criteria

1. Patients unwilling to provide informed consent.
2. Patients unable to attend regular follow-up visits.
3. Patients with extensive post-burn keloids.
4. Pregnant or lactating women and women planning pregnancy.
5. Patients with active inflammation, infection, or ulceration in or around the keloid.
6. Immunocompromised patients.
7. Patients with uncontrolled systemic illnesses such as diabetes mellitus, hypertension, malignancy, chronic inflammatory diseases,

renal failure, liver failure, or severe mental disorders.

8. Patients who had received any treatment for keloids within the preceding 12 months.
9. Patients with unrealistic treatment expectations.

Treatment Groups

- **Group I:** Cryotherapy alone.
- **Group II:** Cryotherapy + Intralesional Triamcinolone Acetonide (40 mg/ml).
- **Group III:** Cryotherapy + Intralesional 5-**Fluorouracil** (50 mg/ml).
- **Group IV:** Cryotherapy + Intralesional Triamcinolone Acetonide (0.1 ml, 40 mg/ml) + 5-Fluorouracil (0.9 ml, 50 **mg**/ml).
- **Group V:** Cryotherapy + Intralesional Triamcinolone **Acetonide** (20 mg/ml) + Silicone Gel Sheets.

Statistical Analysis

The collected data were entered into Microsoft Excel and analyzed using Statistical Package for the Social Sciences (SPSS) software version 20.0. Descriptive statistics were used to summarize demographic and clinical characteristics of the study population. Continuous variables such as POSAS scores were expressed as mean ± standard deviation (SD), while categorical variables were presented as frequencies and percentages. Comparisons between treatment groups regarding treatment response, recurrence rates, and adverse effects were performed using the Chi-square test. Changes in POSAS scores before and after treatment were evaluated and compared among the five study groups. A p-value of less than 0.05 was considered statistically significant. The results were presented in the form of tables and graphs to facilitate interpretation and comparison of the efficacy and safety of the various treatment modalities used in the management of keloids.

RESULTS

Table 1: Baseline Demographic and Clinical Characteristics (n=100)

Variable		Value
Age	18–20 years	9 (9%)
	21–30 years	45 (45%)
	31–40 years	35 (35%)
	41–50 years	6 (6%)
	51–60 years	5 (5%)
Gender	Male	51 (51%)
	Female	49 (49%)
Duration	≤1 year	53 (53%)
	1–2 years	22 (22%)
	2–5 years	25 (25%)
Family History	Positive	12 (12%)
	Negative	88 (88%)

Table 2: Clinical Profile of Keloids (n=100)

Variable	Number (%)
Chest	42 (42%)
Ear	10 (10%)
Back	10 (10%)
Shoulder	8 (8%)
Forearm	6 (6%)
Thigh	6 (6%)
Arm	5 (5%)
Abdomen	4 (4%)
Hand	4 (4%)
Neck	2 (2%)
Leg	2 (2%)
Face	1 (1%)
Spontaneous	43 (43%)
Infection	20 (20%)
Burn	15 (15%)
Ear piercing	10 (10%)
Trauma	5 (5%)
Surgery	5 (5%)
Tattoo	2 (2%)
Cosmetic disfigurement	85 (85%)
Pruritus	65 (65%)
Skin discoloration	52 (52%)
Pain	8 (8%)

Table 3: Baseline and Final POSAS Scores

Group	Treatment Modality	Baseline POSAS	24 Week POSAS	Reduction
Group 1	Cryotherapy	52.45	28.35	24.1
Group 2	Cryotherapy + TAC 40 mg/ml	51.8	25.35	26.45
Group 3	Cryotherapy + 5-FU	50.1	22.8	27.3
Group 4	Cryotherapy + TAC + 5-FU	52.15	22.75	29.4
Group 5	Cryotherapy + TAC + Silicone Sheet	52.05	22.1	29.95

Table 4: Treatment Response Comparison Among Groups

Treatment Response	Group 1	Group 2	Group 3	Group 4	Group 5	Total
Excellent	2 (10%)	4 (20%)	3 (15%)	4 (20%)	6 (30%)	19 (19%)
Good	6 (30%)	11 (55%)	12 (60%)	14 (70%)	12 (60%)	55 (55%)
Fair	8 (40%)	3 (15%)	2 (10%)	1 (5%)	1 (5%)	15 (15%)
Poor	4 (20%)	2 (10%)	3 (15%)	1 (5%)	1 (5%)	11 (11%)

Table 5: Mean Scar Parameters at 24 Weeks

Parameter	G1	G2	G3	G4	G5
Vascularity	3.3	2.15	2.5	2.6	2.95
Pigmentation	3.23	6.5	3	3.05	3.2
Thickness	3.45	1.8	2.3	2.1	2
Pliability	3.55	1.75	2.05	2.55	1.55
Itching	1.5	1.05	0.95	1	1
Pain	1	1.05	2.8	1	1

Table 6: Duration of Lesion and Treatment Outcome

Outcome	≤2 Years (n=64)	2–5 Years (n=36)	Total
Excellent	11 (17.2%)	8 (22.2%)	19
Good	42 (65.6%)	10 (27.8%)	52
Fair	6 (9.4%)	11 (30.6%)	17
Poor	5 (7.8%)	6 (16.7%)	11

Table 7: Adverse Effects Among Treatment Groups

Group	Side Effects Present n (%)	Common Adverse Effects
Group 1	7 (35%)	Erythema, edema
Group 2	20 (100%)	Hypopigmentation, erythema
Group 3	15 (75%)	Pain, ulceration, hyperpigmentation
Group 4	11 (55%)	Erythema, hyperpigmentation
Group 5	7 (35%)	Mild erythema

Table 8: Recurrence and Overall Efficacy

Group	Treatment	Excellent + Good Response (%)	Recurrence (%)
Group 1	Cryotherapy	40	75
Group 2	Cryotherapy + TAC	75	0
Group 3	Cryotherapy + 5-FU	75	15
Group 4	Cryotherapy + TAC + 5-FU	90	10
Group 5	Cryotherapy + TAC + Silicone Sheet	90	0

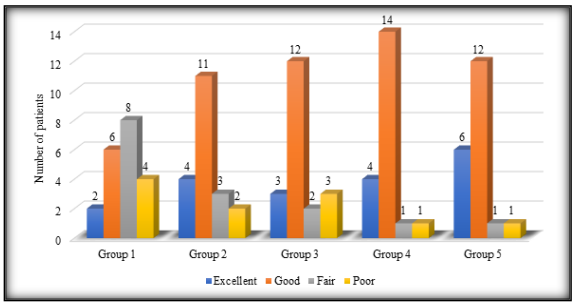

Figure 1: Treatment Response Comparison Among Groups

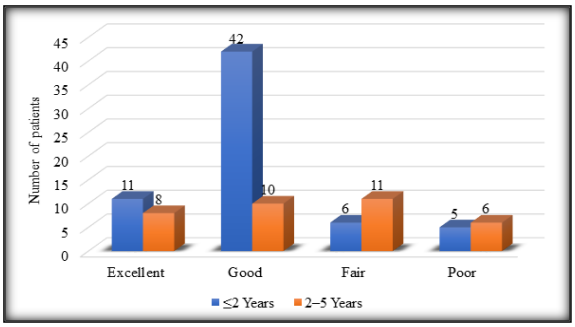

Figure 2: Duration of Lesion and Treatment Outcome

A total of 100 patients with keloids were included in the study. The majority of patients belonged to the 21–30 years age group (45%), followed by 31–40 years (35%), indicating that keloids were most common among young adults. Only 9% of patients were aged 18–20 years, while 6% and 5% belonged to the 41–50 years and 51–60 years age groups, respectively. The gender distribution was nearly

equal, with 51 males (51%) and 49 females (49%). Regarding duration of lesions, more than half of the patients (53%) had keloids of ≤1 year duration, while 22% had lesions of 1–2 years duration and 25% had lesions persisting for 2–5 years. A positive family history of keloids was noted in 12% of patients, whereas 88% had no family history, suggesting that most cases occurred sporadically.

The chest was the most commonly affected site, accounting for 42% of all lesions. Other frequently involved sites included the ear (10%), back (10%), shoulder (8%), forearm (6%), thigh (6%), and arm (5%). Less common sites were the abdomen (4%), hand (4%), neck (2%), leg (2%), and face (1%). Regarding etiology, spontaneous occurrence was the most common cause (43%), followed by infection (20%), burns (15%), ear piercing (10%), trauma (5%), surgery (5%), and tattooing (2%). Cosmetic disfigurement was the most frequently reported complaint, affecting 85% of patients, followed by pruritus (65%) and skin discoloration (52%). Pain was reported by only 8% of patients. These findings indicate that cosmetic concerns and itching were the predominant symptoms associated with keloids.

All treatment groups demonstrated a substantial reduction in POSAS scores after 24 weeks of therapy. Group 1 (Cryotherapy alone) showed a reduction of 24.10 points, with the mean POSAS score decreasing from 52.45 to 28.35. Group 2 (Cryotherapy + Triamcinolone) showed a greater reduction of 26.45 points. Group 3 (Cryotherapy + 5-Fluorouracil) achieved a reduction of 27.30 points. The maximum improvements were observed in Group 4 (Cryotherapy + Triamcinolone + 5-Fluorouracil) and Group 5 (Cryotherapy + Triamcinolone + Silicone Gel Sheet), with reductions of 29.40 and 29.95 points, respectively. Group 5 demonstrated the lowest final POSAS score (22.10), indicating the best overall clinical improvement.

Assessment of treatment response revealed considerable differences among the treatment groups. Excellent response was observed in 19% of patients overall, with the highest proportion in Group 5 (30%), followed by Groups 2 and 4 (20% each). Good response was the most common outcome, occurring in 55% of patients. Group 4 demonstrated the highest proportion of good responses (70%), followed by Groups 3 and 5 (60% each). Fair responses were more common in Group 1 (40%) than in the other groups. Poor response was observed in 11% of patients overall, with the highest frequency in Group 1 (20%). These findings suggest superior efficacy of combination therapies compared to cryotherapy alone.

At the end of treatment, scar assessment parameters showed marked improvement in all groups. The lowest vascularity score was observed in Group 2 (2.15), indicating better control of erythema. Pigmentation scores were generally comparable across groups except Group 2, which demonstrated a higher pigmentation score (6.50), reflecting post-treatment pigmentary changes. Thickness was lowest in Group 2 (1.80), while Group 5 showed the best pliability score (1.55), indicating softer and more flexible scars. Itching scores were reduced to nearly minimal levels in all groups, ranging from 0.95 to 1.50. Pain scores remained low in all groups except Group 3 (2.80), where pain associated with 5-fluorouracil injections was more common. Overall, combination therapies resulted in better scar characteristics than cryotherapy alone.

Treatment outcomes were influenced by lesion duration. Among patients with lesions ≤2 years duration, 65.6% achieved a good response and 17.2% achieved an excellent response. In contrast, among patients with lesions of 2–5 years duration, only 27.8% achieved a good response, although 22.2% achieved an excellent response. Fair and poor responses were more frequent in longer-duration lesions, accounting for 30.6% and 16.7%, respectively. These findings suggest that earlier intervention is associated with more favorable treatment outcomes.

The incidence of adverse effects varied among treatment modalities. Group 2 exhibited adverse effects in all patients (100%), primarily hypopigmentation and erythema. Group 3 had adverse effects in 75% of patients, with pain, ulceration, and hyperpigmentation being the most common complaints. Group 4 showed adverse effects in 55% of patients, predominantly erythema and hyperpigmentation. In contrast, Groups 1 and 5 demonstrated the lowest incidence of adverse effects (35% each), consisting mainly of mild erythema and edema. These findings indicate that while combination therapies are highly effective, some treatment modalities may be associated with a higher rate of local adverse effects.

Analysis of overall efficacy demonstrated that Group 4 and Group 5 achieved the highest rates of successful outcomes, with 90% of patients showing either excellent or good responses. Groups 2 and 3 achieved success rates of 75%, whereas Group 1 showed the lowest efficacy at 40%. Recurrence rates varied considerably among treatment groups. Cryotherapy alone demonstrated the highest recurrence rate (75%), indicating limited long-term effectiveness. No recurrence was observed in Groups 2 and 5, while recurrence rates were 15% in Group 3 and 10% in Group 4. These findings suggest that combination therapy, particularly cryotherapy combined with triamcinolone and silicone gel sheets, provides the most effective and durable treatment outcomes with minimal recurrence.

DISCUSSION

In the present study, the majority of patients belonged to the 21–30 years age group (45%), followed by the 31–40 years age group (35%). Similar observations were reported by Shaheen et

al,[11] who found that keloids predominantly affected young adults in the second and third decades of life. This age predilection may be attributed to greater skin tension, increased collagen synthesis, and a higher frequency of trauma and inflammatory skin conditions during this period. The near-equal gender distribution observed in our study (51% males and 49% females) is comparable to the findings of Gauglitz et al,[12] who reported no significant sex predilection in keloid formation. Family history was positive in 12% of patients, which is consistent with the genetic susceptibility described by Brown et al,[13] emphasizing the role of hereditary factors in keloid pathogenesis.

The chest was the most frequently involved anatomical site (42%), followed by the ear and back (10% each). Similar findings were reported by Gangemi et al,[14] who identified the chest, shoulders, and upper back as the most common sites due to increased skin tension and susceptibility to repeated trauma. The predominance of spontaneous lesions (43%) in the present study is comparable to the observations of Mankowski et al,[15] who reported that a significant proportion of patients could not recall a definite precipitating injury. Cosmetic disfigurement (85%) and pruritus (65%) were the most common presenting complaints, similar to the results of Arno et al,[16] who emphasized the substantial psychosocial burden and symptomatic discomfort associated with keloids.

All treatment groups demonstrated significant reductions in POSAS scores after 24 weeks of treatment, with the greatest improvement observed in Group 5 (Cryotherapy + Intralesional Triamcinolone + Silicone Gel Sheet) and Group 4 (Cryotherapy + Triamcinolone + 5-Fluorouracil). These findings are in agreement with the study by Saha et al,[17] who reported superior scar improvement with multimodal therapy compared with monotherapy. Similarly, Davison et al,[18] observed that combining cryotherapy with intralesional agents produced greater reductions in scar thickness, erythema, and overall scar scores than cryotherapy alone. The substantial reduction in POSAS scores observed in our study further supports the effectiveness of combination therapy in achieving optimal scar remodeling.

Excellent or good responses were achieved in 74% of patients overall, with the highest response rates observed in Groups 4 and 5. Cryotherapy alone demonstrated the lowest proportion of favorable outcomes. These findings closely resemble those reported by Manuskiatti and Fitzpatrick,[19] who demonstrated significantly higher clinical improvement rates with combination treatment protocols compared with single-modality therapy. The enhanced efficacy observed in Groups 4 and 5 may be attributed to the synergistic effects of cryotherapy-induced tissue destruction, corticosteroid-mediated suppression of fibroblast activity, and the antifibrotic effects of 5-fluorouracil or silicone gel sheets.

The assessment of individual scar characteristics revealed superior improvement in vascularity, thickness, pliability, itching, and pain among patients receiving combination therapy. Similar findings were reported by Nanda and Reddy,[20] who observed marked reductions in scar thickness and improvement in pliability following combined intralesional corticosteroid and adjunctive therapy. The improved pliability noted in Group 5 may be explained by the prolonged hydration and occlusive effects provided by silicone gel sheets, which contribute to collagen remodeling and scar softening.

Patients with lesions of shorter duration (≤2 years) demonstrated better therapeutic outcomes than those with longer-standing lesions. This observation is consistent with the findings of Shaheen et al,[11] who reported that recently developed keloids respond more favorably to treatment than mature lesions. Chronic keloids typically contain dense collagen bundles and established fibrosis, making them more resistant to therapeutic intervention. Therefore, early diagnosis and treatment remain important factors in improving clinical outcomes.

The highest incidence of adverse effects was observed in Group 2, followed by Groups 3 and 4. Hypopigmentation, erythema, pain, ulceration, and hyperpigmentation were the most frequently encountered complications. Similar adverse-effect profiles have been documented by Davison et al,[18] and Manuskiatti and Fitzpatrick,[19] who reported pigmentary alterations and local injection-related reactions as common complications of intralesional therapy. Despite the higher frequency of adverse effects, most reactions were mild, transient, and did not necessitate discontinuation of treatment.

Recurrence was highest in the cryotherapy-alone group (75%), whereas no recurrence was observed in Groups 2 and 5. These findings corroborate the observations of Gangemi et al,[14] who demonstrated that monotherapy is associated with significantly higher recurrence rates compared with combination regimens. Similarly, Saha et al,[17] reported lower recurrence rates following combined corticosteroid and adjunctive therapies. The absence of recurrence in Group 5 highlights the potential role of silicone gel sheets as an effective maintenance therapy by minimizing fibroblast activity and preventing excessive collagen deposition. Overall, the present study confirms that combination treatment modalities provide superior efficacy, improved scar characteristics, and lower recurrence rates compared with cryotherapy alone.

CONCLUSION

The present study demonstrated that all treatment modalities resulted in clinical improvement in patients with keloids; however, combination therapies were significantly more effective than cryotherapy alone. Among the five treatment

groups, cryotherapy combined with intralesional triamcinolone acetonide and silicone gel sheets, as well as cryotherapy combined with intralesional triamcinolone and 5-fluorouracil, produced the greatest reduction in POSAS scores and the highest rates of excellent and good responses. These combination regimens also showed superior improvement in scar characteristics such as thickness, pliability, vascularity, and symptomatic relief. Cryotherapy alone was associated with the lowest efficacy and the highest recurrence rate. Although adverse effects were more frequent in some combination therapy groups, they were generally mild and manageable. Early-stage lesions responded more favorably than long-standing keloids, highlighting the importance of timely intervention. Overall, multimodal treatment approaches provide better therapeutic outcomes, lower recurrence rates, and improved patient satisfaction in the management of keloids.

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