SKIN

ORIGINAL RESEARCH

A Comparative Analysis of Intralesional Injection Triamcinolone Acetonide, Injection Bleomycin, and Radiofrequency Ablation in the Treatment of Keloids

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ABSTRACT

Introduction Keloids are benign overgrowths of fibrous tissue that arise from abnormal wound healing. In addition to symptoms like itching, pain, and texture changes, keloids can cause cosmetic disfigurement and psychological distress, particularly when located on exposed body parts. Numerous treatment modalities exist, but comparative data regarding efficacy and side effect profiles remain limited.
Aims & Objectives This study aimed to compare the efficacy and side effect profile of intralesional triamcinolone acetonide (TAC), intralesional bleomycin, and intralesional radiofrequency ablation (RFA) in the management of keloids.
Methods A total of 117 patients with keloids were enrolled and randomized into three treatment groups: Group A (TAC), Group B (bleomycin), and Group C (RFA). Nine patients were lost to follow-up. Treatment efficacy was assessed using the Patient and Observer Scar Assessment Scale (POSAS), and side effects were monitored throughout the study period.
Results All three groups showed significant reductions in POSAS scores compared to baseline. Therapeutic effectiveness was highest in Group A (100%), followed by Group B (80.6%) and Group C (72.2%) ($p = 0.004$). Side effects were reported in 72% of patients in Groups A and B, and 83.3% in Group C. No recurrence was observed during the 8-week follow-up after treatment completion.
Conclusion All three modalities demonstrated effectiveness in keloid treatment. Triamcinolone showed the greatest efficacy with a relatively favorable side effect profile. Bleomycin was moderately effective, while RFA, though effective, was associated with the highest rate of side effects.
Limitations Unblinded design, small sample size, short follow-up duration, and potential observer/patient bias.

INTRODUCTION

Keloids are benign dermal lesions resulting from aberrant wound healing, characterized by excessive collagen and extracellular matrix (ECM) deposition that extends beyond the boundaries of the original injury.[1] They most commonly arise after burns, trauma, piercings, or surgical interventions, but may also develop spontaneously in genetically predisposed individuals.[2] While histologically

composed of disorganized type I and III collagen, keloids differ from hypertrophic scars in their persistent, uncontrolled growth and lack of spontaneous regression.[3]

The incidence of keloids ranges from 5–16%, with a higher prevalence in individuals of African and Asian descent.[4] Although their exact pathogenesis remains unclear, a complex interplay of genetic, demographic, and environmental factors is implicated. Keloids often affect areas subject to high tension or trauma, such as the chest, shoulders, and earlobes, and are frequently associated with symptoms like pruritus, pain, and cosmetic disfigurement, significantly impacting patients' quality of life.[5]

Despite the availability of numerous treatment modalities, keloid management remains challenging due to high recurrence rates and variable therapeutic responses. Traditional therapies include intralesional corticosteroids-most commonly, triamcinolone acetonide (TAC), which exert anti-inflammatory and anti-mitotic effects to reduce scar volume and firmness.[6] However, adverse effects such as skin atrophy, hypopigmentation, and telangiectasias can limit their use.[7]

In recent years, intralesional bleomycin has emerged as a promising alternative. This antitumor antibiotic induces apoptosis, inhibits collagen synthesis, and reduces neovascularization in keloid tissue.[8] Although generally safe at low intralesional doses, bleomycin can cause localized pain, blistering, and rarely systemic effects.[9]

Radiofrequency ablation (RFA) is a newer modality in which thermal energy is applied to induce controlled tissue necrosis. In keloid management, RFA offers the advantage of targeted tissue destruction with minimal damage to surrounding skin, potentially reducing recurrence.[10, 11]

Given the lack of a universally accepted treatment and the variable efficacy of available options, this study was conducted with the aim to compare the therapeutic outcomes of intralesional triamcinolone acetonide, intralesional bleomycin, and radiofrequency ablation in the management of keloids. By evaluating these modalities in terms of efficacy, recurrence, and adverse effects, we intended to contribute to evidence-based treatment strategies for this complex and recurrent condition.

METHODS

Study Design and Setting

This open-label, randomized controlled trial was conducted over one year in the Department of Dermatology, Venereology & Leprosy in a tertiary care centre. Eligible patients presenting with clinically diagnosed keloids were enrolled and randomized into three treatment arms using block randomization (sealed envelope method).

Sample Size and Participants

A total of 117 patients were recruited, based on a calculated minimum sample size of 107. Participants were evenly allocated into three groups (n=39 each):

- Group A: Intralesional triamcinolone acetonide
- Group B: Intralesional bleomycin
- Group C: Radiofrequency ablation (RFA)

Inclusion and Exclusion Criteria

Inclusion criteria: Adults (≥18 years) with keloids willing to provide written informed consent, were included in the study.

Exclusion criteria: Facial or very small keloids (<2 mm), pregnancy or lactation, recent treatment within 3 months, and known allergy to study drugs or anaesthetics.

Ethical Considerations

The study was approved by the institutional ethics committee and conducted in accordance with the ICMR and Declaration of Helsinki guidelines. Written informed consent was obtained from all participants.

Study Procedures

Baseline demographic and clinical data of all the study participants were recorded using a structured proforma. After counselling and taking informed written consent, participants received the following interventions:

- **Group A:** Intralesional triamcinolone acetonide (40 mg/mL), 0.1 mL/cm² injected using a 31-gauge needle, max 6 mL/session.
- **Group B:** Intralesional bleomycin (1 IU/mL), prepared by diluting 15 IU in 15 mL sterile saline, administered intralesionally, similarly to triamcinolone.
- **Group C:** Intralesional radiofrequency ablation using a 4 MHz RF generator and modified IV cannula technique, following local anaesthesia with 2% lignocaine.

Each group received a maximum of four sessions at 3-week intervals or until complete flattening of lesion. All procedures were performed under aseptic conditions.

Outcome Measures

Patients were assessed using the Patient and Observer Scar Assessment Scale (POSAS) at baseline, weeks 3, 6, and 9 (during treatment), and at 4 and 8 weeks post-treatment. Additional outcomes included were:

- Percentage reduction in POSAS score (>50% improvement defined as a good response)
- Global Physician and Patient Satisfaction Scores based on standardized photographs and post-treatment questionnaires
- Adverse events, recorded during and after treatment sessions

Follow-Up

Patients were followed for 2 months post-treatment with assessments done every 4 weeks. Improvement was measured via POSAS score reduction, clinical photographs, and satisfaction surveys.

RESULTS

A total of 108 patients were included, equally distributed among three groups (Group A, B, and C; n=36 each). The overall gender distribution was 44.4% male and 55.6% female, with no statistically significant difference across groups (p=0.478). The mean age was comparable among groups (34.19±13.54 in Group A, 33.44±12.12 in Group B, and 34.91±13.74 in Group C; p=0.240). Most participants were educated up to the graduate level (40.7%), and 8.3%

held postgraduate degrees, with no significant difference in educational status across groups (p=0.102). Occupation-wise, homemakers constituted the largest group (33.3%), followed by students (25.9%) and those in private jobs (24.1%) (p=0.357). The duration of illness varied, with 33.3% reporting symptoms for 1–2 years, and no significant group differences were observed (p=0.340). A positive family history was present in 25% of patients (p=0.678). Most participants (88.9%) had no relevant personal history, while a minority reported smoking (4.6%), alcohol use (3.7%), or both (2.8%), without significant variation between groups (p=0.310). **Table 1** depicts the demographic profile of study participants.

Table 1. Demographic profile of patients

Variables		Group A (n=36)	Group B (n=36)	Group C (n=36)	Total	Test of sig.	P value
Gender	Male	14 (38.9%)	18 (50%)	16 (44.4%)	48 (44.4%)	X^2=0.456	0.478
	Female	22 (61.1%)	18 (50%)	20 (55.6%)	60 (55.6%)		
Age	Mean ± SD	34.19±13.54	33.44±12.12	34.91±13.74	34.18±13.04	F=3.598	0.240
Education	Post graduate	3 (8.3%)	4 (11.1%)	2 (5.6%)	9 (8.3%)		
	Graduate	14 (38.9%)	17 (47.2%)	13 (36.1%)	44 (40.7%)		
	Senior secondary	9 (25%)	9 (25%)	12 (33.3%)	30 (27.8%)		
	Primary school	9 (25%)	6 (16.7%)	7 (19.4%)	22 (20.4%)	X^2=0.897	0.102
	Illiterate	1 (2.8%)	0	2 (5.6%)	3 (2.8%)		
Occupation	Student	12 (33.3%)	10 (27.8%)	6 (16.7%)	28 (25.9%)		
	Homemaker	14 (38.9%)	9 (25%)	13 (36.0%)	36 (33.3%)		
	Farmer	0	4 (11.1%)	6 (16.7%)	10 (9.3%)	X^2=0.753	0.357
	Private job	7 (19.4%)	10 (27.8%)	9 (25%)	26 (24.1%)		
	Govt.job	3 (8.3%)	3 (8.3%)	2 (5.6%)	8 (7.4%)		
Duration	< 1 year	10 (27.8%)	9 (25%)	4 (11.1%)	23 (21.3%)		
	1 – 2 years	7 (19.4%)	17 (47.2%)	12 (33.3%)	36 (33.3%)		
	2 – 3 years	12 (33.3%)	3 (8.3%)	6 (16.7%)	21 (19.4%)	F=2.598	0.340
	3 – 5 years	3 (8.3%)	3 (8.3%)	11 (30.6%)	17 (15.7%)		
	5 – 10 years	3 (8.3%)	0 (0%)	2 (5.6%)	5 (4.6%)		
	>10 years	1 (2.8%)	4 (11.1%)	1 (2.8%)	6 (5.6%)		

Family History	Present	12 (33.3%)	9 (25%)	6 (16.7%)	27 (25%)	X^2=1.456	0.678
	Absent	24 (66.7%)	27 (75%)	30 (83.3%)	81 (75%)		
Personal history	None	32 (86.1%)	32 (88.9%)	32 (88.9%)	96 (88.9%)		
	Smoking	2 (5.6%)	2 (5.6%)	1 (2.7%)	5 (4.6%)	X^2=1.57	0.310
	Alcohol	1 (2.8%)	1 (2.7%)	2 (5.6%)	4 (3.7%)		
	Both	1 (2.8%)	1 (2.7%)	1 (2.7%)	3 (2.8%)		

Clinical Profile of Keloid Patients

In this study, acne was the most common inciting factor for keloid development (38.9%), followed by ear piercing (16.7%). However, 13.9% of patients were unable to identify any specific trigger.

The duration of keloids ranged from 6 months to 40 years, with a mean duration of 4.81 ± 5.82 years. Most patients (45.4%) had keloids for more than two years.

Regarding treatment history, 70% of patients were treatment-naive. Prior treatments included intralesional corticosteroids (15%), topical Ayurvedic preparations (11%), and surgical excision (3.7%). All participants were off treatment for at least three months prior to enrolment.

A positive family history of keloids was reported in 25% of patients. As for personal habits, 4.6% reported smoking, 3.7% consumed alcohol, and 2.8% had both habits.

Most participants (87%) had no comorbidities. Diabetes mellitus and hypothyroidism were observed in 4.6% each, hypertension in 1.85%, and carcinoma breast in 0.92%.

The chest (especially the presternal area) was the most commonly affected site (42.6%), followed by the pinna (17.6%), back and abdomen (8.3% each), upper limb (6.5%), and lower limb and breast (5.6% each). The least involved site was the pubic area (1.9%).

A total of 245 keloids were documented among the 108 patients. Most patients (45.4%) had a single lesion, 21.3% had two, and 33.3% had more than two lesions.

The most common presenting complaint was pruritus (79.6%), followed by pain (67.6%), burning sensation (30.5%), and cosmetic concerns (20.3%).

Outcome Comparison

A. Patient and Observer Scar Assessment Scale (POSAS)

POSAS scores showed a consistent and statistically significant reduction across all three groups from baseline to the end of the 17-week study period (including an 8-week post-treatment follow-up).

- **Group A** showed a reduction from 74.47 ± 10.83 at baseline to 18.06 ± 4.91 at week 17.
- **Group B** decreased from 80.86 ± 10.72 to 24.22 ± 11.70.
- **Group C** improved from 77.31 ± 9.48 to 22.94 ± 10.55. Significant improvement was evident

as early as 3 weeks post-treatment initiation ($p < 0.05$ at multiple time points). Improvements were observed in both patient and observer components of POSAS, with all parameters (e.g., pain, itching, pigmentation, thickness, pliability) showing statistically significant changes ($p = 0.001$) **(Table 2).**

Table 2. Mean POSAS score in the three groups

	Wk 0	Wk 3	Wk 6	Wk 9	FU 1	FU 2
Group A	74.47±10.83	57.00±14.34	43.69±13.08	32.78±11.09	20.72±6.5	18.06±4.9
Group B	80.86±10.71	62.47±9.82	50.50±11.38	38.17±10.97	26.67±11.68	24.22±11.70
Group C	77.31±9.48	56.06±11.97	42.67±13.30	32.06±13.33	24.08±10.87	22.94±10.54
Total	77.55±10.59	58.51±12.40	45.62±12.97	34.33±12.05	23.82±10.15	21.74±9.80
P value	0.036	0.059	0.019	0.062	0.044	0.018

B. Treatment Effectiveness

Treatment was considered effective (≥50% reduction in POSAS) in 100% of Group A, 80.6% of Group B, and 72.2% of Group C patients ($p = 0.004$). This reflects a superior response in Group A **(Table 3)**.

C. Correlation with Demographic Factors

No significant correlation was observed between treatment effectiveness and age, sex, disease duration, or baseline POSAS scores ($p > 0.05$).

Table 3. Mean POSAS score in the three groups

	Group A	Group B	Group C	Total
Effective	36 (100%)	29 (80.6%)	26 (72.2%)	91 (84.3%)
Not effective	0	7 (19.4%)	10 (27.8%)	17 (15.7%)
Total	36 (100%)	36 (100%)	36 (100%)	108 (100%)

D. Relapse

No recurrences were observed in any of the groups during the 8-week post-treatment follow-up.

E. Grade of Improvement

At the end of the study, most patients in Group A (69.4%) achieved Grade 4 improvement (>75% POSAS reduction), followed by Group B and C (both 52.8%). Grade 3 improvement (51–75%) was also common, particularly in Groups A and B **(Table 4).**

Table 4. Grade of improvement in the three groups

Grade of improvement	Group A	Group B	Group C
Grade 0 (no reduction)	0	0	0
Grade 1 (<25% reduction)	0	0	0
Grade 2 (25-50% reduction)	0	7 (19.4%)	10 (27.8%)
Grade 3 (51-75% reduction)	11 (30.6%)	10 (27.8%)	7 (19.4%)
Grade 4 (>75% reduction)	25 (69.4%)	19 (52.8%)	19 (52.8%)

F. Patient Satisfaction

At study completion, the majority of patients across all groups reported high satisfaction. Group A had the highest proportion of patients (66.7%) reporting excellent improvement (>75%). Statistically significant differences were observed in patient satisfaction scores between Group A and Groups B ($p = 0.057$) and C ($p = 0.017$), with overall significance across groups ($p = 0.014$) **(Figure 1)**.

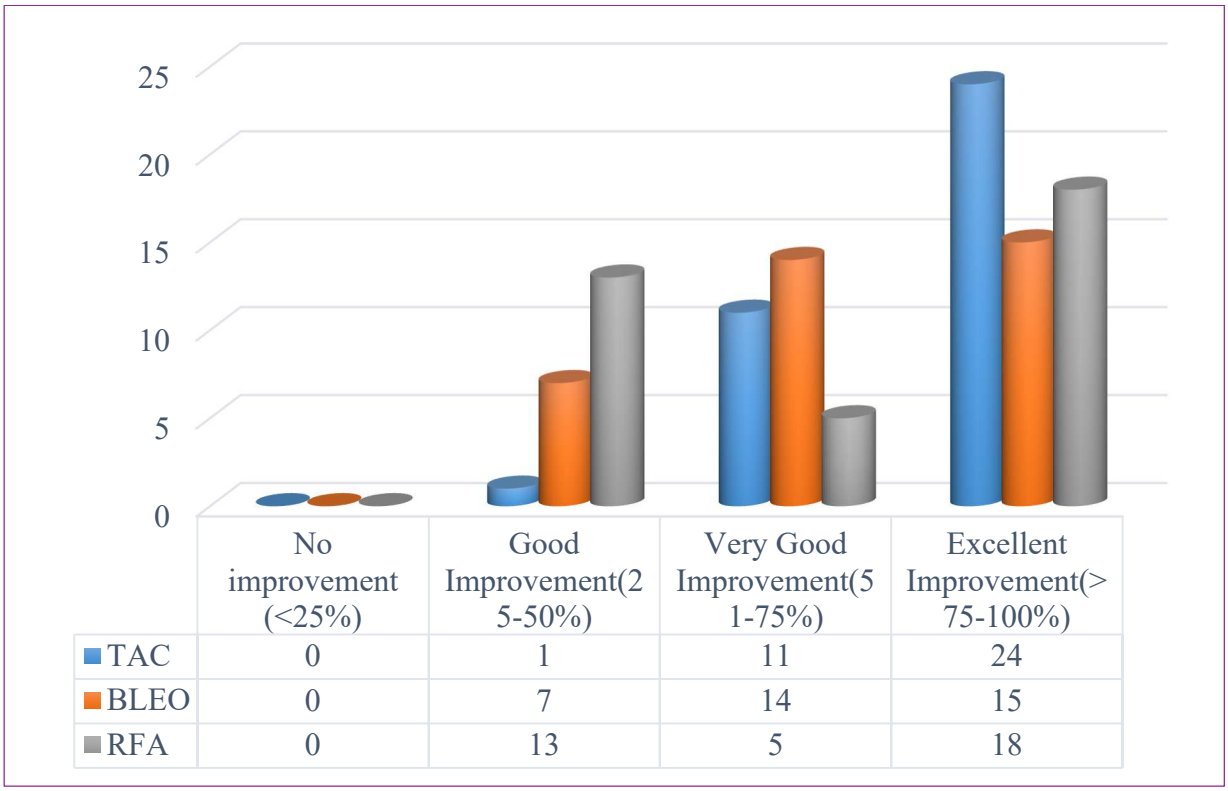
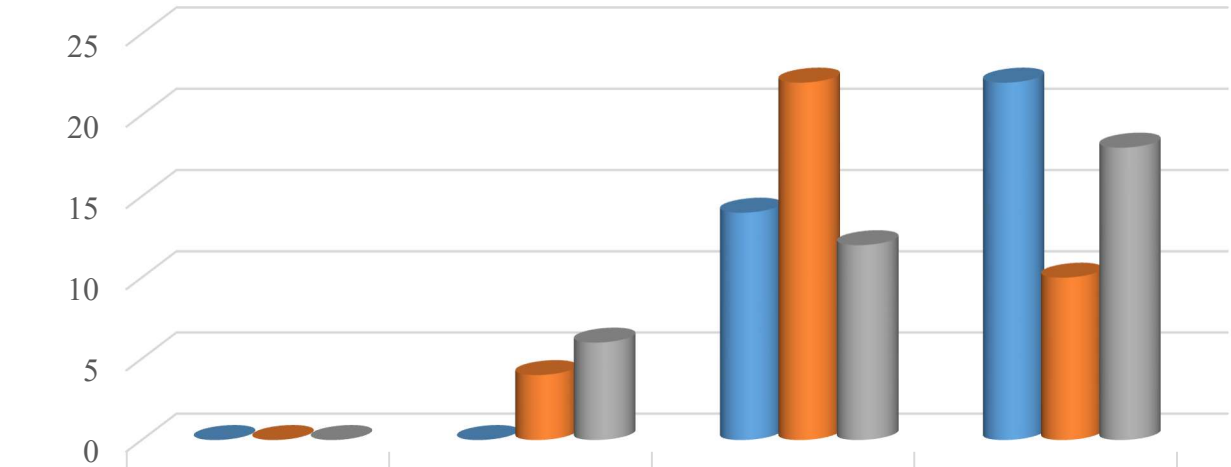


Figure 1. Patient's satisfaction score among the three studied group

G. Physician Satisfaction

Physician-rated outcomes based on post-treatment clinical photographs were consistent with patient-reported outcomes. Group A showed the highest proportion of excellent improvement (61.1%), followed by Groups C (50%) and B (27.8%). Inter-group differences were statistically significant overall ($p = 0.012$), especially between Groups A and B ($p < 0.009$) **(Figure 2)**.



	No improvement (<25%)	Good Improvement(25-50%)	Very Good Improvement(51-75%)	Excellent Improvement(>75-100%)
TAC	0	0	14	22
BLEO	0	4	22	10
RFA	0	6	12	18

Figure 2. Physician's satisfaction score among the three studied group

DISCUSSION

Keloids represent a unique fibroproliferative disorder with variable clinical behavior and treatment response. The present study assessed the efficacy and safety of three treatment modalities—intralesional triamcinolone acetonide (TAC), intralesional bleomycin, and radiofrequency ablation (RFA) in patients with keloidal scars.

In our cohort, the most commonly affected demographic was females in their third decade, consistent with prior studies by Khan et al., Kabel et al., and Payapvipapong et al., which attribute this trend to hormonal influences and cultural factors such as skin piercing.[12, 13, 14] The chest was the most frequent site of involvement, aligning with existing literature that implicates high-tension anatomical areas in keloid formation.[15, 16]

Among all therapeutic groups, TAC demonstrated the highest treatment efficacy (100%) based on POSAS scores, followed by bleomycin (80.6%) and RFA (72.2%). Patient and physician satisfaction scores mirrored these findings. These results are consistent with those of Kaushal et al., Khan et al., and Albalat et al., who reported similar trends in TAC efficacy.[17, 12, 18] The superior performance of TAC in our study may be

partly due to the higher dosage (40 mg/mL) and its favorable impact on pigmentation, a parameter considered in POSAS.[7, 19]

Bleomycin, while slightly less effective than TAC, showed good clinical response and satisfaction, corroborating studies by Mahrous et al. and Aggarwal et al.[20, 21] Although hyperpigmentation was a common adverse effect, the use of local anaesthetics minimized pain-related side effects, contrasting with previous findings where injection pain was more prevalent.[8, 22]

Intralesional radiofrequency ablation (RFA), a novel and minimally invasive modality, showed promising outcomes. While its efficacy was slightly lower compared to TAC and bleomycin, it achieved substantial scar reduction with satisfactory patient response. However, it was associated with a higher incidence of side effects, particularly ulceration and erythema. Variability in RFA outcomes across studies, such as those by Aggarwal et al. and Fruth et al., may be attributed to differences in anatomical sites treated, energy parameters, and procedural techniques.[23, 24]

No recurrences were observed in any group during the 8-week post-treatment follow-up period. Although this is encouraging, longer follow-up is essential to assess the true recurrence potential of these therapies.

The variation in outcomes among different studies also underscores the need for standardized protocols in keloid treatment trials, especially regarding dosing regimens, objective outcome measures, and follow-up durations.

Limitations of our study include a relatively short follow-up period and the absence of long-term recurrence data. Additionally, the sample size may limit the generalizability of findings. Further randomized controlled trials with extended follow-up and objective scar-assessment tools are warranted.

CONCLUSION

All three treatment modalities demonstrated clinical effectiveness in reducing keloid severity. TAC emerged as the most effective therapy, followed by bleomycin and RFA. While RFA showed lower efficacy and higher side effects, it holds promise as a non-invasive alternative, particularly with protocol optimization. Future studies exploring combination therapies and longer-term outcomes will help refine individualized keloid treatment strategies.

Conflict of Interest Disclosures: None

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