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Comparative Evaluation of Therapeutic Efficacy and Safety of Intralesional Triamcinolone Acetonide Alone Versus Modified Intralesional Radiofrequency with Triamcinolone Acetonide in The Treatment of Keloids

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ABSTRACT

Background: Keloids are fibroproliferative disorders resulting from an aberrant wound-healing process. They are notorious for their resistance to conventional treatments and their tendency to recur. While intralesional corticosteroids remain a mainstay in treatment, newer combination techniques are being investigated to enhance outcomes.

Objective: To compare the therapeutic efficacy and safety of intralesional triamcinolone acetonide (TAC) monotherapy versus modified intralesional radiofrequency (mRF) with TAC injection in patients with keloids.

Materials and Methods: A prospective comparative study was conducted between 1st May 2024 to 31st October 2024. Thirty patients with keloids were enrolled and randomized into two equal groups: Group A received intralesional TAC (40 mg/mL), and Group B underwent a modified intralesional RF technique with TAC. Four treatment sessions were conducted at 4-week intervals, with outcomes evaluated by Patient and Observer Scar Assessment Scale (POSAS).

Results: Group B exhibited a greater reduction in POSAS scores 71.53% compared to Group A (65.32%). Group B also showed a more significant reduction in keloid size and technique was well tolerated in treatment of keloids.

Conclusion: Modified intralesional RF with TAC is a superior modality to TAC alone for treating keloids, offering better efficacy and safety with minimal complications.

Keywords: *Keloids, Triamcinolone acetonide, Modified Intralesional Radiofrequency, POSAS*

1. INTRODUCTION

Keloids are common cutaneous disorders resulting from abnormal wound healing. This fibroproliferative condition is characterized by excessive collagen production and disorganized extracellular matrix deposition in response to cutaneous injury, trauma, surgery, or inflammation [1]. Keloids tend to extend beyond the margins of the original wound, do not regress spontaneously, and have a higher recurrence rate after treatment [2,3]. The pathophysiology of the lesions involves multiple factors, including genetic predisposition, abnormal fibroblast proliferation, persistent inflammation, and dysregulation of growth factors such as transforming growth factor-beta (TGF-β) and vascular endothelial growth factor (VEGF) [4]. Due to their chronicity and tendency to recur, keloids pose therapeutic challenges and can significantly impact the quality of life, particularly when located on cosmetically or functionally important areas.[5] Numerous therapeutic modalities have been

employed for their management, including pressure therapy, cryotherapy, silicone gel sheeting, laser therapy, intralesional corticosteroids, 5-fluorouracil, bleomycin, and surgical excision with or without adjuvant therapy [6]. Among these, intralesional corticosteroids especially triamcinolone acetonide (TAC) remain the cornerstone of treatment. TAC exerts anti-inflammatory and antiproliferative effects by reducing collagen and glycosaminoglycan synthesis, inhibiting fibroblast proliferation, and suppressing proinflammatory cytokines [7,8]. However, the response to TAC alone may be partial or suboptimal, necessitating combination therapies.To enhance therapeutic efficacy, combination treatments are increasingly being explored. One such emerging modality is intralesional radiofrequency (RF) therapy. RF technology delivers controlled thermal energy to the dermis and deeper tissues, resulting in collagen denaturation, tissue remodelling, and induction of a wound healing cascade that favours scar softening and regression [9]. When delivered intralesionally using a modified technique, RF energy can directly target the fibrotic core of keloids, facilitating corticosteroid diffusion and effectiveness [10]. The synergistic use of modified technique of RF with intralesional TAC holds potential for superior results compared to either modality alone. By thermally disrupting the dense fibrotic tissue, RF may enhance corticosteroid diffusion and efficacy. Moreover, the targeted application reduces systemic absorption and local adverse effects. However, clinical studies evaluating this combination approach using a standardized and reproducible method are limited. Therefore, the present study aims to comparatively evaluate the therapeutic efficacy and safety of intralesional TAC injection alone versus a modified intralesional RF technique with TAC in the treatment of keloids. The study also explores the potential synergistic benefits of this combination therapy and its implications for routine clinical practice

2. AIM AND OBJECTIVES

To evaluate the therapeutic efficacy and safety of intralesional triamcinolone acetonide injection alone versus intralesional radiofrequency using modified technique with intralesional triamcinolone acetonide

3. METHODOLOGY

A prospective comparative Study conducted from 1st May,24 to 31st October,24 in which 30 Patients of keloids were enrolled from outpatient dermatology department of Integral institute of medical sciences, Lucknow who fulfilled the following criteria were included in the study: Patients in the age group of 18 to 60 years and patient giving informed consent for therapy while Pregnant/Lactating Females, Local/Systemic Infection, Immunocompromised Patient, Extensive Keloids (> 10% Body surface area) were excluded from study. patients were randomly divided into two groups of 15 patients each. In group A IL triamcinolone acetonide (TAC) (40mg/ml) was given up to blanching with a dosage of 0.5ml/cm^2. Total dose of 1ml given by a 2ml syringe. In group B IL radiofrequency by modified technique with triamcinolone acetonide was injected. In group B, two components were used- 2 ml syringe and an intravenous canula (IVC) from which leur lock plug and flash back chamber were removed and discarded. A small window was created at the proximal end and undersurface of the plastic canula towards the tip (as shown in images I & II).[11] The energy is delivered through the hole on the undersurface of canula and IVC was introduced into the bulk of keloid from one side. Then a probe of RF machine was touched upon window made in iv cannula through which radiofrequency energy was delivered to the tissue for 4-5 seconds, subsequently TAC was injected intralesionally till blanching (as shown in image III). In both groups total 4 sittings every 4 weeks and post-treatment follow-up after 1 month was done. All patients were evaluated for therapeutic outcome by photographically and by 'Patient and Observer Scar Assessment Scale' (POSAS). During every treatment session and during post-treatment follow-up. Adverse events regarding treatment were also recorded on every visit.

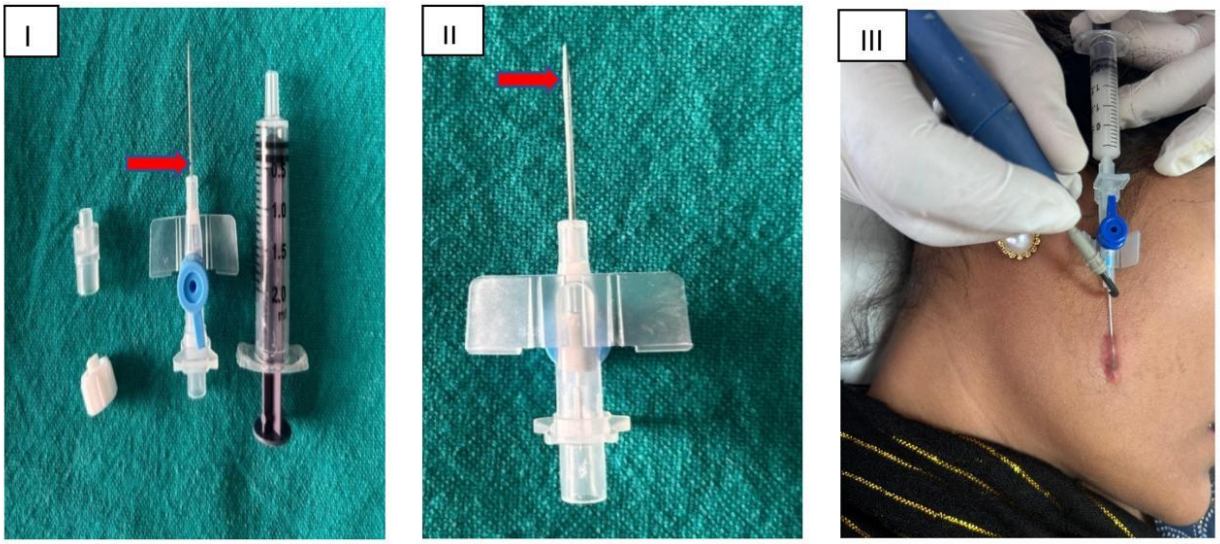

Image I: A 2 ml syringe and an intravenous cannula with a tiny window in its plastic sheath close to the proximal end (red

arrow) where the RF probe touches the metallic needle; Image II: An intravenous cannula with a tiny window in its plastic sheath close to the underside of the distal end of the cannula(red arrow) where RF energy is delivered; Image III: The RF machine's probe touched the window of the cannula using intralesional TAC to apply radiofrequency to a keloid.

Scoring was done using the POSAS (Patient and Observer Scar Assessment Scale). The POSAS consists of two scales: the observer scale and the patient scale. Each scale includes 6 parameters.

Table 1: Parameters of POSAS

Patient Scale	Observer Scale
1. Pain	Vascularization
2. Pruritus	Pigmentation
3. Color	Thickness
4. Thickness	Surface Area
5. Irregularity	Relief
6. Stiffness	Pliability

Based on these parameters Percentage change in the POSAS score from baseline at each visit was calculated as:

$$\frac{\text{POSAS Baseline - POSAS during Follow Up}}{\text{POSAS Baseline}} \times 100\% = \%\ \text{change from baseline}$$

Table 2: Grades of improvement by reduction in POSAS Score [12]

Grade	Response	Reduction in POSAS Score
0	No response	No reduction
1	Mild response	<25% reduction
2	Moderate response	25% to 50% Reduction
3	Good response	51% to 75% Reduction
4	Very good response	>75% Reduction

Statistical Analysis

Data were analysed using SPSS v24. Continuous variables were expressed as mean ± SD, and categorical variables as percentages. Chi-square test, Fisher's exact test, Mann-Whitney U test, paired t-test, and independent t-test were used as appropriate. A p-value <0.05 was considered statistically significant.

OBSERVATION AND RESULTS

Table 3: Demographic profile of patients

Age-wise distribution		
Age group	**Group A**	**Group B**
18-24 Yrs	8	9
25-30 Yrs	4	2
>30 Yrs	3	4
Gender		
Male	9	8

Female	6	7

Table 4: Clinical characteristics of patients

Location		
Site	**Group A**	**Group B**
Chest	10	8
Upper limb	3	4
Lower limb	1	2
Other	1	1
Duration of lesion		
<1 year	8	9
1- 2 years	4	5
>2 years	3	1
Predisposing factors		
Trauma	4	3
Burn	1	1
Surgery	2	4
Infection	1	1
Spontaneous	7	6

Table 5: Grade of improvement

Grade	**Number of pts in Group A**	**Number of pts in Group B**
1	1	1
2	2	1
3	4	2
4	8	11

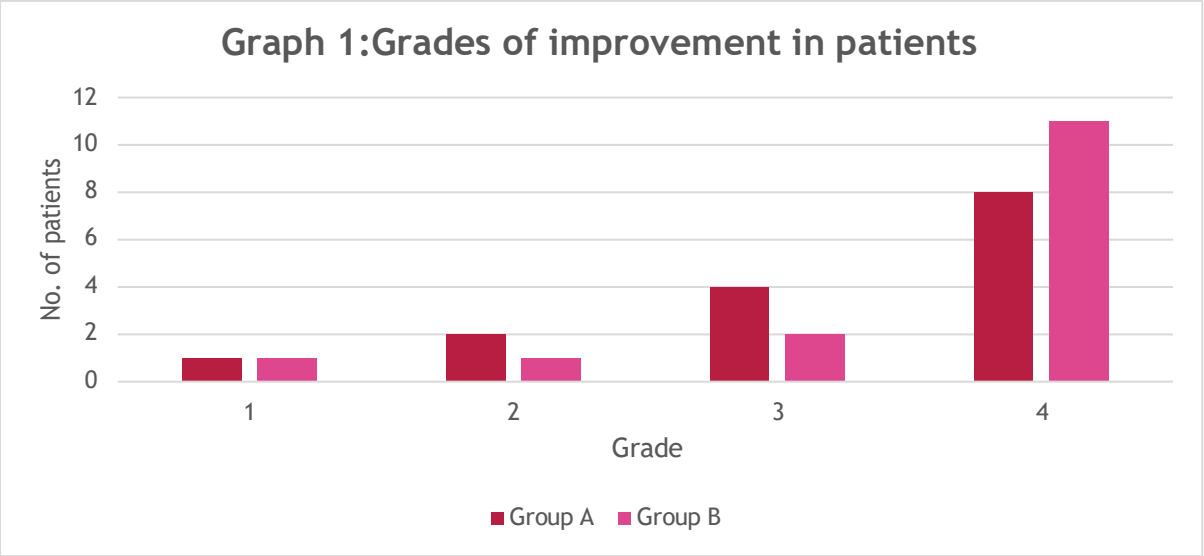

Table 6: Trends in reduction in mean POSAS

Visit	Group A	Group B
1st	64.60	65.80
2nd	54.40	49.66
3rd	37.46	35.33
4th	22.40	18.73

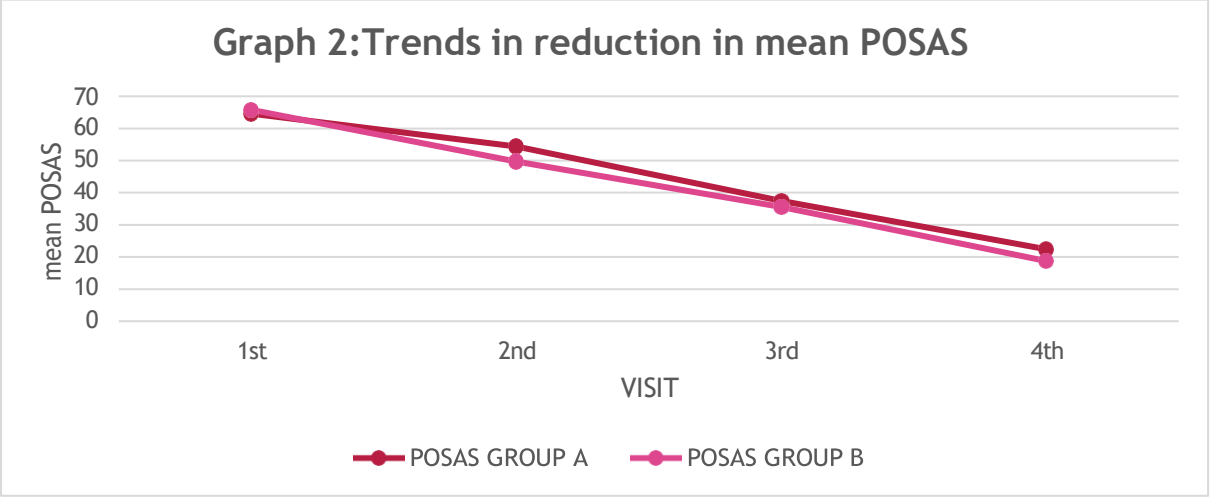

Table 7: Adverse effects

Adverse effect	Group A	Group B
Pain	5	6
Ulcer	0	2
Telangiectasia	6	4
Atrophy	4	3
Hypopigmentation	2	1

Photographic documentation

Images 1A & 1B showing therapeutic efficacy of Group A (TAC alone) showing very good response after 4 treatment session

1A) Before session

1B) After 4 sessions

Images 2A & 2B showing therapeutic efficacy of Group A (TAC alone) showing very good response after 4 treatment session

2A) Before session

2B) After 4 sessions

Images 3A & 3B showing therapeutic efficacy of Group B (TAC + modified RF) showing very good response after 4 treatment session

3A) Before session

3B) After 4 sessions

Images 4A & 4B showing therapeutic efficacy of Group B (TAC + modified RF) showing very good response after 4 treatment session

4A) Before session

4B) After 4 sessions

4. DISCUSSION

Keloids are continue to pose significant therapeutic challenges due to their chronic nature, cosmetic disfigurement, and high recurrence rates. While intralesional corticosteroids, particularly triamcinolone acetonide (TAC), remain the mainstay of treatment, monotherapy often yields partial or suboptimal responses. In recent years, efforts have been directed toward combination therapies to improve efficacy and reduce recurrence. This study evaluated the clinical effectiveness and safety

of a novel combination approach modified intralesional radiofrequency (mRF) with TAC injection compared to TAC monotherapy.

Our findings demonstrate that both treatment groups showed a reduction in POSAS (Patient and Observer Scar Assessment Scale) scores over four treatment sessions, indicating clinical improvement. However, Group B (mRF + TAC) exhibited a significantly greater reduction in scores at each visit compared to Group A (TAC alone), suggesting a superior therapeutic response. By the fourth session, the mean POSAS score in Group B reduced from 65.80 to 18.73 (71.53%), while in Group A it declined from 64.60 to 22.40 (65.32%) ($P<0.05$). We could not find any study in the literature that compare intralesional TAC versus modified RF with TAC.

The enhanced response in Group B may be attributed to the ability of RF energy to thermally disrupt the dense fibrotic collagen matrix within the lesion, promoting tissue remodelling and enhancing the penetration of subsequently administered corticosteroids. The modified technique used in this study employing an intravenous cannula with a precisely created window enabled targeted and safe intralesional delivery of RF energy, minimizing collateral tissue damage.

No major adverse effects were reported in either group, indicating good tolerability and safety of both treatment modalities. The innovative modification of the RF delivery system further contributes to the technique's reproducibility and potential for widespread use in routine clinical settings, especially in resource-limited environments.

Limitations of this study include the small sample size and short-term follow-up, which precluded assessment of long-term recurrence rates. Additionally, while POSAS provides a validated composite score incorporating both patient and clinician perspectives, objective parameters such as ultrasonographic scar thickness or histopathological evaluation could further strengthen the assessment of treatment response.

5. CONCLUSION

This prospective comparative study highlights the enhanced efficacy of a modified intralesional radiofrequency technique with triamcinolone acetonide injection in the management of keloids. The combination therapy demonstrated superior clinical outcomes compared to TAC monotherapy, with significant reduction in POSAS scores and favourable safety profile. The findings suggest that intralesional RF may augment corticosteroid efficacy by facilitating deeper drug penetration and promoting scar remodelling. Incorporating this combination approach into clinical practice may offer a valuable alternative for patients with refractory or cosmetically distressing scars. Further large-scale, long-term studies are warranted to confirm these results and evaluate recurrence rates.

Conflict of interest Nil

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