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Efficacy of Intralesional 5-Fluorouracil with Triamcinolone and Fractional Co2 Laser with Intralesional Triamcinolone in the Treatment of Keloid

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ABSTRACT

Introduction: Keloids are abnormal fibroproliferative scars caused by excessive collagen deposition after dermal injury. They extend beyond the original wound margins, rarely regress, and are often associated with pain, pruritus, cosmetic concerns, and psychological distress. Management remains challenging due to high recurrence rates and adverse effects. This study compares the efficacy and safety of fractional CO_2 laser with intralesional triamcinolone versus intralesional triamcinolone combined with five-fluorouracil.

Methodology: This prospective, randomized interventional study included forty-six patients with clinically diagnosed keloids, divided into two equal groups. Group A received fractional CO_2 laser followed by intralesional triamcinolone at three-week intervals for four sessions. Group B received intralesional five-fluorouracil with triamcinolone in a fixed ratio at similar intervals. Outcomes were assessed using the Vancouver Scar Scale over twelve weeks, along with documentation of adverse effects.

Results: Baseline characteristics were comparable between groups. Both groups showed significant intragroup reduction in scar scores. Group B demonstrated earlier improvement, while Group A showed gradual but sustained response from mid-treatment onward. However, there was no significant difference in final outcomes between groups. Adverse effects varied, with Group A showing more pigmentary changes and atrophy, while Group B was mainly associated with procedural pain.

Conclusion: Both treatment modalities are effective with comparable overall efficacy. However, differing safety profiles suggest that therapy should be individualized based on patient factors, lesion characteristics, and tolerance to adverse effects.

Keywords: *Keloid, Fractional CO laser, Triamcinolone acetonide, 5-Fluorouracil, Vancouver Scar Scale.*

INTRODUCTION

During normal wound healing, collagen synthesis and degradation are maintained in a tightly regulated balance; disruption of this equilibrium leads to abnormal scar formation such as hypertrophic scars and keloids. [1] Both conditions arise from an exaggerated healing response in genetically predisposed individuals following physical, pathological, or foreign body-related insults. Keloids are characterized by persistent, excessive collagen deposition extending beyond the original wound margins, whereas hypertrophic scars remain confined and may regress over time. [2] Keloids consist of dense, irregular collagen bundles due to uncontrolled fibroblast activity, making them a therapeutically challenging condition. [3] Although benign, keloids can cause cosmetic disfigurement, pain, pruritus, and psychological distress, significantly impairing quality

of life. [4] They are more common in individuals with darker skin phototypes and positive family history, suggesting a genetic predisposition, often inherited in an autosomal dominant pattern with incomplete penetrance. [5,6] Keloids commonly affect the sternum, shoulders, and earlobes and may also be associated with certain genetic syndromes. [7] Pathophysiologically, increased fibroblast proliferation and collagen synthesis are mediated by overexpression of growth factors such as TGF-β, VEGF, and CTGF, along with mast cell–mediated histamine release. [6,8] Despite multiple treatment modalities, no single therapy offers a definitive cure, and recurrence rates remain high. [2] Intralesional triamcinolone acetonide (TAC) is widely used due to its anti-inflammatory and antiproliferative effects but is associated with adverse effects such as dermal atrophy and pigmentary changes. [9,10] Combination therapy with 5-fluorouracil (5-FU) has shown improved outcomes by inhibiting fibroblast proliferation and modulating growth factor activity. [11] Fractional CO_2 laser therapy has emerged as a promising modality by inducing collagen remodeling and enhancing drug delivery. [12] However, comparative evidence between these treatment approaches remains limited, particularly in the Indian population. Therefore, this study aims to compare the efficacy and safety of fractional CO_2 laser combined with intralesional triamcinolone acetonide versus intralesional triamcinolone combined with 5-fluorouracil in the management of keloids.

MATERIAL AND METHODS

Study Design and Setting

This hospital-based prospective, comparative, randomized interventional study was conducted in the Department of Dermatology, Venereology and Leprosy, Prasad Institute of Medical Sciences, Lucknow, after obtaining approval from the Institutional Ethics Committee and Review Board. The study was conducted over a period of 18 months. Patients with clinically diagnosed keloids attending the outpatient department were screened and enrolled based on the daily OPD load.

Study Participants

Patients aged >18 years, of either sex, with clinically diagnosed keloids and willing to provide written informed consent were included in the study. A total of 46 patients were enrolled and equally allocated into two treatment groups, with 23 patients in each group.

Inclusion Criteria

Patients fulfilling the following criteria were included:

- Age >18 years.
- Either sex.
- Clinically diagnosed keloid.
- Willingness to participate in the study and provide informed consent.

Exclusion Criteria

Patients with any of the following conditions were excluded:

- Keloid lesions measuring >10 cm.
- Pregnancy or lactation.
- Secondary infection at the keloid site.
- History of chronic diabetes mellitus.
- History of treatment for keloids within the preceding one year.

Randomization and Allocation

Eligible participants were randomly allocated into two groups using the closed-envelope method. Each group consisted of 23 patients. Baseline clinical evaluation was performed before initiation of treatment. Patients were subsequently assessed at three-week intervals for a maximum duration of 12 weeks or until flattening of the scar, whichever occurred earlier. A final evaluation was performed four weeks after completion of therapy.

Baseline Clinical Assessment

Before initiation of treatment, a detailed clinical history was obtained regarding the onset and progression of the keloid, associated symptoms, possible etiological factors, and family history. A detailed examination of the keloid was performed, and clinical photographs were obtained after informed consent.

Vancouver Scar Scale Assessment

Treatment response was evaluated using the Vancouver Scar Scale (VSS) at baseline and at each follow-up visit. The VSS assesses four scar characteristics: pigmentation, vascularity, pliability, and height.

Pigmentation was graded as 0 = normal pigmentation, 1 = hypopigmentation, and 2 = hyperpigmentation. Vascularity was graded as 0 = normal, 1 = pink, 2 = red, and 3 = purple. Pliability was graded from 0 to 5, corresponding to normal, supple, yielding, firm, banding, and contracture, respectively. Scar height was graded as 0 = flat, 1 = <2 mm, 2 = >2 to <5 mm,

and 3 = >5 mm. Lower VSS scores indicated greater clinical improvement. Post-treatment VSS scores were compared with baseline scores to determine treatment response.

Pre-procedure Preparation
Topical anesthetic cream was applied 30–60 minutes before the procedure, whenever required. Patients were appropriately counselled regarding the treatment procedure, expected response, and possible adverse effects at each visit.

Group A: Fractional CO_2 Laser with Intralesional Triamcinolone
Patients in Group A (n=23) received four sessions of fractional CO_2 laser therapy at three-week intervals, followed by intralesional triamcinolone acetonide.

The fractional CO_2 laser parameters were:

- Power: **30 W**
- Duration: **1 ms**
- Interval: **5 ms**
- Distance: **0.5 mm**

After appropriate aseptic preparation and use of protective eyewear, a single pass of fractional CO_2 laser was delivered over the keloid lesion. This was followed by intralesional administration of triamcinolone acetonide (40 mg/mL) using an insulin syringe with a 31-gauge needle at multiple points within the lesion.

Group B: Intralesional 5-Fluorouracil with Triamcinolone
Patients in Group B (n=23) received intralesional injections containing a combination of 5-fluorouracil (5-FU; 50 mg/mL) and triamcinolone acetonide (40 mg/mL) in a 9:1 ratio. The injections were administered at similar three-week intervals using a multiple-puncture technique.

Post-procedure Care and Adverse-Effect Monitoring
Following each treatment session, all patients were advised to apply a topical antibacterial agent for three days. Patients were instructed to report any adverse symptoms occurring after treatment. Treatment-related adverse effects, including pigmentary changes, vascular changes, skin atrophy, and procedural pain, were documented during follow-up visits.

Outcome Assessment
The primary clinical outcome was the change in Vancouver Scar Scale score from baseline during follow-up. VSS scores were assessed at baseline and at 3, 6, 9, and 12 weeks. Both intergroup differences and within-group changes over time were evaluated. Treatment-related adverse effects were also recorded and compared between the two groups.

Statistical Analysis
Statistical analysis was performed using Epi Info software. Quantitative variables were expressed as mean ± standard deviation (SD), whereas qualitative variables were summarized as frequencies and percentages. Normality of quantitative data was assessed using the Kolmogorov–Smirnov test. The Chi-square test was used to compare categorical variables. The independent-samples t-test was used for intergroup comparison of continuous variables, whereas the paired t-test was used for intragroup comparison of VSS scores over time. A p-value <0.05 was considered statistically significant.

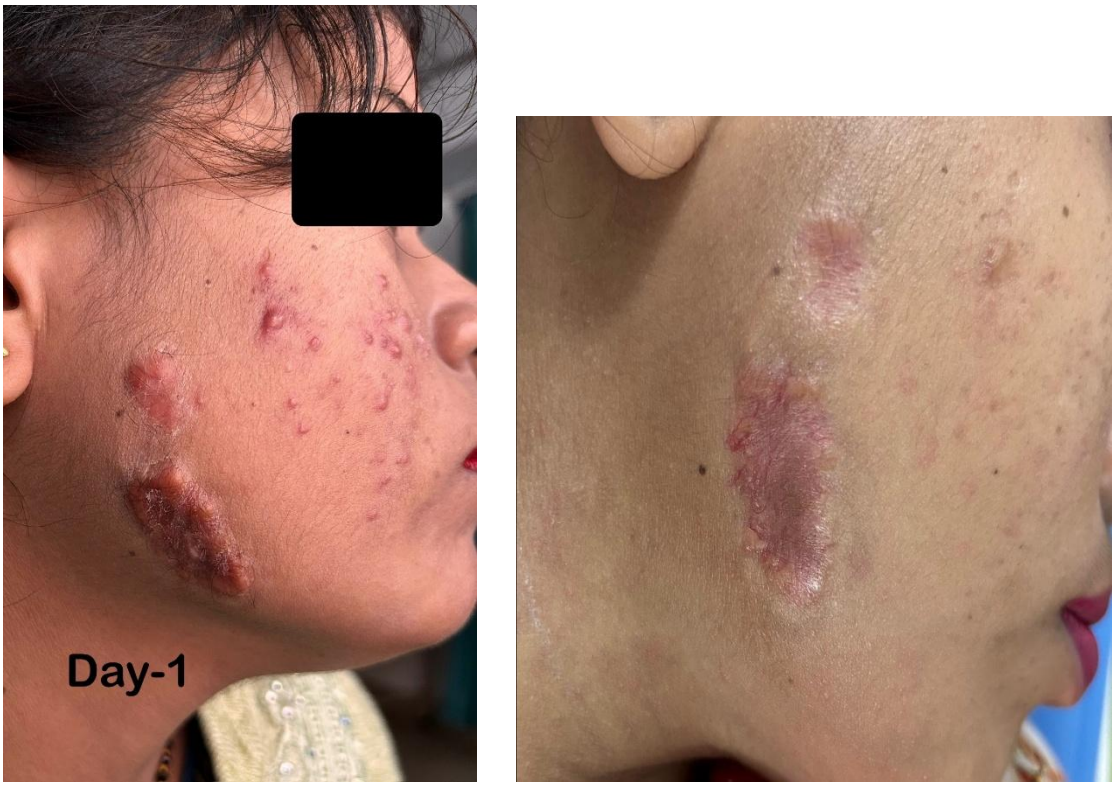

Figure 1: Group A Pt. Before, after respectively

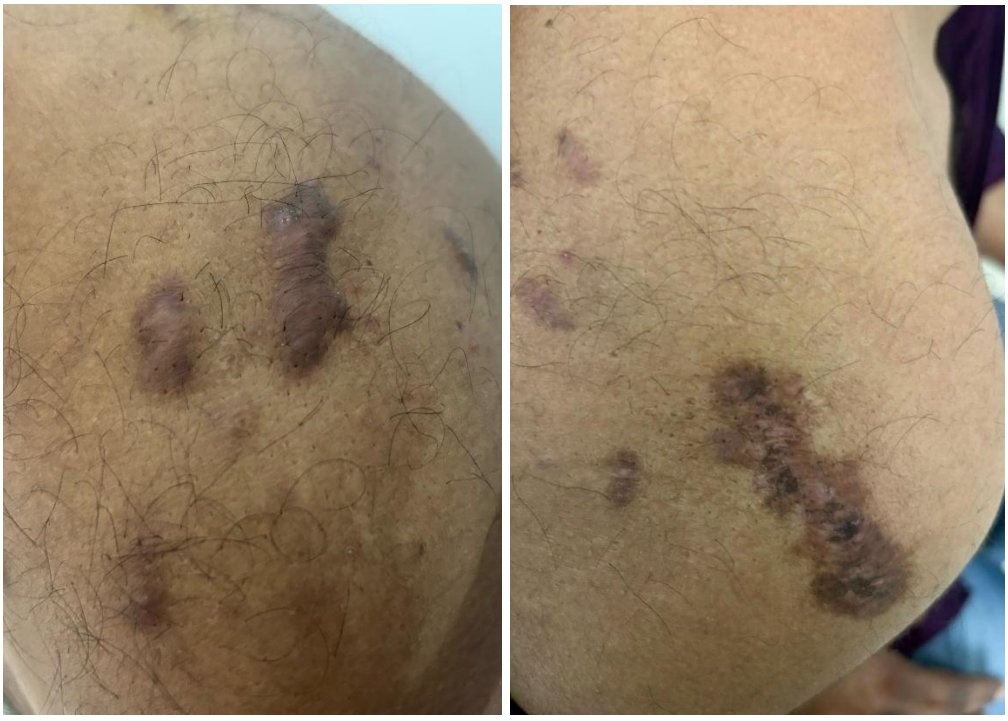

Figure 2: Group B Pt. Before, after respectively

RESULTS

TABLE-1: Distribution of duration and anatomical location of keloids among patients in Group-A and Group-B.

Parameter	Category	Group-A (N=23)	%	Group-B (N=23)	%	Chi-square	p-value
Duration of Keloid	1–3 years	9	39.1	5	21.7	1.714	0.424
	3–5 years	12	52.2	16	69.6		
	>5 years	2	8.7	2	8.7		
	Total	23	100.0	23	100.0		

	Mean ± SD	3.89 ± 2.36		4.00 ± 2.27			
	Min–Max	1–10		1–10			
Location	Arm	0	0.0	1	4.3		
	Back	2	8.7	1	4.3		
	Both Knees	0	0.0	1	4.3		
	Breasts	0	0.0	1	4.3		
	Chest	4	17.4	4	17.4		
	Face	1	4.3	1	4.3		
	Left Ankle	0	0.0	1	4.3		
	Left Breast	1	4.3	0	0.0		
	Left Buttock	1	4.3	0	0.0		
	Left Elbow	0	0.0	1	4.3		
	Left Feet	1	4.3	0	0.0		
	Left Shoulder	1	4.3	0	0.0		
	Left Thigh	1	4.3	1	4.3		
	Left Wrist	1	4.3	0	0.0		
	Neck	1	4.3	0	0.0		
	Right Arm	1	4.3	0	0.0		
	Right Chest	0	0.0	1	4.3		
	Right Elbow	0	0.0	2	8.7		
	Right Hand	1	4.3	2	8.7		
	Right Hand & Elbow	0	0.0	1	4.3		
	Right Knee	2	8.7	2	8.7		
	Right Knee & Elbow	1	4.3	0	0.0		
	Right Shoulder	3	13.0	1	4.3		
	Right Thigh	1	4.3	1	4.3		
	Shoulder	0	0.0	1	4.3		
	Total	23	100.0	23	100.0		

The mean duration of keloids was 3.89 ± 2.36 years in Group A and 4.00 ± 2.27 years in Group B, with an identical range of 1–10 years in both groups. In Group A, 9 (39.1%) patients had keloids for 1–3 years, 12 (52.2%) for 3–5 years, and 2 (8.7%) for >5 years; corresponding values in Group B were 5 (21.7%), 16 (69.6%), and 2 (8.7%), respectively. The difference in duration distribution was not statistically significant (χ^2=1.714, p=0.424). Regarding anatomical location, the chest was the most frequent individual site in both groups, accounting for 4 (17.4%) patients in each group. In Group A, this was followed by the right shoulder in 3 (13.0%), back and right knee in 2 (8.7%) each, and face, left breast, left buttock, left feet, left shoulder, left thigh, left wrist, neck, right arm, right hand, right knee & elbow, and right thigh in 1 (4.3%) patient each. In Group B, right elbow, right hand, and right knee occurred in 2 (8.7%) patients each, while arm, back, both knees, breasts, face, left ankle, left elbow, left thigh, right chest, right hand & elbow, right shoulder, right thigh, and shoulder occurred in 1 (4.3%) patient each.

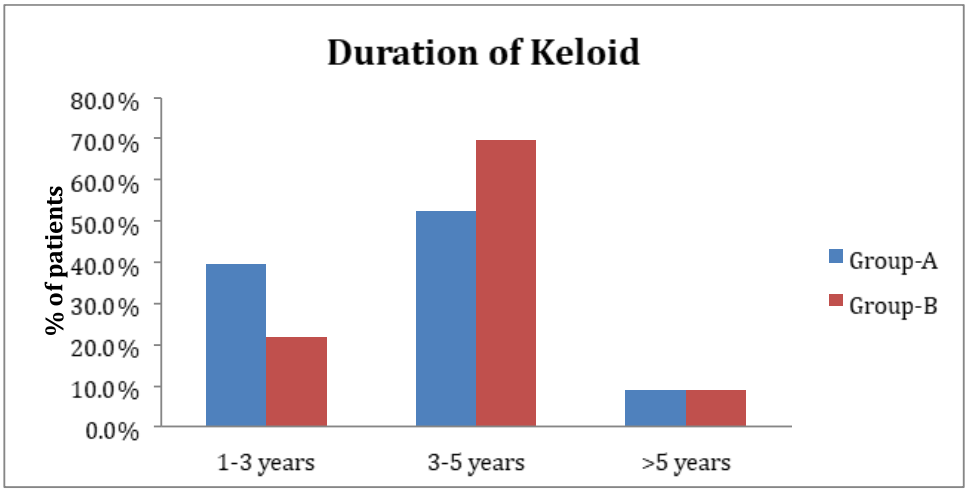

FIGURE-3: The study population's distribution based on the duration of keloid formation (years)

TABLE-2: Assessment of normality of Vancouver Scar Scale (VSS) scores at baseline and during follow-up in both groups using Kolmogorov–Smirnov test.

Vancouver Scar Scale scores	Group-A			Group-B		
	N	KolmogorovSmirnov Z	p-value	N	KolmogorovSmirnov Z	p-value
VSS Baseline	23	.840	.480	23	.713	.689
VSS 3 weeks	23	1.028	.241	23	.828	.499
VSS 6 weeks	23	.966	.309	23	.563	.909
VSS 9 weeks	23	.727	.666	23	.652	.790
VSS 12 weeks	23	1.051	.219	23	.659	.778

The Kolmogorov–Smirnov test showed that VSS scores were normally distributed at all assessment points in both groups, as all p-values were >0.05. In Group A, the Kolmogorov–Smirnov Z values at baseline, 3, 6, 9, and 12 weeks were 0.840, 1.028, 0.966, 0.727, and 1.051, with corresponding p-values of 0.480, 0.241, 0.309, 0.666, and 0.219, respectively. In Group B, the corresponding Z values were 0.713, 0.828, 0.563, 0.652, and 0.659, with p-values of 0.689, 0.499, 0.909, 0.790, and 0.778, respectively. Thus, the normality assumption was satisfied for subsequent parametric analyses.

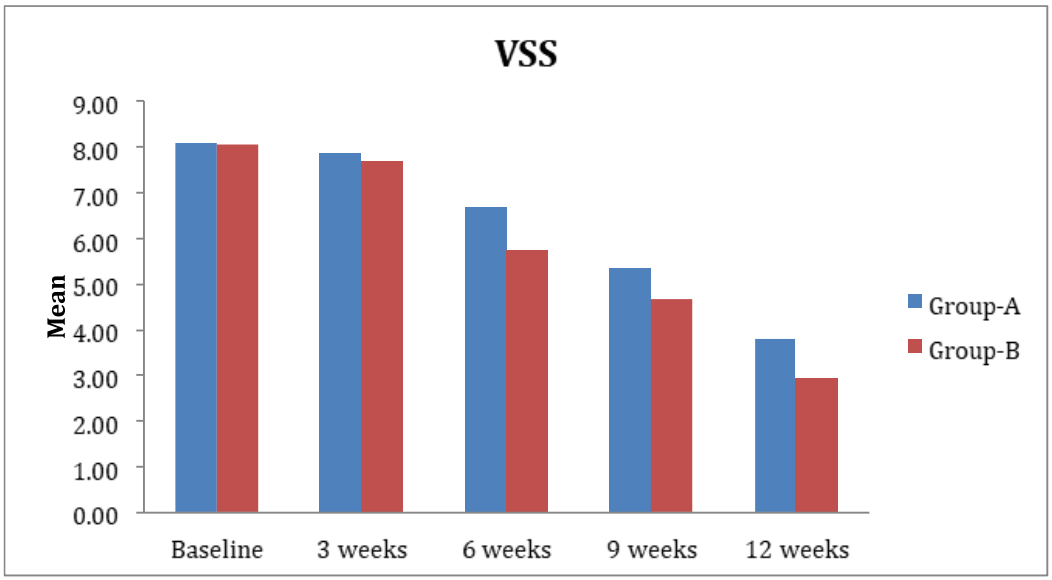

FIGURE-4: Bar graph showing improvement in the VSS of each group following treatment

TABLE-3: Intergroup comparison of Vancouver Scar Scale (VSS) scores at baseline and during follow-up.

Scar characteristics		Group-A	Group-B	t-value	p-value
VSS Baseline	Mean	8.09	8.04	.081	.936
	Standard Deviation	1.50	2.08		
	Minimum	6.00	5.00		
	Maximum	11.00	12.00		
VSS 3 weeks	Mean	7.83	7.65	.315	.754
	Standard Deviation	1.64	2.08		
	Minimum	5.00	4.00		
	Maximum	11.00	12.00		
VSS 6 weeks	Mean	6.65	5.74	1.541	.130
	Standard Deviation	1.87	2.14		
	Minimum	2.00	3.00		
	Maximum	10.00	11.00		
VSS 9 weeks	Mean	5.30	4.65	1.075	.288
	Standard Deviation	1.84	2.25		
	Minimum	2.00	1.00		
	Maximum	8.00	10.00		
VSS 12 weeks	Mean	3.78	2.91	1.357	.182
	Standard Deviation	1.98	2.35		
	Minimum	0.00	0.00		
	Maximum	8.00	9.00		

At baseline, the mean VSS score was **8.**09 ± 1.50 in Group A and 8.04 ± 2.08 in Group B, with ranges of 6.00–11.00 and 5.00–12.00, respectively; the difference was not significant (t=0.081, p=0.936). At 3 weeks, the mean scores decreased to 7.83 ± 1.64 (range 5.00–11.00) and 7.65 ± 2.08 (range 4.00–12.00), respectively (t=0.315, p=0.754). At 6 weeks, the corresponding scores were 6.65 ± 1.87 (2.00–10.00) and 5.74 ± 2.14 (3.00–11.00; t=1.541, p=0.130). At 9 weeks, mean VSS was 5.30 ± 1.84 (2.00–8.00) in Group A and 4.65 ± 2.25 (1.00–10.00) in Group B (t=1.075, p=0.288). By 12 weeks, scores had further decreased to 3.78 ± 1.98 (0.00–8.00) and 2.91 ± 2.35 (0.00–9.00), respectively (t=1.357, p=0.182). Although Group B showed numerically lower VSS scores from 3 weeks onward, none of the intergroup differences reached statistical significance at any assessment point (all p>0.05).

TABLE-4: Intragroup comparison of Vancouver Scar Scale (VSS) scores over time in Group-A and Group-B using paired t-test.

VSS Scores		Mean	SD	Minimum	Maximum	t-value	p- value
Group A	VSS Baseline	8.09	1.50	6.00	11.00	ref	
	VSS 3 weeks	7.83	1.64	5.00	11.00	1.545	.137
	VSS 6 weeks	6.65	1.87	2.00	10.00	5.927	.0001**
	VSS 9 weeks	5.30	1.84	2.00	8.00	9.668	.0001**
	VSS 12 weeks	3.78	1.98	0.00	8.00	12.839	.0001**
Group B	VSS Baseline	8.04	2.08	5.00	12.00	ref	
	VSS 3 weeks	7.65	2.08	4.00	12.00	2.859	.009**
	VSS 6 weeks	5.74	2.14	3.00	11.00	15.722	.0001**
	VSS 9 weeks	4.65	2.25	1.00	10.00	17.285	.0001**
	VSS 12 weeks	2.91	2.35	0.00	9.00	22.373	.0001**

In Group A, the mean VSS score decreased from 8.09 ± 1.50 at baseline to 7.83 ± 1.64 at 3 weeks; however, this initial reduction was not statistically significant (t=1.545, p=0.137). A significant reduction was observed by 6 weeks, when the mean VSS decreased to 6.65 ± 1.87 (t=5.927, p=0.0001), followed by further reductions to 5.30 ± 1.84 at 9 weeks (t=9.668, p=0.0001) and 3.78 ± 1.98 at 12 weeks (t=12.839, p=0.0001). The respective ranges were 6.00–11.00 at baseline, 5.00–11.00 at 3 weeks, 2.00–10.00 at 6 weeks, 2.00–8.00 at 9 weeks, and 0.00–8.00 at 12 weeks.

In Group B, improvement occurred earlier. The mean VSS score decreased from 8.04 ± 2.08 at baseline to 7.65 ± 2.08 at 3 weeks, and this reduction was already statistically significant (t=2.859, p=0.009). The mean score further declined to 5.74 ± 2.14 at 6 weeks (t=15.722, p=0.0001), 4.65 ± 2.25 at 9 weeks (t=17.285, p=0.0001), and 2.91 ± 2.35 at 12 weeks (t=22.373, p=0.0001). The corresponding ranges were 5.00–12.00, 4.00–12.00, 3.00–11.00, 1.00–10.00, and 0.00–9.00. Thus, Group B demonstrated statistically significant improvement from 3 weeks onward, whereas Group A showed statistically significant improvement from 6 weeks onward.

TABLE-5: Comparison of treatment-related adverse effects between Group-A and Group-B.

Side Effects	Group-A		Group-B		Chi-Squar e	p- value
	N	%	N	%		
Hypopigmentation	7	30.4%	0	0.0%	46.000	.0001**
Hypopigmentation and increased vascularity	10	43.5%	0	0.0%		
Hypopigmentation and skin atrophy	6	26.1%	0	0.0%		
Pain on injection	0	0.0%	14	60.9%		
None	0	0.0%	9	39.1%		
Total	23	100.0 %	23	100.0 %		

Treatment-related adverse effects differed significantly between the two groups (χ^2=46.000, p=0.0001). In Group A, 10 (43.5%) patients developed hypopigmentation with increased vascularity, 7 (30.4%) developed hypopigmentation alone, and 6 (26.1%) developed hypopigmentation with skin atrophy. None of the Group A patients experienced pain on injection or remained free of adverse effects. In contrast, in Group B, 14 (60.9%) patients experienced pain on injection, while 9 (39.1%) reported no adverse effects. No patient in Group B developed hypopigmentation, increased vascularity, or skin atrophy. Thus, the adverse-effect profiles of the two treatment modalities were distinctly different, with pigmentary/atrophic changes predominating in Group A and procedural pain predominating in Group B.

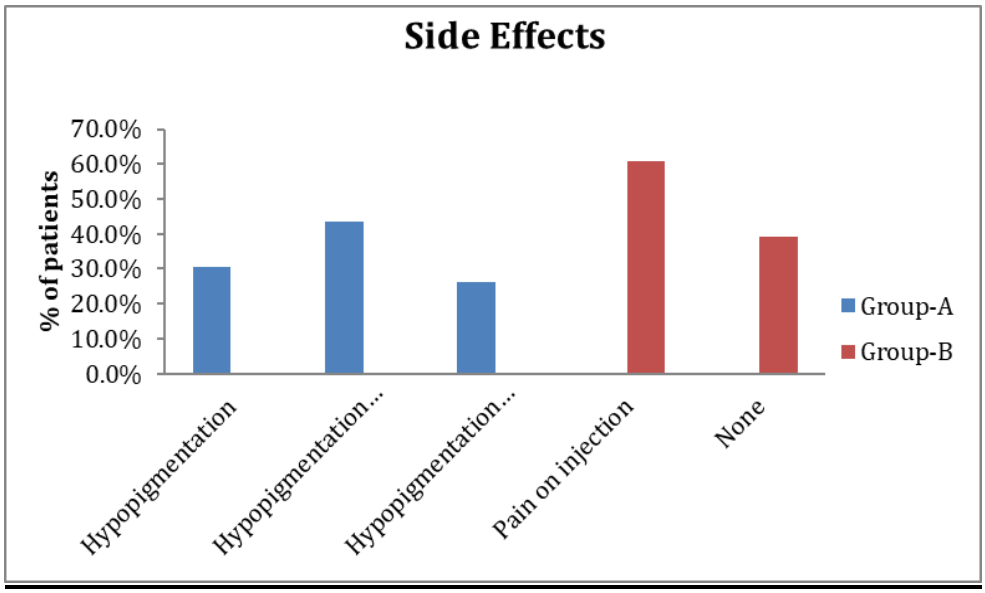

FIGURE-5: Side effects of Group- A & B

DISCUSSION

Keloids are abnormal wound healing responses characterized by excessive, disorganized collagen and glycoprotein deposition. They often follow an autosomal dominant pattern with incomplete penetrance and develop in predisposed individuals, either spontaneously or after trauma. Their formation involves increased fibroblast activity, growth factors, cytokines, and genetic influences. Clinically, keloids cause cosmetic disfigurement, pain, pruritus, and restricted mobility, significantly affecting quality of life. Most patients were in the 21–30 years age group, with mean ages of 30.78 ± 10.93 years in Group A and 26.61 ± 6.44 years in Group B, with no significant difference ($p = 0.266$). This is consistent with Nemeth A [3] and others [6,13], while Reinholz et al. [10] reported slightly higher ages. Jiang et al. [11] also noted variability due to demographic factors. There was no significant gender difference (Chi-square = 0.789; $p = 0.375$), indicating no sex predilection, in line with Shih and Bayat [8] and Jiang et al. [11]. Monteiro et al. [14] reported slight female predominance, likely due to healthcare-seeking behavior. In the present study, most patients had keloids of 3–5 years' duration (52.2% in Group A and 69.6% in Group B), with mean durations of 3.89 ± 2.36 and 4.00 ± 2.27 years, respectively, showing no significant difference (Chi-square = 1.714; $p = 0.424$). This is consistent with Monteiro et al. [14] and others [9] who reported presentation with long-standing lesions. In contrast, Jiang et al. [11] included studies with shorter durations, suggesting that earlier lesions may respond better. Overall, these findings support that keloids are typically chronic at presentation. In the present study, the chest was the most common site (17.4% in both groups), followed by shoulder and knee, with overall predominance of truncal and upper extremity involvement. These findings are consistent with Berman and Flores [15], who reported higher occurrence in high-tension areas such as the chest and shoulders. In contrast, Bran et al. [5] observed higher earlobe involvement, especially in young females, attributed to ear piercing. In this prospective randomized study, two treatment modalities were compared using the Vancouver Scar Scale (VSS). Group A received fractional CO_2 laser with intralesional triamcinolone, while Group B received triamcinolone with 5-fluorouracil. Both groups were comparable at baseline, ensuring internal validity. Over 12 weeks, both groups showed significant intragroup reduction in VSS scores. Group A demonstrated improvement from the 6th week onward, consistent with Mahfood et al. [16] and Tirgan et al. [17], highlighting delayed but sustained effects of laser-assisted therapy. In contrast, Group B showed earlier improvement by the 3rd week, similar to findings by Saleem et al. [18], due to the anti-proliferative action of 5-FU. However, no significant difference in final VSS scores was observed, indicating comparable efficacy of both treatments. The present study showed a significant difference in adverse effects between the two groups. In Group A, pigmentary and atrophic changes were common, with hypopigmentation (30.4%), hypopigmentation with vascularity (43.5%), and hypopigmentation with atrophy (26.1%), and no patient was free from side effects. These findings are supported by Reinholz et al. [10], who reported frequent steroid-related complications. However, Walsh et al. [19] noted that such effects can be minimized with appropriate dosing and technique. In contrast, Group B (intralesional 5-fluorouracil 50 mg/mL with triamcinolone 40 mg/mL in a 9:1 ratio) mainly showed procedural pain (60.9%), while 39.1% had no adverse effects and no pigmentary or atrophic changes were observed. These findings are consistent with Reinholz et al. [10], who reported pain as the most common side effect with minimal pigmentary changes. These results highlight that no treatment is completely free from side effects, and individualized therapy with proper counselling and post-procedure care is essential for optimal outcomes.

CONCLUSION

Both treatment modalities demonstrated comparable overall efficacy; however, their mechanisms, onset of action, and side-effect profiles differed significantly. Fractional CO_2 laser with intralesional triamcinolone produced gradual yet sustained

improvement, although it was associated with higher rates of pigmentary and atrophic changes. In contrast, the combination of 5-fluorouracil with triamcinolone showed an earlier clinical response with fewer long-term cutaneous adverse effects, but greater procedural discomfort. Therefore, treatment selection should be individualized, taking into account patient-specific factors such as skin type, scar characteristics, pain tolerance, and cosmetic concerns. Thus, this study adds valuable comparative evidence to keloid management and highlights the importance of a multimodal, patient-centered approach.

However, the present study had certain limitations. Firstly, the sample size was relatively small, which may limit the generalizability of the findings. Moreover, the follow-up duration was limited to 12 weeks, which was insufficient to assess long-term efficacy and recurrence rates, an important consideration in keloid management. In addition, the study did not evaluate the role of adjunctive therapies such as photobiomodulation or gene-targeted interventions, which may further influence treatment outcomes. Therefore, larger studies with extended follow-up are required for a more comprehensive evaluation.

CONFLICT OF INTEREST: All authors declare no conflict of interest.

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ETHICAL APPROVAL: As per international standards or university standards written ethical permission has been collected and preserved by the author(s).

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