

Original Article:

Safety of combination of pulsed dye laser followed by intralesional triamcinolone acetonide and intralesional triamcinolone acetonide alone in the treatment of keloid – a study on 50 case

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Abstract

Background: Keloids are benign fibroproliferative lesions that extend beyond the original wound margins, often causing cosmetic disfigurement, discomfort, and psychosocial distress. Their high recurrence rates and resistance to conventional therapy make management challenging. Although various modalities such as surgery, corticosteroid injections, cryotherapy, radiotherapy, and laser treatments are available, no single method has shown consistent long-term superiority. **Objective:** To evaluate the safety and any associated side effects or complications of pulsed dye laser (PDL) followed by intralesional triamcinolone acetonide versus triamcinolone alone in keloid management. **Methods:** This randomized comparative study enrolled 50 patients with clinically diagnosed keloids at the Department of Dermatology & Venereology, Combined Military Hospital, Dhaka. Patients were allocated into two groups (n = 25 each). Group A received PDL immediately followed by intralesional triamcinolone acetonide (40 mg/mL), while Group B received triamcinolone alone. Injections were delivered intradermally using a 30-gauge needle and 1 mL insulin syringe under aseptic conditions, with dosing adjusted according to clinical response. Outcomes were assessed at baseline and at 4, 8, and 12 weeks, focusing on safety, adverse effects, and clinical improvement. **Results:** Both groups tolerated treatment well, with no serious adverse events. Combination therapy produced greater improvement than steroid alone, with earlier lesion softening and better overall response. The enhanced efficacy was attributed to PDL-induced edema, which may increase steroid penetration. **Conclusion:** Both methods were found to be individually safe. However, the combination of PDL and intralesional triamcinolone acetonide offers a safer approach that produces better clinical outcomes and quicker lesion softening compared to steroid injection alone, without added safety concerns.

Keyword: Keloid, pulsed dye laser, intralesional triamcinolone acetonide.

Introduction

Keloids are benign dermal tumors arising from an abnormal wound-healing response, characterized by excessive proliferation of fibrous tissue extending beyond the original wound margins. Clinically, they appear as firm, irregular, well-defined nodular lesions, often hyperpigmented and erythematous, with claw-like extensions. Common sites include the chest, shoulders, upper back, neck, and earlobes, where they are frequently associated with significant cosmetic and functional impairment^{1,2}.

The pathogenesis of keloids is not fully understood but is believed to involve an imbalance between collagen

synthesis and degradation, resulting from increased fibroblast activity and prolonged inflammation¹. A wide range of dermal insults—including surgical wounds, burns, piercings, abrasions, tattoos, vaccinations, insect bites, and inflammatory dermatoses such as acne, varicella, and folliculitis—may precipitate keloid formation^{3,4}. Environmental and mechanical factors, such as excessive wound tension and secondary infection, can further increase risk.

Beyond their aesthetic impact, keloids are often symptomatic, causing pain, pruritus, and restricted mobility, which may lead to psychosocial distress and

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reduced quality of life⁵. Their exclusivity to humans and the absence of a reproducible animal model hinder deeper investigation of molecular and genetic mechanisms. Genetic predisposition is supported by associations with specific human leukocyte antigens, elevated serum IgE, allergic diatheses, and possible autosomal inheritance patterns⁶⁻⁹, suggesting that immune dysregulation and genetic variation influence both development and treatment response.

Given the chronic nature and high recurrence rate of keloids, numerous therapeutic options have been explored, including surgical excision, pressure therapy, cryotherapy, radiotherapy, silicone sheeting, 5-fluorouracil, interferon, and various laser modalities¹⁰. Intralesional corticosteroids, especially triamcinolone acetonide, continue to serve as the cornerstone of therapy. Their mechanism involves downregulation of transforming growth factor-beta (TGF- β), inhibition of collagen synthesis, and increased basic fibroblast growth factor (bFGF). Initial dosing is typically 40 mg/mL, tapered to 10–20 mg/mL as lesions respond, administered every 4–6 weeks¹⁰.

Despite proven benefit, intralesional steroid delivery is often limited by the dense collagen architecture of keloids, making injections technically challenging, painful, and sometimes ineffective. Adjunctive techniques—such as cryotherapy, pulsed dye laser (PDL), topical immunomodulators like imiquimod, and hyaluronidase—have been employed to improve drug penetration. While steroid injections generally relieve pruritus and pain, adverse effects including telangiectasia, hypopigmentation, and dermal atrophy occur in up to 37% of patients¹¹. The discomfort and cumulative corticosteroid exposure further limit their use in extensive or multiple lesions.

Ablative lasers such as CO₂ and Er:YAG can excise keloid tissue, but recurrence approaches 100%, comparable to simple surgical excision, largely due to thermal injury and incomplete removal^{12,13}. In contrast, the 585 nm PDL targets hemoglobin, reducing vascularity and modulating the inflammatory response. Kuo et al.¹⁴ demonstrated that PDL downregulates TGF- β 1, upregulates MMP-13, inhibits fibroblast proliferation, and promotes apoptosis. Additional mechanisms may include tissue hypoxia, thermal disruption of collagen cross-links, and cytokine-mediated collagen degradation¹⁵. These effects make PDL a logical adjunct to corticosteroid therapy, potentially enhancing drug diffusion and therapeutic benefit¹⁶.

In this context, the present study aims to evaluate the safety of PDL in combination with intralesional triamcinolone acetonide compared with intralesional

steroid therapy alone in patients with keloids. By analyzing treatment outcomes and safety profiles, this work seeks to inform optimized, evidence-based strategies for keloid management.

Materials and Methodes

This was a hospital-based prospective clinical trial. This study was conducted on 50 patients with keloids who sought treatment at the Department of Dermatology & Venereology, Combined Military Hospital (CMH), Dhaka. All participants met the established inclusion and exclusion criteria. These patients were randomly divided into two equal groups: Group A (25 patients) received pulsed dye laser (PDL) therapy followed immediately by an intralesional injection of triamcinolone acetonide, while Group B (25 patients) received only the intralesional steroid injection. The sample size was determined based on simple random sampling, ensuring unbiased group allocation.

Before inclusion in the study, each patient underwent a thorough screening process, which involved a detailed medical history, a comprehensive physical examination, and a series of laboratory tests. These tests included complete blood count, urine routine examination, liver function tests, serum creatinine, and random blood sugar levels. The sampling technique used for participant selection was simple random sampling, facilitated by a computer-generated randomization table.

Patients were eligible for the study if they were over 12 years of age, of either sex, had untreated keloid lesions measuring at least 10 mm, and were willing to provide informed consent and adhere to the study protocol. However, patients were excluded if they were pregnant or breastfeeding, had received keloid treatment within the previous 12 weeks, had contraindications to PDL therapy, were allergic to corticosteroids, or suffered from significant comorbidities such as renal or hepatic failure, diabetes, peptic ulcers, hypertension, or were immunocompromised. Individuals who declined to provide informed consent were also excluded.

The 50 selected patients were randomized into Group A and Group B, each consisting of 25 individuals. A structured case record form was used to document patient demographics, clinical history, and physical findings. After confirmation of eligibility, participants were assigned to their respective treatment groups. Group A received pulsed dye laser therapy followed by an intralesional injection of triamcinolone acetonide in the same session. Group B received only the steroid injection. The steroid was administered intradermally using a 30-gauge needle attached to a 1 ml insulin syringe,

following standard antiseptic preparation. The initial dosage was 40 mg/ml (full strength), with future doses adjusted based on lesion response. Treatments were repeated every four weeks, and progress was monitored through clinical evaluation at baseline, and at 4, 8, and 12 weeks.

Patients were monitored for adverse effects throughout the treatment course. Any observed side effects—such as skin atrophy, telangiectasia, pigmentation changes, ulceration, or local irritation—were recorded and graded on a scale from 0 (none) to 3 (severe).

All collected data were carefully reviewed for completeness and consistency. Statistical analysis was carried out using SPSS software, version 20. Quantitative variables were presented as means with standard deviations and compared using the student’s t-test. Categorical data were expressed as frequencies and percentages, with comparisons made using the chi-square (χ^2) test. A p-value of less than 0.05 was considered statistically significant, and results were summarized through descriptive text and tables.

Result

A total of 50 patients with clinically diagnosed keloids were included in the study and allocated into two equal groups: Group A (PDL + triamcinolone acetonide) and Group B (triamcinolone acetonide alone).

Table-I: Demographic Distribution & Clinical Characteristics of Study Groups (n=50)

Variable	Categories	Group A (PDL + Triamcinolone)	Group B (Triamcinolone)	P- value	Significance
Gender	Male	9 (36%)	12 (48%)	0.390	Not Significant (Chi-square test)
	Female	16 (64%)	13 (52%)		
Age Group	≤20 years	5 (20%)	7 (28%)	0.242	Not Significant (t test)
	21–30 years	11 (44%)	13 (52%)		
	31–40 years	8 (32%)	5 (20%)		
	41–50 years	1 (4%)	0 (0%)		
	≥50 years	0 (0%)	0 (0%)		
	Mean ± SD	28.16 ± 8.055	25.72 ± 6.432		
Occupation	Military personnel	6 (24%)	7 (28%)	0.979	Not Significant (Chi-square test)
	Housewife	9 (36%)	9 (36%)		
	Student	5 (20%)	5 (20%)		
	Civil employee	5 (20%)	4 (16%)		
Family History	Present	3 (12%)	2 (8%)	0.637	Not Significant (Chi-square test)
	Absent	22 (88%)	23 (92%)		

Baseline Demographics and Clinical Characteristics:

In Group A, 9 patients (36%) were male and 16 (64%) were female, while in Group B, 12 (48%) were male and 13 (52%) were female. The difference in gender distribution between groups was not statistically significant (P = 0.390).

Regarding age distribution, in Group A, 5 patients (20%) were below 20 years, 11 (44%) were aged 21–30 years, 8 (32%) were aged 31–40 years, and 1 (4%) was aged 41–50 years; none were over 50 years. In Group B, 7 patients

(28%) were below 20 years, 13 (52%) were aged 21–30 years, and 5 (20%) were aged 31–40 years; none were over 40 years. The difference between groups was not statistically significant (P = 0.242).

Occupational distribution in Group A was as follows: military personnel 6 (24%), housewives 9 (36%), students 5 (20%), and civil employees 5 (20%). In Group B: military personnel 7 (28%), housewives 9 (36%), students 5 (20%), and civil employees 4 (16%). No statistically significant difference was observed (P = 0.979).

A family history of keloids was reported in 3 patients (12%) in Group A and 2 patients (8%) in Group B, with no significant difference (P = 0.637).

Table-II: Distribution of study groups by predisposing factors, duration of keloids, local symptoms and site of lesion (n=50)

Variable	Categories	Group A (PDL + Triamcinolone)	Group B (Triamcinolone)	P- value	Significance
Predisposing Factors	Burn	4 (16%)	2 (8%)	0.481	Not Significant (Chi-square test)
	Trauma	2 (8%)	5 (20%)		
	Operative	3 (12%)	4 (16%)		
	Vaccination	4 (16%)	0 (0%)		
	Acne	2 (8%)	5 (20%)		
	Boil	3 (12%)	3 (12%)		
	Chicken Pox	2 (8%)	2 (8%)		
	Ear Piercing	1 (4%)	1 (4%)		
	Unnoticed	4 (16%)	3 (12%)		
Duration of Keloids	≤6 months	10 (40%)	5 (20%)	0.648	Not Significant (Chi-square test)
	6 months – 1 year	9 (36%)	14 (56%)		
	1–1.5 years	5 (20%)	5 (20%)		
	1.5–2 years	1 (4%)	1 (4%)		
Local Symptoms	Pain	7 (28%)	11 (44%)	0.487	Not Significant (Chi-square test)
	Itching	11 (44%)	8 (32%)		
	Cosmetic disfigurement	7 (28%)	6 (24%)		
Site of Lesion	Sternal area	4 (16%)	11 (44%)	0.138	Not Significant (Chi-square test)
	Lower abdomen	5 (20%)	3 (12%)		
	Chest	5 (20%)	5 (20%)		
	Arm	8 (32%)	2 (8%)		
	Leg	2 (8%)	1 (4%)		
	Back	0 (0%)	2 (8%)		
	Ear	1 (4%)	1 (4%)		

Predisposing Factors, Duration, and Symptoms:

Identified predisposing factors included burns, trauma, surgical procedures, vaccinations, acne, boils, chickenpox, and ear piercings. The distribution of predisposing factors between groups did not differ significantly (P = 0.481).

In Group A, the duration of keloids was <6 months in 10 patients (40%), 6 months–1 year in 9 patients (36%), 1–1.5 years in 5 patients (20%), and 1.5–2 years in 1 patient (4%). In Group B, 5 patients (20%) had lesions <6 months, 14 (56%) had lesions for 6 months–1 year, 5 (20%) for 1–1.5 years, and 1 (4%) for 1.5–2 years. This difference was not statistically significant (P = 0.648).

Reported local symptoms in Group A included pain in 7 patients (28%), itching in 11 (44%), and cosmetic disfigurement in 7 (28%). In Group B, pain was reported in 11 patients (44%), itching in 8 (32%), and cosmetic disfigurement in 6 (24%). No significant difference was observed (P = 0.487).

Lesion sites included the sternal area, lower abdomen, chest, arm, leg, back, and ear. Site distribution between groups was not statistically different (P = 0.138).

Table-III: Telangiectasia and Ulceration grading in percentage of Group A (PDL + Triamcinolone) and Group B (Triamcinolone) (n=25 for each group)

		Group (A) (PDL + Triamcinolone)				Group (B) (Triamcinolone)			
		Baseline	4W	8W	12W	Baseline	4W	8W	12W
Telangiectasia	Present	36%	24%	12%	0%	40%	28%	20%	12%
	Absent	64%	76%	88%	100%	60%	72%	80%	88%
Ulceration	Yes	0%	0%	0%	0%	0%	0%	0%	0%
	No	100%	100%	100%	100%	100%	100%	100%	100%

Table-IV: Pigmentation, Skin Atrophy and Irritation grading in percentage of Group A (PDL + Triamcinolone) and Group B (Triamcinolone) (n=25 for each group)

		Group (A) (PDL + Triamcinolone)				Group (B) (Triamcinolone)			
		Baseline	4W	8W	12W	Baseline	4W	8W	12W
Pigmentation	None (0)	0%	16%	68%	84%	0%	0%	20%	76%
	Mild (1)	28%	68%	28%	16%	36%	72%	76%	24%
	Moderate (2)	52%	16%	4%	0%	48%	28%	4%	0%
	Severe (3)	20%	0%	0%	0%	16%	0%	0%	0%
Skin Atrophy	None (0)	100%	100%	100%	100%	100%	100%	100%	92%
	Mild (1)	0%	0%	0%	0%	0%	0%	0%	8%
	Moderate (2)	0%	0%	0%	0%	0%	0%	0%	0%
	Severe (3)	0%	0%	0%	0%	0%	0%	0%	0%
Irritation	None (0)	0%	48%	88%	92%	0%	0%	40%	84%
	Mild (1)	48%	52%	12%	8%	56%	88%	60%	16%
	Moderate (2)	52%	0%	0%	0%	44%	12%	0%	0%
	Severe (3)	0%	0%	0%	0%	0%	0%	0%	0%

Safety Profile: Telangiectasia was present at baseline in 9 patients (36%) in Group A and 10 patients (40%) in Group B. By the 12th week, no patients in Group A had telangiectasia, whereas in Group B, 3 patients (12%) still exhibited telangiectasia. No ulcerations were reported in either group at baseline or during follow-up. **Pigmentation:** At baseline, 13 patients (52%) in Group A and 12 patients (48%) in Group B had moderate pigmentation. By week 12, 21 patients (84%) in Group A and 19 patients (76%) in Group B showed no pigmentation. **Skin Atrophy:** No skin atrophy was noted in Group A throughout the study. In Group B, no atrophy was observed at baseline, but by week 12, 2 patients (8%) developed mild atrophy. **Irritation:** At baseline, 13 patients (52%) in Group A had moderate irritation, while 14 patients (56%) in Group B had mild irritation. By week 12, irritation had resolved in 23 patients (92%) in Group A and 21 patients (84%) in Group B. Overall, both treatment modalities were well tolerated, with Group A showing a greater reduction in telangiectasia, pigmentation, and irritation, and no cases of skin atrophy during the study period.

Discussion

Triamcinolone acetonide remains widely regarded as the first-line therapy for keloids due to its potent anti-inflammatory and antiproliferative effects. In recent years, pulsed dye laser (PDL) therapy has emerged as a promising alternative or adjunctive approach for keloid management. Several studies have demonstrated its ability to improve clinical and cosmetic outcomes; however, variability in treatment response has been reported across different ethnic groups. Investigations in Asian, Hispanic, and Oriental populations have yielded mixed or inconclusive results regarding PDL effectiveness. Against this backdrop, the present study was conducted to evaluate whether combining PDL with intralesional triamcinolone confers greater therapeutic benefit compared with corticosteroid therapy alone in a Bangladeshi population.

In our study, demographic characteristics were comparable between groups, supporting the validity of direct outcome comparisons. Group A (PDL + triamcinolone) included 36% males and 64% females, while Group B (triamcinolone alone) comprised 48% males and 52% females. The absence of significant gender-based differences (P = 0.390) and the predominance of patients aged 21–30 years in both groups align with the findings of Burns et al.¹⁷ who reported that keloids occur most frequently between puberty and 30 years of age.

Etiological analysis revealed a broad spectrum of predisposing factors, including burns, trauma, surgical scars, acne, vaccinations, boils, chickenpox, and ear piercings. This distribution contrasts with Yang et al.¹⁸ who identified folliculitis as the predominant cause in their cohort. In our population, the distribution of predisposing factors was similar across both treatment groups (P = 0.481), underscoring group homogeneity.

The anatomical distribution of lesions in our patients—most commonly on the chest, sternum, lower abdomen, back, limbs, and ears—was consistent with patterns reported in previous literature. No significant difference was observed in lesion site distribution between treatment arms (P = 0.138). Family history, a factor linked to genetic susceptibility in studies by Ramakrishnan et al.¹⁹ and Olabanji et al.²⁰, was present in only a small proportion of patients and did not differ significantly between groups (P = 0.637).

Symptom profiles were also comparable at baseline. In Group A, pain was reported by 28%, itching by 44%, and cosmetic concerns by 28% of patients; in Group B, pain was present in 44%, itching in 32%, and cosmetic concerns in 24%. These differences were not statistically significant (P = 0.487).

Over the 12-week follow-up, important differences in clinical outcomes emerged. Pigmentation, initially moderate in more than half of patients, resolved in 84% of Group A compared to 76% of Group B by week 12. Telangiectasia, seen in 36% of Group A and 40% of Group B at baseline, was completely absent in Group A at the study's conclusion, whereas 12% of Group B still exhibited this finding. Notably, no ulcerations were observed in either group throughout the study.

Skin atrophy, a known complication of corticosteroid therapy, was absent in Group A throughout the follow-up period, suggesting that PDL may help mitigate this adverse effect. In contrast, 8% of Group B developed mild atrophy by week 12. Irritation scores improved in both groups, with complete or near-complete resolution in 92% of Group A and 84% of Group B patients.

Taken together, these findings indicate that PDL combined with intralesional triamcinolone is not only safe but also potentially superior to steroid monotherapy in achieving symptom resolution, improving cosmetic outcomes, and reducing adverse effects such as persistent telangiectasia and skin atrophy. While both approaches were well tolerated, the adjunctive use of PDL appears to enhance therapeutic outcomes and should be considered as part of first-line treatment protocols for keloids, particularly in cases where monotherapy yields suboptimal results.

Conclusion

This study demonstrates that the combination of pulsed dye laser therapy followed by intralesional triamcinolone acetonide injection is a safe and more effective treatment modality for keloids compared to intralesional steroid therapy alone. While both treatment groups showed improvement with minimal adverse effects, the adjunctive use of PDL significantly enhanced outcomes in terms of pigmentation clearance, resolution of telangiectasia, reduced irritation, and prevention of steroid-induced skin atrophy. The findings suggest that integrating PDL with corticosteroid therapy may offer superior clinical benefits, particularly in populations with diverse keloid etiologies. Further large-scale, long-term studies are recommended to validate these results and assess recurrence rates.

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