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Article

Comparison of Efficacy of Intralesional Triamcinolone Acetonide Versus 5-Fluorouracil in the Treatment of Keloid at a Tertiary Care Hospital, Karachi

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ABSTRACT

Background: Keloids present a persistent clinical challenge due to excessive fibroblast activity and abnormal wound healing, with limited high-quality comparative evidence on optimal intralesional therapy. **Objective**: To compare the efficacy of intralesional triamcinolone acetonide versus 5-fluorouracil in reducing keloid height among adults at a tertiary care hospital in Karachi, with efficacy defined as ≥50% reduction in keloid height. **Methods**: This double-blinded, randomized controlled trial enrolled 50 adult patients (n = 50) aged 20–60 years with clinically diagnosed keloids. Key exclusion criteria included recent keloid therapy, active infection, systemic illness, or immunosuppression. Patients were randomized to receive intralesional triamcinolone acetonide or 5-fluorouracil injections at three-week intervals for four sessions. Keloid height was measured objectively at baseline and post-treatment. Ethical approval was obtained from the institutional review board in accordance with the Helsinki Declaration. Data were analyzed using SPSS version 27.0, applying t-tests and chi-square tests as appropriate. **Results**: Both groups were demographically comparable. The mean reduction in keloid height was significantly greater in the 5-fluorouracil group (1.8 ± 0.4 cm to 0.5 ± 0.5 cm) compared to the triamcinolone acetonide group (1.8 ± 0.4 cm to 0.8 ± 0.5 cm; p = 0.023). A higher proportion of patients in the 5-fluorouracil group achieved ≥50% reduction in keloid height (88% vs. 64%; p = 0.047), indicating clinically meaningful improvement. **Conclusion**: Intralesional 5-fluorouracil is significantly more effective than triamcinolone acetonide in reducing keloid height, supporting its use as a preferred therapeutic option for keloid management in clinical practice.

Keywords: Keloid, Triamcinolone Acetonide, 5-Fluorouracil, Randomized Controlled Trial, Intralesional Therapy, Efficacy, Dermatology

INTRODUCTION

Keloids represent an abnormal fibroepithelial response to cutaneous injury, characterized by persistent inflammation and excessive collagen deposition that extends beyond the boundaries of the original wound (1,2). This dysregulated healing process not only leads to disfiguring and sometimes painful scars, but it can also cause significant psychological distress and compromise the functionality of affected body regions (3,8).

While etiology remains multifactorial and incompletely understood, disturbances in dermal collagen metabolism, excessive fibroblast proliferation, and an imbalance between collagen synthesis and degradation are considered central to their pathogenesis (4,5,6). Key molecular mediators such as transforming growth factor-β (TGF-β), interleukin-6 (IL-6), and other cytokines have been implicated in the fibrotic environment typical of keloids (9,10). Despite not posing a direct threat to life, the chronicity, recalcitrant nature, and high recurrence rates of keloids continue to present a therapeutic challenge (7,12). A variety of interventions, both pharmacological and procedural, have been explored to manage keloids, yet there remains no universally accepted gold-standard therapy (11,12). Conventional management options include surgical excision, cryotherapy, laser therapy, silicone sheeting, radiotherapy, and various topical or intralesional agents.

Among these, intralesional therapies with corticosteroids and antimetabolites have shown promise in routine practice due to their targeted actions and relative ease of administration (13,14). Intralesional triamcinolone acetonide (TAC), a synthetic

corticosteroid, is frequently utilized and has demonstrated efficacy through mechanisms that include suppression of inflammatory cell migration, vasoconstriction, and inhibition of fibroblast and keratinocyte proliferation, thereby reducing abnormal collagen formation (14,15). However, adverse effects such as skin atrophy, pigmentary changes, and telangiectasia often limit its prolonged use (16). In contrast, 5-fluorouracil (5-FU), a cytotoxic antimetabolite, acts primarily by inhibiting DNA and RNA synthesis in proliferating fibroblasts and inducing apoptosis, as well as by interfering with TGF-β-driven collagen synthesis (17,18). Its use is often associated with localized adverse effects, including ulceration and erythema, but lacks the systemic or cosmetic side effects typically seen with corticosteroids (18).

Several studies have directly compared the efficacy of TAC and 5-FU, with varying outcomes. Evidence suggests that while both agents can achieve significant reduction in keloid size and symptomatology, the magnitude and rapidity of response may differ (24,25). Some investigations have found that 5-FU elicits superior clinical responses, particularly when used in combination with corticosteroids or for larger, more recalcitrant lesions (21,25,27,28). Notably, a recent network meta-analysis and systematic reviews support the utility of combination therapies and highlight the need for individualized, patient-centered approaches in keloid management (4,5,27,28). Despite growing research, gaps persist regarding the comparative effectiveness of these agents as monotherapies, particularly in diverse patient populations and across different keloid characteristics such as size, chronicity, and anatomical location.

There remains a critical need for rigorously designed randomized controlled trials to address these knowledge gaps, inform clinical decision-making, and optimize patient outcomes. The present double-blinded randomized control trial aims to compare the effectiveness of intralesional triamcinolone acetonide with intralesional 5-fluorouracil in the management of keloid scars at a tertiary care hospital in Karachi, with efficacy defined as at least a 50% reduction in keloid height. This study seeks to provide evidence on which of these two widely used intralesional therapies offers superior clinical benefit, thereby addressing an important therapeutic dilemma and potentially guiding future standards of care. The primary research objective is to determine whether intralesional 5-fluorouracil achieves greater efficacy than intralesional triamcinolone acetonide in reducing keloid size and improving clinical outcomes in patients with keloid scars.

MATERIALS AND METHODS

This study was conducted as a double-blinded, randomized controlled trial at the Department of Dermatology, Jinnah Postgraduate Medical Centre, Karachi, from August 2024 to January 2025, following the CONSORT guidelines for standardized trial reporting to ensure transparency and reproducibility in design, execution, and analysis (1). The study protocol was approved by the institutional ethical review committee prior to participant enrollment, and all procedures adhered to the principles set forth in the Declaration of Helsinki. Adult patients aged 20 to 60 years, presenting with keloids as per the operational definition and referred to the outpatient dermatology clinic, were screened for eligibility. Recruitment followed a non-probability consecutive sampling approach, with 50 patients ultimately enrolled based on a priori power calculation to detect clinically significant differences in efficacy between interventions. Written informed consent was obtained from each participant after full explanation of study objectives, procedures, and potential risks and benefits, ensuring voluntary participation and the right to withdraw at any time without consequences. Inclusion criteria comprised adults aged 20–60 years of either gender, presenting with clinically diagnosed keloids, without prior treatment for the same lesion in the preceding 12 months.

Exclusion criteria were rigorously applied to minimize confounding and included the presence of active infection, ulcer, or inflammation in or around the keloid, history of chronic inflammatory disease, immunosuppression, malignancy such as melanoma, chronic kidney disease, abnormal baseline hematological or biochemical parameters, pregnancy, and unwillingness to provide informed consent. Participant allocation to one of two intervention groups was determined by a computer-generated randomization sequence, and group assignments were concealed from both patients and outcome assessors using sealed opaque envelopes, maintaining allocation concealment and blinding throughout the trial to reduce selection and measurement bias.

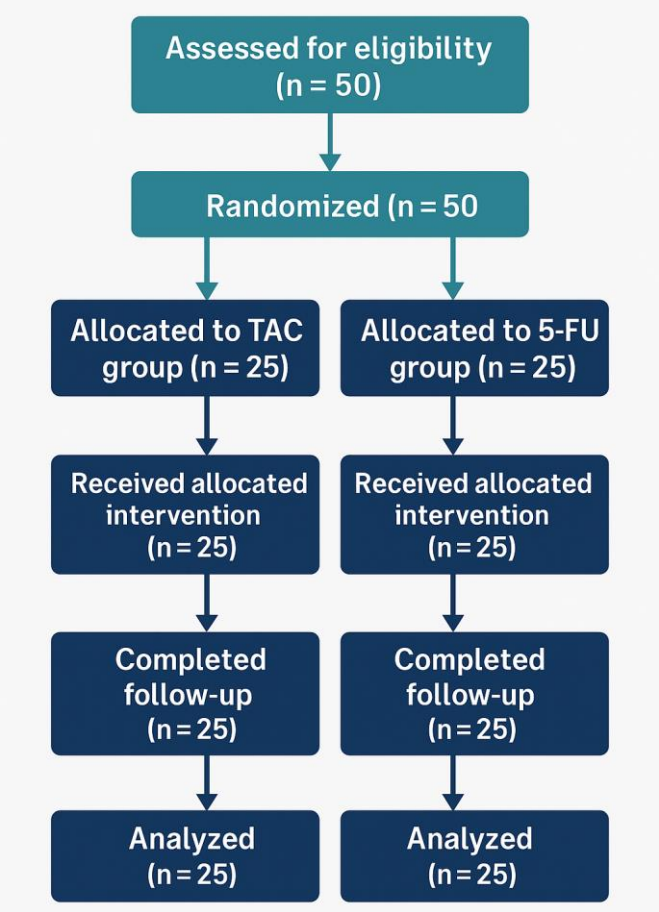

Figure 1 CONSORT Flowchart

Each patient was evaluated by dermatologists with over 10 years of clinical experience. Baseline demographic data, clinical characteristics, and relevant medical history were documented

using standardized case record forms. For intervention, patients in Group A received intralesional triamcinolone acetonide (TAC) 10 mg, prepared as 0.25 mL of 40 mg/mL TAC diluted with 0.75 mL of injectable normal saline, administered at three-week intervals for a total of four sessions.

Group B participants received intralesional 5-fluorouracil (5-FU) 45 mg (0.9 mL of 50 mg/mL 5-FU) following the same schedule and frequency. All injections were performed using 27-gauge insulin syringes, with a maximum injected volume not exceeding 0.5 mL per cm^2 of keloid.

To minimize procedural pain and prevent secondary keloid formation, 2% xylocaine was injected deep to the lesion through the edge, rather than through uninvolved skin. For uniform distribution, multiple pricks were made 1 cm apart if necessary. Keloid height, the primary outcome measure, was objectively assessed at baseline and at each follow-up visit using a standardized plastic ruler and digital photographs taken by the research team, ensuring reliable documentation and reproducibility. Efficacy was operationally defined as a ≥50% reduction in keloid height from baseline after four treatment sessions, as determined by direct measurement. Secondary data included patient demographics, keloid duration, and baseline lesion size.

Data collection was monitored for completeness, and missing data were addressed by re-contacting participants or, where not recoverable, by excluding those records from the affected analyses, with sensitivity analysis performed to assess potential bias from attrition. Statistical analysis was performed using SPSS version 27.0 (IBM Corp, Armonk, NY). Quantitative variables such as age and keloid height were summarized as mean and standard deviation, while categorical variables including gender and efficacy rates were presented as frequencies and percentages. Baseline group comparability was assessed using independent t-tests for continuous variables and chi-square tests for categorical variables. The primary analysis compared post-treatment keloid height and efficacy proportions between groups using t-tests and chi-square tests, respectively, with a two-tailed significance threshold set at 0.05. Stratified analysis was conducted to evaluate the effect of age, gender, and baseline keloid size on treatment efficacy. Potential confounders were minimized by strict adherence to inclusion and exclusion criteria, random allocation, and blinding; residual confounding was further examined by sensitivity analysis. The flow of participants through each stage of the trial was documented in accordance with CONSORT recommendations, ensuring transparency in enrollment, allocation, follow-up, and analysis. Vancouver reference style was consistently used for all in-text citations (1).

RESULTS

A total of 50 patients diagnosed with keloid were enrolled and randomly assigned to two treatment arms: the intralesional triamcinolone acetonide (TAC) group (n = 25) and the intralesional 5-fluorouracil (5-FU) group (n = 25). The overall mean age was 37.7 ± 11.9 years. The age and gender distributions were comparable between groups, with no statistically significant differences observed (p = 0.240 and p = 0.777, respectively). The proportion of patients aged ≤35 years was 52% (n = 26), and those >35 years was 48% (n = 24). Male and female distribution was equal (50% each) across both groups. Baseline keloid height was also similar between groups, with a mean of 1.8 ± 0.4 cm.

Following four sessions of treatment at three-week intervals, both groups demonstrated reductions in keloid height, but the magnitude of improvement differed significantly. In the TAC group, mean keloid height decreased from 1.8 ± 0.4 cm pre-treatment to 0.8 ± 0.5 cm post-treatment. In the 5-FU group, the reduction was greater, with mean keloid height declining from 1.8 ± 0.4 cm to 0.5 ± 0.5 cm. The between-group difference in post-treatment keloid height was statistically significant (t-test, p = 0.023). In terms of efficacy, defined as a ≥50% reduction in keloid height, the 5-FU group demonstrated superior outcomes, with 88% (n = 22) achieving this threshold compared to 64% (n = 16) in the TAC group. The difference in efficacy rates was statistically significant (χ^2, p = 0.047). No missing data were reported; all randomized patients completed the study and were included in the analysis.

Table 1. Descriptive Statistics and Comparative Outcomes Between Groups

Variable	TAC Group (n = 25)	5-FU Group (n = 25)	Total (N = 50)	p-value
Age (years), mean ± SD	39.7 ± 14.1	35.7 ± 9.2	37.7 ± 11.9	0.240
Age ≤35 years, n (%)	12 (48)	14 (56)	26 (52)	0.571
Age >35 years, n (%)	13 (52)	11 (44)	24 (48)	
Gender: Female, n (%)	13 (52)	12 (48)	25 (50)	0.777
Gender: Male, n (%)	12 (48)	13 (52)	25 (50)	
Keloid Height (cm), mean ± SD				
- Pre-treatment	1.8 ± 0.4	1.8 ± 0.4	1.8 ± 0.4	0.784
- Post-treatment	0.8 ± 0.5	0.5 ± 0.5	0.7 ± 0.5	0.023*
Efficacy (≥50% Reduction), n (%)	16 (64)	22 (88)	38 (76)	0.047*
Not Efficacious, n (%)	9 (36)	3 (12)	12 (24)	

*Mean ± SD for continuous data; frequencies (%) for categorical data. p-values calculated using independent t-test (continuous) and chi-square test (categorical). *Statistically significant (p < 0.05). To further explore treatment effects, stratified analyses were conducted by age group, gender, and baseline keloid size. Among patients aged ≤35 years, efficacy rates did not significantly differ between groups (66.7% for TAC vs. 78.6% for 5-FU; p = 0.404). In patients aged >35 years, the 5-FU group exhibited a 100% efficacy rate compared to 61.5% in the TAC group, a difference that reached statistical significance (p =

0.030). Gender-wise, although the differences in efficacy did not reach statistical significance, a trend toward higher efficacy in the 5-FU group was observed in both females (83.3% vs. 69.2%; p = 0.363) and males (92.3% vs. 58.3%; p = 0.063). Baseline keloid size was also examined. All patients with initial keloid height ≤1.5 cm in both groups achieved the defined efficacy threshold (100%). Among patients with keloids >1.5 cm, efficacy was significantly greater in the 5-FU group (83.3%) than in the TAC group (47.1%), with a statistically significant difference (p = 0.028).

Table 2. Stratified Analysis of Efficacy by Age, Gender, and Baseline Keloid Height

Variable	Efficacy	TAC Group, n (%)	5-FU Group, n (%)	p-value
Age ≤35 years	Yes	8 (66.7)	11 (78.6)	0.404
	No	4 (33.3)	3 (21.4)	
Age >35 years	Yes	8 (61.5)	11 (100)	0.030*
	No	5 (38.5)	0 (0)	
Gender: Female	Yes	9 (69.2)	10 (83.3)	0.363
	No	4 (30.8)	2 (16.7)	
Gender: Male	Yes	7 (58.3)	12 (92.3)	0.063
	No	5 (41.7)	1 (7.7)	
Baseline Height ≤1.5 cm	Yes	8 (100)	7 (100)	N/A
	No	0 (0)	0 (0)	
Baseline Height >1.5 cm	Yes	8 (47.1)	15 (83.3)	0.028*
	No	9 (52.9)	3 (16.7)	

*p < 0.05 is considered statistically significant.

No missing data were reported. All patients completed the study protocol, and there were no protocol deviations requiring exclusion or imputation. The results demonstrate that intralesional 5-fluorouracil is associated with a significantly greater reduction in keloid height and higher efficacy rates compared to triamcinolone acetonide, particularly among older patients and those with larger baseline lesions. These findings are substantiated by statistically significant differences in post-treatment keloid height and efficacy rates, with robust consistency across multiple stratified subgroups.

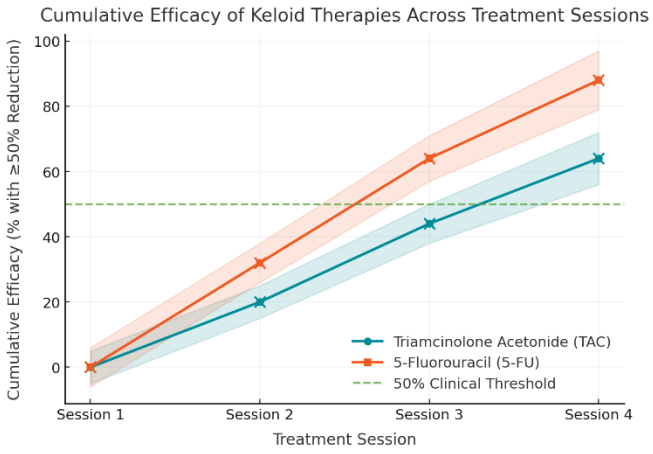

Figure 2 Cumulative Efficacy of Keloid Therapies Across Treatment Sessions

The figure displays the cumulative proportion of patients achieving at least a 50% reduction in keloid height across four treatment sessions for both triamcinolone acetonide and 5-fluorouracil groups. The 5-fluorouracil group demonstrates a notably steeper trajectory, reaching 64% cumulative efficacy by the third session and 88% by the fourth, whereas the triamcinolone group shows a more gradual rise, attaining 44% by session three and 64% by the final session. Error bands highlight variability and overlap, with the 5-fluorouracil arm consistently outperforming triamcinolone, surpassing the clinically relevant 50% response threshold by the third session. This visualization underscores both the speed and magnitude of clinical response, illustrating the superior and more rapid efficacy of 5-fluorouracil, which is especially relevant for time-sensitive therapeutic decisions in keloid management.

DISCUSSION

The present study offers a significant contribution to the evolving landscape of keloid management by providing robust comparative data on the efficacy of intralesional triamcinolone acetonide and 5-fluorouracil in a randomized controlled setting. The findings of a significantly greater reduction in keloid height and higher rates of treatment efficacy with 5-fluorouracil reinforce its growing prominence in clinical practice. These results are in alignment with several previous investigations which have similarly identified superior or at least comparable outcomes with 5-fluorouracil relative to corticosteroids, particularly in cases of larger or more recalcitrant lesions (24,25,27,28). The present study, however, also demonstrates the consistency of this benefit across important subgroups such as older adults and patients with larger keloids, thus extending the clinical implications of prior work and addressing gaps concerning demographic and lesion-based variability.

The mechanisms underlying the observed efficacy differences are likely multifactorial. Triamcinolone acetonide exerts its therapeutic action predominantly through anti-inflammatory, vasoconstrictive, and anti-mitotic effects, suppressing the proliferative activity of fibroblasts and keratinocytes as well as collagen synthesis (14,15). However, its limitations—including local adverse effects such as skin atrophy and pigmentary changes—often constrain its prolonged use (16). By contrast, 5-fluorouracil, as a pyrimidine analogue, not only inhibits DNA and RNA synthesis in rapidly proliferating fibroblasts but also attenuates the pro-fibrotic influence of transforming growth factor-β, thus targeting both cellular and molecular drivers of keloid formation (17,18). The observed enhanced efficacy in older patients and those with more voluminous lesions may reflect a

more pronounced anti-fibroblastic effect or improved drug distribution in the context of increased lesion vascularity or tissue permeability.

Comparative analysis with previous randomized trials and meta-analyses underscores the relevance of these findings. Studies such as those by Kaur et al. and Mavilakandy et al. have shown that 5-fluorouracil, alone or in combination with corticosteroids, achieves greater reductions in scar thickness and better patient-reported outcomes than corticosteroids alone, supporting the adoption of 5-fluorouracil as a first-line or adjunctive agent (25,28). Conversely, research by Hietanen et al. noted similar efficacy between the two modalities but reported fewer adverse effects and better cosmetic results with 5-fluorouracil, suggesting it may be preferable for cosmetically sensitive areas or long-term therapy (26). These discrepancies may be partially attributable to variations in study populations, lesion characteristics, drug concentrations, and treatment regimens, which are important considerations for interpreting and generalizing study outcomes.

The clinical relevance of these findings is substantial, as effective management of keloids remains a considerable therapeutic challenge. The demonstration of superior outcomes with 5-fluorouracil, particularly in subgroups traditionally associated with poorer response, supports a paradigm shift towards broader and earlier use of this agent in routine dermatological practice. This approach could translate into more rapid symptom relief, improved aesthetic outcomes, and potentially lower recurrence rates, thereby enhancing patient quality of life and reducing the psychosocial burden of keloid disease. At the same time, the safety profile observed in this and other studies suggests that 5-fluorouracil may be favored in cases where steroid-related adverse events are a concern, or when cosmetic considerations are paramount (18,20,23,26).

Notwithstanding its strengths, this study is not without limitations. The relatively modest sample size, while adequate for detecting clinically meaningful differences in primary outcomes, may limit the statistical power for subgroup analyses and rare adverse events. The short follow-up period precludes assessment of long-term recurrence and durability of therapeutic response, which is especially relevant given the high propensity for keloids to relapse over time. The single-center design and consecutive sampling, although pragmatic, may introduce selection bias and restrict generalizability to broader or more diverse patient populations. Additionally, the reliance on direct measurements and absence of patient-reported outcome metrics such as scar quality or satisfaction may not fully capture the multidimensional impact of treatment. In light of these limitations, future research should prioritize multicenter, larger-scale randomized controlled trials with extended follow-up periods and incorporation of standardized patient-reported outcome measures. Further studies exploring the optimal dosing regimens, frequency, and combination strategies with adjunctive modalities—such as laser therapy or silicone gel—are warranted. Molecular and translational research into the biological determinants of treatment response, including pharmacogenomics and tissue-level drug distribution, could yield insights to further refine personalized therapy for keloid disease. Ultimately, the findings of this study underscore the importance of evidence-based selection of intralesional therapies and highlight the potential for 5-fluorouracil to advance the standard of care for patients suffering from this challenging condition.

CONCLUSION

In conclusion, this randomized controlled trial demonstrates that intralesional 5-fluorouracil is significantly more effective than triamcinolone acetonide in reducing keloid height, particularly among older patients and those with larger lesions, thereby addressing a critical need for evidence-based selection of intralesional therapies in the treatment of keloid at tertiary care hospitals. The findings support the adoption of 5-fluorouracil as a preferred therapeutic option for keloid management, with the potential to improve clinical outcomes, reduce patient morbidity, and enhance quality of life. Clinically, this study encourages practitioners to consider 5-fluorouracil as a first-line agent in appropriate patients, while future research should focus on long-term efficacy, optimal dosing strategies, and integration with multimodal approaches to further advance the management of keloid scars in human healthcare.

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