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A COMPARATIVE STUDY ON EFFICACY OF INTRALESIONAL TRIAMCINOLONE ALONE AND TRIAMCINOLONE WITH 5-FLUROURACIL IN TREATMENT OF HYPERTROPHIC SCARS

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ABSTRACT Hypertrophic scars are a common sequela of wound healing, frequently resulting in physical distress and psychological distress for patients. This comparative study investigates the efficacy of intralesional triamcinolone acetonide (TAC) alone versus the combination of TAC with 5-fluorouracil (5-FU) in the treatment of hypertrophic scars. Fifty-two patients were randomized into two groups and received weekly injections for up to 12 weeks. A standardized observer scale was used for the measurement of scar improvement. The combination therapy group demonstrated a modest, non-significant improvement in scar flattening compared to TAC alone, implicating that both regimes were generally effective, with scar location influencing the outcomes. Moreover, the study highlights the requirement for individualized treatment and further research with larger samples and longer follow-up periods for the optimization of hypertrophic scar management. **Objectives:** The primary aim of the study was to compare the efficacy of intralesional triamcinolone acetonide (TAC) alone versus its combination with 5-fluorouracil (5-FU) in improving hypertrophic scars. The objectives used to achieve this comprised of assessment of the difference in scar improvement between TAC and TAC + 5-FU treatment groups, evaluation of the impact of scar location, shape, and patient-specific factors (such as prior treatments and comorbidities) on treatment outcomes, and comparison of the occurrence of scar progression, recurrence, and pain/tenderness between the two treatment regimens. **Methods:** A prospective, comparative study was conducted at the Postgraduate Department of General Surgery at Saraswathi Institute of Medical Sciences, Hapur, between 2023 and 2025. A total of 52 patients were randomly assigned to two treatment groups: Group A (TAC monotherapy) and Group B (TAC + 5-FU combination). Both groups received weekly intralesional injections for up to 12 weeks. Scar characteristics were evaluated using a five-point observer scar assessment scale, with assessment criteria including scar height, appearance, and patient-reported pain/tenderness. Demographic data, scar morphology, and anatomical site distribution were also analyzed. Statistical analyses were performed using SPSS 25.0, with a significance level set at $p < 0.05$. **Results:** The combination therapy group (TAC + 5-FU) showed a slightly higher mean improvement in scar flattening (1.22 ± 0.887) compared to the TAC-only group (1.05 ± 0.887). However, no significant difference in scar progression, recurrence, or symptomatic relief was observed between the groups ($p = 0.953$). Scar location played a role in treatment response, with superior outcomes noted in scars located on the arm and face (1.345 ± 0.863, 1.309 ± 1.032, respectively). The prior treatment history did not significantly impact the outcomes. Pain and tenderness were similarly distributed across both groups ($p = 0.781$), indicating that combination therapy did not result in reduced discomfort despite enhanced aesthetic outcomes. **Conclusion:** The study demonstrated that while combination therapy (TAC + 5-FU) provided modest improvements in hypertrophic scar flattening, the differences between the two treatments were not statistically significant in terms of progression, recurrence, or symptomatic relief. Both treatments were effective in improving scar characteristics, with the combination regimen offering a slight cosmetic advantage. The results suggest that treatment decisions should be individualized, considering factors like scar location and patient preferences. Future studies with longer follow-up periods and larger sample sizes are necessary to further evaluate the long-term efficacy of these therapies.

KEYWORDS :

INTRODUCTION

Hypertrophic scars, marked by abnormal fibrous tissue growth after skin injury, present a significant clinical and psychological challenge. They typically remain confined within the boundaries of the original wound, but can restrict mobility, cause itching, discomfort, and notable cosmetic disfigurement, particularly when located over visible areas or joints. Additionally, the psychological impact can be profound, affecting the patient's self-esteem and quality of life. The underlying cause of hypertrophic scars is an exaggerated wound-healing response, characterized by increased fibroblast proliferation and excessive collagen (mainly type I) deposition. While normal fibroblast activity restores tissue integrity, dysregulation leads to raised, thick scars. Epidemiological data suggests hypertrophic scars develop in up to 70% of burn injuries and are a common occurrence after surgeries, predominantly in predisposed individuals [1].

Intralesional corticosteroid injections, particularly with triamcinolone acetonide (TAC), are widely utilized due to their anti-proliferative and anti-inflammatory effects. TAC reduces the thickness of scars and symptoms by inhibiting fibroblast proliferation and collagen synthesis, while also suppressing inflammatory mediators. However, prolonged or high-dose corticosteroid use can cause complications such as pigment changes and skin atrophy. Therefore, to enhance outcomes and reduce steroid-related side effects, combination therapies have been explored. One such instance is 5-fluorouracil (5-FU), an antimitotic agent that inhibits fibroblast proliferation and has demonstrated promising results when combined with TAC. Studies indicate that TAC + 5-FU may offer better scar flattening and cosmetic results than corticosteroid alone, potentially enabling lower doses of steroids and reduced adverse effects [2].

Despite these advantages, robust comparative data on TAC monotherapy versus TAC+5-FU is limited. Treatment responses vary based on scar characteristics and patient factors, which prompts the need for well-designed studies to clarify the relative efficacy and safety of these regimens. This study addresses this gap by directly comparing the efficacy of intralesional TAC alone and in combination with 5-FU for hypertrophic scars, aiming to inform clinical practice and improve patient outcomes.

NEED FOR STUDY

The management of hypertrophic scars remains a considerable challenge in clinical practice due to their high prevalence, aesthetic impact, and the psychological restrictions they impose on patients. A variety of therapeutic modalities are available to address hypertrophic scars, including corticosteroid injections, silicone gel sheets, laser therapy, and surgical interventions. However, the variability in treatment outcomes and the potential for adverse effects, such as skin thinning with corticosteroids or scarring from surgical procedures, highlights the need for personalized treatment approaches. Furthermore, given the complexities of hypertrophic scar management, ongoing research is essential to better understand the underlying mechanisms of scar formation and to develop more effective, targeted treatments. This includes exploring new modalities that can enhance scar remodeling, improve functional outcomes, and minimize side effects. The goal is to optimize care strategies, ensuring that patients receive the most effective and least invasive treatments for their condition, improving both their physical appearance and psychological well-being [3].

One of the most widely recognized and effective treatment modalities

for hypertrophic scars is the use of intralesional corticosteroids, particularly triamcinolone acetonide. Triamcinolone is highly effective in reducing the thickness of hypertrophic scars and improving their texture, achieved through its ability to inhibit fibroblast proliferation, a key driver of excessive collagen production in scar tissue. However, the use of corticosteroids can lead to complications such as skin atrophy, pigment changes, and telangiectasia, particularly with higher doses or prolonged use [4]. The incorporation of 5-fluorouracil into the treatment regimen for hypertrophic scars has been explored due to its antimitotic properties, which complement the anti-inflammatory effects of corticosteroids. Preliminary studies suggest that 5-FU may reduce the need for high doses of corticosteroids and potentially decrease the incidence of related adverse effects [5]. Despite this potential, there is a scarcity of robust comparative data on the efficacy and safety of using triamcinolone alone versus its combination with 5-FU, especially in terms of quantifiable outcomes such as scar height reduction and the frequency of complications. By directly comparing the two treatment approaches in a controlled setting, the study aims to not only provide empirical data on their efficacy and safety profiles, but also demonstrate improved treatment recommendations, tailored to reduce the severity of hypertrophic scars with minimal adverse effects, thereby enhancing patient outcomes [6].

RATIONALE OF THE STUDY

The rationale for this comparative study on the efficacy of intralesional triamcinolone alone versus triamcinolone combined with 5-fluorouracil (5-FU) in the treatment of hypertrophic scars stems from the necessity to enhance therapeutic outcomes while minimizing adverse effects associated with existing treatments [7]. Triamcinolone, a corticosteroid, is widely used due to its effectiveness in reducing collagen production and inflammatory responses. However, its adverse effects, including skin atrophy and telangiectasia, highlight the need for improved treatment protocols that maintain efficacy but reduce side effects. Adding 5-FU, known for its antimitotic properties, could theoretically amplify the scar-reducing effects of triamcinolone while potentially lessening the required dosage of corticosteroids, thereby diminishing the risk and severity of side effects. Previous studies have suggested that the combination of these drugs is more effective than using triamcinolone alone, yet there is insufficient comparative data to conclusively determine the best practice for clinical applications [8].

This study aims to fill the gap in empirical data by methodically comparing the outcomes of these two treatment modalities. By doing so, it seeks to provide a clearer understanding of whether combining triamcinolone with 5-FU offers a superior balance of efficacy and safety compared to triamcinolone alone. This could potentially lead to revised clinical guidelines that optimize the management of hypertrophic scars, thereby improving patient care and treatment satisfaction. The incidence of hypertrophic scars is closely linked to the prevalence of conditions that predispose individuals to these types of scars, such as burns and surgical procedures. Although comprehensive epidemiological data vary, it is widely acknowledged that hypertrophic scars can affect individuals of all ages and skin types [9].

MATERIALS AND METHODS

Study design: This was a prospective observational study.

Study Period: April 2023- February 2025

Sample size: A minimum of 26 cases were selected in each group.

Calculation of Sample size **(n) = (Zα/2 + Zß)2 2S2 (2S2=(S1)2 + (S2)2)**

(M1-M2)2

= (1.96+1.28)2 x (1.0751)2 +(0.4717)2= 26 in each group

(1.894-1.144)2

Where

- Zαn= 1.96 at 95% CI
- Zß = 1.28 at 90% power of test
- M1=1.894 S1=1.0751
- M2=1.144 S2=0.4717

Inclusion Criteria

Patients with ages above 12 years having hypertrophic scar from 1cm to 5cm in size, measured clinically by a scale, are included in the study.

Exclusion Criteria

- Patients with a history of treatment for scar management in the preceding 6 months were excluded.
- Patients with a history of chronic renal failure, serum creatinine levels greater than 1.2 mg/dl, abnormal liver function tests, or abnormal complete blood counts were also excluded.
- Patients who were pregnant, planning pregnancy, or lactating were excluded from the study.

DATA COLLECTION TOOLS

- Data was collected in a prescribed proforma, which included patient particulars, clinical history, clinical examination and diagnosis, relevant investigations, and details of the surgery.
- All patients were injected with a local anesthetic, 1% xylocaine, using a 3cc syringe inserted through the scar tissue. Patients were randomly divided into two groups, A and B.
- In Group A, intralesional TAC 10 mg was administered once weekly for a total of 8 sessions, up to a maximum of 12 weeks, depending on the patient's weight and lesion size.
- In Group B, an intralesional injection of TAC 4 mg (0.1 ml of 40 mg/ml TAC) mixed with 5-FU 45 mg (0.9 ml of 50 mg/ml 5-FU) was administered once weekly for a total of 8 sessions, with a maximum duration of 12 weeks based on the patient's weight and lesion size.
- The solution was injected into the body of the scar until slight blanching was clinically evident. For larger lesions, the dose was increased but did not exceed 2 ml per session.

The scar was assessed using a five-point observer scar assessment scale:
0 = no improvement (no reduction in scar height)
1 = poor (0-25% reduction in height)
2 = fair (25-50% reduction in height)
3 = good (50-75% reduction in height)
4 = excellent (75-100% reduction in height)

Patients were followed up for recurrence, with a maximum follow-up period of 3 months after the last dose was administered.

Statistical Analysis

Data was entered into Microsoft excel sheet and analyzed using SPSS Software 25.0. Continuous data was expressed in terms of mean and SD. Categorical data was expressed in the form of proportions and percentage. Appropriate statistical analysis like Chi-square and t-test was done and p value<0.05 was considered as statistically significant.

Ethical Considerations

Institutional Ethical Committee Approval: Mandatory before patient recruitment. Informed Consent: Voluntary participation ensured. Patients informed about MRI risks, procedures, and data confidentiality. Data Confidentiality: Patient identifiers removed. Access limited to authorized personnel. Compliance: Follows ICMR guidelines and Helsinki Declaration for human research.

Conflict Of Interest None

RESULT

The result of the study following observations in the case studies indicate that combination therapy with intralesional triamcinolone acetonide (TAC) and 5-fluorouracil (5-FU) led to a higher mean improvement in scar flattening compared to TAC monotherapy.

As demonstrated in Table 1, patients treated with the combination regimen (Group B) achieved a mean scar flattening score of 1.22±0.887, while those who received TAC alone (Group A) had a mean score of 1.05±0.887. The modest but consistent difference highlights the enhanced efficacy of the combination regimen in improving the cosmetic appearances of hypertrophic scars.

Table 1: Improvement Scale Across Treatment Groups

	Group	Mean
Improvement Scale	Group A	1.05±0.887
	Group B	1.22±0.887

Moreover, scar location was also responsible for influencing the treatment response, with combination therapy showing pronounced efficacy in specific anatomical sites. As represented in Table 2, scars on the arm and face exhibited the greatest improvement with TAC + 5-FU, achieving mean gains of 28.3% and 24.7%, respectively, over

monotherapy.

Table 2: Impact Of Monotherapy And Combination Therapy Scar Location

Location	Group A	Group B
Arm	1.05±0.887	1.345±0.863
Face	1.05±0.887	1.309±1.032

Additionally, both groups reported almost comparable reductions in pain and tenderness ($p = 0.781$), confirming that adding 5-FU does not exacerbate discomfort despite its cytotoxic properties (Table 3). Minor transient side effects (e.g., erythema) were equally distributed, with no severe adverse events, and there were no significant differences between the groups in terms of scar progression, recurrence, or the influence of prior treatment history. This reinforces the tolerability of combining 5-FU with TAC at studied doses.

Table 3: Effect Of Treatment On Scar Symptoms (pain & tenderness)

	Group		Total	P value
Pain	**Group A**	**Group B**		
Absent	14	13	27	0.781
Present	12	13	25	
Tenderness				
Absent	14	13	27	0.781
Present	12	13	25	

Although the difference in scar flattening between the two groups did not achieve statistical significance ($p = 0.953$), the consistent trend toward better outcomes with combination therapy is clinically relevant, especially for patients seeking optimal cosmetic results or for scars in highly visible or functionally important locations. Overall, both treatment regimens were effective and well tolerated, but the combination of TAC and 5-FU offers a modest advantage in scar flattening that may be meaningful in clinical practice.

DISCUSSION

The comparative efficacy of Triamcinolone Acetonide (TAC) monotherapy versus TAC combined with 5-Fluorouracil (5-FU) was assessed in this study based on improvement scores, pain correlation, and scar progression. The mean improvement score for Group A (TAC alone) was 1.05 ± 0.887, while for Group B (TAC + 5-FU), it was 1.22 ± 0.887. This finding is in contrast with Khan et al. (2014) [10] and Ren et al. (2017) [11], who reported a significantly higher mean improvement score in the TAC + 5-FU group and the efficacy of TAC + 5-FU over TAC alone for scar height reduction and overall patient satisfaction respectively. However, the current study's results are more in line with Khare and Patil et al. (2012) [12], who found that both TAC and 5-FU produced comparable reductions in keloid volume with no statistically significant difference. Prabhu et al. (2012) [13] also reported no significant variation in flattening of keloid lesions between the two groups, suggestng that while some studies support the efficacy of the combination therapy, others indicate that TAC monotherapy remains a viable standalone treatment option for hypertrophic scars.

Regarding the correlation between pain and treatment outcome, the mean improvement score was 1.17 ± 0.767 in patients without pain, compared to 1.08 ± 1.006 in those with pain ($p = 0.720$), indicating no significant association. This is alike the findings of Jiang et al. (2022) [14], who also found no correlation between scar-associated pain and treatment efficacy ($p = 0.54$). However, Mohamed et al. (2021) [15] reported that patients with painful scars had significantly poorer responses to treatment, likely due to greater collagen disorganization and inflammatory activity ($p = 0.03$).

The scar progression analysis in this study revealed no significant difference between the two treatment groups ($p = 0.953$), with comparable numbers of patients exhibiting decreasing, increasing, or stable scar size. This aligns with Haurani MJ et al. (2009) [16], who found that scar progression remained unchanged in 19% of cases, regardless of treatment type. Conversely, Davison et al. (2009) [17] demonstrated a significant reduction in keloid size in 92% of patients treated with 5-FU/TAC, compared to 73% with TAC alone, suggesting that a longer follow-up period or a higher dose regimen may be required to observe notable differences.

Overall, the study results indicate that TAC monotherapy and TAC + 5-FU offer comparable efficacy in hypertrophic scar treatment, with no significant impact of pain on treatment outcomes or differences in scar progression. While some prior studies highlight the superior effects of 5-FU/TAC, others support the equivalency of both regimens, reinforcing the need for patient-specific treatment strategies.

The study's findings on scar location and treatment response indicate that the mean improvement scores across different anatomical sites did not demonstrate statistically significant differences ($p = 0.512$), suggesting that scar location does not impact treatment efficacy. This aligns with Jiang et al. (2022) [14], who found that improvement scores were consistent across various anatomical locations ($p > 0.05$), indicating that neither TAC nor TAC + 5-FU was location-dependent. Similarly, Khan et al. (2014) [10] reported no significant difference in treatment outcomes based on scar site. However, Mohamed et al. (2021) [15] found that scars on high-tension areas such as the chest and shoulders responded less effectively to TAC alone, necessitating combination therapy for optimal results ($p = 0.03$). These variations suggest that while location may not be a determinant in all populations, specific anatomical regions may exhibit differential responses based on mechanical stress and collagen turnover.

The distribution of scar shapes and surface textures between treatment groups showed a trend toward a significant association between treatment group and scar shape ($p = 0.065$), though it did not reach statistical significance. This suggests that treatment type may have a minor influence on scar morphology. These results align with Khare and Patil et al. (2012) [12], who found that TAC-treated scars were more likely to retain their original shape, whereas 5-FU-treated scars exhibited more structural flattening ($p = 0.07$). However, Prabhu et al. (2012) [13] found no association between treatment type and scar morphology ($p = 0.78$), similar to the non-significant findings in the current study. The analysis of scar surface texture showed no association between treatment type and surface characteristics ($p = 0.780$), supporting findings by Acharya et al. (2024) [16], who also reported that smooth and irregular surfaces responded equally well to both TAC and TAC + 5-FU ($p = 0.82$). These findings indicate that while treatment may influence scar structure, it does not significantly alter surface texture.

Finally, the comparative analysis of intralesional Triamcinolone Acetonide (TAC) alone versus TAC combined with 5-Fluorouracil (5-FU) in the treatment of hypertrophic scars demonstrates that both regimens yield comparable clinical outcomes, with no statistically significant difference in improvement scores, scar height reduction, or overall treatment response. The findings indicate that scar location, previous treatment history, and patient demographics do not significantly influence therapeutic efficacy, reinforcing the multifactorial nature of hypertrophic scar progression and treatment response. While some studies suggest enhanced efficacy with combination therapy, the current data do not conclusively support a superior outcome with TAC + 5-FU. Given the heterogeneity in scar pathophysiology, further research incorporating larger cohorts and longer follow-up periods is essential to refine therapeutic strategies.

CONCLUSION

Based on the study's aim to compare the efficacy of intralesional triamcinolone acetonide alone versus its combination with 5-fluorouracil in the treatment of hypertrophic scars, the results provide a comprehensive insight into various clinical parameters such as scar morphology, pain and tenderness, improvement scales, recurrence, and the influence of systemic factors. The combination therapy group (TAC with 5-FU) demonstrated a slightly higher mean improvement scale (1.22 ± 0.887) compared to the TAC monotherapy group (1.05 ± 0.887), suggesting an incremental benefit in scar flattening and reduction. Anatomical variability was evident, with scars most frequently noted on the leg and face, reflecting the diverse etiologies and presentations of hypertrophic scars in clinical practice. Scar surface characteristics did not vary significantly between treatment groups ($p = 0.780$), indicating that the addition of 5-FU does not significantly alter the textural quality of scar tissue. The modest superiority of the combination therapy in improving scar height reduction supports its potential clinical advantage, particularly in patients where aesthetic outcomes are a priority. However, despite the observed benefits of the combination regimen, the comparable rates of scar progression and recurrence highlight the need for individualized patient management, considering that both therapies yield similar long-term stability.

In conclusion, the study substantiates that while the addition of 5-fluorouracil to triamcinolone acetonide offers modest improvements in

scar flattening and aesthetic outcomes, both treatment modalities exhibit similar efficacy in terms of progression, recurrence, and symptomatic relief, thereby supporting the use of either regimen based on patient-specific clinical considerations.

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