

COMPARISON OF THE EFFICACY OF INTRALESIONAL 5% FU VERSUS INTRALESIONAL TRIAMCINOLONE IN PATIENTS PRESENTING WITH KELOID AND HYPERTROPHIC SCAR AT TERTIARY CARE HOSPITAL, KARACHI

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Abstract: *Despite the fact that keloids and hypertrophic scars are frequent benign hyper-proliferative growths of dermal fibroblasts, the clinical concerns, such as physical and psychological issues, are serious and impairing, and there are few effective therapies. Although 5-fluorouracil (5-FU) and intralesional triamcinolone acetonide (TAC) are widely used to manage both scars, their effectiveness is still debatable. To compare the efficacy of intralesional 5% FU versus intralesional triamcinolone in patients presenting with keloid and hypertrophic scar at Tertiary Care Hospital, Karachi. This RCT study was conducted on patients presenting with keloid and hypertrophic scars at the Outpatient Department of Dermatology, JPMC, Karachi, meeting inclusion criteria. A brief history of demographic information and written informed consent were taken from each patient. A total of 158 patients were enrolled in the study and were randomly allocated to Group A, Intralesional triamcinolone group, and B: Intralesional 5% FU group twice weekly for a total of 4 sessions. During each visit, the keloid height was measured, photographed again, and documented. Efficacy was labeled if patients with keloid and hypertrophic scar in either group showed $\geq 50\%$ reduction in height. Comparison of efficacy between groups showed a significant difference as the efficacy rate was higher in patients treated with 5-FU 45mg as compared to the patients administered with TAC 10mg (70.9% vs. 50.6%; P-value=0.009). This analysis revealed that irrespective of the patient's age, sex, illness duration, or lesion site, intra-lesional 5-fluorouracil (5-FU) offered the significant benefit of a faster and more effective response than triamcinolone (TAC) in the treatment of keloids and hypertrophic scars.*

Keywords: 5-Fluorouracil, Triamcinolone, Keloid, Hypertrophic Scar

Introduction

Keloids and hypertrophic scars provide a significant barrier to clinicians in everyday practice despite having a wide variety of treatment modalities. These are some of the most commonly encountered dermatological conditions (Betarbet and Blalock, 2020; Walsh et al., 2023). They are the cause of physical and psychological discomfort for the patients. Wound healing and restructuring happen through a complicated mechanism. Many internal and environmental elements interact closely for it to occur. Conversely, a wound does not always heal as expected, even in ideal conditions (Limandjaja et al., 2020; Walsh et al., 2023). Keloids, which signify an overly enthusiastic healing response, are at one extreme of the range of such aberrant healing. However, Keloids can develop spontaneously and without a trigger (Berman et al., 2017). The lack of an identifiable traumatic incident may indicate the importance of hereditary and environmental variables (Ogawa, 2017). Keloids have a high tendency for recurrence and a lack of systematic therapy, which is seen in the wide range of therapeutic options used, including surgical excision, cryotherapy, low-dose radiation, and topical retinoids. These methods are empirical, and none of them assures a predicted result. Traditional therapies frequently cause recurrence (Elsaie, 2021; Salati, 2019; Tripathi et al., 2020). The effectiveness of contemporary scar therapies like five fluorouracil (5FU), steroid intralesional injections, silicone sheeting, and bleomycin, which all make reasonable claims,

still has to be supported by high-quality clinical studies (Ibrahim and Chalhoub, 2018; Monteiro et al., 2022). Additionally, the adverse effects of standard therapy, such as steroid injections, are frequent and essential. The ideal therapy, in this case, would be simple to administer, inexpensive, and have few adverse effects. Currently, the majority of therapy for these conditions is intralesional steroids. Triamcinolone acetonide (TCA) inhibits protein synthesis and fibroblast migration as part of its therapeutic effect. 5-fluorouracil (5-FU), a potent inhibitor of thymidylate synthase and pyrimidine metabolism that has recently shown some promise in the treatment of keloid, prevents DNA synthesis (Manzoor et al., 2020; Monteiro et al., 2022). According to reports, these unattractive scars may be treated with low-dose intralesional 5-FU (Cavalié et al., 2015). Clinical effectiveness has been reported to range from 50 – 100 percent, and recurrence rates have been observed to range from 9- 50 percent (Ren et al., 2017). A long-term treatment can result in problems including telangiectasia and skin atrophy. Furthermore, the time it takes for a complete response is inconsistent (Wilson, 2013). Hietanen et al. performed research to compare the effectiveness of intralesional 5% FU to intralesional TAC alone to assess therapy for keloid scars and determined that it was 46% versus 60%, respectively (Hietanen et al., 2019b).

The purpose of this research is to compare the effectiveness of intralesional triamcinolone versus intralesional 5% FU in

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patients who present with keloid and hypertrophic scars to determine the context in our region because there is currently a shortage of recent local data that can be used to make decisions. Treatment of keloid and hypertrophic scar is often challenging. The available therapeutic modalities that are currently used for the treatment of keloids and hypertrophic scars are not successful every time. Data from our study would help establish it as a treatment of choice, thereby reducing cost and benefiting the patient both financially and psychologically. Thus, the current analysis was conducted to assess whether the efficacy of intralesional 5% FU is better than intralesional triamcinolone in patients for the treatment of keloid and hypertrophic scar.

Methodology

This “Double-blind Randomized Controlled Trial” was conducted from March 2022 to January 2023 at the Department of Dermatology, JPMC, Karachi. Permission from the institutional ethical review committee was obtained before the study. Patients of age between 20-60 years, either gender, presenting with keloid (Keloid was labeled based on the following criteria: (i) Patients presenting with benign, dermal growths related to previous skin trauma or inflammation. (ii) Patients with keloid ≤ 5 centimeters on any site of the body. (iii) Patients having keloid ≤ 5 years. (iv) Patients with baseline Vancouver scar score of ≥ 5 and hypertrophic scars labeled as (Visible, raised scars that do not invade the surrounding tissues and frequently regress on their own are known as hypertrophic scars (HTSs).) were included in the study. Patient not giving informed consent. Patients who had a history of receiving treatment in the past 12 months for the same keloid and hypertrophic scar, active inflammation, infection, or ulcer in or around the keloid, had chronic inflammatory diseases, Immuno-suppressed, history of melanoma, CKD, abnormal liver function tests and Pregnant patients were excluded. The sample size for the study was $n=158$ patients, with 79 in each group. The sample size was calculated by using the WHO software where the confidence level was 95%, Power 80%, and the efficacy of intralesional 5%-FU versus intralesional triamcinolone was found to be 46% versus 60% for the treatment of keloid.(Hietanen et al., 2019b) Patients were enrolled using the non-probability consecutive sampling technique.

A brief history of demographic information (age, gender, and place of residence) and written informed consent were taken from each patient. Patients were examined by dermatologists with over 10 ten years of experience in this research. A total of 158 patients were enrolled in the study and were randomly allocated to one of two groups using a computer-generated random sequence. Patients in Group A were administered intralesional TAC 10mg (0.25ml of 40mg/ml TAC diluted with 0.75ml injectable normal saline) twice weekly for a total of 4 sessions, and Group B was administered 5-FU 45mg (0.9 ml of 50 mg/ml 5-FU) twice weekly for a total of 4 sessions. Keloid and hypertrophic scar height were measured by a ruler and documented and photographed by the researcher's camera. In each group, 2% xylocaine was injected deep into the lesion by entering through the edge of the lesion and not the normal skin to prevent secondary keloid formation. Injections were performed using 27-gauge insulin syringes, ensuring that

the volume injected did not exceed 0.5 mL per square centimeter of keloid. Whenever necessary, multiple pricks were made 1 cm apart to ensure complete and uniform distribution. Efficacy was labeled if patients with keloid and hypertrophic scar in either group showed $\geq 50\%$ reduction in height as per operational definition. The findings were entered in a pre-designed proforma.

SPSS Version 20 was used to analyze data. Age, duration, and the height of the keloid and hypertrophic scar were computed as means and standard deviations for both groups; for the qualitative variables, including gender, residence, site of lesion, socioeconomic status, occupational status, and efficacy, frequencies, and percentages were determined. Chi-square was used to compare two groups for efficacy. Effect modifiers were controlled through stratification of age, gender, place of residence, lesion site, socioeconomic status, occupational status, and keloid and hypertrophic scar duration. Post-stratification chi-square test was applied, and a p-value of ≤ 0.05 was considered significant.

Results

In this study, 158 patients were included and further divided into two groups. Seventy-nine patients with Keloid and Hypertrophic scar were randomly allocated to Group-A, which were treated with intralesional TAC 10mg twice a week for a total of 4 sessions, and 79 patients were allocated to Group-B, where they administrated with 5-FU 45mg twice weekly for a total of 4 sessions.

All the quantitative characteristics of the patients were presented according to their respective groups. The mean age of patients of Group A was 33.33 ± 9.48 , and Group B was 34.94 ± 9.91 (P-value=0.299). The mean scare height in cm showed for Group-A was 1.60 ± 0.16 cm, and Group-B patients' average scar height was 1.59 ± 0.17 cm (P-value=0.711). The mean disease duration in Group-A was reported to be 1.52 ± 0.68 years; in Group B, it was 1.61 ± 0.82 years (P-value=0.453). Most patients are more than 30 years of age (53.2% vs. 60.8%) in both groups respectively. The disease was reported more in females as compared to male patients (63.3% vs. 67.1%), most of the study subjects were from rural areas (51.9% vs. 53.2%) in respective groups, the employment status of most of the patients was unemployed (54.4% vs. 51.9%) in both of the groups. Overall, 44.3% of patients belonged to the lower-income group. Most of the patients had Keloid 63.3% compared to Hypertrophic scar, which was reported in 39.7% of patients. In Group A, 30.4% of patients were diagnosed with Hypertrophic scar, and 69.6% had Keloid, while in Group B, 43% had Hypertrophic scar, and 57% had Keloid (P-value=0.099). Most patients, 58.9%, presented within one year after disease occurrence. Patients presented within one year were (62% vs. 55.7%) in both groups respectively (P-value=0.419). The site of scars reported as follows: 53.8% of patients had scars in the Pernal area of the body, 25.9% had scars in the trunk area, scars in extremities were found in 12.7% of patients, while few of the patients, 7.6% had scars on their faces. A similar pattern was observed for group-wise distribution of scar sites (P-value=0.934). Table-1

Distribution and comparison of efficacy between groups showed significant differences as the efficacy rate was higher in patients treated with 5-FU 45mg (Group-B) as compared to the patients administrated with TAC 10mg

(Group-A) (70.9% vs. 50.6%; P-value=0.009). The treatment failure rate is higher in Group-A, where half of the patients have not achieved a 50% reduction in the Scar height. Figure-1

A significant difference was observed in patients older than 30, as efficacy was found (42.9% vs. 66.7%) in Group A & B, respectively (P-value=0.023), which indicated that the effectiveness of 5-FU is higher for older patients compared to younger patients. Conversely, TAC and 5-FU reported no major difference in the younger population. A significant difference was observed in female patients as efficacy was found (69.8% vs. 46%) in Group A & B respectively (P-value=0.014). This showed that the effectiveness of 5-FU is higher than the TAC group. For both genders, 5-FU showed relatively higher efficacy. Comparison of residence status stated that efficacy was found among the patients who belonged to Urban areas (50% vs. 73%) in Groups A & B, respectively (P-value=0.014). Efficacy of the treatment groups concerning employment status was stated, where a significant difference was observed in patients who were employed as efficacy was found (41.7% vs. 76.3%) in Group A & B, respectively (P-value=0.002). At the same time, un-employed patients reported an insignificant difference (P-value=0.467).

Efficacy of the treatment groups concerning the type of scar stated, where a significant difference was observed in patients with hypertrophic scars as efficacy found (45.8% vs. 79.4%) in Groups A & B respectively (P-value=0.012). While patients who had Keloid scar reported efficacy as (52.7% vs. 64.4%) with an insignificant difference (P-value=0.309). This indicated that the effectiveness of 5-FU is higher than that of the TAC group in patients with hypertrophic scars, which was reported at 79.4%. Scar duration had no significant differences in patients who presented to the health facility within one year or after one year (P-value<0.05). Similar outcomes were achieved for both duration groups. Presternal scar site where efficacy was reported as (50% vs. 74.4%; P-value= 0.020). Other sites of the scar had not shown a major difference in efficacy, but it can be observed that facial scars have a higher rate of success when treated with 5-FU. Efficacy between both groups for middle-income patients was reported as (37.5% vs. 75%; P-value= 0.009) while other income groups had insignificant differences (P-value>0.05) with superior effectiveness of 5-FU as compared to TAC. Table-2.

Table 1: Demographic and Clinical characteristics of study subjects

Study variables	Group-A (n=79)	Group-B (n=79)	Sig.
Age	33.33(9.48)	34.94(9.91)	0.299
Scar Height (cm)	1.60(0.17)	1.59(0.17)	0.711
Duration	1.52(0.68)	1.61(0.82)	0.453
Age (in years.)			
30 or less	37(46.8%)	31(39.2%)	0.335
More than 30	42(53.2%)	48(60.8%)	
Gender			
Female	50(63.3%)	53(67.1)	0.616
Male	29(36.7%)	26(32.9%)	
Residence			
Rural	41(51.9%)	42(53.2%)	0.873
Urban	38(48.1%)	37(46.8%)	
Occupational Status			
Un-employed	43(54.4%)	41(51.9%)	0.75
Employed	36(45.6%)	38(48.1%)	
Income			
Low	38(48.1%)	32(40.5%)	
Middle	24(30.4%)	24(30.4%)	0.493
High	17(21.5%)	23(29.1%)	
Scar Type			
Hypertrophic	24(30.4%)	34(43%)	0.099
Keloid	55(69.6%)	45(57%)	
Duration of Scar			

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One year or less	49(62%)	44(55.7%)	0.924
More than one year	30(38%)	35(44.3%)	
Site of lesion			
Presterna	42(53.2%)	43(54.4%)	0.934
Trunk	22(27.8%)	19(24.1%)	
Extremities	9(11.4%)	11(13.9%)	
Face	6(7.6%)	6(7.6%)	

Mean (SD), n(%); Independent t-test; Chi-square test applied; Significance level: 0.05.

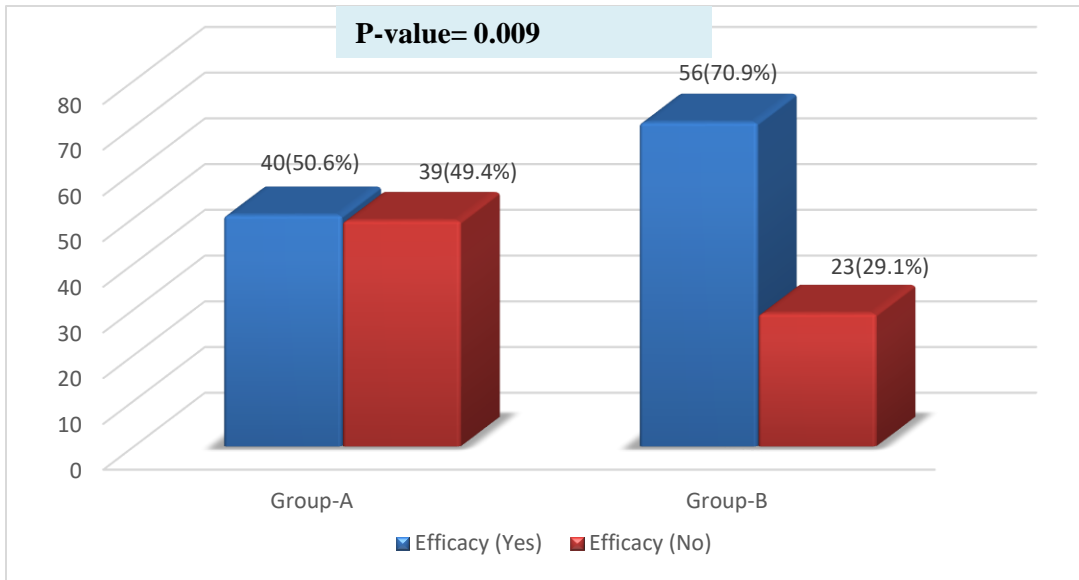


Figure 1: Comparison of Efficacy between study groups

Table 2: Comparison of efficacy between both groups according to associated factors

Associated factors	Efficacy	Groups		Total	Sig.
		Group-A	Group-B		
Age groups					
30 or less	No	15(40.5%)	7(22.6%)	22(32.4%)	0.115
	Yes	22(59.5%)	24(77.4%)	46(67.6%)	
> 30	No	24(57.1%)	16(33.3%)	40(44.4%)	0.023*
	Yes	18(42.9%)	32(66.7%)	50(55.6%)	
Gender					
Female	No	27(54%)	16(30.2%)	43(41.7%)	0.014
	Yes	23(46%)	37(69.8%)	60(58.3%)	
Male	No	12(41.4%)	7(26.9%)	19(34.5%)	0.260
	Yes	17(58.6%)	19(73.1%)	36(62.5%)	
Residence					
Rural	No	20(48.8%)	13(31%)	33(39.8%)	0.097
	Yes	21(51.2%)	29(69%)	50(60.2%)	
Urban	No	19(50%)	10(27%)	29(38.7%)	0.041*
	Yes	19(50%)	27(73%)	46(61.3%)	
Occupational Status					

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Un-employed	No	18(41.9%)	14(34.1%)	32(38.1%)	0.467
	Yes	25(58.1%)	27(65.9%)	52(61.9%)	
Employed	No	21(58.3%)	9(23.7%)	30(40.5%)	0.002*
	Yes	15(41.7%)	29(76.3%)	44(59.5%)	
Scar type					
Hypertrophic	No	13(54.2%)	7(20.6%)	20(34.5%)	0.012*
	Yes	11(45.8%)	27(79.4%)	38(65.5%)	
Keloid	No	26(47.3%)	16(35.6%)	42(42%)	0.309
	Yes	29(52.7%)	29(64.4%)	58(58.0%)	
Duration of Scar					
One year or less	No	24(49.0%)	13(29.5%)	37(39.8%)	0.056
	Yes	25(51.0%)	31(70.5%)	56(60.2%)	
More than one year	No	15(50%)	10(28.6%)	25(38.5%)	0.077
	Yes	15(50%)	25(71.4%)	40(61.5%)	
Scar/Lesion Site					
Presternal	No	21(50%)	11(25.6%)	32(37.6%)	0.020*
	Yes	21(50%)	32(74.4%)	53(62.4%)	
Trunk	No	14(63.6%)	7(36.8%)	21(51.2%)	0.876
	Yes	8(36.4%)	12(63.2%)	20(48.8%)	
Extremities	No	2(22.2%)	4(36.4%)	6(30%)	0.462
	Yes	7(77.8%)	7(63.6%)	14(70.0%)	
Face	No	2(33.3%)	1(16.7%)	3(25.0%)	0.050*
	Yes	4(66.7%)	5(83.3%)	9(75.0%)	
Income					
Low	No	16(42.1%)	8(25.0%)	24(34.3%)	0.133
	Yes	22(57.9%)	24(75.0%)	46(65.7%)	
Middle	No	15(62.5%)	6(25.0%)	21(43.8%)	0.009*
	Yes	9(37.5%)	18(75.0%)	27(56.3%)	
High	No	8(47.1%)	9(39.1%)	17(42.5%)	0.616
	Yes	9(52.9%)	14(60.9%)	23(57.5%)	

Chi-square test applied; Significance level: 0.05

Discussion

Keloids and hypertrophic scars are fibrotic diseases that indicate disrupted wound healing because they produce excessive amounts of extracellular matrix and clearly visible fibroblast growth. Their exact pathophysiology and origin are still poorly known. No single therapeutic strategy effectively treats all keloids (Kabel et al., 2016; Perdanasari et al., 2014). The goal of this study was to determine how well keloids and hypertrophic scars could be treated with intralesional 5-fluorouracil (5-FU) and Triamcinolone (TAC).

TAC administered intralesionally exerts its effects in a variety of ways, including by reducing fibroblast proliferation, enhancing collagen disintegration, regulating inflammation, and reducing endothelial budding (Srivastava et al., 2018; Srivastava et al., 2017). α -1-antitrypsin and α -

2-macroglobulin, which are naturally occurring inhibitors of collagenase in human skin and are more prevalent in keloidal tissue, have also been seen to drastically decrease in levels (Morelli Coppola et al., 2018). The literature has identified a range of doses between 10 and 40 mg as being required for effectiveness. For our research, we opted for a 40 mg dosage. The three adverse TAC effects most often documented are telangiectasia, skin shrinkage, and altered pigmentation (Morelli Coppola et al., 2018; Urioste et al., 1999).

RNA production is disrupted by the antimetabolite 5FU, which prevents fibroblast growth. Furthermore, it inhibits the type I collagen gene expression triggered by transforming growth factor (TGF)(Srivastava et al., 2017). Thymidylate synthetase inhibition is only one of several factors that interfere with the synthesis of DNA and RNA. Positive outcomes have been seen when 5FU is given

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intralesionally in a dosage of 50 mg/mL (Lee et al., 2019). We utilized a 10 mg dose for our study. However, common local adverse effects of 45-FU include discomfort at the injection site, ulceration, burning, and hyper-pigmentation. There have not been any reported systemic side effects of 5-FU, such as anemia, leucopenia, or thrombocytopenia (Bijlard et al., 2015).

Pharmacological therapy, used with other treatments, is the primary method of treating keloids (Kim, 2021). The pharmaceutical medication that is most frequently used as intralesional injections is steroids. To flatten, fade, and lessen symptoms like itching, triamcinolone is injected intralesionally for hypertrophic scars and keloids. The injectable dose might be anything from 10 to 120 mg, depending on the size of the scars (Klomprens and Simman, 2022). In the study conducted by Ali K et al., the average age of patients in the intralesional triamcinolone + 5-fluorouracil group was 31.7 ± 8.1 years, and in the intralesional triamcinolone alone group was $32. \pm 7.8$ years. 52% patients were between the ages of 15 and 30 in the majority of cases. Ages 10 to 30 are the most prevalent in which onset occurs. At the oldest and youngest ages, keloids develop less commonly (Ali et al., 2016). Similarly to this study, our findings also showed the same age pattern, where the mean age of patients was 33.33 ± 9.48 years and 34.94 ± 9.9 years for Groups A & B, respectively. The majority of patients in our study were older than 30 years, which contradicted this study's findings. Also, in this study, out of 62 patients, 38 (61.29%) were females, and 24 (38.71%) were males, with a male-to-female ratio of 1.58:1. It was also observed in many that scars occur commonly between 2nd and 3rd decades of life with male predominance. Gender distribution was also reflected in our study findings, as there was a higher prevalence of Keloid and Hypertrophy scars in females than in males (Ali et al., 2016).

A study performed by Darougeh et al. Regarding size reduction and the incidence of problems, intra-lesional Triamcnenolone coupled with 5-fluorouracil has demonstrated superior effectiveness to Triamcnenolone alone (55% vs. 20%). (Darougeh et al., 2009) In our study, efficacy in terms of more than 50% reduction in initial keloid or hypertrophic scars after the end of 4 weeks of treatment) of Group A (intralesional triamcnenolone) was 40(50.6%) while in Group B (5-fluorouracil) was 56(70.9%) with P-value= 0.009.

According to Zhuang Z et al., 5-FU can provide a long-lasting response, although TAC may be useful for treating keloids and hypertrophic scars in the short term. Verapamil, 5-FU, and TAC could work better. Compared to 5-FU, 5-FU plus TAC, or bleomycin, TAC injections at concentrations of 20 mg/ml or 40 mg/ml are more likely to result in telangiectasia, whereas 5-FU or verapamil is less likely to induce skin atrophy. (Zhuang et al., 2021)

Keloids have significant recurrence rates. Although the current standard of care for keloids is an injection of triamcinolone (TAC), it has been estimated that roughly 50% of keloids are steroid-resistant. This study additionally tested the efficacy of intralesional injections of 5-fluorouracil (5-FU) and triamcinolone in a double-masked, randomized, controlled trial in addition to our analyses. Injections of intralesional TAC or 5-FU were used to treat 53 keloid scars on 43 people over six months. The 5-FU and

TAC groups' 6-month remission rates (46% and 60%) did not differ substantially. (Hietanen et al., 2019b)

Local adverse effects were more common in the TAC group than in the 5-FU group in this previously conducted study. Skin atrophy occurred in 44% of the TAC group and 8% of the 5-FU group ($p < 0.05$). Moreover, telangiectasia occurred in 50% of the TAC group and 21% of the 5-FU group ($p < 0.05$). After treatment, the TAC group's keloid vascularity reduced but not in the 5-FU group, as shown by spectral imaging and immunohistochemistry staining for blood vessels ($p < 0.05$). (Hietanen et al., 2019a) In addition, this study showed that independent of the patient's age, gender, the severity of the illness, or the location of the lesion, intralesional injection of 5-FU was superior to intralesional TAC injection in the treatment of keloids and hypertrophic scars.

According to a comprehensive evaluation by Bijlard E. et al., 5-FU treatment was helpful in 45 to 96% of patients, even though only TAC:5-FU may be superior to TAC alone. Due to the poor quality of the data, more research is required to demonstrate the advantage of repeated intralesional TAC versus TAC alone in a range of doses and timings (Bijlard et al., 2015).

Previous studies for the best treatments for keloid and hypertrophic scars include TAC and 5-FU. Comparing TAC and 5-FU treatment alone, 5-FU appears to give a balanced advantage of a quicker and more effective response with fewer side effects. The goal of treatment must be improved efficacy and safety, which can be achieved by combining one or more modalities.

Numerous studies have been done on keloid and hypertrophic scar treatment. No long-term solution is provided by any of the contemporary and accessible treatments. Currently, the standard treatment is (TAC). Our research shows that 5-fluorouracil provides better outcomes than TAC. The short follow-up period is a drawback of this study. In our study, every patient was monitored for four weeks until their therapy ended, during which no recurrence was reported. Doing a more extended follow-up in such a prospective research is challenging. Our interactions with these patients have led us to assume that this is likely the result of the patient's reluctance to return after being convinced that his "condition" has been "solved" in some way. Prolonged prospective research focusing on recurrence may be more beneficial in this case.

Conclusion

This analysis revealed that irrespective of the patient's age, sex, illness duration, or lesion site, intra-lesional 5-fluorouracil (5-FU) offered the significant benefit of a faster and more effective response than triamcinolone (TAC) in the treatment of keloids and hypertrophic scars. Therefore, it might be recommended that 5-FU be administered regularly in these patients instead of intralesional triamcinolone to reduce scar size and without any complications, which would eventually lower their morbidity. For skin locations that are sensitive aesthetically, 5-FU injections may be preferred.

Declarations

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Data Availability statement

All data generated or analyzed during the study are included in the manuscript.

Ethics approval and consent to participate

Approved by the department Concerned.

Consent for publication

Approved

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Conflict of interest

The authors declared absence of conflict of interest.

Author Contribution**BAHADUR SHAH (Resident)**

Study Design, Review of Literature.

Conception of Study, Development of Research Methodology Design, Study Design, Review of manuscript, final approval of manuscript.

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Coordination of collaborative efforts.

Conception of Study, Final approval of manuscript.

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Manuscript drafting.

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Conception of Study, Development of Research Methodology Design, Study Design, Review of manuscript, final approval of manuscript.

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Data entry and Data analysis, drafting article.

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