The Egyptian Journal of Hospital Medicine (July 2025) Vol. 100, Page 3893-3901

Intralesional Injection of Triamcinolone Acetonide Alone versus Triamcinolone Acetonide in Combination With 5-Flurouracil in Treatment of Keloid / A Randomised Comparative Clinical Study

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ABSTRACT

Background: Keloid is an abnormal fibrous tissue overgrowth that spreads beyond the original wound margins. In spite of the availability of multiple therapeutic modalities, keloid management is still a challenge for healthcare professionals due to the high recurrence rates.

Aim: To evaluate the efficacy of intralesional injection (ILI) of triamcinolone acetonide (TAC) alone versus its combination with 5flurouracil (5FU) in treatment of keloid and to evaluate side effects of each modality.

Patients and Methods: This study included 186 participants with keloid due to different causes. The cases were randomly assigned into two groups, group 1 (that included 93 patients received intralesional combination of TAC and 5FU) and group 2 (that included 93 cases received intralesional TAC alone). All cases were examined before each injection and a final assessment was conducted thirteen weeks following first dose using Vancouver Scar Scale (VSS), Verbal Rating Scale (VRS), pain, itching and patients' satisfaction.

Results: Mean VSS in group 1 was statistically significantly diminished than that in group 2 during the follow-up. Regarding pain and itching, there was insignificant difference between both groups during the follow-up. Regarding patient satisfaction, (96.8%) of group 1, and (92.5%) of group 2 were satisfied. Regarding side effects, ulcer was significantly higher in group 1 while hypopigmentation was significantly increased in group 2.

Conclusion: Combination of both TAC and 5FU were demonstrated to be effective in keloid management due to different causes.

Keyword: Triamcinolone Acetonide, 5-Flurouracil, Keloid, Intralesional Injection.

INTRODUCTION

A keloid is a well-defined area of fibrous tissue overgrowth that spreads beyond the main defect [1]. In addition, it is characterized by extensive collagen deposition with subsequent affection of the whole healing process [2]. Keloids are a significant cause of morbidity and psychological distress in cases [3]. Out of one hundred million scars developing annually, eleven million may become keloids. Prevalence differs broadly, being the highest among American-origin Black and Hispanic populations (4.5%–16%) and being the least among the English population (0.09%). Thirty percent of affected cases complain of itching or pain [4].

Pathophysiology of keloid is still not well-identified, but several mechanisms are believed to be compromised. Based on several literatures, it has been displayed that keloidogenesis could be triggered by several systemic (such as puberty, pregnancy, hypertension (HTN), and several genetic factors) and local (such as site, delay in wound healing process, wound depth, and mechanical forces, which include skin tension) factors [5].

Keloid management comprises multiple approaches; however, until present, there is no acceptable approach to their management [6].

Intralesional injection (ILI) of corticosteroids has been considered the most frequently utilized therapeutic option, and TAC is the most utilized ILI steroid. The response widely differed, ranging from 50% to 100% regression and a recurrence rate of approximately 33% and 50% following one and five years, correspondingly. Frequent adverse events of ILI of steroids are pain, atrophy, and hypopigmentation. In recent years, ILI of TAC and cryotherapy has been considered the initial therapeutic line in the context of non-auricular keloids [7,8]. Five-fluorouracil (5FU) is an anti-neoplastic therapy that suppresses DNA and RNA synthesis. Also, it causes fibroblast apoptosis. Additionally, 5FU suppresses type I collagen gene expression caused by TGF-β [9]. Some promises have been offered by 5FU. It seems to cause a safe shrinking of keloids without tissue atrophy and telangiectasia in comparison with corticosteroids. They act by affecting pyrimidine metabolism, as a result suppressing fibroblast proliferation [10].

Of note, 5FU alone has been recorded to have a 45%–78% recurrence rate [11,12]. Satisfactory outcomes were recorded following the use of a combined regimen of ILI of TAC and 5FU, with a single study citing up to 96% of cases accomplishing satisfactory outcomes [13]. Also, skin erythema and ulceration are common complications with 5FU, which could be managed by injection of both 5FU and TAC [11].

AIM OF THE WORK

To evaluate the efficacy of ILI of TAC alone versus its combination with 5-flurouracil in treatment of keloid and to asasess patient satisfaction and side effects of each modality.

PATIENTS AND METHODS

This was a comparative prospective randomised clinical trial conducted at the outpatient clinic of Dermatology, Andrology and STDS Department, Mansoura University Hospitals. The present study conducted on 186 patients with pervious keloid due to different causes, the study population were divided

Received: 22/04/2025
Accepted: 19/06/2025

randomly into two equal groups, group **1** (5FU+TAC) included 93 patients received ILI of TAC (40 mg/ml) and 5FU (50 mg/ml) in a ratio of 1:9 and group **2** (TAC group) included 93 patients received ILI of TAC 40 mg/ml. This study comprised cases aged 18 to 60 years form both genders with any type of keloid either spontaneous or surgical, with keloids of >6 months' duration and were diagnosed based on history and physical examination.

We excluded patients with age less than 18 years old, patients received any other treatment modality for keloids within six weeks before the study, lactating or pregnant females, patients with hypertrophic scars, who had active inflammation, infections or ulcers close to the keloid, with immunosuppression, with chronic illness, renal or liver failure and who had hypersensitivity to triamcinolone acetonide or 5-flurouracil.

Ethical consideration

An oral informed consent was obtained from all subjects after explaining the study design. The whole study design was approved by the IRB, Faculty of Medicine, Mansoura University. Confidentiality was respected. Patients had the right to leave the study at any time. Collected data weren't used for any other purpose. The Helsinki Declaration was followed throughout the course of the investigation.

Methods

All participants were subjected to full history taking comprising personal history (Age, name, gender, occupation, residence), present history (onset, course and duration of keloid, site, numbers of keloid lesions and recurrent lesion if present), history of systemic diseases (DM, HTN, dyslipidemia and treatment of systemic diseases, history of autoimmune disease or any other dermatological disease), Past history (past medical disease, and its nature, duration, treatment), drug history and family history of any similar conditions.

All participants were subjected to full dermatological examination including assessment of site of keloid, number and size of lesions, etiology of keloid spontaneous, infective and traumatic and presence of other dermatological diseases, ulcers or burn.

Treatment Protocol

Cases were divided in two equal groups group 1 (5FU+TAC) included subjects received ILI of combination of TAC (40 mg/ml) (epirelefan vial®, EIPICO, Egypt) and 5flurouracil (50 mg/ml) (utoral vial®, Hikma Specialized Pharmaceuticals, Egypt) in a ratio of 1:9 every 3 weeks and group 2 (TAC) included subjects received ILI of TAC 40 mg/ml (epirelefan vial®, EIPICO, Egypt) every 3weeks.

Technique

Sterilization to site of injection by sterile alcohol cotton was done for all participants. Injections were made with 31G insulin syringe such that volume injected didn't exceed 0.5 ml / square centimeter of keloid. Several pricks were conducted one cm apart to confirm complete and uniform distribution. A maximum of two ml was injected every session. Injections were administered every three weeks till 24 weeks or till the keloid resolved.

Evaluation of Patients

All cases were assessed before each injection, and a final assessment was conducted 30 weeks after the initial dose. Objective evaluation was conducted using VSS and VRS and subjectively by evaluating pain and itching. In addition, side effects at the injection time and other complaints throughout the treatment course were documented. Assessment of treatment response was conducted through clinician assessment. Digital photographs of the affected region were acquired at baseline, before every session following 30 weeks from the first session for assessment of treatment response. All cases were assessed before every injection, and a final assessment was conducted 30 weeks following the first dose.

The cases were noted for adverse events. The cases were asked to record back if any other adverse events happened in the next two days. At each visit, the cases were evaluated for pain, bulla formation, oedema, ulcer formation, secondary infection, flattening, reduction in keloid size evaluated as the length and breadth in cm, and recurrence.

Statistical Analysis

The collected data were revised, coded, and tabulated using SPSS (Released 2017. IBM SPSS Statistics for Windows, Version 25.0. Armonk, NY: IBM Corp., USA). Data were analysed according to the data type. Shapiro-Wilk test was conducted to test the normality of numerical data distribution. Mean±SD, median, and range were used for numerical data. Frequency and percentage were used for non-numerical data. Student T Test was utilized to assess the significance of the difference between two group means. U test was utilized to evaluate the significance of the difference of a non-parametric variable between both groups. The Chi-Square test was employed to evaluate the relationship between two categorical variables. When the expected count was below five in more than twenty percent of cells, the association between two qualitative variables was evaluated using the Fisher Exact test. A p value is considered significant if <0.05.

RESULTS

The present study conducted on 186 cases divided into 2 groups group 1 (ILS+5FU): composed of 93 cases and group 2 (ILS) composed of 93 cases. Table (1) shows that there was insignificant difference between both groups concerning age, sex, residence, stoppage previous therapy to keloid, keloid etiology, while there was significant difference regarding previous therapy modality to keloid and site of keloids between both groups.

Table (1): Comparison of sociodemographic characteristics, present history, keloid etiology and site of keloids of studied groups

	ILS+5FU N=93	**ILS N=93**	**Test of significance**
Age/ years			t=1.33
Mean ±SD	30.11±12.68	26.85±9.98	p=0.187
Sex n (%)			
Male	25(48.1)	16(42.1)	χ^2=0.316
Female	27(51.9)	22(57.9)	P=0.574
Residence n (%)			
Urban	14(26.9)	7(18.4)	χ^2=0.887
Rural	38(73.1)	31(81.6)	P=0.346
Previous therapy to keloid Stopped since Median (min-max)	4 months (4 months -1 years)	4 months (4 months -6 months)	Z=1.08 P=0.281
Previous therapy to keloid			
No	66(71)	88(94.6)	Mc=19.42
Intralesional steroid	24(25.8)	4(4.3)	P=0.001*
ILS+ fractional laser	2(2.2)	0	
Intralesional steroid +5FU	1(1.1)	1(1.1)	
Keloid examination Site			
Neck	4(4.3)	8(8.6)	Mc=35.59
Sternum	8(8.6)	1(1.1)	p<0.001*
Upper limb	40(43.0)	18(19.4)	
Lower limb	9(9.7)	12(12.9)	
Abdomen	4(4.3)	2(2.2)	
Chest	2(2.2)	14(15.1)	
Shoulder	5(5.4)	20(21.5)	
Back	7(7.5)	5(5.4)	
Face	11(11.8)	12(12.9)	
Breast	3(3.2)	1(1.1)	
Keloid Etiology			
Post inflammation	1(1.1)	3(3.2)	Mc=6.65
Spontaneous	9(9.7)	14(15.1)	P=0.758
Postburn	31(33.3)	28(30.1)	
Post vaccine	1(1.1)	0	
Post trauma	19(20.4)	13(14.0)	
Post-surgical	14(15.1)	12(12.9)	
Post piercing	6(6.5)	9(9.7)	
Post acne scar	7(7.5)	7(7.5)	
Post scratch	3(3.2)	2(2.2)	
Post cryotherapy / electrocautery	1(1.1)	3(3.2)	
Post insect bite	1(1.1)	2(2.2)	

t: Student t test, χ^2=Chi-Square test, Z: U test, MC: Monte Carlo test, *: Statistically significant

Table **(2)** demonstrates that there were insignificant differences regarding systemic diseases, dermatological diseases, and family history between both groups.

Table (2): Comparison of past history between studied groups

Past history	**ILS+5FU** N=52	**ILS** N=38	**Test of significance**
	N (%)	N (%)	
Systemic disease	4(7.7)	3(7.9)	P=1.0
Dermatological disease	7(13.5)	1(2.6)	P=0.132
Family history of similar condition	14(26.9)	4(10.5)	P=0.066

Used test: Fisher exact test

Table **(3)** shows that there were insignificant differences regarding the Vancouver Scar Scale at 0 weeks, while the mean Vancouver Scar Scale in group 1 (ILS+5FU) at 3, 6, 9, 12, 15, 18, 21, 24, and 30 weeks was significantly lower compared to group 2 (ILS).

Table (3): Comparison of VSS between studied groups

Total score VSS	**ILS+5FU**	**ILS**	**p value**
0 weeks	6.37±1.52	6.34±1.89	0.932
3 weeks	5.04±1.88	6.05±2.13	0.0007*
6 weeks	4.58±2.0	5.89±2.05	0.001*
9 weeks	4.15±1.95	5.88±2.05	0.001*
12 weeks	3.96±1.99	5.68±2.15	0.001*
15 weeks	4.07±1.92	5.68±2.37	0.001*
18 weeks	4.26±1.85	5.62±2.28	0.001*
21 weeks	4.0±1.66	5.45±1.96	0.001*
24 weeks	3.85±1.62	5.50±1.87	0.001*
30 weeks	2.67±1.69	5.32±1.72	0.001*

Used test: Student t test, Data are expressed as Mean ±SD, *: Statistically significant

Table **(4)** shows that there was a statistically significantly higher mean regarding the vascularity domain of the Vancouver Scar Scale at 0, 3, 6, 9, 12, 15, 18, 21, 24, and 30 weeks in group 2 (ILS) rather than in group 1 (ILS+5FU). While regarding the pigmentation domain of VSS, there was a statistically significantly higher mean in group 2 (ILS) at 3, 6, 9, 12, 15, 18, 21, 24, and 30 weeks.

Regarding pliability domain of Vancouver Scar Scale and height domain of Vancouver Scar Scale, there were statistically significantly higher means in group 2 (ILS) at 0, 3, at 6, 9, 12, 15, 18, 21, 24, and 30. This suggests that the combination therapy resulted in greater and more consistent improvement in scar height than intralesional steroids.

Table (4): Comparison of vascularity, pigmentation, pliability domains of Vancouver Scar Scale between studied groups.

	ILS+5FU	ILS	p value
Vascularity domain of Vancouver Scar Scale			
0 week	0.558±0.99	1.89±1.15	0.003*
3 weeks	0.545±0.95	1.43±1.12	0.001*
6 weeks	0.533±1.01	1.39±1.13	0.001*
9 weeks	0.464±0.85	1.14±1.16	0.001*
12 weeks	0.438±0.83	0.959±1.20	0.001*
15 weeks	0.365±0.81	0.794±1.13	0.002*
18 weeks	0.322±0.74	0.747±1.05	0.008*
21 weeks	0.301±0.791	0.609±1.09	0.001*
24 weeks	0.269±0.72	0.537±1.03	0.001*
30 weeks	0.242±0.67	0.419±0.95	0.001*
Pigmentation domain of Vancouver Scar Scale			
0 week	0.753±0.97	1.190±0.98	0.06
3 weeks	0.495±0.86	1.0±1.04	0.008*
6 weeks	0.506±0.86	0.964±0.99	0.03*
9 weeks	0.438±0.83	0.931±0.98	0.002*
12 weeks	0.428±0.82	0.860±0.98	0.03*
15 weeks	0.318±0.73	0.859±0.85	0.001*
18 weeks	0.235±0.65	0.852±0.99	0.001*
21 weeks	0.133±0.507	0.816±0.99	0.001*
24 weeks	0.231±0.65	0.816±0.98	0.001*
30 weeks	0.491±0.86	0.756±0.98	0.001*
Pliability domain of Vancouver Scar Scale			
0 week	2.96±0.529	2.94±0.60	0.797
3 weeks	1.84±0.88	2.15±0.81	0.012*
6 weeks	1.40±0.91	1.69±0.68	0.02*
9 weeks	1.33±0.80	1.59±0.62	0.035*
12 weeks	1.16±0.80	1.53±0.62	0.01*
15 weeks	1.02±0.81	1.51±0.65	0.004*
18 weeks	1.0±0.84	1.46±0.57	0.015*
21 weeks	0.935±0.72	1.42±0.59	0.013*
24 weeks	0.889±0.75	1.36±0.49	0.04*
30 weeks	0.625±0.63	0.827±0.48	0.019*
Height domain of Vancouver Scar Scale			
0 week	2.35±0.63	2.14±0.58	0.017*
3 weeks	1.02±0.98	1.51±0.75	0.001*
6 weeks	0.81±0.89	1.21±0.79	0.003*
9 weeks	0.56±0.79	1.01±0.76	0.001*
12 weeks	0.661±0.79	1.0±0.79	0.03*
15 weeks	0.568±0.72	0.946±0.66	0.018*
18 weeks	0.558±0.74	0.964±0.69	0.03*
21 weeks	0.433±0.62	0.857±0.72	0.03*
24 weeks	0.423±0.64	1.07±0.26	0.001*
30 weeks	0.161±0.39	0.322±0.49	0.019*

Used Test: Student t test, Data are expressed as Mean ±SD, *: Statistically significant

Regarding pain score and itching score, table **(5)** displays that there was insignificant difference between both groups at 0, 3, 6, 9, 12, 12, 15, 18, 21, 24 and 30 weeks. Regarding patient satisfaction, there was insignificant differences between both groups.

Table (5): Comparison of pain and itching scores and patient satisfaction among studied groups

Pain	**ILS+5FU**	**ILS**	**p value**
0 week	0(0-3)	0(0-2)	0.125
3 weeks	0(0-2)	0(0-2)	0.681
6 weeks	0(0-1)	0(0-2)	0.259
9 weeks	0(0-1)	0(0-1)	0.287
12 weeks	0(0-1)	0(0-1)	0.773
15 weeks	0(0-2)	0(0-2)	0.761
18 weeks	0(0-2)	0(0-1)	0.733
21 weeks	0(0-2)	0(0-1)	0.305
24 weeks	0(0-2)	0(0-1)	0.241
30 weeks	0(0-0)	0(0-1)	0.317
Itching			
0 week	6(6.5)	4(4.3)	0.516
3 weeks	2(2.2)	3(3.2)	1.0
6 weeks	2(2.2)	3(3.2)	1.0
9 weeks	1(1.4)	2(2.9)	0.609
12 weeks	0	1(2.0)	0.467
15 weeks	0	2(5.4)	0.206
18 weeks	0	2(7.1)	0.200
21 weeks	0	2(9.5)	0.165
24 weeks	0	1(7.1)	0.350
30 weeks	0	0	1.0
Patient satisfaction			
Not satisfied Satisfied	3(3.2) 90(96.8)	7(7.5) 86(92.5)	0.330

Used tests: Mann Whitney U test, Fisher exact test. Data are expressed as median (min-max) or number (%)

Regarding side effects in both groups, table **(6)** shows that ulcer was significantly higher in group 1 (ILS+5FU), than group 2 (ILS), while hypopigmentation was significantly higher in group 2 than group and there was no significant difference regarding other side effects.

Table (6): Comparison of side effects between studied groups

Assessment of side effects	**ILS+5FU n=93 (%)**	**ILS n=93(%)**	**Test of significance**
Atrophy	0	3(3.3)	p=0.247
Hypopigmentation	0	5(5.6)	p=0.059
Stria	0	0	p=1.0
Telangiectasia	0	2(2.2)	p=0.497
Ulcer	10(10.8)	0	p=0.002*
Precipitation of tac	0	0	p=1.0
Abscess	2(2.2)	0	p=0.497

Used test; Fisher exact test, *statistically significant

DISCUSSION

Several therapeutic options for keloid are emerged, which include silicone-based products, cryotherapy or ILI of steroids [14]. The frequent use of ILI of TAC has several effects causing keloid regression [15]. 5FU could be given intralesional in a dosage of 50 mg/mL and has demonstrated promising results [19]. So, the current study was conducted.

The present study included 186 participants with keloid. The cases were randomly allocated into two groups, group (1) that received intralesional combination of TAC and 5FU and group (2) that received intralesional TAC alone.

Our study displayed that the mean age was 30.11±12.68 years and 26.85±9.98 years in group 1 and group 2 respectively, with insignificant difference between both groups concerning age (P=0.187). This was linked to the more liability to trauma in young subjects whose skin possesses more elastic fibers, and as a result greater skin tension. In addition, the rate of collagen synthesis is significantly increased in young subjects [20].

In the current study, there was higher female predominance in both groups as females represented 51.9% and 57.9% in group 1 and group 2 respectively.

This coped with **Noishiki *et al.*** [21] who showed higher female predominance with a male to female ratio of 1:2. In addition, female sex was believed to drive keloidogenesis due to physiologic causes. The male and female cases didn't vary significantly with regard to age of onset (24.5±14.4 versus 25.1±15.1 years) (P>0.05). In another study, there were 56.7% females and 43.3% males [5].

In this study, the most common cause of keloid in group 1 (ILS+5FU) was post burn (33.3%), followed by post trauma (20.4%) and in group 2 (ILS), the most common cause of keloid was post burn (30.1%), followed by spontaneous causes (15.1%), post trauma (14%), with no statistically significant differences between both groups (P=0.758).

A lot of cases develop severe itching following their burn. Research has shown that itching sensation is significantly increased with larger burn areas [22]. However, in the study conducted by **Acharya *et al.*** [23] the commonest cause in the two groups was post acne scars followed by traumatic scars.

In the current study, there was insignificant difference between both groups with regard to the improvement of pain and itching along the duration of follow up. Both groups had improvement in the pain and itching as compared to baseline, but the improvement was higher and early noticed in the combination group. Also, **Sharma *et al.*** [9] showed that (54%) keloids experienced an improvement in cosmetics, (100%) keloids showed an improvement in pruritus, (45%) keloids displayed an improvement in movement restrictions, (100%) keloids displayed an improvement in pain, and (77%) keloids attained an improvement in tenderness post-treatment.

Our study demonstrated that there was insignificant difference between both groups regarding the subjective assessment of patient satisfaction, with 3.2% of Group 1 (ILS+5FU) and 7.5% of Group 2 (ILS) reporting dissatisfaction, and 96.8% of Group 1 (ILS+5FU) and 92.5% of Group 2 (ILS) reporting satisfaction (p=0.193). The current findings agreed with **Acharya *et al.*** [23] who displayed that good to excellent subjective improvement was significantly more in the combined group compared to the TAC group over a period of 12 weeks.

In the current study, the reported complications in group 1 were ulcer in 10 cases (10.8%) and abscess in 2 cases (2.2%) while in group 2, the complications were atrophy in 3 cases (3.3%), hypopigmentation in 5 cases (5.6%) and telangiectasia in 2 cases (2.2%). Ulcer was significantly higher in group 1 while hypopigmentation was significantly higher in group 2.

This came in the same line with a study conducted by **Acharya *et al.*** [23]. In the TAC group, (87%) developed adverse events, while in the combined group (44%) developed adverse events (p = 0.00). Hyperpigmentation was recorded in 45.2% cases in the TAC group and 40.6% in the combined group. (p = 0.716). A single case in the combined group developed pain post-treatment. No systemic adverse events were detected and the local adverse events were mild. **Srivastava *et al.*** [24] noticed that, after keloid management by combined use of 5FU and TAC, telangiectasia, atrophy, and ulceration were recorded in 5%, 10%, and 20% of the cases, respectively.

In the current study, the VSS displayed a significant reduction in the two groups along the duration of follow up compared with the baseline indicating improvement in both groups. However, the VSS scores showed a high statistically significant decrease in the combination group starting from 3 weeks and persisting until the end of follow up at 30 weeks. This denotes that via combination of 5-FU and TAC, we were able to have the benefit of their synergistic effect to achieve a more effective result with fewer adverse events.

The current findings were in agreement with **Acharya *et al.*** [23] who reported that, combination injections of TAC and 5FU showed better results in reducing VSS scores compared to TAC injections alone. The difference between the two groups was evident after 12 weeks of follow-up.

The same findings were also reported in another study that conducted by **Davison *et al.*** The study reported that cases undergoing the 5FU/steroid with surgical removal had a 92% average reduction in lesion size compared with 73% in the group of cases who didn't receive 5FU. Cases receiving 5FU/steroid without surgical removal had an average lesion size reduction of 81% [25].

The current study displayed a significant reduction in the VSS scores across all four domains in both groups during the follow-up period compared with baseline indicating improvement in both groups. However, the

combination group exhibited statistically lower scores across all four domains.

Khalid *et al.* [26] conducted their study on a total of 120 cases, who were divided into group A (n=60), which received ILI of TAC, and group B, which received 5-FU and TAC. The results displayed that the mean decrease in the scar height in group B, 1.144 + 0.4717, was significantly better than that of group A, 1.894 + 1.0751 (t = 4.78, p = 0.00). Group B was associated with a significant increase in the degree of improvement compared to group A (77.2% versus 49%) (p = 0.002).

Another study included 60 cases who were enrolled and assigned to three groups. All treatment groups demonstrated notable reductions in VSS scores across all parameters at each evaluation point. These improvements were consistently observed throughout the study and were maintained until the final assessment. The rates of improvement varied across treatment groups as following, for height 5-FU showed the most significant improvement, for vascularity TAC demonstrated the greatest efficacy, for pliability and pigmentation, the combination therapy (T + F) yielded the best outcomes **[13].**

The two drugs were compared in a previous study by **Hietanen *et al.* [27]** who compared the efficacy of ILI of 5FU and triamcinolone injections. There was insignificant difference in the remission rate at six months between the 5FU and TAC groups.

In another study, the efficacy of ILI of 5FU alone (group A) was compared to ILI of TAC combined with 5FU (group B). The results showed a good to excellent response in 96% of cases in Group B, compared to 72% in Group A **[28]**. Another study conducted by **Ren *et al.* [29]** displayed that combined use of TAC+5FU is more efficient compared to TAC only.

CONCLUSION

We concluded that both triamcinolone acetonide and 5-flurouracil were shown to be efficient in treatment of keloids due to different causes. However, there was better improvement with the combination of the two drugs than with triamcinolone acetonide alone. Both groups were comparable regarding the pain sensation due to the drug application through ILI.

Recommendations

Provide awareness about the process of effective healing to decrease the burden of keloids. Performing further multicenter studies with larger sample size. Performing further studies with more prolonged duration of follow up for better assessment of the results. Performing further prospective studies to assess the value of different treatment regimens in the management of keloids. Application of the tested drugs through other less invasive technique apart from the intralesional injection to decrease the incidence of pain.

Conflict of interest: None.
Funding: None.
Reviewer disclosures: None.

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