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Original article

Comparison between Intralesional Triamcinolone and Intralesional Methotrexate in the Treatment of Keloid

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SUMMARY

Introduction/Aim. Keloid is a benign proliferative lesion of the dermal connective tissue. It is a challenging clinical problem, despite multiple therapies reported until now. The aim of the study was to determine the efficacy of intralesional methotrexate in the treatment of keloid in comparison to intralesional triamcinolone.

Methods. This is an interventional comparative therapeutic study carried out at the Department of Dermatology in Al-Kindy Teaching Hospital, from April 2019 to January 2021. A total of 28 patients with 56 lesions were enrolled in this study; their ages ranged from 16 to 60 years, and they were satisfied with the selection criteria. Lesions were classified into two groups: Group A - 28 lesions treated with intralesional methotrexate and Group B - 28 lesions treated with intralesional triamcinolone. The treatment sessions were scheduled every four weeks. The Vancouver Scar Scale was used for the evaluation. A calculation of the mean decrease in total score was performed, and photographs were taken.

Results. In both study groups, a significant reduction in height and pliability was seen in lesions treated with triamcinolone compared to lesions treated with methotrexate but no significant difference between the two drugs in vascularity and pigmentation were seen at the end of the study. Means of Vancouver Scar Scale in both groups after six months of treatment decreased significantly, and better results were seen with triamcinolone in comparison to methotrexate.

Conclusion. The two modes of therapy were effective, however, better results were seen with triamcinolone in the treatment of keloid.

Keywords: **keloid, triamcinolone, methotrexate, Vancouver Scar Scale**

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INTRODUCTION

Keloid is thought to involve an aberrant collagen deposition that extends beyond the original wound margins. They rarely resolve spontaneously and have a poor response to treatment (1). Many factors, including specific HLA subtypes, blood type A II, Fitzpatrick skin types V-VI, and age ranging from 10 to 30 years old have been linked to a proclivity for keloid formation (2).

Aspects of initial wound management, such as delayed debridement, heavy inflammation, and excessive wound tension, have also been linked to the formation of keloid scars (2). Currently, there is little agreement among doctors about the best treatment option for keloid therapy. Recent research have suggested that a multimodal approach is required to achieve successful resolution and reduce recurrence rates (3).

Many factors play a significant role in keloid formation. The genetic predisposition is the most important one. Other factors are blood groups, the anatomical site, melanin, the type of skin injury, the age of onset and sex (4).

Standard treatments include occlusive dressings, compression, intralesional corticosteroid injections and laser (5, 6).

Triamcinolone acetonide (TAC) is the most commonly used corticosteroid in the treatment of keloid scars.

Intralesional corticosteroid injections improve scar pliability, reduce scar volume and height, and alleviate itching and pain associated with scars. Despite their benefits, intralesional steroid injections can result in a variety of adverse side effects, both local, such as telangiectasias, pigmentary changes (hypopigmentation and hyperpigmentation), skin necrosis and ulcerations, skin and subcutaneous fat atrophy, ineffectiveness and injection pain, and systemic, such as the Cushing's syndrome (7).

Methotrexate (MTX) is a folic acid analogue (amethopterin or 4 amino N10 methyl pteroylglutamic acid) with anti-proliferative [DHFR mediated] and anti-inflammatory (non DHFR mediated) effects. In the anti-inflammatory pathway, a purine nucleoside called adenosine is released, which has the ability to fight the inflammatory process (8). Reduced nucleic acid formation in activated T cells and keratinocytes is responsible for the antiproliferative, cytotoxic, and antineoplastic effects (9).

AIM

The aim of the study was to determine the efficacy of intralesional methotrexate in the treatment of keloid in comparison to intralesional triamcinolone.

PATIENTS AND METHODS

This interventional comparative therapeutic study was carried out at the Department of Dermatology at Al-Kindy Teaching hospital during the period April 2019 - January 2021.

Ethical and official approval: The nature and target of this study were explained to each patient and a formal consent was taken from each patient before starting the therapy. Administrative approval was granted from The Arab Board of Health Specializations and the Department of Dermatology and Venereology at Al-Kindy Teaching Hospital.

In total there were 28 patients with 56 lesions, with age range from 16 to 60 years, of which 24 lesions were observed in 12 females and 32 lesions were observed in 16 males.

They met the selection criteria and they were classified into two groups: Group A - 28 lesions treated with methotrexate 5 mg (0.5 ml of 50 mg per 5 ml vial) and Group B - 28 lesions treated with triamcinolone 40 mg per 1ml vial.

Investigations (complete blood count, liver function test, renal functions test and random blood sugar) were measured at every visit.

Photographs were taken of each patient's lesions at every visit by the phone camera Samsung Galaxy.

Inclusion criteria

Extension of the growth of keloid beyond the boundaries of the original lesion or injury, patients with more than one keloid and lasting more than one year, the last modality of treatment used at least six months before, either no response or recurrence.

Exclusion criteria

Pregnant women or those who wanted to be pregnant and lactating women, significant hepatic dysfunction, significant renal dysfunction, active infectious disease, blood dyscrasia.

A questionnaire was distributed to all patients included in the study, filled out by the researcher. History details and demographic data were gathered in the questionnaire as age, gender, and duration of the lesion.

Seventy percent ethanol was used as a topical antiseptic agent before injection; a disposable insulin syringe with a 27-gauge needle was used to be inserted into the keloid, and no local anesthesia was applied.

Group A was treated with intralesional methotrexate 5 mg (0.5 ml of 50 mg per 5 ml vial) into the keloid with adequate pressure till blanching was see in; this was repeated at multiple sites on the keloid. Drug Manufactured Kocak Farma Liac Ve Kemya Sanayi A.S Organize Sanayi Bolgesi Cerkezoky Tekirdag Turkey.

Group B was treated with intralesional triamcinolone 40 mg per 1 ml vial (manufactured by Bristol-Myers Osquibb-Roma-Italy) injected into the keloid with pressure till blanching was seen and it was repeated on the multiple sites on the keloid. Follow-up: patients were seen every 4 weeks to be injected intralesionally. The therapy was carried out in duration of 6 sessions maximally.

Folic acid tablets were given to all patients to be used once daily (5 days only) except on the session day. The follow-up was done six months after treatment sessions to watch for any recurrence of keloid depending on the compliance of the patients.

Evaluation of treatment efficacy: Evaluation of the lesions was done according to the Vancouver Scar Scale which consists of four parameters: pliability, height, vascularity, and pigmentation. Every parameter scores from zero and higher and the total score range from zero to thirteen. Decreasing values represent better clinical results.

Pliability was assessed subjectively by palpation. Height was measured by tape measure. Vascularity was rated by visual inspection. Pigmentation was measured by inspecting the lesion and the difference in the color of the surrounding skin.

The readings of measurement of the 1st visit, 3rd visit and 6th visit (the end line visit) were used in statistical analysis to find out the significance of differences between the measurements.

Statistical analysis

The collected data were introduced into Microsoft Excel sheets 2016 and loaded into SPSS v25 software; the descriptive statistics was presented using tables and graphs.

The Chi-Square test was used to find out the significance of associations between related categorical variables. Repeated measures ANOVA was used to find the significance of differences between each of the measured scale variables of each drug in different stages of treatment. ANCOVA was used to find out which drug was better at the end-line treatment after adjustment of baseline measurement of both drugs. The repeated measures ANOVA and ANCOVA were applied to each item of VSS separately and it was applied to the VSS which was calculated by adding pliability, height, vascularity, and pigmentation. A P-value less than 0.05 was considered as a discrimination point for significance.

RESULTS

Twenty-eight patients, 16 males (57.1%) and 12 females (42.9%) were enrolled in this study (Table 1) from the outpatient clinic of the Dermatology Department in Al-Kindy Teaching Hospital. The proportion of males was higher than females. Their ages ranged between 16 - 60 years; the interventional study showed that the mean age of the study patients was 34.98 + 12.08 years as seen in Figure 1.

The mean duration of the disease was 2.86 + 1.59 years as seen in Figure 2. Figure 3 shows the keloid scars at the baseline visit and at the end-line visit. It was also observed that the more recent the keloid the better response. No complete flattening in lesions treated with MTX or TAC was seen, which is demonstrated in Figure 4 and 5.

Table 1. *Distribution of studied cases according to gender*

		Count	Column N %
Gender	Male	16	57.1%
	Female	12	42.9%

Figure 1. *The mean age of studied patients*

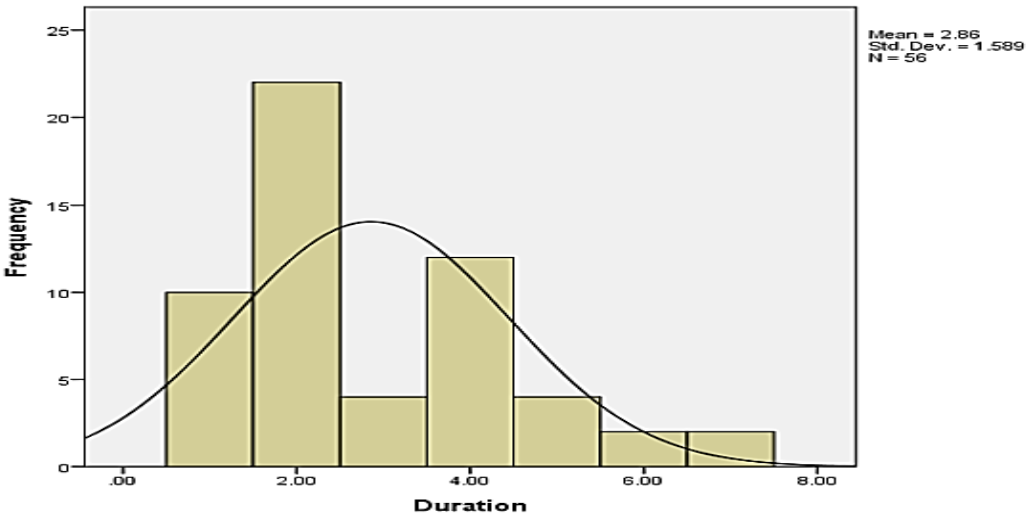

Figure 2. *The mean duration of the disease*

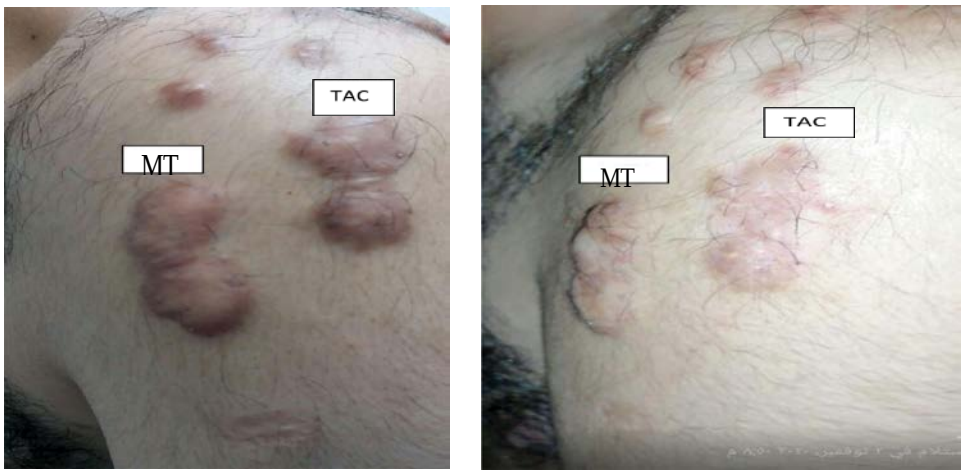

Figure 3. *Keloid scars at the baseline visit and at the end-line visit*

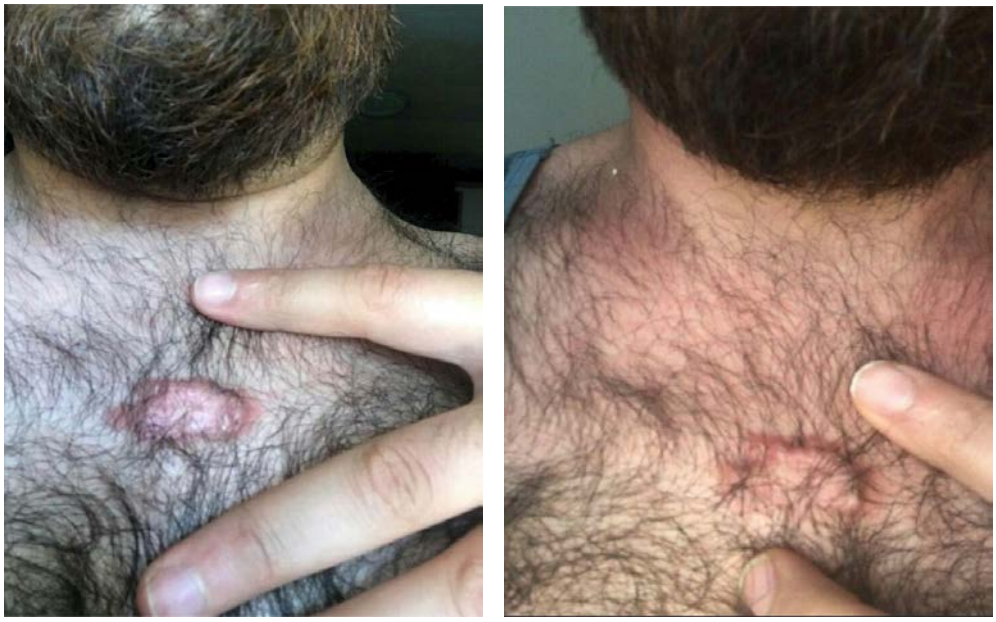

Figure 4. *A keloid scar before MTX injections and after 6 MTX injections*

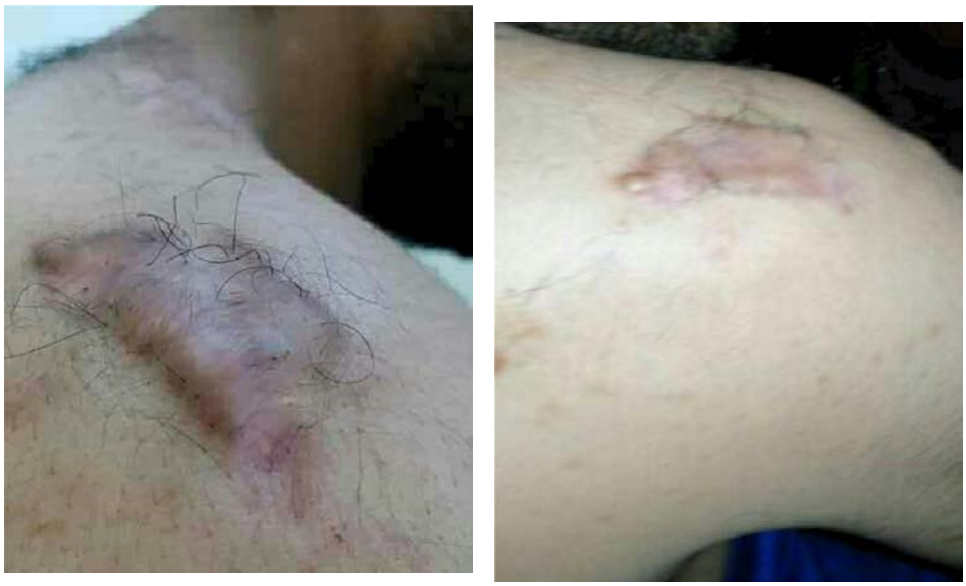

Figure 5. *A keloid scar before TAC injections / after 6 TAC injections*

Pliability: Repeated measures ANOVA test in Table 2 shows that the mean of the pliability of lesions measured after 6 months of patients treated with methotrexate or triamcinolone were significantly lower than the pliability of lesions measured at the first visit and after 3 months, $p < 0.001$ in all comparisons.

Covariance (ANCOVA) analysis in Table 3 shows that the estimated end-line measured pliability of lesions treated by triamcinolone was significantly lower than the corresponding lesions treated by methotrexate after adjustment of baseline measurements of pliability in both groups, $p = 0.001$.

Height: Repeated measures ANOVA test in Table 4 shows that the mean of the height of lesions measured after 6 months of patients treated by methotrexate or triamcinolone were significantly lower than the height of lesions measured at the first visit or after 3 months, $p < 0.001$ in all comparisons.

Covariance (ANCOVA) analysis in Table 5 shows that the estimated end-line measured height of lesions treated by triamcinolone was significantly

lower than the corresponding lesions treated by methotrexate after adjustment of baseline measurements of height in both groups, p = 0.001.

Vascularity: Repeated measures ANOVA test in Table 6 shows that the mean of vascularity of lesions measured after 6 months of patients treated by methotrexate or triamcinolone was significantly lower than the vascularity of lesions measured at first or after 3 months, p < 0.001 in all comparisons.

Covariance (ANCOVA) analysis in Table 7 shows that the estimated end-line measured vascularity of lesions treated by triamcinolone was not significantly lower than the corresponding lesions treated by methotrexate after adjustment of baseline measurements of vascularity in both groups, p = 0.662.

Table 2. *Differences between means of pliability according to the type of drug and time of examination using repeated measure ANOVA*

Treatment group	Examination time	Mean	Std. Dev.	P value	Pairwise comparison P value		
					V1&V2	V2&V3	V1&V3
Methotrexate	First visit	3.03	0.74	0.001	0.161	0.001	0.001
	After 3 months	2.96	0.79				
	After 6 months	1.75	0.51				
Triamcinolone	First visit	3.07	0.71	0.001	0.001	0.001	0.001
	After 3 months	2.21	0.68				
	After 6 months	0.35	0.48				

Table 3. *Differences between means of pliability of lesions treated by methotrexate and triamcinolone at end-line visit using covariance (ANCOVA) analysis*

Treatment group	Estimated baseline mean	Estimated end line		95% CI		P value
		Mean	SE	L B	U B	
Methotrexate	3.1	1.75	0.081	1.593	1.920	0.001
Triamcinolone		0.35	0.081	0.187	0.514	

CI = Confidence interval, SE = Standard error, LB = Lower bound, UP = Upper bound

Table 4. *Differences between means of height of lesions measured by mm according to the type of drug and time of examination using repeated measure ANOVA*

Treatment group	Examination time	Mean	Std. Dev	P value	Pairwise comparison P value		
					V1 &V2	V2 &V3	V1 &V3
Methotrexate	First visit	2.67	0.475	0.001	0.01	0.001	0.001
	After 3 months	2.46	0.50				
	After 6 months	1.35	0.48				
Triamcinolone A	First visit	2.71	0.46	0.001	0.001	0.001	0.001
	After 3 months	1.96	0.63				
	After 6 months	0.42	0.63				

Table 5. *Differences between means of height of lesions treated by methotrexate and triamcinolone measured by mm at the end-line visit using covariance (ANCOVA) analysis*

Treatment group	Estimated baseline mean	Estimated end line		95% CI		P value
		Mean	Std. Error	LB	UB	
Methotrexate	2.63	1.363	0.104	1.153	1.572	0.001
Triamcinolone		0.423	0.104	0.214	0.632	

CI = Confidence interval, SE = Standard error, LB = Lower bound, UP = Upper bound

Table 6. *Differences between means of vascularity of lesions according to the type of drug and time of examination using repeated measures ANOVA*

Treatment group	Examination time	Mean	Std. Dev.	P value	Pairwise comparison P value		
					V1&V2	V2&V3	V1 &V3
Methotrexate	**First visit**	2.46	0.83	0.001	0.001	0.001	0.001
	After 3 months	1.82	0.61				
	After 6 months	0.85	0.59				
Triamcinolone	**First visit**	2.32	0.77	0.001	0.001	0.001	0.001
	After 3 months	1.39	0.91				
	After 6 months	0.71	0.80				

Table 7. *Differences between means of vascularity of lesions treated by methotrexate and triamcinolone at the end-line visit using covariance (ANCOVA) analysis*

Treatment group	Estimated baseline mean	Estimated endline		95% CI		P value
		Mean	Std. Error	LB	UB	
Methotrexate	2.39	0.820	0.109	0.602	1.038	0.662
Triamcinolone		0.752	0.109	0.534	0.970	

CI = Confidence interval, SE = Standard error, LB = Lower bound, UP = Upper bound

Pigmentation: Repeated measures ANOVA test in Table 8 shows that the mean of pigmentation of lesion measured after 6 months in patients treated with methotrexate was not significantly lower than the pigmentation of lesions measured at second measurement, $p = 0.161$, but it was significantly lower than that of the first measurement, $p = 0.022$, while the means of pigmentation were significantly lower in all followed readings in triamcinolone measurements, $p < 0.001$ in all comparisons.

Covariance (ANCOVA) analysis in Table 9 shows that the estimated end-line measured pigmentation of lesions treated by triamcinolone was not significantly lower than the corresponding lesions treated by methotrexate after adjustment of baseline measurements of pigmentation in both groups, $p = 0.161$.

VSS Assessment: The VSS mean of lesions treated by MTX at the first visit was 9.89 and it decreased significantly at the end of treatment. The VSS mean was 5.17, while the VSS mean of lesions treated by TAC at the first visit was 9.6 and it decreased significantly at the end of the visits to be 2.37. The P value at the end-line visit was 0.001 for both drugs as seen in Table 10. Repeated measures ANOVA test in Table 10 shows that the mean of VSS of lesions measured after 6 months of patients treated with methotrexate or triamcinolone were significantly lower than VSS of lesions measured at the first visit and after 3 months, $p = 0.001$ in all comparisons.

Table 8. *Differences between means of pigmentation of lesions according to the type of drug and time of examination using repeated measures ANOVA*

Treatment group	Examination time	Mean	Std. Dev.	P value	Pairwise comparison P value		
					V1 &V2	V2 &V3	V1 &V3
Methotrexate	First visit	1.71	0.71	0.024	0.022	0.161	0.006
	After 3 months	1.35	0.95				
	After 6 months	1.21	0.99				
Triamcinolone	First visit	1.57	0.83	0.002	0.184	0.002	0.001
	After 3 months	1.35	0.95				
	After 6 months	0.85	0.65				

Table 9. *Differences between means of pigmentation of lesions treated by methotrexate and triamcinolone measured at the end-line visit using covariance (ANCOVA) analysis*

Treatment group	Estimated baseline mean	Estimated end line		95% CI		P value
		Mean	SE	LB	U B	
Methotrexate	1.64	1.188	0.151	0.885	1.491	0.161
Triamcinolone		0.883	0.151	0.580	1.186	

CI = Confidence interval, SE = Standard error, LB = Lower bound, UP = Upper bound

Table 10. *Differences between means of VSS of lesions according to the type of drug and time of examination using repeated measures ANOVA*

Treatment group	Examination time	Mean	Std. Dev.	P value	Pairwise comparison P value		
					V1&V2	V2&V3	V1&V3
Methotrexate	First visit	9.8929	1.83261	0.001	0.001	0.001	0.001
	After 3 months	8.6071	1.77094				
	After 6 months	5.1786	1.46701				
Triamcinolone	First visit	9.6786	1.86694	0.001	0.001	0.001	0.001
	After 3 months	6.9286	2.46349				
	After 6 months	2.3571	2.00396				

Table 11. *Differences between means of VSS of lesions treated by methotrexate and triamcinolone measured at the end-line visit using covariance ANCOVA analysis*

Treatment group		Mean	Std. Error	95% confidence interval		P value
				Lower Bound	Upper Bound	
MTX	9.399	5.136 a	0.305	4.524	5.748	0.001
TAC		2.399 a	0.305	1.787	3.011	

Covariance (ANCOVA) analysis in Table 11 shows that the estimated end-line measured VSS mean of lesions treated by triamcinolone was significantly lower than the corresponding lesions treated by methotrexate after adjustment of baseline measurements of VSS in both groups, p = 0.001.

Side effects: Pain at the time of injection was seen in both groups, however, the main side effects seen with TAC were atrophy, hypopigmentation and acne rash in some patients.

Figure 3 shows the keloid scars at the baseline visit and at the end-line visit.

Recurrence rate: The recurrence rate of lesions treated with MTX was 25%, while for lesions treated with TAC, the recurrence rate was 17.9%, as shown in Table 12.

Table 12. *The association between drug and recurrence rate*

Treatment group	Yes		No		P value
	N	%	N	%	
Methotrexate	7	25.0%	21	75.0%	0.515
Triamcinolone	5	17.9%	23	82.1%	

DISCUSSION

The study showed that methotrexate can be used as an effective intralesional treatment for keloid with fewer side effects than steroids, however, no complete resolution to the keloid scars was observed. This might be explained by the long time needed for MTX to be active (10).

In a study performed by Dr Ahmed Abdul Aziz in 2005, twenty-five patients with 25 lesions were recruited, aged between 16 - 75 years (mean 30.48 years ± 13.23). His results showed that intralesional MTX is an effective modality in keloid therapy, which is similar to our results. A response rate (moderate and minimal) of 72% was reported and the best results were obtained with early lesions. Mohammed Uzair et al. (11) reported different results in their study performed on 80 patients, where the mean age was 25.96 ± 6.98 years.

Vancouver scale assessment: In December 2014, Dr Khalifa E Sharquie et al. (12) used keloid debulking combined with intralesional injection of MTX and triamcinolone versus intralesional MTX and triamcinolone. They found that the mean of the score before treatment was 9.63 and the mean of the score after treatment was 4.40, and the p value was less than 0.0001 for patients treated with intralesional MTX and triamcinolone. For patients treated with keloid debulking combined with intralesional MTX and triamcinolone, the mean score before treatment was 9.09 and after treatment was 2.32. Both types of treatment were effective on all lesions. While group B received an 80 percent moderate response, group A received a 50 percent moderate response. Similarly, in the current study, the VSS mean of lesions treated with MTX was 9.89 at the first visit and decreased significantly by the end of the treatment, with the VSS mean being 5.17. The VSS mean of lesions treated by TAC at the first visit was 9.6 and it decreased significantly at the end of the visits to 2.37. The p value at the end line visit was 0.001 for both drugs.

In the recent study, the estimated end-line measured pliability and height in lesions treated by triamcinolone were significantly lower than the corresponding lesions treated by methotrexate after adjustment of baseline measurement of pliability and height in both groups. The P value was 0.001 (significant), while the results show that the estimated end-line measured vascularity and pigmentation of lesions treated by triamcinolone was not significantly lower than the corresponding lesions treated by methotrexate after adjustment of base-line measurements of vascularity and pigmentation in both groups as the p value was 0.662 and 0.161, respectively (not significant).

In our study, the evaluation was performed by VSS every four weeks for six months with follow-up after six months from the last session. Pliability and height significantly reduced in both study groups (A and B), and the mean of vascularity of lesions measured after six months in patients treated by group A or B (MTX or TAC) were significantly lower than the vascularity of lesions measured at the first visit or after three months; p < 0.001 in all comparisons. The estimated end-line measured vascularity of lesions treated by TAC was not significantly lower than the corresponding lesions treated by MTX. The mean of pigmentation of lesions treated by MTX measured after six months was not significantly lower than the pigmentation of lesions measured after three months, p = 0.161, however, it was significantly lower than the first measurement, p = 0.022. This may be due to the slow action of MTX, while the means of pigmentation were significantly lower in all readings in TAC measurement, with p < 0.001 in all comparisons.

The recurrence rate in this study was 25% in lesions treated with 5 mg methotrexate while it was 17.9% in lesions treated with 40 mg triamcinolone. Another research by Tatian Gandolfide Olvereira et al. (13) found no recurrence in five of 11 patients treated with surgery and 2.5 mg methotrexate injection for six months postoperatively. Six cases had partial recurrence.

CONCLUSION

Keloids are a distressing aesthetic problem to patients, especially when it occurs over the exposed parts of the body. It is sometimes associated with irritant pruritus, so treatment of keloid is still mandatory.

Prevention remains the best strategy in predisposed patients.

Intralesional methotrexate can be used in the treatment of keloid, showing a significant effect with fewer side effects than intralesional triamcinolone, but no complete resolution has been seen with intralesional methotrexate.

The use of methotrexate for the treatment of keloid with long follow-up period is recommended in further studies. Also, we recommend the use of other modes of treatment for keloid as a substitute to triamcinolone because it could have a comparable effect to MTX.

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Poređenje intralezionog triamcinolona i intralezionog metotreksata u lečenju keloida

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SAŽETAK

Uvod/Cilj. Keloid je benigna proliferativna lezija vezivnog tkiva u koži. Predstavlja izazovan klinički problem uprkos mnogobrojnim terapijama koje su do sada opisane. Cilj ove studije bilo je određivanje efikasnosti intralezionog metotreksata u lečenju keloida u poređenju sa intralezionim triamcinolonom.
Metode. Ovo je interventna komparativna terapeutska studija urađena na Departmanu za dermatologiju u Univerzitetskoj bolnici Al-Kindy, u periodu od aprila 2019. godine do januara 2021. godine. U studiju je uključeno ukupno 28 bolesnika sa 56 lezija; bolesnici su bili stari od 16 do 60 godina i bili su zadovoljni kriterijumima za ukjlučivanje u studiju. Lezije su bile podeljene u dve grupe: grupu A, u kojoj je 28 lezija bilo tretirano intralezionim metotreksatom, i grupu B, koja je takođe obuhvatila 28 lezija koje su lečene intralezionim triamcinolonom. Tretmani su rađeni na četiri nedelje. Za procenu ožiljaka korišćena je Vankuverska skala za procenu ožiljaka (engl. *Vancouver Scar Scale*). Izračunata je srednja vrednost smanjenja ukupnog skora i napravljene su fotografije ožiljaka.
Rezultati. U obema ispitivanim grupama zabeleženo je značajno smanjenje visine i elastičnosti lezija lečenih triamcinolonom u poređenju sa lezijama lečenim metotreksatom. Ipak, na kraju studije nije zabeležena značajna razlika između ovih dvaju lekova u pogledu vaskularnosti i pigmentacije. Srednje vrednosti dobijene na Vankuverskoj skali za procenu ožiljaka značajno su pale u obema grupama nakon šest meseci lečenja, dok su bolji rezultati uočeni kod primene triamcinolona u poređenju sa metotreksatom.
Zaključak. Obe metode lečenja bile su efikasne; međutim, bolji rezultati zabeleženi su kod primene triamcinolona u lečenju keloida.

Ključne reči: **keloid, triamcinolon, metotreksat, Vankuverska skala za procenu ožiljaka**