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Original Research Article

The efficacy of intralesional triamcinolone acetonide (20mg/ml) in the treatment of keloid

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ABSTRACT

Background: Management of keloid is difficult as well as challenging. Intralesional triamcinolone acetonide (TAC) injections have remained a gold standard in non-surgical management of keloid. TAC is generally used in the concentration of 40mg/ml, which causes adverse effects such as local dermal atrophy and hypopigmentation. Aim was to study efficacy and adverse effects of TAC in treatment of keloid, in a lesser concentration of 20mg/ml.
Methods: An open label study was conducted from November 2015 to May 2017 on 25 subjects of either gender, in the age group 11-55 years, at a medical college hospital. Intralesional injection TAC 20 was administered in the keloid at an interval of 3 weeks, for a total of 6 sessions, over a period of 18 weeks. Vancouver scar scale (VSS) was used to assess the improvement and SPSS 21 for statistical analysis.
Results: Mean age of keloid subjects was 30.72 years and median duration of keloid was 8 months. The mean VSS score before treatment was 8.36 which reduced to 3.20 after treatment. Mean percentage change in VSS score was 62.79%, which was very highly significant ($p < 0.001$). Physician's assessment was 'Very Good' in 52.0% and 'Excellent' in 5 (20%). Adverse effect of atrophy was seen in 3 (12%), hypopigmentation in 11 (44%) and telangiectasia in 4 (16%).
Conclusions: Intralesional injection triamcinolone acetonide 20mg/ml gives very good to excellent improvement in the majority of patients of keloid. Local adverse effects seen were hypopigmentation, atrophy and telengiectasia.

Keywords: Adverse effects, Efficacy, Keloid, Triamcinolone (20mg/ml), Vancouver scar scale

INTRODUCTION

Keloids are characterized by firm, mildly tender, bosselated nodules or plaques occurring more frequently on shoulders, chest, neck, upper arms and face.[1] They are benign overgrowth of fibrous tissue that usually develops after healing of a skin injury and extends beyond the original defect.[2] The uncontrolled growth of keloid continues progressively, and the patients experience itch and pain. The fibrous keloid progresses to gain a larger size, leads to cosmetic disfigurement, functional impairment, and affects the quality of life adversely.[3]

It is supposed that corticosteroids owing to their anti-inflammatory properties are helpful in suppressing hypertrophic scars and the keloid.[4] The corticosteroids diminish collagen and glycosaminoglycan synthesis, inhibit fibroblast growth and enhance collagen and fibroblast degeneration.[5,6]

Triamcinolone acetonide (TAC) is the most commonly used intralesional corticosteroid for the treatment of keloids and is considered to be the first line therapy for the treatment of keloids.[7] TAC is used in different concentrations ranging from 10 to 40mg/ml. Different studies recommend different intervals between successive injections and the number of injections may vary from four to eight.[8]

Intralesional injection TAC 40mg/ml is more commonly used, as the concentration of 40mg/ml is very effective in controlling keloid. However Local side effects such as dermal atrophy, telengiectasia, hypopigmentation and pain at the site of injection due to TAC 40mg/ml are common. Pain can be avoided by use of topical anesthesia and/or regional injections of local anesthetic around the scars.[9] Hypopigmentation is not a problem in non-pigmented western skin but is significant in pigmented skin.

Aim was to study the efficacy and the adverse effect of intralesional injection triamcinolone acetonide in treatment of keloid, in concentration of 20mg/ml.

METHODS

The study was carried out on 25 patients in Dermatology OPD of a medical college hospital in North India from November 2015 to May 2017 (one year and six months). Patients of keloid of either gender, in the age group 11 to 55 years, were included in the study. Patients with local infection, immune-compromise, pregnancy or lactation and those who had received treatment for keloid during previous 6 months were excluded. Sample size was calculated on the basis of decrease in volume of the keloid.[10]

Injection Triamcinolone acetonide 20mg/ml (TAC 20) was injected intralesionally at an interval of 3 weeks, for a total of 6 sittings over a period of 18 weeks. Injection Triamcinolone acetonide 40mg/ml was diluted using lignocaine with adrenaline, in equal proportions, to get a final concentration of 20mg/ml. The lesion was infiltrated with the drug suspension, using a disposable insulin syringe and 26-gauge needle, till complete and uniform blanching of the lesion, was achieved. The subject was not administered any sedation or analgesia prior to the injection.

The details of the subject including the Fitzpatrick skin type, duration, site, number and parameters such as height, pliability, vascularity and pigmentation of the keloid assessed on Vancouver Scar Scale (VSS), were recorded in a predesigned "Case record form." VSS was assessed before treatment and three weeks after completion of the treatment.

VSS is a validated and widely used tool to document a change in appearance of the scar, in clinical practice and research.[11-13] Parameters of the keloid such as vascularity, pliability, pigmentation and height are assessed, in order to determine the score. The score allotted for pliability is from 0 to 5, score for height and vascularity from 0 to 3 and for pigmentation from 0 to 2, to give a maximum possible score of 13. The decreasing mean value of the total score indicates clinical improvement, in the scar.

Scar height was measured with calipers, and scar pliability assessed by palpation; scar vascularity rated by visual inspection, and the rate of refill, after blanching it. Blanching was achieved by a transparent plastic sheet with VSS score sheet, pasted on it. Scar pigmentation was assessed after blanching and comparing the scar color with the surrounding skin.[13] The percentage reduction in VSS was graded according to the Quartile score with ≤25% reduction in VSS graded as Poor, 26-50% reduction as Good, 51-75% reduction Very good and >75% reduction as Excellent response.

Data was analyzed using Statistical Package for Social Sciences (SPSS) version 21.0. Wilcoxon signed rank was used to assess the outcome and 'p' value less than 0.05 was considered to be a statistically significant change.

RESULTS

A total of 25 subjects of keloid of either gender, were treated with intralesional injection of triamcinolone acetonide 20mg/ml (TAC-20). All the 25 subjects completed the study. Male were 52%, female 48% and the mean age was 31.76±13.08 years. Family history of keloids was present in 4 (16.0%). The majority (60.0%) of the subjects had Fitzpatrick Skin type IV. Duration of keloid ranged from 1 to 36 months with a median duration of 7 months.

Table 1: Demographic data.

Keloid patients		Value
Gender	Male	13 (52%)
	Female	12 (48%)
Age (year)	11 to 55	Mean 31.76±13.08
Family history	Positive	4 (16.0%)
	Negative	21 (84%)
Skin Photo-type	Type IV	15 (60.0%)
	Type V	10 (40.0%)
Duration (months)	1 to 36	Median 7

The majority (92%) had one or two keloids and 2 (8%) of the subjects had more than three keloids.

Table 2: Number of keloids.

Patients	Number of Keloids
18 (72%)	1
5 (20%)	2
0 (0%)	3
1 (4%)	4
1 (4%)	5

The majority (90%) of keloids were either on the chest or shoulders.

Table 3: Location of keloids.

Location on the body	No. of keloids (30)
Chest	16 (52 %)
Shoulder and arm	11 (38 %)
Face and ear	3 (10 %)
Back	0 (%)
Thigh and leg	0 (%)

An assessment of Vancouver Scar Scale (VSS) score was carried out at the baseline i.e. before the treatment, and at 3 weeks after the last (sixth) injection, i.e. at 18 weeks from the first injection: Before starting the treatment, at the baseline, mean VSS score was 8.36±1.60 (Median 8.0), which reduced to 3.20±1.92 (Median 3.00) at final follow up, thus showing a mean change of -5.16±1.63 (62.79%). On evaluating the data, it was found to be statistically significant ($p<0.001$).

Table 4: VSS score following treatment with intralesional injection of triamcinolone acetonide.

VSS score (n=25)	Median	Mean	SD
At baseline	8.00	8.36	1.60
4.5 months (final follow up)	3.00	3.20	1.92

Mean±SD -5.16±1.63 % change -62.79%; z=4.401; $p<0.001$

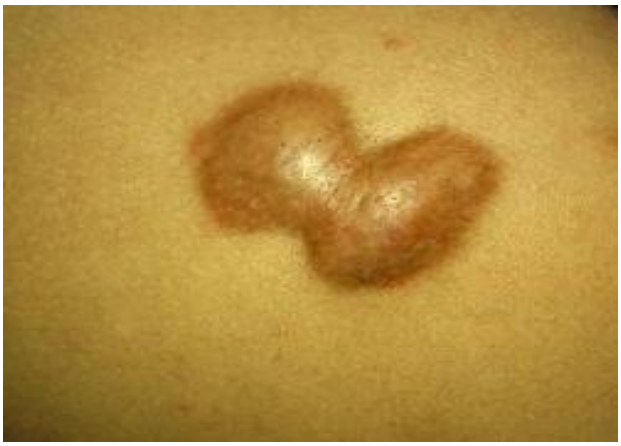

Figure 1: Pretreatment photograph of keloid on back of shoulder.

Physician rated outcome was 'Very good' to 'Excellent' in 18 (72%) and 'Good' in 5 (20%) subjects. There were 2 (8%) cases in which outcome was evaluated as 'Poor'.

Table 5: Physician rated outcome.

Assessment	n = 25
Poor	2 (8%)
Good	5 (20%)
Very good	13 (52%)
Excellent	5 (20%)

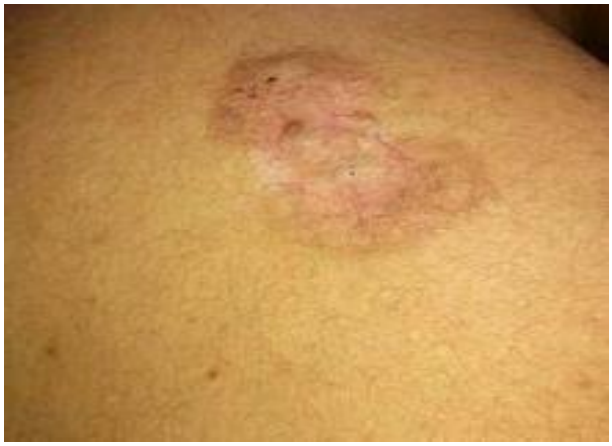

Figure 2: Post-treatment photograph after TAC-20 (excellent response).

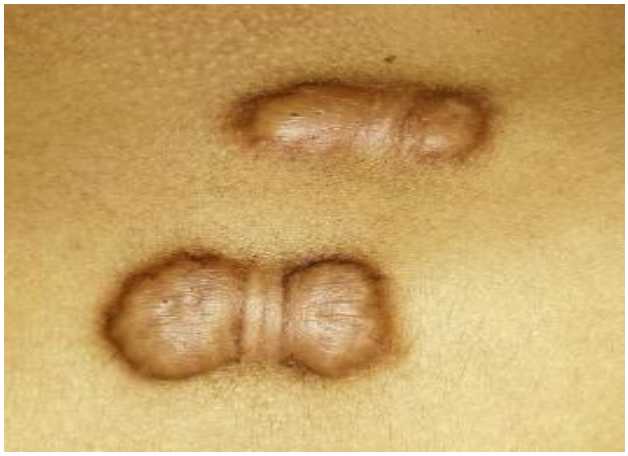

Figure 3: Pretreatment photograph of keloid.

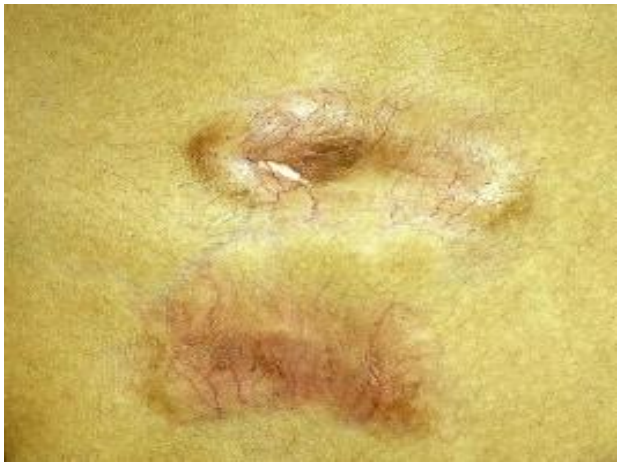

Figure 4: Post-treatment photograph of keloid after TAC20 (very good response but with atrophy and telengiectasia).

Pain was the most common adverse effect as reported by 21 (84%) patients. Hypopigmentation was observed in 11 (44%), telengiectasia in 4 (16%), and dermal atrophy in 3 (12%) of the subjects (Table 6).

Table 6: Adverse effects.

Adverse Effects	n = 25
Pain	21(84%)
Hypopigmentation	11 (44%)
Telangiectasia	4 (16%)
Dermal atrophy	3 (12%)

DISCUSSION

Pathogenesis of the keloid is still not well understood.[14] A variety of treatment modalities such as silicone gel sheeting, intralesional injections, cryotherapy, surgical manipulation, laser and radiotherapy are used, but no particular treatment is suitable or effective in all cases and keloid it tends to recur, irrespective of the treatment used.[8] Drugs like bleomycin, interferon, 5-fluorouracil when used intralesionally, have a better efficacy, but are costly and cause severe drug reactions. Surgery and laser therapy have limitations and radiotherapy causes malignancy.[15]

Corticosteroids seem to be effective as they diminish collagen and glycosaminoglycan synthesis, inhibit fibroblast growth, enhance collagen and fibroblast degeneration and have powerful anti-inflammatory effect.[4-6] The anti-inflammatory effect of TAC in addition to inhibition of collagen and glycosaminoglycan synthesis, and degeneration of fibroblast/collagen might be giving it an edge, however the drug causes local adverse effects such as dermal atrophy, telengiectasia and hypopigmentation in large number of patients.

Inability to measure amount of drug used with respect to area as well as thickness of keloid, has been a major limitation in this study as in most other studies. Consequently, complete blanching of the keloid, was considered to be the end point, for the dose of the drug injected intralesionally.

TAC is cost effective and practical and has become first-line treatment for keloid, in spite of many limitations. Studies have reported that lower dose of TAC, i.e. 20mg/ml reduces the side effects of TAC without jeopardizing the efficacy.[16-18]

In this study, majority of the subjects were in the age group <30 years; males being slightly more than females. Uzair et al and Ahuja et al also observed predominance of keloid in the younger age group.[19,20] The duration of keloids in majority of subjects was less than 12 months. The majority showed a very good to excellent response conforming observations from studies.[21,22] The Keloid were found to be most common on the chest (60%), followed by shoulder (20%), arm (18%) and face (10%) similar to observations.[23]

In the present study following intralesional TAC 20, a majority (62.79%) of patients of keloids showed significant mean reduction in VSS. The observations were in conformity with that of Uzair et al.[19] The improvement observed was comparable to TAC 40mg/ml used by Chatterjee A and Shanthi M et al.[15,20] The improvement in keloid with TAC 20 mg/ml was observed to be similar to TAC 40mg/ml used in other studies.[15,19,20,23,24]

Immediate pain at the site of injection was the commonest side effect with TAC 20 as reported by 84% of the subjects. However, the pain was mild, transitory and resolved within few hours, which is attributed to dilution with lignocaine and adrenaline which causes a sustained hypoesthesia and therapeutic effect at the site, locally. Hypopigmentation was observed in 44%, atrophy in 12% and telengiectasia in 16% of the subjects treated by TAC 20; this was comparable to other studies.[25-27] Manuskiatti et al and Jannati et al using TAC-20, reported hypopigmentation in 20%, atrophy in 10% and telengiectasia in 20% of patients.[23,28] Bilal et al using TAC 40mg/ml reported hypopigmentation (29%), atrophy (4%) and telengiectasia (25%).[29] An occurrence of atrophy in 18% of cases was from studies.[20]

In the present study with TAC 20, hypopigmentation was observed in 44 % of the subjects. The incidence of hypopigmentation in the study was much higher as compared to other studies probably because all subjects in this study, were of Fitzpatrick skin type IV and V. Most other studies do not mention the skin phototype of the subjects.

Limitations of the study includes therapeutic effect of injection TAC was studied over a period of only 18 weeks for a patient, which may be inadequate. Post treatment follow up of patient should be of a longer period to judge the recurrence.

CONCLUSION

TAC 20mg/ml gives very good to excellent response in a majority of patients and the improvement is comparable to the result with TAC 40mg/ml as reported by other workers. TAC 20 also causes adverse effects such as hypopigmentation, telengiectasia and atrophy. However adverse effects with TAC 20 are less compared to TAC 40. Immediate postoperative pain occurs but is mild and transitory.

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Conflict of interest: None declared
Ethical approval: The study was approved by the Institutional Ethics Committee

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