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Comparison of Intralesional Triamcinolone Acetonide and Combination of 5-Fluorouracil and Triamcinolone in Treatment of Keloids

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ABSTRACT

Background: *Keloids are a common problem with significant recurrence. Despite many options available, there is no standard acceptable treatment for keloid. This study has compared the intralesional triamcinolone acetonide and a combination of 5-fluorouracil in the treatment of keloids.* ***Methods:*** *This is a randomized study. 60 patients were randomly allocated into two groups. Group 1-TAC+5FU, Group 2-TAC alone. The intralesional injection was given every 3 weeks till 24 weeks.* ***Results:*** *There was a reduction in scar height, vascularity, pigmentation, and pliability. Improvement in terms of height, vascularity, and pliability was faster with TAC+5FU.* ***Conclusion:*** *TAC+5FU combination was effective in keloids in comparison to Triamcinolone* Acetonide *(TAC) alone. The combination offered the balanced benefits of faster and more effective responses.*

Keywords: Keloid, Triamcinolone acetonide, 5-Fluorouracil

INTRODUCTION

Keloids occur as a result of abnormal wound healing. Keloid is an abnormal fibrous tissue outgrowth that extends beyond the borders of the wound. It is an abnormal proliferation of scar tissue that forms at the site of cutaneous injury. It does not usually regress spontaneously and possesses a high chance of recurrence after excision [1]. It is caused by minor trauma to the skin like ear piercing, abrasion, tattoos, burns, injection site, and the surgical site. It occurs anywhere in the body but the most common areas are the sternum, shoulder, earlobes, and cheeks.

The exact cause of this disorder remains elusive despite ongoing research and hypothesis. Keloids are known for lack of standardized treatment and high recurrence rate, this is evident in a wide range of available treatment modalities, like surgical excision, cryotherapy, low-dose radiotherapy, silicon sheets, intralesional steroids, 5 FU, and *bleomycin*. Triamcinolone Acetonide (TCA), a long-acting Glucocorticoid has been the most popular drug in

Keloid treatment, alone or in combination. It suppresses the inflammatory process in the wound, diminishes collagen and Glycosaminoglycan synthesis, and fibroblast growth factors are inhibited and enhance collagen and fibroblast degeneration [2,3]. 5-Fluro Uracil (5-FU) It is a pyrimidine analog first introduced in the treatment of keloid by Fitz-Patrick. It inhibits deoxyribonucleic acid synthesis by irreversibly inhibiting thymidine synthase. 5-FU is believed to hinder type-1 collagen gene expression and the effects of TGF-β 1.

Combining TAC and 5-FU has been suggested to have a rapid response in scar flattening. This study was undertaken to compare the combination of Triamcinolone acetonide and 5-FU with Triamcinolone acetonide alone in keloid treatment.

METHODS

This is a single-blind randomized prospective study conducted in the department of plastic and reconstructive surgery, government general hospital, Kurnool. Patients attending the Outpatient Department (OPD) in the department of plastic and reconstructive surgery for one year, from June 2021 to June 2022.

Inclusion Criteria:

- The age group of 10 years-50 years attending the OPD with keloids.
- Size of less than 10 cm.
- Greater than 6 months duration.

All the patients were willing to undergo treatment and follow-up:

- Pregnant and lactating female
- Patients having active inflammation, and ulcers.
- Immunocompromised patients.

Detailed history and demographic parameters were recorded including Etiology and region of keloid. A total of 60 patients were divided into two groups of 30 patients each.

The first group was treated with an injection combination of Triamcinolone acetonide (40 mg/ml)+5-FU (50 mg/ml), the second group with Triamcinolone acetonide (40 mg/ml) injected with an *Insulin* syringe 0.5 ml/m^2 of keloid. Multiple pricks 1 cm apart. This was administered every 3rd week till 24 weeks. The patient received no other therapies like laser therapy, pressure garments, or scar massages during the study. The evaluation was done objectively using the Vancouver Scar Scale (VSS). Vascularity, pigmentation, pliability, and height were assessed. Height was measured with calipers, pliability was assessed with palpation, vascularity was assessed with a visual inspection, and pigmentation was scored. Pain and pruritus were scored.

Data analysis Microsoft-xl 2007, and analyzed by SPSS version 20.0. p-value <0.05 was considered statistically significant.

RESULTS

A total of 60 patients were randomly divided into two groups, every 30 patients (Table 1-3).

Group 1: The combination of Triamcinolone acetonide (40 mg /ml)+5-FU (50 mg/ml).

Group 2: Triamcinolone Acetonide (40 mg /ml).

Age

Table 1 Majority of the patients were of the age group 21 years-30 years

Age group	Group 1	Group 2
Oct-20	6	3
21-30	16	15
31-40	4	5
41-50	4	7

Table 2 Sex distribution

Gender	Group 1	Group 2
Female	16	18
Male	14	12

Table 3 Site of lesion

Site of lesion	Number
Chest	20
Upper extremity	8
Ear lobe	10
Face	6
Shoulder	6
Back	6
Lower extremity	4

The majority of keloids were on the chest followed by ear lobes (Table 4 and 5).

Table 4 Vancouver scar scale for pigmentation, vascularity, pliability and height-Group 1

Vancouver parameter	0 week	3 week	9 weeks	18 weeks	24 weeks	Post drug
Skin pigmentation	2	1.76	0.03	0	0	0
Skin vascularity	1.8	1.36	0.25	0	0	0
Skin pliability	2.33	1.56	0.3	0	0	0
Scar height	1.63	1.26	0.19	0	0	0

Table 5 Vancouver scar scale for pigmentation, vascularity, pliability and height-Group 2

Vancouver parameter	0 week	3 week	9 weeks	18 weeks	24 weeks	Post drug
Skin pigmentation	2	1.5	0.2	0.2	0.2	0
Skin vascularity	1.89	1.15	0.07	0	0	0
Skin pliability	2.26	1.3	0.04	0	0	0
Scar height	1.67	1.19	0.07	0	0	0

There was a recording of pigmentation, vascularity, pliability, and height at every assessment. A statistically significant difference in vascularity and pliability was noted after 6th week, while height and pigmentation were noted after 3rd week. Height, vascularity, and pliability were faster with 5-FU +TAC (Figure 1 and Table 6).

Table 6 Adverse effects

Adverse effects	Group 1	Group 2
Telangiectasia	1	5
Skin atrophy	1	3
Skin ulceration	4	2
Systemic adverse effects	0	0

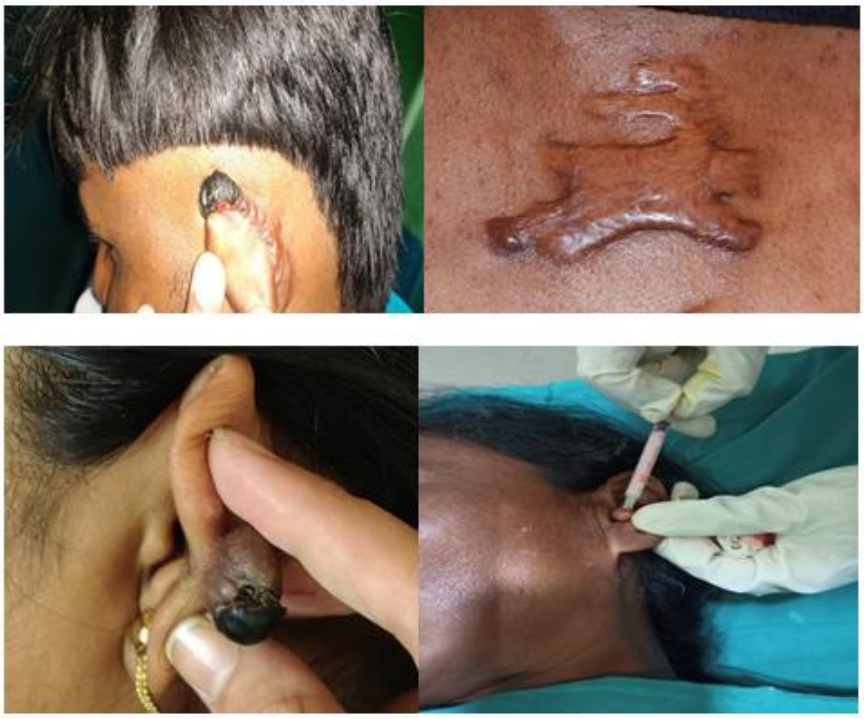

Figure 1 Skin ulcers were more in TAC+5-FU

DISCUSSION

Keloid is an abnormal fibrous tissue outgrowth that extends beyond the borders of the wound. They are a cause of cosmetic and physical and psychological embarrassment to the patient. Intra-lesional TAC acts by decreasing fibroblast proliferation, increasing collagen disintegration, and suppressing inflammation. 5-FU is an antimetabolite that interferes with ribonucleic acid synthesis, and inhibits fibroblast proliferation [4,5].

As a combination TAC has been added to 5-FU in the ratio of 1:9. This dose reduces the side effects of 5FU by its anti-inflammatory nature, consequently, it is hypothesized that the benefits of faster responses of 5FU can be obtained with the combination. The combination regimen has been proven to be better than TAC alone.

A recent meta-analysis by Ren et al concluded that TAC+5FU is safer and more effective than TAC alone. Kontochristopolus G found that 50% improvement with combination therapy of TAC+5FU. Berman B et al, in their study, found significant improvement with combination therapy [6-9].

We have attempted standardization, and comparison using an acceptable scar assessment scale. A lower rate of adverse effects was seen with combination, with no systemic side effects. The limitation was a short follow-up [10]. A combination of TAC+5FU offered balanced benefits of faster and more effective response and fewer adverse effects [11].

CONCLUSION

A combination of TAC+5FU offered balanced benefits of faster and more effective response and fewer adverse effects. The response in treatment was excellent who had keloids of less than two-year duration, and small size. Combination of TAC+5FU has added an advantage over TAC alone.

DECLARATIONS

Conflict of Interest

The authors declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

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