



Research Article

A Prospective Study to Compare the Outcome of Intralesional Triamcinolone Alone and Intralesional Triamcinolone with 5 Fluro-Uracil Combination in Cases of Hypertrophic Scar and Keloid

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Abstract

Objective: A prospective study to compare the outcome of Intralesional triamcinolone alone and intralesional triamcinolone with 5 fluro-uracil combination in cases of hypertrophic scar and keloid.

Material and Methods: The present study was carried in Department of general surgery S.S. Medical College and Associated S.G.M. Hospital, Rewa (M.P.) Total 66 study patients were included in present study. The studied patients were selected from Surgical O.P.D and I.PD during the period from June 2016 to May 2017.

Depending upon the size, site, duration of lesion, age and sex of the patient, the lesion were treated by intralesional triamcinolone alone and intralesional and 5 fluro-uracil combination in cases of hypertrophic scar and keloids". Patients will be categorized into 2 groups:

Group A: Patients with hypertrophic scar and keloid treated with intralesional triamcinolone.

Group B: Patients with hypertrophic scar and keloid treated with intralesional triamcinolone+ 5-fluorouracil.

Evaluation of results for all the 66 patients will be done on the basis of visual inspection and by comparing serial photography.

Results: The 66 subjects in the study were divided into two equal groups of 33(50%) each. Good to excellent results were seen in 18(54.54%) cases in Group A compared to 27(81.81%) in Group B.

Conclusion: A combination regime of intralesional triamcinolone with 5-fluorouracil, found that the combination regime has better results than intralesional triamcinolone alone, in treatment of keloids and hypertrophic scars.

Keywords: 5-Fluorouracil, Hypertrophic scar, Keloid.

Introduction

Hypertrophic scar and keloid are commonly encountered complaints in dermatological practice¹. These abnormal lesions are clinically challenging to treat and can be a source of significant distress to both patients and providers². Lesions exhibit no gender preference, but principally emerge in younger individuals and ethnicities with darker complexions, such as African Americans, Asians, and Hispanics³. An estimated 5–16% of African Americans and Hispanics experience keloid lesions¹. Additional risk factors include a personal history of proliferative scars, a family history of Hypertrophic scar and keloid, and inflammation in and around a wound site⁴. These lesions may depict an aberrant wound-healing response to external physical trauma and represent an underlying complication of the extracellular matrix remodeling process^{3,5}. Lesions can present anywhere on the skin surface where physical trauma has occurred; however the ear lobes, face, arms, shoulders, back, and chest are the most commonly afflicted anatomic locations. Hypertrophic scar and keloid are differentiated clinically by the extent of tissue overgrowth with respect to the boundaries of the original wound⁶. Hypertrophic scar are white to pink colored and persist along the margins of the original wound⁷. Contrastingly, keloid lesions are deep red to purple and have the capacity to proliferate well beyond the original borders of the wound⁸.

A wide range of therapies exist for ranging from intralesional steroid injection, surgical excision, cryotherapy, laser therapy, radiation therapy, application of silicone gel sheets, imiquimod, 5-fluorouracil(5-FU), bleomycin, retinoid, mitomycin C, and interferon-alpha2b.

Even though several modalities of treatment are available for managing keloids, none of the treatments is effective in all patients. Due to unsatisfactory results with individual therapy of the above mentioned modalities combination of two therapies have been used and found to be more effective.⁹⁻¹¹ Intralesional steroid injections

have been the mainstay of treatment for a long time due to its tolerability and effectiveness, but some latest studies have found that Intralesional steroid in combination with 5-fluorouracil is more efficacious and acceptable to patients due to the faster results achieved in comparison to intralesional steroid alone. However there is a paucity of literature comparing the efficacy of intralesional steroid versus intralesional steroid and 5-fluorouracil combination in the treatment for hypertrophic scars^{9,10}.

Through this study we will assess, and compare the efficacy of both regime (triamcinolone, and triamcinolone with 5 flourouracil,) in treatment of hypertrophic scar and keloid.

Materials and Methods

The present study “A prospective study to compare the outcome of intralesional triamcinolone alone and intralesional triamcinolone and 5 fluro-uracil combination in cases of hypertrophic scar and keloid” was carried in Department of general surgery S.S. Medical College and Associated S.G.M. Hospital, Rewa (M.P.) Total 66 study patients were included in present study. The studied patients were selected from Surgical O.P.D and I.PD during the period from June 2016 to May 2017 using following inclusion and exclusion criteria.

Inclusion criteria

- Patient 12 years and above with hypertrophic scar and keloid.

Exclusion criteria

1. Patient below 12 years.
2. Patients with any co morbidities such as cardiovascular diseases, diabetes mellitus, any liver and renal diseases.
3. Patient taking treatment for the hypertrophic scar and keloid in the last 3 months.
4. Pregnant women.
5. Patient hypersensitive to drugs.
6. Patient didn't come for follow-up.
7. Patient didn't give consent

On their attendance chief complaints with duration was noted .Previous history for burn,

trauma, surgery septic lesion e.g boil etc was noted in detail about its mode and duration .Vitals were noted in general examination and following this a thorough local examination was done. In local examination, we noted the size, shape, surface, consistency of the lesion. Skin and joints surrounding the lesion was examined whether the scar was extending beyond the original trauma site, any limitation in functioning of joint were recorded in the proforma. The diagnosis of hypertrophic scar or keloid was made .Patients haemoglobin, total leucocyte count, urine analysis, blood sugar and renal and liver function test will be estimated.

Depending upon the size, site, duration of lesion, age and sex of the patient, the lesion were treated by intralesional triamcinolone alone and intralesional and 5 fluoro-uracil combination in cases of hypertrophic scar and keloids". Patients will be categorized into 2 groups:

Group A: Patients with hypertrophic scar and keloid treated with intralesional triamcinolone.

Group B: Patients with hypertrophic scar and keloid treated with intralesional triamcinolone+ 5-fluorouracil.

Evaluation of results for all the 66 patients will be done on the basis of visual inspection and by comparing serial photography.

Statistical Analysis

Collected data were entered in the Ms Excel spreadsheet, coded appropriately cleaned for any possible errors in SPSS (Statistical Package For Social Studies) for Windows Version 20.0.

All tests were performed at a 5% level significance, thus an association was significant if the value was less than 0.05(p value <0.05).

Results

TABLE No-1 Distribution of patients according to the type of Lesions

S.No	Type of Lesion	No. of Cases	Percentage
1	Hypertrophic scar	28	42.2
2	Keloid	38	57.8
3	Total	66	100

It is evident from the above table that we had maximum number of patients who had keloid 57.8% followed by patients who had hypertrophic scar 42.2%.

Table No-2 Distribution of patients according to treatment

S.No	Group	Treatment	No of patients
1	A	Intralesional triamcinolone alone	33
2	B	Intralesional triamcinolone and 5 fluorouracil combination	33
Total			66

It is evident from the above table that we had 33 patients with hypertrophic scar and keloid treated with intralesional triamcinolone alone (Group A) and 33 patients with intralesional triamcinolone and 5 –FU combination (Group B) .

Table no-3 Distribution of patients of Hypertrophic scar according to treatment modality

S.No	Treatment	No of cases	%
1	Group A	16	57.1%
2	Group B	12	42.9%
Total		28	100%

It is evident from the above table that out of 28 patients of hypertrophic scar 16 were treated by intralesional triamcinolone alone 57.1% while 12 (42.9%) cases treated with intralesional triamcinolone with 5-FU combination.

Table No-4 Distribution of patients of Keloid according to treatment modality

S.No	Treatment	No of Cases	%
1	Group A	17	44.7%
2	Group B	21	55.3%
Total		38	100%

It is evident from the above table that out of 38 patients of hypertrophic scar 17 (44.7%) were treated by intralesional triamcinolone alone while 21(55.35%) cases treated with intralesional triamcinolone with 5-FU combination.

Table No -5 Outcome of treatment in Group A and Group B Patients with Hypertrophic scar

S.No	Treatment	Very Good	Good	Poor	No Response	Total
1	Group A	0	9	6	1	16
2	Group B	2	8	2	0	12
Total		2	17	8	1	28

It is evident from above table that total out of 28 patient 16 patients were treated with intralesional triamcinolone alone (Group A), symptomatic improvement occurred in 9 cases while result of 6 patients were cosmetically unsatisfactory and 1 patient show no improvement while 12 patients

were treated with intralesional triamcinolone and 5-FU(Group B), cosmetically satisfactory response with relief of symptoms was seen in 2 patients while symptomatic improvement occurred in 8 cases while result of 2 patients were cosmetically unsatisfactory

Table No-6 Outcome of treatment in Group A and Group B Patients with Keloid

S.No	Treatment	Very Good	Good	Poor	No Response	Total
1	Group A	1	8	8	0	17
2	Group B	3	14	4	0	21
Total		4	22	12	0	38

It is evident from above table that total out of 38 patient 17 patients were treated with intralesional triamcinolone alone (Group A), cosmetically satisfactory response with relief of symptoms was seen in 1 patient while symptomatic improvement occurred in 8 cases while result of 8 patients were cosmetically unsatisfactory while 21 patients

were treated with intralesional triamcinolone and 5-FU(Group B), cosmetically satisfactory response with relief of symptoms was seen in 3 patients while symptomatic improvement occurred in 14 cases while result of 4 patients were cosmetically unsatisfactory.

Table No 7 Total outcome of treatment in Group A and Group B patients with hypertrophic scar

S.No	Treatment	Success (V.Good/good)	Failure(Poor/No Response)	Total
1	Group A	9(56.25%)	7(43.75%)	16
2	Group B	10(83.33%)	2(16.66%)	12

It is evident from above table patient of hypertrophic scar treated with intralesional triamcinolone alone (Group A) was successful in

9 cases while treatment with intralesional triamcinolone and 5-FU combination (Group B) was successful in 10 cases

Table No 8 Total outcome of treatment in Group A and Group B Patients with Keloid

S.No	Treatment	Success (V.Good/good)	Failure(Poor/No Response)	Total
1	Group A	9(52.94%)	8(47.05%)	17
2	Group B	17(80.95%)	4(19.04%)	21

It is evident from above table patient of hypertrophic scar treated with intralesional triamcinolone alone (Group A) was successful in

9 cases while treatment with intralesional triamcinolone and 5-FU combination (Group B) was successful in 17 cases.

Table No-9 Outcome of treatment in Group A and Group B

S.No	Treatment	Very Good	Good	Poor	No Response	Total
1	Group A	1	17	14	1	33
2	Group B	5	22	6	0	33
Total		6	39	20	1	66

It is evident from above table that out of 66 patients 33 patients were treated with intralesional triamcinolone alone (Group A) out of which 1 cases showed complete relief of symptoms along with flattening of scar , 17 of them showed symptomatic relief with partial flattening of scar while 14 had cosmetically unsatisfactory results

and 1 had no response while 33 patients treated with intralesional triamcinolone and 5-FU (Group B) out of which 5 cases showed flattening of scar with relief of symptoms.22 of them showed subjective relief of symptoms of itching and pain with partial flattening ,in 6 cases there was cosmetically unsatisfactory result

Table no-10 Total outcome of treatment in Group A and Group B

S.No	Treatment	Success (very Good +Good)		Failure (Poor+No Response)	
1	Group A	18	54.54%	15	45.45%
2	Group B	27	81.81%	6	18.18%

It is evident from the above that 33 patients in Group A treated with intralesional triamcinolone alone success was obtained in 63.64% cases and failure in 36.36% cases while 33 patients in Group B treated with intralesional triamcinolone and 5-

FU success was obtained in 81.81% cases and failure in 18.18% cases.

Difference observed in the response seen in Group A and B was statistical significance using chi square test (5.657) with P value < 0.05 with degree of freedom 1.

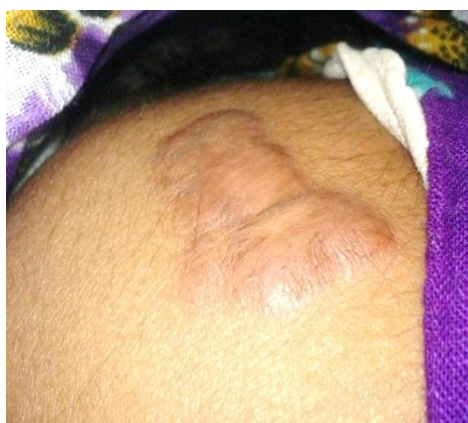


Fig1 before intralesional triamcinolone



Fig 2 after intralesional triamcinolone



Fig 3 before intralesional triamcinolone+ 5FU



Fig 4 after intralesional triamcinolone+ 5FU

Discussion

The problem of unsightly scar, raised, wide scars, thick scars, cicatrizing scars, pigmented scars, keloids and contracture are common occurrence. They are not only cosmetic problem but at any times they can cause considerable morbidity due to associated symptoms like itching pain etc. Human beings are still far away from the position where they can claim that they cannot obtain a perfect scar not they can always be successful in treating or curing these lesions. However, various studies have been undertaken by various workers to analyze patients of these scars with reference to age, sex, presenting complaints, locations, and different modalities of treatment. In present study we compare the outcome of intralesional triamcinolone alone and intralesional triamcinolone and 5 fluorouracil combination in case of hypertrophic scar and keloid which was carried over duration of 1.0 year on 66 patients.

Response of patients to treatment regimens

In the present study that primary outcome evaluated was the percentage of flattening as well regression in size and subjected symptoms (itching and pain) of keloid in hypertrophic scar as a main parameter of efficacy.

The two treatment regimen groups, group A, (triamcilone alon) and group B (combination of triamcilone and 5-fluorourecil) were comparable with respect to age sex, site and duration of lesion.

In Group A: Intralesional triamcinolone acetamide

Out of 33 patients 18 (54.54%) patients showed very good to good response followed by 15(45.45%) patients poor to no response. Relief of symptoms were in all patients.

Brain et al¹² in his study found that use of intralesional triamcinolone acetamide (10-40mg/ml) injection was associated with significant response rate in 50-100% of cases.

In the study of Grffith 37 patients treated with triamcinolone acetamide complete flattening of lesions in 19(51%) patient and partial dissolution (softening in 15(40%) patients. In all instances there was a relief of symptoms.¹³

In the study of Grffith et al, out of 61 patient,42 (69%) patients showed complete flattening (excellent response) of lesions and in 13 (21%) patients lesion became softer. Dramatic relief of symptoms was seen in all patients.¹⁴

In Group B: Intralesional triamcinolone and 5-FU combination

Out of 33 patients, 27 (81.81%) patients showed very good to good response followed by 6 (18.18%) patients showed poor response.

A study by Asilian A, et al had showed that the combination of TAC (40 mg/mL) and 5-FU (50 mg/mL) (1:9) once weekly for 2 months, injected strictly intralesionally, shown to be superior to exclusive weekly injection of TAC 40 mg/mL.¹⁵

Darougheh A et al¹⁰ found that combination of TAC (40 mg/mL)/5-FU (50 mg/mL) (1:9) had better results with respect to reduction in size and redness, compare to the injection of TAC 40 mg/mL alone in keloids and hypertrophic scars,.

Davison SP et al¹⁶. suggested that intralesional injection of a combination of 5-FU (50 mg/mL) and TAC (40 mg/mL) for the treatment of keloids were superior to the TAC alone.

Treatment outcome in Group A and B Regimen

In our study, when we compared both groups for treatment response we found that out of 33 patients, 18 (54.54%) patients of group A had very good to good response compare to 27 (out of 33) patients (81.81%) of group B experienced very good to good response.

In group A, we noted that 18 patients (45.45%) had poor/no response, compare to group B patients, in which 6 patients (18.18%) had poor/no response.

Difference observed in the response seen in Group A and B was statistical significance using chi square test (5.657) with P value < 0.05 with degree of freedom 1.

Many other studies had also shown that combination of triamcinolone with 5-fluorouracil had better treatment efficacy compare to triamcinolone alone^{10,11}.

Conclusion

As keloid and hypertrophic scar both affect badly to the social, and personal life of patients, there is a great need of a regime which has better efficacy compare to other regime. In our study we compare a combination regime of intralesional triamcinolone with 5-fluorouracil, to the conventional intralesional triamcinolone alone, and found that the combination regime has better results, in treatment of keloids and hypertrophic scars, which decreases the impact of disease on patients life, burden of disease in community.

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