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A comparative study of efficacy of intralesional triamcinolone, topical silicone gel sheet and intralesional triamcinolone plus topical silicone gel sheet in treatment of keloid or hypertrophic scar

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A B S T R A C T

Background: There is no universally accepted treatment resulting in permanent hypertrophic or keloid scar ablation. Multiple modalities of treatment have been advocated. Most of these modalities have a variable and transient success. Hence there is need for evaluation of better modalities to achieve good cosmetic acceptability. **Aim**: To study the efficacy and safety of intralesional triamcinolone, topical silicone gel sheet and intralesional triamcinolone plus topical silicone gel sheet in treatment of keloid or hypertrophic scar. **Methods**: Total 150 patients with keloid or hypertrophic scar, randomly divided into three groups (50 each), treated with intralesional triamcinolone (Group A), topical silicone gel sheet (Group B) and intralesional triamcinolone plus topical silicone gel sheet (Group C) for a maximum period of 6 month. The groups were compared for reduction in size and the side effects. Ultrasonography of the lesions using 10-12 MHz Linear transducer was done to assess the baseline dimension before starting the treatment & at the end of the study period. Clinical improvement was assessed by photography & measurement scale serially till the scar flattened at each visit. **Results**: The overall therapeutic response in terms of size reduction in group C was found to be better and statistically significant (p value < 0. 01) compare d to group A & B. Conclusion: Combination therapy was more effective with faster results and few side effects.

Keywords: Keloid, Silicone gel sheet, Ultrasonography, Intralesional triamcinolone

Introduction:

Keloids and hypertrophic scars (HSc) are dermal fibroproliferative disorders characterized by excesses deposition of collagen in the dermis and the subcutaneous tissues that results in disfigurement, contractures, pruritus and pain. Because keloids are cosmetically disfiguring and associated with itching, pain, treatment is necessary.

Treatment of keloids is challenging for dermatologist; no standard treatment protocol exits. Though triamcinolone has been used as gold standard since 1980's, its efficacy is high in initial doses ranging from 50% to 90%, but keloids tend to relapse with triamcinolone (TAC) after initial good response. Other various treatment modalities available are Intralesional 5-Fluorouracil, Bleomycin, Interferon α2β, verapamil, imiquimod 5% cream, pressure therapy, Silicone products (cream, gel sheet, silastic sheet, orthosis and garments), radiotherapy, cryosurgery, lasers (Carbon dioxide laser, Pulsed Dye Laser (PDL)) and surgical excision.

Currently, silicone gel sheets are also emerging as an equally effective treatment modality with fewer side effects and advantages of easy administration, even for sensitive skin and in children. After thorough searching of literature, there were

only few studies found on comparison of intralesional triamcinolone vs. topical silicone gel sheet in Keloid or Hypertrophic scars. None of the study compared the combination of topical gel sheet plus intralesional triamcinolone with either of the modality in keloid/ Hsc.

Hence our primary objectives were to evaluate & compare the efficacy of intralesional triamcinolone, topical silicone gel sheet and combination of both in the treatment of keloid/ HSc. Secondary objectives were to evaluate side effects, recurrences & epidemiology of patients of keloid or hypertrophic scar.

Methods & material:

Study design

This was a hospital-based interventional comparative study conducted in outpatient department of dermatology over a period of 1 year from July 2018 to June 2019. Clearance for the study was obtained from the institutional ethics committee.

Sample size : Total 150 patients (50 patients in each category).

Sample size was calculated at 95% confidence interval assuming an expected 70% or more efficacy (as per findings of a previous study) of each procedure and taking 20% relative allowable error. Sample size was calculated using the formula for sample size for estimation of proportion– 2 Where = Standard normal deviate for 95% confidence interval (taken as 1.96)

P = expected efficacy of each procedure (assumed as 70%) E = relative allowable error (taken as 20% of P) Sample size was calculated to be to be minimum 43 subjects. Considering 10% attrition, sample size was enhanced and rounded off to 50 subjects for each procedure.

All patients with keloids, irrespective of age of patient, size or site of the keloid were included in the study after due consent. Pregnant and lactating mothers and patients with concomitant illnesses like renal failure, hepatic failure, acid peptic disease, diabetes, and hypertension, and immunocompromised patients, were excluded from the study.

Detailed history, clinical examination & baseline investigation of enrolled patients were done. The sample size of 150 patients was randomized into three groups of 50 patients in each group by simple randomization method using random allocation software for window.

Group A included 50 patients treated with intralesional triamcinolone (40 mg/ ml) in a dosage according to the size of their keloid/ HSc and the age of the patient at interval of 2 weeks, maximum up to 12 sittings, Group B included 50 patients treated with topical silicone gel sheet according to the size of their keloid or hypertrophic scar for 12-24 hours a day maximum for 6 month and will be evaluated at every 2 weeks interval and Group C included 50 patients treated with combination of topical silicone gel sheet 12-24 hours a day maximum for 6 month along with intralesional triamcinolone acetonide administered at intervals of 2 weeks, maximum up to 12 sittings.

Ultrasonography of the lesions using 10-12 MHz Linear transducer was done to assess the baseline dimension before starting the treatment & at the end of the study period. Clinical improvement was assessed by photography & measurement scale serially till the scar flattened at each visit. Also at every visit, lesions were examined regarding their pain, oedema, bullae formation, ulceration, secondary infection, pigmentary changes, flatness and recurrence.

At the end of study period, the response to treatment in terms of flattening of the lesions were categorized as excellent: > 76 % improvement; good: 51- 75% improvement; fair: 26- 50% improvement; and poor: <25 % improvement.

All the patients were followed up for 6 months to note the recurrence of lesions. The results achieved were recorded on the prescribed Proforma and subjected to relevant statistical analysis at the end of the study.

Statistical Analysis:

Results were expressed as number and percentage for each category. Categorical data was analysed by chi- square test to correlate between the groups. P-value of 0.05 or less was considered for

statistical significance. P-value of more than 0.05 was considered for statistical non- significance.

Results:
150 patients (50 each in group A, B & C) were enrolled in the study after informed consent, 13 patients were lost to follow up of which 6 from Group A, 4 from group B & 3 from Group C respectively.

Out of 6 patients who were lost to follow up in Group A, 4 discontinue due to severe pain and 2 discontinued due to lack of improvement and 3 patients were lost for follow up in Group B due to lack of improvement. Out of 4 patients who were lost to follow up in Group C, 2 discontinued due to severe pain and 2 discontinued due to unknown reason. Overall, majority of the patients 42% (n= 6 3) were in the age group of 21 -30 years. Out of which Group A had 50% (n= 25), Group B had 36% (n= 18) & Group C had 40% (n= 20) patients respectively. The range of patients in the study was 3year to 72year. Over all male to female ratio was found 1: 1. 3 1. Overall majority of keloids were seen over the chest in 36% (n = 5 3), followed by lower extremity in 25% (n = 38), upper extremity in 21% (n= 32), face in 7% (n= 11), back in 6% (n= 9), ear lobe in 3% (n= 4) and abdomen in 2% (n= 3).

In this study commonest predisposing factor for keloid/ HSc was trauma in 29% (n = 4 3) patient s, followed by idiopathic occurrence in 23% (n= 35), infection in 15% (n= 23), acne in 10% (n= 15), burn in 11% (n= 17), post- surgical scars in 9% (n= 12) and ear piercing in 3% (n= 4) patients respectively. In our study there was significant difference between response of Group- A Vs. Group- C and Group- B Vs. Group- C. Group- C showed better results in terms of size reduction compare d to both Group A & Group B which was statistically significant (P- value < 0.05) (Table 1).

Table– 1: Treatment outcomes in all regimens

	Excellent	Good	Fair	Poor	Total	Chi Square	P Value	Interpretation
	30(68 %)	6(14 %)	5 (11 %)	3(7%)	44*			
Group B	25(54 %)	10(22%)	8(17 %)	3(7%)	46*			
Group C	43(91 %)	2(4%)	1(2%)	1(2%)	47*	16.64	0.0107 1	Significant
Total	98	18	14	7	137*			
%Age	72%	13%	10%	5%	100%			
Comparison between		Group A & B				2.103	0.5512	Not Significant
Comparison between		Group B & C				16. 5 3	0.000881 3	Significant
Comparison between		Group A & C				7. 89 1	0.04831	Significant

*Out of 150 patients, 13 patients were lost to follow up of which 6 from Group A, 4 from Group B & 3 from Group C respect iv e l y
The difference in overall response according to duration of lesion & three groups was found significant (p < 0.05). (Table 2)

Table:2- **Duration of lesions and outcome**

	0- 2 Year	> 2 Year	Total	Chi-Square	P- Value	Interpretation
Excellent	73(80 %)	25(54 %)	98	13.5	0.003665	Significant
Good	7(8%)	11(24 %)	18			
Fair	9(10 %)	5(11 %)	14			
Poor	2(2%)	5(11 %)	7			
Total	91	46	137*			

Excellent response (irrespective of grouping) was seen maximum in 83% (n=24) patients who had lesions over the upper extremity followed by chest in 70% (n=32) & poor response was seen maximum in 33% (n=1) patients out of the total 3 patient of abdomen keloid. (Table:3)

Table: 3 Site of lesions and outcome

	Excellent	Good	Fair	Poor	Total	Chi Square	P Value	Interpretation
Chest	32	10	2	2	46			
%Age	70%	22%	4%	4%	100 %			
Upper Extremity	24	3	1	1	29			
%age	83%	10%	3%	3%	100 %			
Lower Extremity	25	2	7	3	37			
%age	68%	5%	19%	8%	100 %	21.81	0.2405	Not Significant
Ear Lobe	2	0	1	0	3			
%age	66%	0%	33%	0%	100 %			
Face	8	1	2	0	11			
%age	73%	9%	18%	0%	100 %			
Back	5	2	1	0	8			
%age	63%	25%	13%	0%	100 %			
Abdomen	2	0	0	1	3			
%age	67%	0%	0%	33%	100 %			
Total	98	18	14	7	137			

In Group- A, 45% (n=20) patients developed atrophy, 14% (n=6) showed hypopigmentation, 9% (n=4) showed depigmentation, 7% (n=3) had erythema, 41% (n=8) showed telangiectasia, 11% (n=5) had ulceration and 44% (n=15) had hyperpigmentation respectively. Ulceration healed with the use of topical antibiotics in 10- 15 days without discontinuation of treatment.

In Group B, 15% (n=7) patients developed atrophy, 4% (n=2) had hypopigmentation, 2% (n=1) had depigmentation, 9% (n=4) showed telangiectasia and 35% (n=12) had hyperpigmentation respectively. None of the patient had erythema and ulceration in Group- B.

In Group- C, 30% (n=14) patients developed atrophy, 9% (n=4) had hypopigmentation, 4% (n=2) had depigmentation, 2% (n=1) had erythema, 27% (n=13) showed telangiectasia, 2% (n=1) had ulceration and 21% (n=7) had hyperpigmentation respectively.
In this study, there was statistically significant difference in side effects in form of atrophy, telangiectasia & ulceration between Group A and Group B (p- value < 0.05). Beside this there was statistically significant difference in telangiectasia between Group B & Group C (p- value < 0.05). (Table: 3-4)

Table- 4: Side effects

	Yes	No	Total	Chi Square	P- Value	Interpretation
Group A	31(70 %)	13(30 %)	44*			
Group B	15(33 %)	31(67 %)	46*			
Group C	20(43 %)	27(57 %)	47*	13.81	0.001004	Significant
Total	66(48 %)	71(52 %)	137*			
Comparision between Group A & Group B				12.89	0.0003302	Significant

Comparision between Group B & Group C	0.9795	0.3223	Not Significant
Comparison between Group A & Group C	7.181	0.007366	Significant

Overall, 36% patient showed recurrences irrespective of grouping. Group B & Group C showed statistically significant difference (P- value< 0 .05). (Table-5)

Table- 5: Recurrence

	Yes	No	Total	Chi Square	P-Value	Interpretation
Group A	15(34 %)	29(66 %)	44			
Group B	23(50 %)	23(50 %)	46			
Group C	12(26 %)	35(74 %)	47			
Total	50(36 %)	87(64 %)	137	6.167	0.04580	Significant
Comparision between Group A & Group B				2.333	0.1267	Non- Significant
Comparision between Group B & Group C				5. 93	0. 01 4 8 9	Significant
Comparision between Group A & Group C				0.7978	0.3718	Non- Significant

Pre & Post DLQI score was more in Group C (13.36) in compare to Group A (11.5) and Group B (10.5). Thus, the study confirmed that the patient satisfaction rate was more in Group C patients at the end of the treatment. (Table- 6)

Table: 6 DLQI

	Pre DLQI Score		**Post DLQI Score**		**Difference**
	Mean	**S.D.**	**Mean**	**S. D.**	
Group A	16.59	± 1. 96	5.09	± 2. 45	11.50
Group B	16.93	± 1. 83	6.43	± 2. 76	10.50
Group C	17.30	± 2. 22	3.94	± 1. 62	13.36

Discussion:

In our study, age range was 3 years to 72 years & around 60% of patients were within the age of 30 years. That may be due to more chances of trauma & more cosmetic concern in these age group. Male to female ratio was 1.31: 1 (F: M). This is in accordance with earlier studies by **Arnold *et al* 1**, and **Cosmon *et al* .2** In our study the higher incidence in females probably reflects a greater cosmetic concern about the keloid and more due to ear piercing in females. Most common site of keloid was chest (36%) and least common site was Abdomen (2%). **These finding similar to study of Brain *et al* 3**, **Muir *et al* 4** & **Bayat *et al* 5.** Trauma was the commonest factor seen in 29% of the patients followed by idiopathic occurrence (23%) and infection (15%).

RESPONSE OF PATIENTS TO RESPECTIVE REGIMENS:

In our study, the primary outcome evaluated was the percentage of flattening as well regression in size of keloid, as a main parameter of efficacy. The three treatment regimens were comparable with respect to age, sex, site and duration of lesion, with statistically non-significant difference (p> 0.05).

In Group A: **Intralesional triamcinolone acetonide.** Out of 50 patients, 6 patients lost to follow up. Out of remaining 44 patients, 30 (68%) patients showed excellent response **(figure- 1)** followed by good response in 6 (14%) patients and fair response in 5 (11%) patients. **Brain *et al* 3** found significant response rate in 50- 100 % of cases & **Griffith *et al* 6** revealed complete flattening of lesions in 51% patients. In another study of **Griffith *et al* 7**, 69%) patients showed complete flattening (excellent response) of lesions.

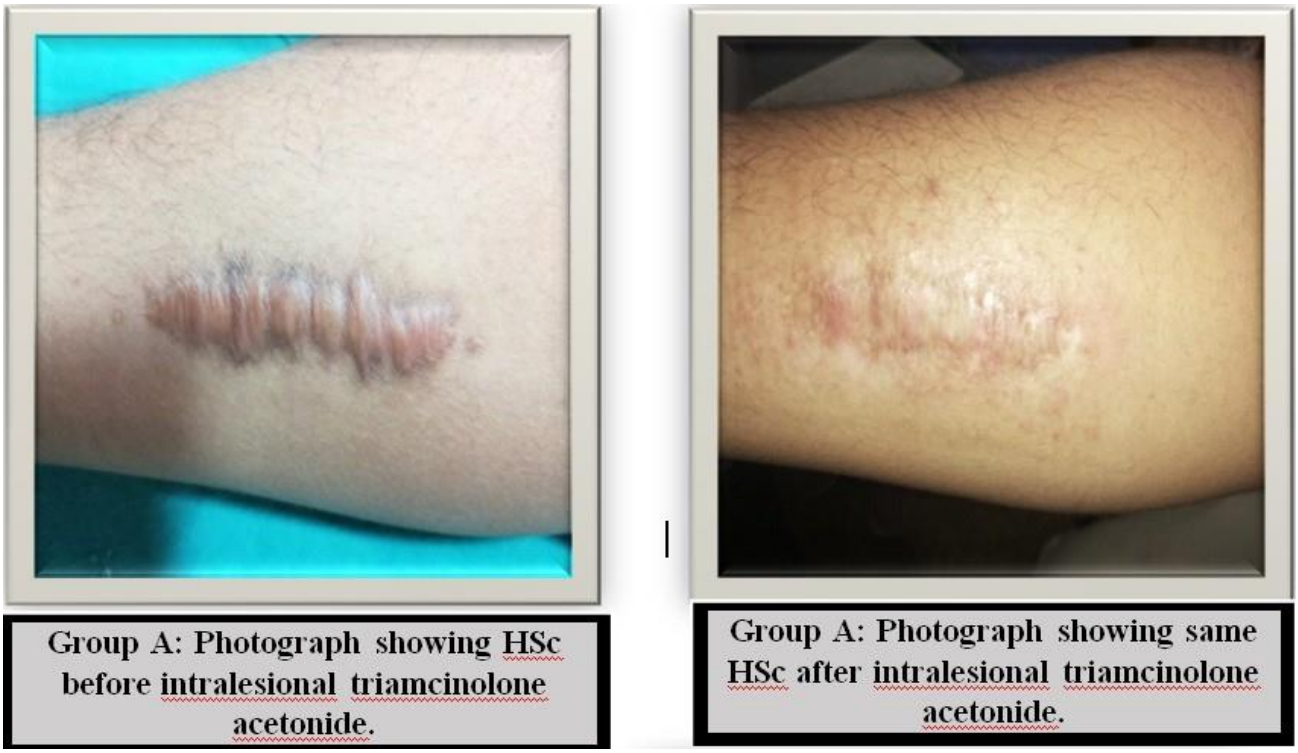


Figure 1:- Showing Hypertrophic scar before and after intralesional triamcinolone therapy.

In Group B: **Topical silicone gel sheet** - Out of 50 patient, 4 patients lost to follow up. Out of remaining 46 patients, 25 (54%) showed excellent response followed by good response in 10 (22%) patients **(figure- 2)**, fair response in 8 (17%) patients and poor response in 3 (10%) patients. A study by **Dockery *et al* 8** in Seattle reported overall success rate as being high, with 95% greatly or somewhat improved with topical silicone gel sheeting to scars on the lower extremities. **N Puri *et al* 9** & **Katz BE *et al* 10** showed excellent response in 60% & 56 % patients respectively, when applied the silicone gel sheet over scars. **Lee *et al* 11** compared the treatment of hypertrophic scars, postoperative scars, tattoo scars and keloids using two types of silicone gel sheeting. Both treatments resulted in an improvement of 90% in color and texture, 80% in regularity and 50% in thickness. Overall improvement in at least two parameters was reported for 80% of the scars after six months.

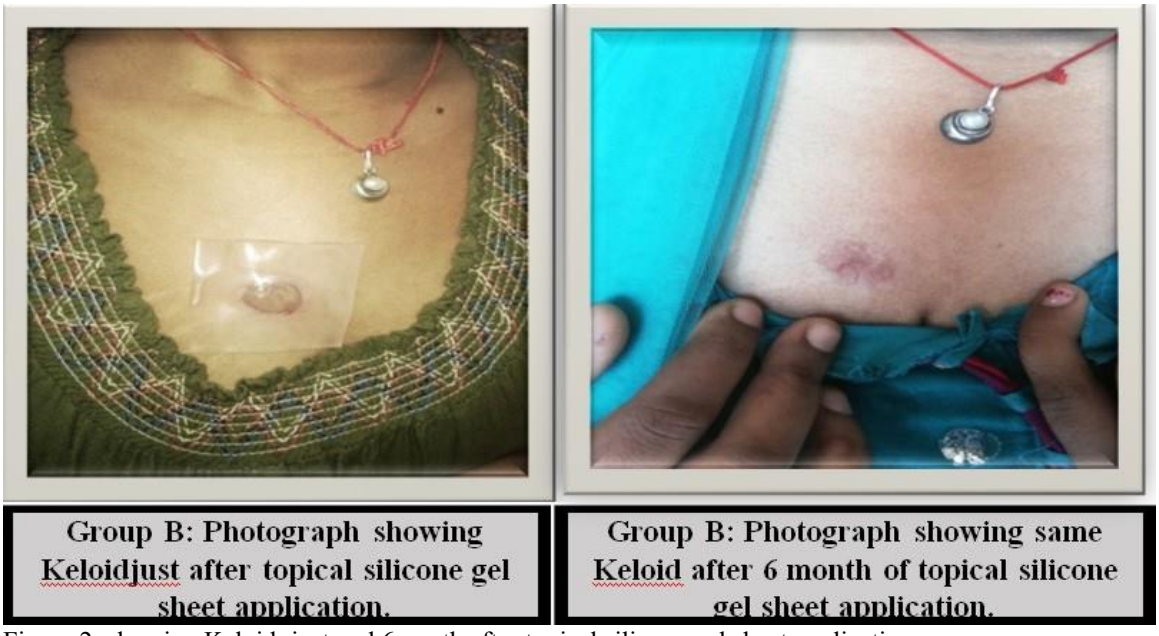
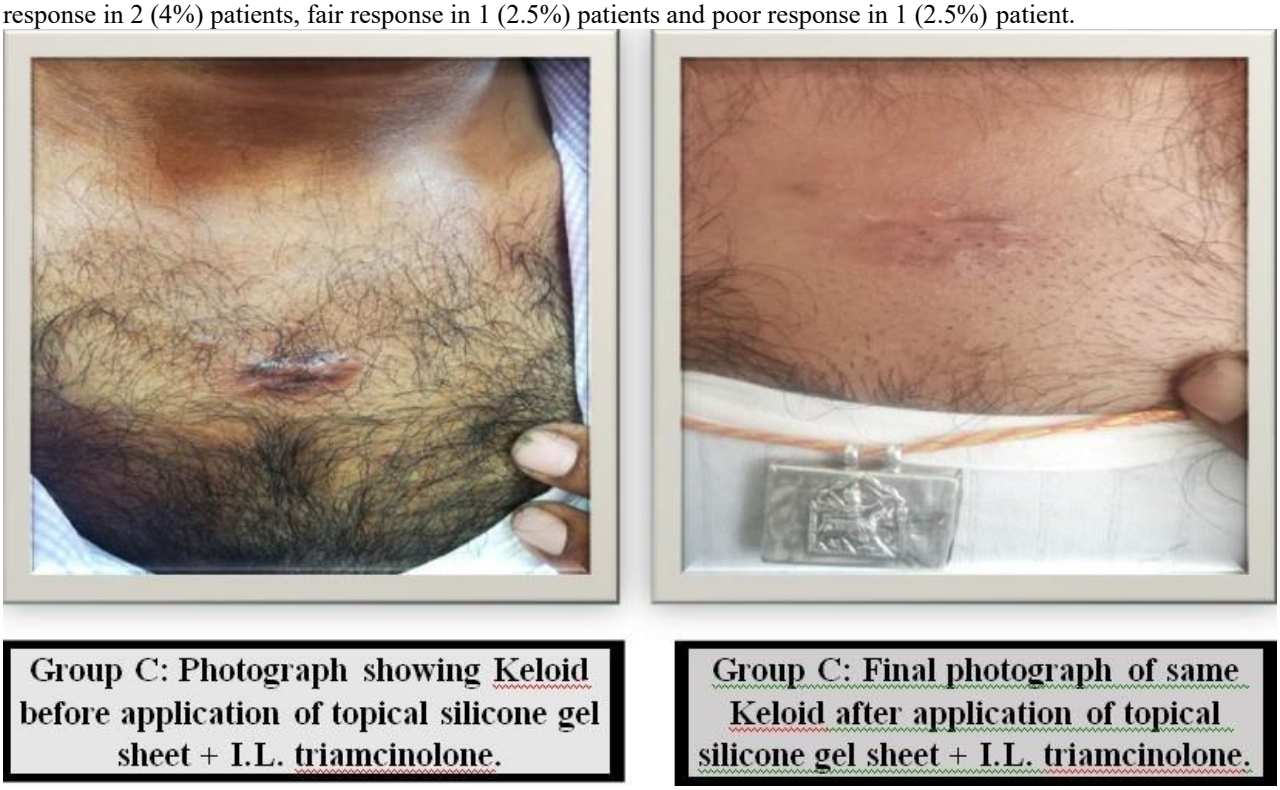


Figure 2: showing Keloid just and 6month after topical silicone gel sheet application.

In Group C: Topical silicone gel sheet plus intralesional triamcinolone. Out of 50 patient, 3 patients lost to follow up. Out of remaining 47 patients, 43 (91%) showed excellent response **(figure- 3)** followed by good response in 2 (4%) patients, fair response in 1 (2.5%) patients and poor response in 1 (2.5%) patient.



Group C: Photograph showing Keloid before application of topical silicone gel sheet + I.L. triamcinolone.

Group C: Final photograph of same Keloid after application of topical silicone gel sheet + I.L. triamcinolone.

Figure 3: Showing Keloid before and after intralesional triamcinolone and topical silicone gel sheet combination therapy.

Treatment outcome in all groups: Group C patients showed 91% (43/47) excellent response. Second best results seen in Group A, in which 68% (30/44) patient showed excellent response. In this study there was significant difference found between response of Group A vs. Group C patients and Group B Vs. Group C patients. Group C patients who were applied topical silicone gel sheet plus intralesional triamcinolone, were found most effective in compare to Group A & Group B patients respectively & it was statistically significant also (p value < 0.05). That's possibly due to the additive effect of different mechanism of action of both topical silicone gel sheet & intralesional triamcinolone acetonide. There was no significant difference (p value > 0.05) between Group A & Group B.

Duration of lesion and outcome: This study showed that irrespective of treatment regimens the patients with keloids of < 2 years duration showed maximum (80%) excellent results. In this study there was significant difference found between efficacy of regimens and duration of lesion (P < 0.05). These results are similar to study of **Ketchum *et al*,** 12. In our study there was no significant difference found between efficacy of regimens and site of lesion.

SIDE EFFECTS: Side effects were also studied to assess the safety of the regimens. Maximum number of side effects i.e., atrophy at injection and telangiectasia were seen in Group A patients, in 70% (n= 31) patients followed by 43% (n= 20) in Group C patients. Side effects were least in 15 (33%) patients in Group B. 101

Group A had statistically significant difference in side effect in form of atrophy, telangiectasia & ulceration in compare to Group B (p- value < 0.05). Beside this, Group C also had statistically significant telangiectasia in compare to Group B (p-value < 0.05). Other side effects in all three regimens were comparable.

Griffith *et al* 7 in his study reported that use of intralesional triamcinolone acetonide for treatment of keloid was associated with atrophy in 10(16.4 %) out of 61 patients and peripheral depigmentation in 2(3.2%) patients. Our side effects with triamcinolone were comparable with **Griffith *et al* 6** study.

In Group B, out of 46 patients only 7 patients had atrophy, 12 patients had hyperpigmentation at injection site and 4 had telangiectasia. None of the patient had erythema or ulceration. Side effects were minimal in compare d to Group A & Group C as Group B did not had steroid in their regimen.

Katz BE *et al* 10 in his study found that side effects were minimal with silicone gel sheeting in all those 14 patients who applied topical silicone gel sheet. Thus, it is safe and effective treatment for hypertrophic and keloid scars. In the study of **Iris Westra *et al* 13**, most prominent side effect was itching or irritated skin. Twenty- seven patients (12.1 %) reported being inconvenienced by the diminished adhesive power of the sheet, which can be posed as a side effect of the usability. In Group C, patients had more side effect compared to Group B but less than that of Group A patients. However, this data was not statistically significant (p value > 0.05). 14(30 %) patients had atrophy,13(28 %) patient had telangiectasia,7(15 %) had hyperpigmentation and 4(%) had hypopigmentation. Erythema & ulceration was seen only in 1(2%) patient. In this study overall recurrences seen in 36%. Maximum recurrence was seen in Group B (50%), followed by in Group A (34%). Least recurrence was noted in Group C in 12 (26%) patients only. Use of intralesional triamcinolone acetonide was associated with recurrence rate of 9- 50% in a study by **Brain *et al* 3** and 18% in **Griffith *et al* 7** study.

Katz BE *et al* 10 in his study found that eleven of fourteen fresh hypertrophic scars (79%) did not recur after surgery during a similar follow-up period.

Limitations:
This was a unicentric study with small sample size & with no blinding at all. The study also didn't differentiate between keloid & hypertrophic scar. Only the size reduction was included as final outcome parameter.

Conclusion:
Intralesional triamcinolone, topical silicone gel sheet and and their combination are all effective in keloid & hypertrophic scars. A combination therapy seems to offer the balanced benefit of faster and more efficacious response with lesser adverse effects when compared to individual therapy. Treatment has to be individualized and can be combined with one or more modalities to aim for better efficacy and safety.

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