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A CLINICAL STUDY OF ROLE OF TRIPLE THERAPY IN MANAGEMENT OF KELOIDS

Plastic Surgery

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ABSTRACT

BACKGROUND:- Wound healing is a dynamic biological process and if it goes wary, ends up with keloids whose treatment is complex and controversial.

OBJECTIVES: The aim is to study the efficacy of triple therapy-combination of Intra-lesional triamcinolone injections, Surgical excision and silicone gel sheets in the management of keloids and their outcome in patients at Gandhi Hospital, Secunderabad between 2015 to 2017.

METHODS:- 20 patients belonging to both sexes, age between 5 to 60 years were included and patients with comorbid conditions were excluded from the study.

RESULTS: 40% of patients belonged to the age group of 21-30 years 90% were females and the most common site of keloid was ear in 90% of cases.

CONCLUSION: -Triple therapy for Keloids is an effective treatment protocol with 5% recurrence and post op POSAS Score less than 15.

KEYWORDS

Keloid, triple therapy, recurrence

INTRODUCTION: -

Keloid is a firm, irregularly shaped, thickened, hypertrophic, fibrous pink or red growth extends beyond the original defect. In course of time keloid becomes brown, sometimes hyper-aesthetic often it is extremely tender, painful, pruritic, hard and stationary and commonly seen on pre-sternum, shoulder and earlobe. They may be single or multiple and often varying in size and number. The first recorded description of Keloid like scars appears in the Smith Papyrus[1] "the existence of swelling on the breast, large, spreading, hard, touching them is like touching a ball of wrappings

Keloids classically occur on certain parts of the body, specifically, on the shoulder, anterior chest wall and earlobes. Surface tension and sebaceous gland density are among the characteristics that have been hypothesized to predispose these anatomical sites to keloid formation. Keloids effect only the Homosapiens and may develop even after the most minor of skin wounds such as insect bites, acne and injuries. The time lag between injury and keloid formation is variable, though majority tend to form within the first year after inciting skin wound. Furthermore, keloids rarely regress with time. Multiple modalities of treatment are available, used alone or, in combination with uncertainty of each treatment. Conservative Topical preparations such as Steroids, Retinoic acid, Tacrolimus, Imiquimod and Invasive methods like Intralesional 3,4 5 injections of Steroids ,5-Fluorouracil, Bleomycin, Hyaluronidase, 6 Verapamil, Interferons are used in treatment of keloids. Cryotherapy, Surgery, Excision with autografting, Excision with auto flap (keloid fillet flap), radiation, silicone gel, pressure therapy, Surgery Plus 5-Fluorouracil, Imiquimod. Cryosurgery plus intralesional steroids. LASER treatment - Pulsed dye, Nd: YAG, 7,8CarbonDioxide, penicillamine,b-aminopropionitrile,and colchicine, vitamin A and D. Various combination therapies of Carbon Dioxide Laser Plus Steroids, Surgery Plus Radiation Therapy Surgery Plus Compression Earrings Surgery Plus Silicone Gel Sheeting have been tried.

There is no universally accepted treatment resulting in permanent keloid scar ablation. No treatment for Keloid is considered to be 100% effective Multiple modalities of treatment[4] have been advocated. Most of these modalities have a variable and transient success. Hence there is a need for evaluation of the best modalities of treatment to achieve a good cosmetic acceptability. In addition to the therapeutic aspects there is a need to evaluate age, sex, site predisposing factors and family history in this study.

MATERIALS AND METHODS: -

Methods: In prospective study, 20 cases of Keloids cases belonging to both sexes attending Plastic surgery OPD at Gandhi hospital, Hyderabad between 2015 – 2017 were selected for the study.

EXCLUSION CRITERIA:

Age below 5 and above 60, Immunosuppressed individuals, Pregnant and lactating women, Patients with extensive keloids following burns, Patients not willing for follow up, Patients with systemic illness like uncontrolled Diabetes mellitus, Hypertension, Mental disorder, Malignancy.

Study procedure:

A written informed consent was obtained prior to treatment. All Patients satisfying inclusion and exclusion criteria were subjected to routine blood tests like complete blood picture, liver and renal function tests before starting the treatment. No abnormalities detected.

All cases with keloid over the entire body were considered for the study. In all auricular keloids with bilateral presentation, any one side of patients' preference was included in the study All the patients were treated with a preformed treatment **Protocol which is as follows**.

The day treatment was started was marked Day 0
Day 0 - Intralesional Triamcinolone
Day 30 - Intralesional Triamcinolone
Day 60 - Intralesional Triamcinolone
Day 90 - Surgical excision + Inj Triamcinolone into wound edges application of silicone gel sheet for a min of 12 hrs/day

Day 134 - Inj Triamcinolone into wound edges + advised daily application of silicone gel sheet for a min of 12 hrs/day application of silicone gel sheet for a min of 12 hrs/day application of silicone gel sheet for a min of 12 hrs/day

Day 210 – Assessment of Results In the initial phase injection of intralesional Triamcinolone acetonide [5](40mg/ml) was given diluted in ratios with equal quantity of 2% lignocaine and given as 10mg per cm^2

at every 4 weeks for 3 doses.

Initially the area of keloid is cleaned with a spirit swab and allowed to dry. Now with a loaded insulin syringe drug is injected per cm^2 area or till area injected blanches maximum dose being 2 ml (80mg) of triamcinolone acetonide. Corticosteroid was injected into the mid-dermis to avoid irreversible atrophy of the epidermis.

Reduction in size was measured after 3 doses[3] Such injections were repeated every 4th week for 3 doses.

Four weeks after the last dose keloid excision[6] was planned under anaesthesia.

The patients underwent intra- lesional excision of keloid with resurfacing of defect using keloid fillet flap or an autograft. Intra-lesional steroid was injected into margins of the wound intra-operatively. Steroid used was triamcinolone acetonide 40 mg/ml, diluted in ratios with equal quantity of 2% lignocaine and given as 10mg per cm^2.

Special emphasis was laid on achieving a tension-free closure, accurate coaptation of skin edges, adequate haemostasis, atraumatic handling of tissues and asepsis. A pressure dressing was applied at the end of surgery for 48 hours.

Suture removal was done on the 14th day.
On the 14th day, the 4th dose of steroid was given in to the wound edges and the patient was commenced on silicone sheet application. On the pinna, microporous tape was used to hold the sheets in situ. This was worn for 12 hours per day at night-time for 6 months. Post operatively the patient presented to Out-patient Department (OPD) after 6, 10 and 14 weeks for the subsequent steroid doses and thereafter at 6, 9 and 12 months for review.

Study Tools

Patients were examined using serial measurements of maximum dimension of scar in three perpendicular planes using callipers and serial photographic documentation.

Pre-treatment volume of keloid (length x breadth x height) and volume after completion of treatment (6 months Post-op) was recorded followed by calculation of % reduction in volume.

A subjective assessment using Patient Observer Scar Assessment Scale (POSAS) and an objective assessment by an independent observer using Beausang scale was performed at each visit. For POSAS assessment, the patient and observer assessed the operated ear while looking at a mirror in standard lighting in the OPD. For Beausang scale, an independent observer, blinded to time from surgery, assessed the patient in OPD.

Follow up was done after completion of treatment and recurrence if any is noted. Predesigned proforma including demographics, detailed history, clinical examination, and serial measurements were used for patients recruited.

RESULTS:

The study was done on 20 patients with keloids and the following observations were made.

AGE:-

Table No 1: Age Distribution in keloids (N=30)

S.NO	Age (Years)	No. of Cases (%)
1	10-20	7(35%)
2	21-30	8(40%)
3	31-40	5(25%)
4	41-50	0(0%)
5	51-60	0(0%)

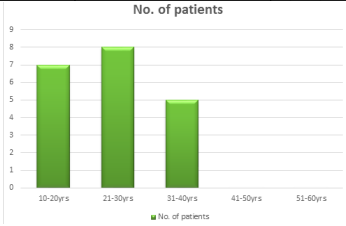


Figure No 1: Bar Diagram showing Age Distribution in keloids (N=20)

Most common age group affected by keloid in our study was 21-30 years accounting to 40%SEX

Table2:Sex distribution in keloids(n=20)

S. NO	Sex	No. of Cases (%)
1	Male	2(10%)
2	Female	18(90%)

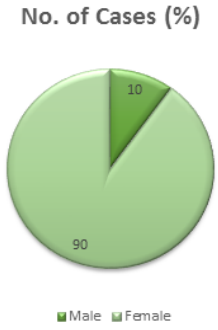


Figure 2: Sex distribution among keloids(n=20)

Above diagram shows males are less commonly affected than females in present study.

90% of the cases presented were females.

DURATION OF DISEASE

Table No 3: Disease Duration in keloids (n=20)

S.NO	Duration of the Disease (months)	No. of Patients (%)
1	< 6	3 (15%)
2	6-12	9 (45%)
3	> 12	6 (30%)
4	1-2 yrs	2 (10%)

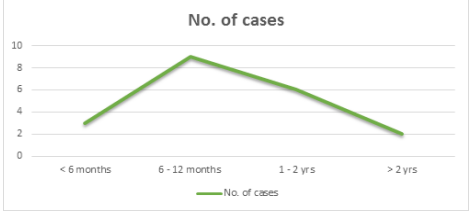


Figure 3: Graph showing duration of disease (n=20)

45% of the cases had a history of 6-12 months duration followed by 30% of cases having a history of 1-2yrs duration.

PREDISPOSING FACTORS

Table no 4: Predisposing factors for keloid formation.

S.NO	Factors	No. of Patients(%)
1	Spontaneous	5 (25%)
2	Infection	0 (0%)
3	Ear piercing	14(70%)
4	Burn Injury	1 (5%)

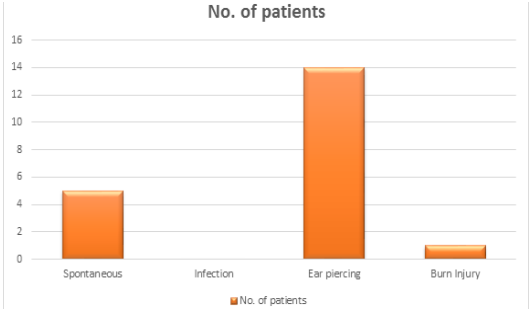


Figure 4: Diagram showing predisposing factors for keloids(n=20)

Most common predisposing factor in present study was Ear Piercing which accounted to 70% of cases. In 30% of cases growth was spontaneous.

SITE

Table 5: Site of lesion

Site		No. of Cases	Percentage
Auricular	Rt	8	40%
	Lt	3	15%
	Bilateral	7	35%
Dorsum of Rt hand		1	5%
Post Trunk		1	5%

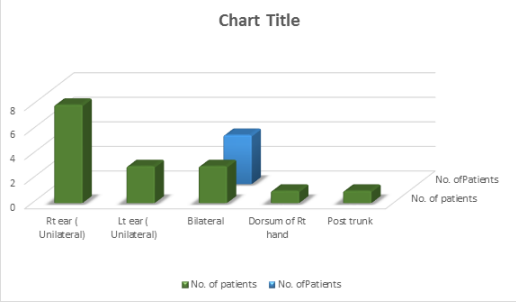


Figure 5: Diagram showing site of lesion for keloids(n=20)

90% of cases had auricular keloids of which 40% of cases had unilateral Rt auricular keloid and 15% of the cases had unilateral left auricular keloids

SIZE

Size of the keloid was taken in three dimensions and volume of the lesion calculated on day 0.

Table 6: Size (cm3) in all cases

SI no	Size	No of keloids	Percentage
1	<1	3	15%
2	1-10	14	70%
3	>10	3	15%

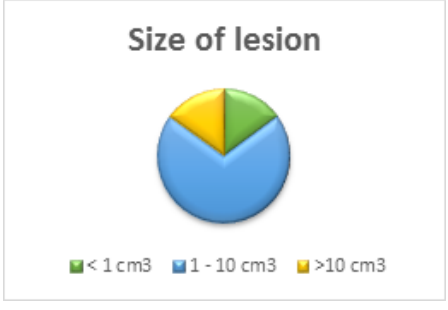


Figure 6: Diagram showing the size (in cms) variations

In maximum no of cases (70%) the lesion size varies between 1- 10cm^3

DOSAGE OF ILK GIVEN

Table 7: Dosage of intralesional triamcinolone(40mg/ml) administered

Dosage	No. of cases	Percentage
0-0.5ml	7	35%
0.6-1ml	12	60%
1.1-2ml	1	5%

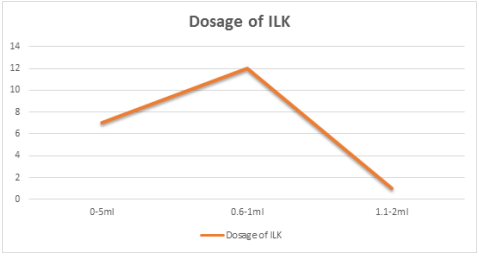


Fig 7: Diagram showing the ILK dosage administered

Most of the cases (95%) were administered triamcinolone dosage up till 1ml calculated as per the size of the lesion. In only one case the dosage was needed to be increased to 2ml.

Reduction in size & Scar assessment

Percentage reduction in the size of the lesion was measured after taking serial three dimensional measurements of the lesion pre and postoperatively.

Table 8: Table showing Patient response to the treatment protocol

S.No	Reduction in volume(%)	POSAS scoring Max - 15
1	96.9%	12
2	98.1%	14
3	92.5%	15
4	98.8%	12
5	99.2%	12
6	95.6%	13
7	99.6%	15
8	93.6%	14
9	95.2%	15
10	98.9%	15
11	90.6%	12
12	98.7%	12
13	93.7%	13
14	98.4%	14
15	96.9%	14
16	95.5%	12
17	97.6%	14
18	97.3%	12
19	99.2%	15
20	97.8%	13

85% of the cases showed > 95% volume reduction in the size of the lesion. All the cases had atleast 90% reduction in the volume of the lesion.

In all the cases POSAS scoring was less than 15 denoting a high rate of patient satisfaction

COMPLICATIONS

Table 9: Table showing complication encountered during study

Complication	No.of Cases	Percentage
Menstrual irregularities	4	20%
Acne	4	20%
Itching	5	25%
Skin excoriation	1	5%
Pain	1	5%

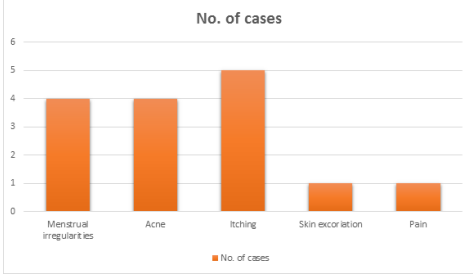


Fig 9: Graph showing the cases with complications and its incidence.

Itching was seen in 25% of cases which was the commonly seen complication followed by menstrual irregularities and acne which were seen in 20% of cases. Often both menstrual irregularities and acne were seen in the same case In one year follow up of the 20 cases, there was recurrence of lesion at the same site in one patient.

In the present study recurrence rate was 5%.

DISCUSSION

AGE WISE DISTRIBUTION:

In this study 40% of patients belonged to the age group of 21-30 years followed by 35% patients in age group of 11-20 years. The age range was 5-60 years.

In the study of **Brain et al** and **Murray** [7] the onset of keloid was seen most commonly between 10 and 30 years of age and uncommon at age extremes.

Ketchum et at [8] found that 88% of the keloid occur in patients less than 30 years of age group, because youngsters are frequently subjected to trauma. There is more tension in younger skin and also the increased rate of collagen synthesis in younger individuals.

Thus, keloids are more common in second and third decade of life

SEX WISE DISTRIBUTION:

Sex distribution	Present study	Ketchmen et al	Darzi et at
M: F	1: 9	1:1	0.6: 1

Out of 20 patients, 90%patients were females and 10% patients were males, with a ratio of 1:9 (M: **F).**

Ketchm et at [8] found almost equal incidence among both males and females.

Darzi et al [9] his study of 65 patients, 61.5% patients were females and 38.5% patients were males.

DURATION OF KELOIDS:

In 45% of patients the duration of disease was 6-12 months followed by >12 months in 30% of patients and <6 months in 15% of patients.10% of cases showed > 2yrs duration.

Muir[10] found that in majority of patients the duration of keloid belonged to 3-6 months.

In this present study the longer duration of lesions can be attributed to the negligence and ignorance on the part of the patients.

SITE OF LESION:

In this study the most common site of keloid was ear which constituted 90% of the cases. 35% of these cases had bilateral lesions and 55% of cases had unilateral lesions of which 40% were on rt ear and 15% were on the left ear. 5% of the cases were on dorsum of rt hand and 5% of the cases were on posterior trunk.

According to **Brain et-al'** study, the most frequently involved sites for the keloids are the bilateral ear lobes. Muir[133] in his study found higher incidence of keloids over the ear. **Boyat et al**[11] found that keloids occur most commonly on the chest, shoulder, upper back, nape of the neck and ear lobes (bilaterally).

PREDISPOSING FACTOR:

In this study trauma (ear piercing) was the commonest factor seen in 70% of the patients followed by spontaneous (25%). 5% cases had a history of burn injury Trauma is the most frequently associated factor according to the study of Murray[13]

Many theories have been advanced to explain the aetiology of keloid. in most patients, trauma was the major provoking factor in the study of Kelly2. Infection has been also incriminated as a contributing factor in the formation of keloid in **Kelly2** study. Even though some individuals may report spontaneous keloid formation, it may be that the initial skin wound that incited its development has been forgotten.

Thus, in **present study Trauma (ear piercing)** was most common predisposing factor as study by Murray.

RESPONSE OF PATIENTS TO THE REGIMEN:

In the present study, the primary outcome evaluated was the percentage of reduction in volume of keloid, as a main parameter of efficacy.

Percentage reduction in volume	Present study	Nanda et a1135	Gupta et al
<90% (Poor)	0	7.1%	16.6%
90 – 95% (Fair)	30%	14.3%	25%
96 – 100% (Good)	70%	71.4%	25%

In Nanda et a1[12] study majority of patients i.e., 71.4% patients showed good response, followed by 14.3% fair response, and 7.1% patients showed poor response.

In **Gupta et** a1[13] study, out of 24 patients 8 (33%) patients showed an excellent outcome, 6 (25%) patients each showed good and fair response and 4 (16.6%) patients showed a poor response. The symptoms disappeared in 17 (70.8%) patients and improved in 3(12.5%) patients.

Kontochristopoulos et a1[14] in his study found that out of 20 patients, 17 (85%) patients showed more than 50% improvement.

Comparison of recurrence between different studies

Study Group	(Recurrence)
Present study	1
A.Darougheh et al[m]	0

Thus, the present study shows more recurrence compared to A. Darougheh et al, but is statistically not significant (p>0.05). This could be because the follow up period in present study was 1 year where as it was only 6 months in A. Darougheh et al[15] study.

In 11 cases associated complications were seen of which 5 cases were systemic complications which were menstrual irregularities and acne. Six cases showed local complications of which 4 cases presented complaints of pain, 1 case showed mild skin excoriation and 1 case complained pain locally.

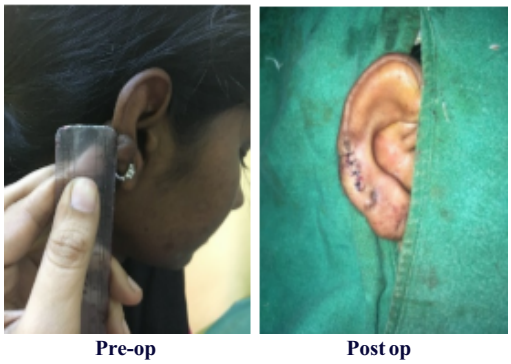
CONCLUSION: - Different treatment modalities are used for keloids. However, not a single method has been found completely successful. Therefore, we combined these triple techniques of Intralesional triamcinolone acetonide with surgery and silicone gel sheet applications to improve therapeutic outcomes .

Ear (90%) is the most common site involved. Trauma (ear piercing) is the main precipitating factor in 70% followed by spontaneous occurrence in 25% cases. Percentage volume reduction in the size of lesion was >95% in 70% of the cases. Post op POSAS scoring did not exceed 15 in all the cases denoting good patient and observer satisfaction. The recurrence rates were as low as 5% with the treatment protocol followed. The present study has shown that The Triple therapy for Keloids is an effective treatment protocol with 5% recurrences and good patient and observer satisfaction for a follow up period of maximum 1 yr.

Case:1

Pre-op **Post-op**

Case:2



Pre-op **Post op**

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