How to Cite:
Gul, S., Junaid, S., Kashif, M., Izhar, M., Farooq, N., & Zahoor, F. (2023). Keloid with intra-lesional steroid injection: Trying a new way. *International Journal of Health Sciences*, *6*(S9), 4671–4679. https://doi.org/10.53730/ijhs.v6nS9.13935

Keloid with intra-lesional steroid injection: Trying a new way

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***Abstract*---**Introduction: Keloids are the result of an overgrowth of dense fibrous tissue that usually develops after healing of a skin injury. The exact pathogenesis of Keloids is unknown and their occurrence is spontaneous. The uncontrolled overgrowth of dense fibrous tissue extends beyond the borders of original wound and does not regress. No single therapeutic modality has been proven to be most effective for treatment therefore this study is plan to use intralesional steroids injection in keloid and measure the efficacy and to see if it is a better and cost effective method and also to determine its utility for clinical practice in dermatology in future. Objective: To determine the efficacy of intralesional steroid injections in keloids with dental syringe. Settings: Dermatology department, Jinnah Medical College Hospital in outpatient department (OPD). Duration: 06 months from 14th April'2018 to 14th Oct' 2018. Design: Cohort Study. Subject and Methods: A total of 79 patients with having keloid were included in this study. During each visit, the size of the keloid was recorded centimeter using the Vernier's calipers, in terms of length, breadth, and height Injection triamcinolone acetonide was used in strength of

Manuscript submitted: 18 Oct, 2022, Manuscript revised: 31 Nov 2022, Accepted for publication: 15 Dec 2022

40 mg/ml. Injections was given at monthly intervals and patients was asked for regular follow up for 6 months at least. More than 50% reduction in volume was regarded as efficacy positive. All the data was collected on questionnaire. Results: The average age of the patients was 32.11±5.74 years. There were 44(55.7%) male and 35(44.3%) female. Efficacy of intralesional steroid injections in keloids with dental syringe was 88.24%. Conclusion: In conclusion, intralesional steroid is an effective and safe treatment for keloids of all sizes and any duration.

***Keywords*---**Keloids, Intralesional steroid injections, Dental syringe.

Introduction

Keloids are the result of an overgrowth of dense fibrous tissue that usually develops after healing of a skin injury. The exact pathogenesis of Keloids is unknown and their occurrence is spontaneous. The uncontrolled overgrowth of dense fibrous tissue extends beyond the borders of original wound and does not regress.

Around a 100 million patients worldwide develop Keloids post-operatively each year as a result of 55 million elective operations and 25 million operations after trauma [1]. There is no sex predilection with highest incidence being in second to third decade of life [2, 3].However Bayat and colleagues compared profiles of patients of Afro-Caribbean origin with Keloids at single versus multiple sites and found later to be more common in younger age group and they also found significant associated family history in 50% of patients [4]. Dark skinned people have been observed to be more susceptible to development of Keloids with incidence being 6-16% in African population [5].

Formation of Keloids leads to pruritus, pain, contractures and excessive scarring and hence can dramatically affect patient's quality of life both physically and psychologically. There are multiple therapeutic modalities for Keloids including compression dressings, intralesional steroid injection, cryosurgery, excision, radiation therapy, laser therapy [6], interferon therapy [7],5-flourouracil, doxorubicin, bleomycin, verapamil, onion extract and combination of hydrocortisone, silicon and vitamin E. other recent therapies include are pulsed dye laser, interferon α2b,and cultured autografts [8].

No single therapeutic modality has been proven to be most effective for treatment but intralesional injection of steroids is still one of the most effective methods [9].In a study conducted in Tehran in 2012 on 40 patients, 5-FU tattooing was found more effective than intralesional TAC [10]. There are also studies that show that combination of intralesional triamcinolone with 5-flourouracil or intralesional triamcinolone in combination with onion extract gel is more effective rather I/L triamcinolone alone [11,12].Study conducted by Lee JH from korea found efficacy of 86.0% with combination of I/L triamcinolone and IFN-α2b and 73.4% with triamcinolone alone [13].

In a study from japan which was conducted from 1985 -2003 to study long term outcome of I/L triamcinolone in keloids, 39% showed good results[14]. Latest study from India by Avinash Prabhu mean reduction in volume of keloid was 57.48% with 5flurouracil and 71.23% with I/L triamcinolone using an insulin syringe[15].

In our local setup , in dermatologist clinic I/L triamcinolone is the most widely used for treating keloids in outpatient basis but in past Clinicians had found this procedure of injecting intralesional steroid most challenging due to the hard consistency of collagen in the Keloid. Different ways and techniques have been described and were being used. A sterile disposable syringe or insulin syringe is usually used for this purpose but a remarkable amount of pressure is required to facilitate the injection that may result in the needle getting dislodged from the syringe resulting in wastage of medicine. Also there is disadvantage of short length of insulin syringe and it is liable to breakage because of pressure and may get impacted in keloid. The technique of using dental syringe to facilitate the steroid injection in Keloid scar was first described in 1989 [16] and it has been used successfully with good results because of its fine and longer needle and a good holding grip that results in injection being administered with pressure without the dislodgment of needle[16].

There are studies which describe the technique of using dental syringe [17] but there is paucity of data locally and internationally which describe the efficacy using a dental syringe, therefore We decided to use dental syringe for injecting triamcinolone in keloid and measure the efficacy and to see if it is a better and cost effective method and also to determine its utility for clinical practice in dermatology in future. The effectiveness of treatment will be measured in volume reduction of keloid over a period of 6 months.

Objective

To determine the efficacy of intralesional steroid injections in keloids with dental syringe

Operational Definitions

Efficacy positive*:* Efficacy positive was defined as more than 50% reduction in volume of keloid at the end of 6 months

Efficacy negative: efficacy negative was considered as less than 50% reduction in volume of keloid at the end of 6 months

Dental syringe*:* It is a metallic instrument with a metallic grip and plunger, in which a disposable dental cartridge filled with injection, is inserted and a disposable fine long needle is screwed at one end.

Material & Methods

Study Design: Prospective Cohort Study

Settings: This study was conducted at dermatology department, Jinnah Medical College Hospital in outpatient department (OPD).

Duration Of Study: 06 month from 14th april 2018 to 14th Oct 2018.

Sample Size: Sample size of 79 adult subjects meeting inclusion criteria was required for this study, on the basis of previous study by Avinash prabhu[15] With

efficacy(p) of 71.23%, confidence limit (d)as 10%, using computer program “Open Epi version 2” for calculation of sample size

Sampling Technique: Non probability consecutive sampling

Sample Selection:

Inclusion criteria:

- Patients having keloid from more than 6 months to 12 months of duration
- Patients with either sex group
- Age group of 20-40 years
- Keloids with length > 4cm , width > 2cm and height>0.6cm (4.8cm^3)

Exclusion criteria:

- Pregnant and lactating mother
- Patients with some concomitant illness (renal failure, hepatic failure, acid peptic disease, diabetes, and hypertension, and immunocompromised patients)
- Patients who have taken previously any treatment for keloids

Data collection procedures:

The 79 patients diagnosed with keloid, meeting the inclusion criteria were included in the study after informed consent. Details of the patients such as name, age, gender, and duration of keloid was recorded in the Performa. During each visit, the size of the keloid was recorded centimeter using the Vernier's calipers, in terms of length, breadth, and height Injection triamcinolone acetonide was used in strength of 40 mg/ml. Injections was given at monthly intervals and patients was asked for regular follow up for 6 months at least**.** More than 50% reduction in volume was regarded as efficacy positive **.**All the data was collected on specified form by the researcher (questionnaire).
Formula for calculating reduction in volume is

$$\frac{\text{Initial volume–volume after 6 months} \times 100}{\text{Patient's initial volume}}$$

Statistical Analysis

The data feeding and analysis was performed on computer package SPSS (statistical package of social sciences) version 13.0. Clinical characteristics were summarized in terms of frequencies and percentages for qualitative variables (gender and efficacy). Mean ± S.D was for quantitative variables (age, duration of disease). Stratification was done with regard to age, gender, to see the effect of outcome and post-stratification Chi-Square was applied. $P<0.05$ was considered as significant.

Results

A total of 79 patients with having keloid from more than 6 months to 12 months of duration were included in this study. Most of the patients were above 30 years of age. The average age of the patients was 32.11±5.74 years and average

duration of disease was 9.66±1.5 months. Out of 79 cases, 44(55.7%) were male and 35(44.3%) were female. Out of 79 cases, lost to followed was observed in 11 cases and volume of keloid at 6th months was not computed while 68 were followed and volume of keloid was observed there for efficacy of intralesional steroid injections in keloids with dental syringe was 88.24% (60/68) as shown in figure. Stratification analysis of these 68 patients with respect to age groups gender and duration of disease was observed but significant effect was not observed on efficacy shown in table 1.

Table 1: Efficacy of intralesional steroid injections in keloids with dental syringe with respect to duration of disease

n=68

Duration of Disease	Efficacy Of Intralesional Steroid Injections		Total
	Yes n=60	No n=8	
8 to 10	45(90%)	5(10%)	50
11 to 12	15(83.3%)	3(16.7%)	18

Chi-Square=0.56; p=0.45

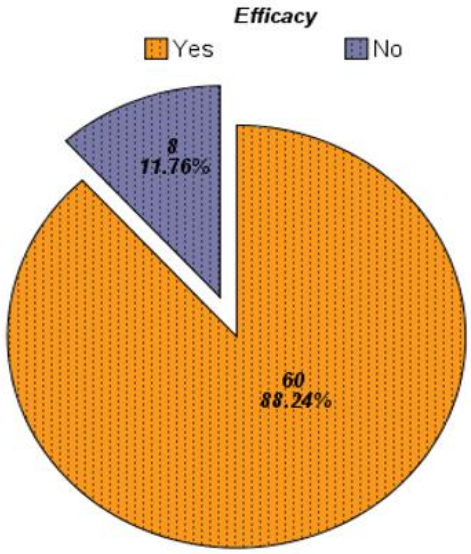

Figure 1: Efficacy of intralesional steroid injections in keloids with dental syringe
n=68 [11 loss to follow-up]

Fig9a: case 1, before I/L injection of triamcinolone

Fig9b: case1, after 6 month I/L injection of trimacinolone

Discussion

Keloids and hypertrophic scars are benign conditions, in which there is excessive proliferation of dermal fibroblasts[18]. Patients often present with severe itching, tenderness, pain, sleep disturbance, anxiety, depression, disruption of daily activities, and esthetic concerns. However, the basis for keloid and hypertrophic scar formation has not been fully understood[19]. It has been noted in literature that the fibroblasts that present in keloid and hypertrophic scar tissue produce increased amounts of collagen compared to the normal fibroblasts. Thus, suppression of this uncontrolled fibroblast activity in keloid and hypertrophic scar may be essential in their treatment.[18]

There is no universally accepted treatment for keloids.[18] Multiple therapeutic modalities, with variable success, have been reported, with intralesional steroids and 5-fluorouracil being two among them. An intralesional steroid injection is more commonly used. It is used either alone or as an adjunct to cryosurgery or surgical excision [20] or in combination with 5-fluorouracil.[17] Corticosteroids reduce fibroblast proliferation, collagen synthesis, and glycosaminoglycan synthesis, and suppress pro-inflammatory mediators.[20,21] The most commonly used corticosteroid is triamcinolone.

The average age of the patients was 32.11±5.74 years and average duration of disease was 9.66±1.5 months. Out of 79 cases, 44(55.7%) were male and 35(44.3%) were female. In Prabhu et al [15] study male were 75.9% and female were 24.1%.

In this study efficacy of intralesional steroid injections in keloids with dental syringe was 88.24% (60/68). Study conducted by Lee JH from Korea found efficacy of 86.0% with combination of I/L triamcinolone and IFN-α2b and 73.4% with triamcinolone alone (13).

Darzi MA observed that intralesional triamcinolone acetonide produced symptomatic relief in 72% and complete flattening in 64% of the lesions.[22] However, Kill J noticed complete flattening of the lesions and cessation of itching in 52 (100%) of the cases.[23] The study conducted by Nanda S observed more than 50% improvement in the size in almost 80% of cases that were been treated with 5-flurouracil. The side effects that they noticed were, in the form of pain at the site of injection in 100% of the patients, ulceration in 21.4%, and a burning sensation in 7.1%. Kontochristopoulos G reported more than 50% improvement in size in 85% of the patients, with complication of pain in 100%, hyperpigmentation in 100%, and ulceration in 30% of the cases that were being treated with 5-fluorouracil.[24]

In the group treated with 5- fluorouracil there was, on an average, 57.48% reduction in size as compared to 71.23% in the triamcinolone acetonide group. This difference was statistically significant (P value - 0.04) on an analysis with the unpaired student t-test. In studies evaluating intralesional triamcinolone acetonide there were volume changes ranging from 50 – 100%.[22,23] The effectiveness of 5-fluorouracil, as evaluated in other studies, has ranged from a 50 – 70% change in keloid size.[24]

Conclusion

In conclusion, intralesional steroid is an effective and safe treatment for keloids of all sizes and any duration. Although the recurrence rates are as yet unknown, we noted efficacy of intralesional steroid injections in keloids with dental syringe was 88.24% improvement in the majority of cases. Hence, adjuvant intralesional steroid should be considered for the postoperative therapy of keloids, in particular in patients in whom previous TAIL has failed.

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