ORIGINAL ARTICLE

Comparison of single intra operative versus an intra operative and two post operative injections of the triamcinolone after wedge excision of keloids of helix

Muhammad Mustehsan Bashir, Hazqeel Ahmad, Nadeem Yousaf, Farid Ahmad Khan

Abstract

Objective: To compare single intra-operative versus an intra-operative and two post-operative injections of triamcinolone after wedge excision of keloids of helix.

Methods: The randomised controlled trial was conducted at the King Edward Medical University, Lahore, from January, 2011, to March, 2014, and comprised female patients over 14 years of age presenting with post-piercing keloids of helix not treated previously by any means and amenable to wedge excision. The subjects were divided into Group A who were given a single intra-operative injection of triamcinolone, and Group B who had an intra-operative and two post-operative injections of triamcinolone. Extra-lesional wedge excision of keloids was done, followed by infiltration of flaps and wound base with 0.5-1cc of triamcinolone 40mg/cc. Group B patients were given additional injections of triamcinolone at 1st and 2nd monthly visits. Both groups were observed for the evidence of hypertrophy or complications. Development of hypertrophy within one year of completion of treatment was considered recurrence.

Results: The 70 patients in the study were divided into two equal groups of 35(50%) each. The mean age of Group A was 22.34±4.95 years and that of Group B was 22.88±4.22 years (p=0.624). The Mean size of the keloids was 2.54±0.516 cm^2 in Group A and 2.61±0.569 cm^2 in Group B (p=0.613). Recurrence rate in Group A was 3(8.5%) and 2(5.7%) in Group B (p= 0.64). The complication rate was 3(8.5%) in Group A and 8(22.8%) in Group B (p=0.10).

Conclusion: Single injection of triamcinolone was as effective as three in reducing recurrence with less complication rate.

Keywords: Keloid, Helix, Wedge excision, Ttriamcinolone. (JPMA 65: 737; 2015)

Introduction

Ear piercing is common and multiple piercing of the ear has gained popularity. This involves "high" piercing through the cartilage of the upper third of the pinna.[1] Keloid formation is recognised complication of ear piercing and patients commonly present to plastic surgeons. Interestingly, some patients develop keloids at their ear cartilage piercing sites, whereas the common sites for keloid formation like earlobe, back, front of chest and shoulders are spared.[2] Keloids developing in ear cartilage piercing sites are called keloids of the helix and those developing in earlobe piercing site are called earlobe keloids.[3,4] A study classified clinical scars into normal mature scar, immature scar, linear hypertrophic scar (HS), widespread HS, minor keloid and major keloid.[5] Wounds subjected to prolonged inflammation due to repeated trauma, infection or foreign body, are at risk of minor keloids. Primary keloids of the helix in patients who do not have keloids at earlobe piercing site and other sites like back, front of chest and shoulders, are minor keloids.[2]

Plastic Surgery Department, KEMU, Mayo Hospital, Lahore.

Correspondence: Muhammad Mustehsan Bashir. Email: mmbashir1@gmail.com

Keloids represent a challenging problem, with many treatment modalities advocated. Ear keloids, including keloids of earlobe and keloids of helix, can cause both cosmetic deformity and psychological trauma to the patient because of their highly visible location.[6] The primary determinant in choosing a treatment protocol should be a low recurrence rate particularly in case of ear keloids. Indeed, excision of keloid without an adjuvant treatment to minimise recurrence results in a failure rate of 45% to 100%. Therefore, the establishment of a reliable and safe technique for keloid excision with a low recurrence rate is especially critical for ear keloids. The extensive literature available on decreasing recurrence in the treatment of keloids deals with excision combined with compression therapy, corticosteroid and/or 5 flourouracil injections, cryotherapy and post-operative radiation.[7]

The use of corticosteroids as an adjunct to excision has a long history of use. Most commonly employed regimen is the use of three post-operative injections of corticosteroid. Studies investigating the use of corticosteroids as an adjuvant to excision have shown different recurrence rates ranging from 3% to 16.6%.[8] Unfortunately, these studies have failed to identify the recurrence rates in keloids of earlobe and keloids of helix separately. This differentiation is

necessary as term keloid is not a homogenous biological entity.[5] Recognition of different morphological phenotypes is necessary in understanding pre-disposition and aiding diagnosis, treatment and prognosis of keloids.

Hypopigmentation, telangiectasia, necrosis, ulceration and wound dehiscence are the reported side effects of repeated local application of a low-dose depot preparation. It has been found that single intra-operative dose of steroids is most critical to arrest inflammatory response and produce minimal side effects.[9] With this background the present study was planned to determine the outcome of single intra-operative versus an intra-operative and two post-operative injections of triamcinolone after wedge excision of keloids of helix.

Patients and Methods

The randomised controlled trial was conducted at the Department of Plastic and Reconstructive Surgery, Mayo Hospital, King Edward Medical University, Lahore, from January, 2011, to March, 2014, and comprised female patients over 14 years of age presenting with post-piercing keloids of the helix not treated previously by any means and amenable to wedge excision without incurring cosmetic deformity of the ear. The sample size was calculated by taking the expected proportion of recurrence in ear keloids treated by excision with two doses of post-operative steroid injections as 20% and the expected proportion of recurrence in ear keloids treated by excision with intra- and two doses of post-operative steroid injections as 2.1% with 90% confidence interval (CI) and taking power of study as 80%.[10] Patients having recurrent keloids of helix and/or keloids at other sites like lobule, front of chest, back and shoulders, were excluded. Patient having family history of keloids or known hyper-sensitivity to triamcinolone and lidocaine were also excluded. The study protocol was approved by the institutional ethics committee. Patients fulfilling the inclusion criteria were picked up using consecutive sampling. Informed consent was taken from all the patients. Patients were randomly allocated into two groups by using computer-generated random number table; Group A having patients who were given single per-operative injection of triamcinolone, and Group B having patients who were given one per-operative and two post-operative injections of triamcinolone. All patients were operated under local anaesthesia using lignocaine 2% with 1:100000 adrenaline. Extra-lesional wedge excision of keloids was done including cartilage and about 1mm normal tissue. This was followed by infiltration of flaps and wound base with 0.5-1cc of triamcinolone 40mg/cc with the volume given proportional to incision length. Afterwards, the wound was closed primarily with polypropylene monofilment suture (6/0). All patients were seen on 7th to 10th post-operative day for the removal of stitches. Later on, the patients were followed up monthly for a minimum period of 1 year. During follow-up Group B patients were given additional injections of triamcinolone at 1st and 2nd monthly visits. At each follow-up, both groups were observed for the evidence of hypertrophy, which was defined as raised scar above the level of adjacent skin limited to or extending beyond the original borders, and complications like hypopigmentation, telangiectasia, necrosis, ulceration and wound dehiscence in the healed scar. Patients were told to return earlier than scheduled follow-up in case of any evidence of hypertrophy. Recurrence was defined as development of hypertrophic scar, which was defined as raised scar above the level of adjacent skin limited to or extending beyond the confines of original wound, up to a minimum follow-up of 1year after the completion of treatment.[9]

For patients developing recurrence in either group, injections were continued at monthly intervals in an attempt to arrest the inflammatory process. Compression in the form of specially designed ear rings was applied to these cases.

SPSS 16 was used for statistical analysis. Qualitative variables like recurrence and complications were expressed as frequency and percentages. Quantitative variables like age distribution and size of the keloids in the two groups were presented as mean ± standard deviation. Chi Square or Fisher's exact test was used to compare the distribution of qualitative variable in the two groups. Independent sample t test was used to compare the means in two groups. $P<0.05$ was considered significant.

Results

There were 70 patients in the study who were divided into two equal groups of 35(50%) each. The mean age of Group A was 22.34±4.95 years and that of Group B was 22.88±4.22 years (p=0.624). The Mean size of the keloids was 2.54±0.516cm^2 in Group A and2.61±0.569cm^2 in Group B (p=0.613) (Table-1). Recurrence rate in Group A was 3(8.5%) and 2(5.7%) in Group B (p= 0.64). The complication rate was 3(8.5%) in Group A and 8(22.8%) in Group B (p=0.10) (Table-2). The follow-up ranged from 12 months to 26 months with a mean of 17.44±3.13 months.

Table-1: Distribution of age and size of keloids in two groups.

	Group of the patients		P value
	Single injection (n=35)	Three injections (n=35)	
Mean age of the patients	22.34±4.95 years	22.88±4.22 years	0.624
Mean size of the keloids	2.54±0.516 cm^2	2.61±0.569 cm^2	0.613

Independent sample t test
p≤0.05 considered significant.

Table-2: Frequency distribution of recurrence and complications in two groups.

Groups	Recurrence		Complications	
	Yes	No	Yes	No
Single injection(n=35)	3(8.5%)	32(91.5%)	3(8.5%)	32(91.5%)
Three injections(n=35)	2(6%)	33((94%)	8(23%)	24(77%)
P value	0.64	0.10		

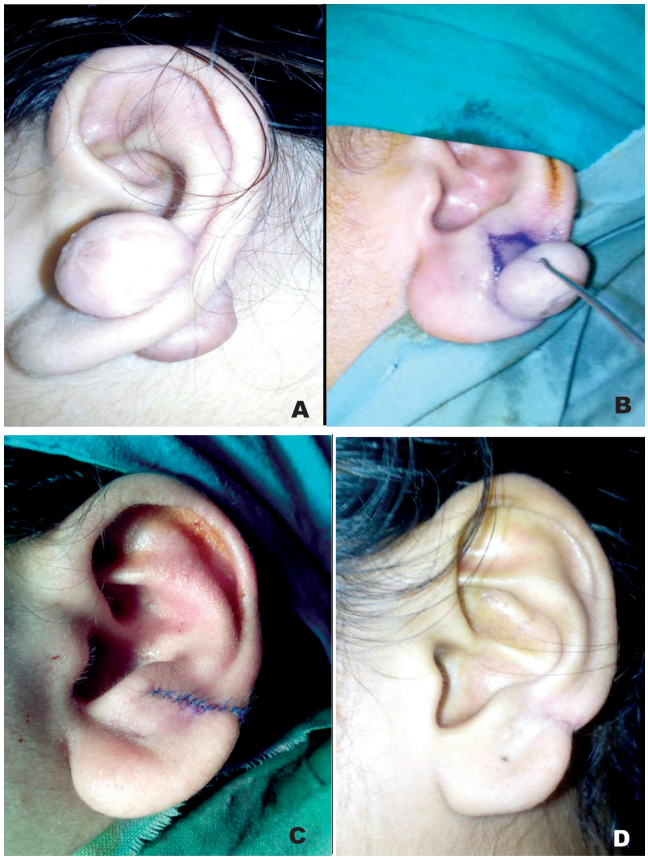

Figure-1: A) Before Treatment. B) Wedge excision marked per operatively. C) Wound closure per operatively. D) After follow-up of 1 year.
This 23 years old female had history of post piercing keloids of left helix. She underwent wedge excision followed by single intra operative injection of triamcinolone. Notching at free margin is visible.

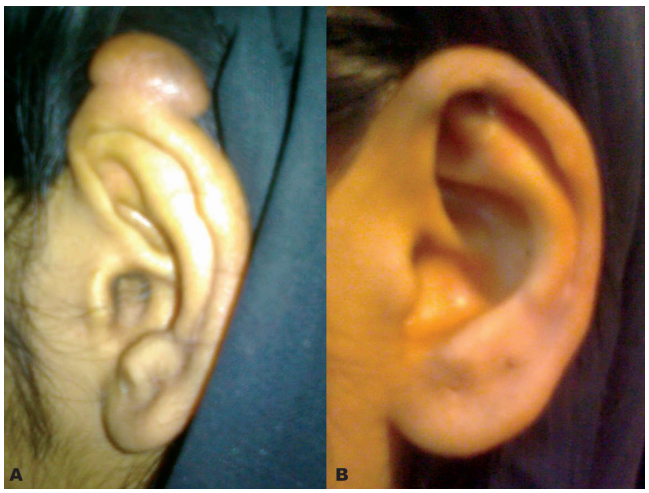

Figure-2: A) Before Treatment. B) 1 year post Treatment.
This 21 years old female presented with post piercing Lt Ear cartilage keloid for last one year. She had wedge excision of the keloids followed by three injections of triamcinolone. Hypopigmentation of the scar is visible.

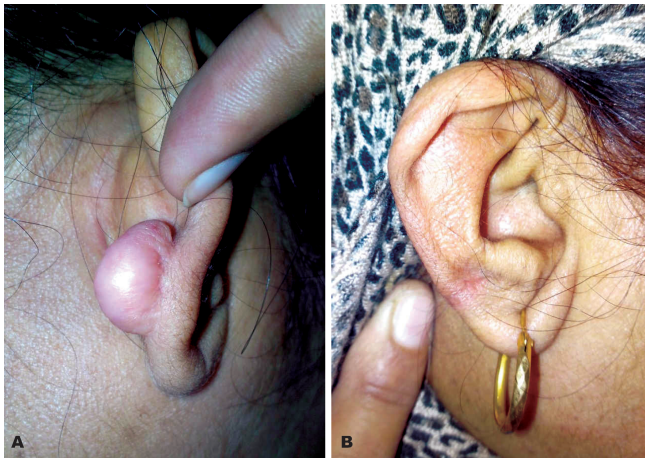

Figure-3: A) Before treatment. B) At the end of Treatment.
This 34 years old female had post piercing keloids of right helix for 8 months. She underwent wedge excision of the keloid followed by three post operative injections. Atrophy of the skin is visible.

Discussion

Keloid scars are known to have measurable morbidity and significant cosmetic implications because they are relatively resistant to treatment, with high recurrence rates. Keloids of the ear represent a particular problem because,as these lesions are excised, recurrences can be frustrating for the surgeon as the consecutive resections result in tissue deficiency, making a satisfactory reconstruction hard to accomplish.[9]

Steroid injection in the residual wound rim is a commonly used adjunct following excision of post-piercing ear keloids. It has a low morbidity, is cost-effective, easy to administer, and provides reliable and durable results. Steroids are believed to act by decreasing the level of collagenase inhibitors, thereby increasing collagen degeneration. Early application of steroids in the wound has anti-inflammatory effects which decreases fibroblast and collagen release.[11] Intra-lesional steroids have been used pre-operatively, post-operatively as well as per-operatively. So, timing of steroid with surgery as well as dose frequency in the post-operative period is a matter of question.[8,9,12,13]

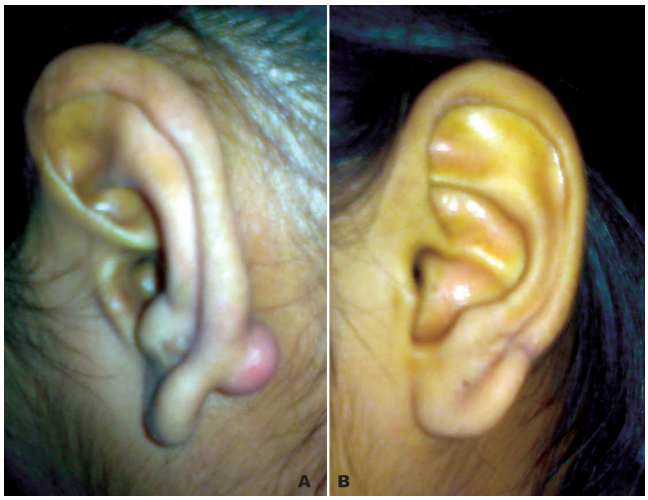

Figure-4: A) Before treatment. B) After treatment.
This 20 years old female had history of post piercing keloids of helix for 1 year. Wedge excision of the keloid was done followed by single intra operative injection of triamcinolone. Satisfactory result after 1 year of follow up.

Thorough exploration of the literature about addition of steroid as an adjunct to surgery revealed only two studies that advocated delivering an intra-operative dose.[12-14] Considering this, Rosen et al[9] developed a primary protocol of treatment of ear keloids. This protocol consisted of excision of the ear keloid followed intra-operative and post-operative steroid injections. Believing the information that installation of steroid into the wound should be carried out at the time of the operation to arrest the initiation of hypertrophy and keloid, Rosen et al included those keloids in its analysis that received only one intra-operative injection of steroids. The study found a recurrence of 8.6% (6/69) in primary keloids following the protocol of excision plus steroid injections (range 1-7 injections with a mean of 1.97).The findings underscored the importance intra-operative injection, but it did not consider the recurrence in auricular and lobular keloids separately which was a limitation.[9] In a Korean study,[8] outcome of surgery and peri-operative intra-lesional corticosteroid injections for treating earlobe keloids was reported. The protocol included pre-operative intra-lesional triamcinolone acetonide (TA) injections administered twice at a 1-month interval followed by intra-lesional excision. This was followed by post-operative intra-lesional TA injection starting at a 2 week time point after surgery and an injection was given every month for several months, depending on the patient's clinical progress. This protocol did not include "the most critical" intra-operative steroid injection.[8] The study showed a recurrence rate of 16.6% which was higher than an earlier study by Rosen et al.[9]

Much of the clinical and scientific research in the field of keloid scaring is flawed because investigators have failed to define their research material as minor keloids and major keloids.[15] Treating lobular and auricular keloids with same treatment protocol may under-treat the lobular keloids and over-treat the auricular keloids. The best outcome measures for any treatment protocol are success (recurrence or no recurrence) and frequency of complications. Infrequent dosing results in high recurrence whereas over-dosing results in serious wound infections as well as other local adverse effects.[10] The aggressive treatment of auricular keloids may produce success at the expense of more complications. This was the basis of our hypothesis that single per-operative injection of triamcinolone may be as effective as an intra-operative and two post-operative injections of triamcinolone in reducing recurrence. Moreover, the complication rate may be less with single injection compared to three injections of triamcinolone.

To the best of our knowledge, the present study is the first one to focus exclusively on the treatment of post-piercing keloids of helix. The study found a recurrence rate of 9% in keloids treated by single intra-operative injection of triamcinolone, whereas the recurrence rate was 6% in keloids treated by an intra-operative and two post-operative injections of triamcinolone. This difference in recurrence was statistically insignificant (p=0.643). This finding adds to the growing body of literature favouring "the critical" intra-operative dose of triamcinolone.

It is common knowledge that maximum fibroblast activity is seen in early stages of wound healing. It has been suggested that if the fibroblast activity could be down-regulated during early phase of healing process, the recurrence rate could be decreased.[6] A randomized controlled trial was designed to compare excision of earlobe keloids with intra- and post-operative steroids (group I) versus intra-lesional excision with post-operative steroids (group II). The proportion of recurrence was found to be high among group II keloids (18.2%) compared to group I keloids (2.8%) in 1st one-year follow-up and the difference was statistically significant (p= 0.049). In a total follow-up of two years it was higher (21.2%) in group II than group I (8.3%), but the difference was not statistically significant (p=0.177).[10] The findings of this study have further strengthened the recommendation of use of intra-operative dose of steroids.

Intra-lesional Triamcinolone injection is associated with multiple unpleasant effects, including atrophy, telangiectasia and pigmentary changes, which are not satisfactory adverse effects for most patients.[16] In the current study, the complication rate was 8.5% in the keloids treated by single intra-operative injection of triamcinolone, whereas it was 23% in keloids treated by an intra-operative and two post-operative injections. This

difference in complication rate was statistically insignificant. The most frequent complication noted was hypopigmentation followed by skin atrophy. Wound dehiscence was observed in two cases treated by three injections. These findings suggest that multiple post-operative injections increase the risk of local side effects. Other studies have reported similar findings.[8-10]

One limitation of the current study is the duration of follow-up. Even though most reports do not show results beyond a year after treatment, it is apparent that keloid reappearance can take place in years to follow. Logistically, lasting follow-up in this type of study is difficult. The second problem was patients' counselling about the wedge excision as they had concerns about cosmetic disfigurement of the ear. As mentioned in the literature, keloids with narrow bases (1cm or less), lesions located on the margin of the helix and lesions with dumbbell extension to both the surfaces, a simple wedge excision followed by undermining the base and closure with interrupted sutures is recommended.[17] For keloids with wide bases, flaps and grafts may be required to close the post-operative site without tension.[3] Our patients' keloids were mostly of narrow base, though some of them were looking large in size. Problem of notching at the edge is commonly encountered following wedge excision along any free margin. This problem was also observed in our cases (Figures-1-4). Having seen this, we always add a small z plasty along the free margin of helix. This has served the purpose well. Another limitation of the study is that one cannot generalise the findings. This is due to the fact that consecutive sampling was used instead of simple random sampling. Moreover it was a single-centre study. Thus findings can only be applied to patients with specific inclusion criteria.

Besides, 5-Fluorouracil (5-FU) is a pyrimidine analogue and has an anti-metabolite activity. It has been confirmed that 5-FU stops fibroblast proliferation in tissue culture.[18] It has been unveiled that 5-FU administered intra-lesionally is effectual in reducing the activity of fibroblasts in keloids. Recently it has been used as an adjunct to excision of keloids of ear.[6] Randomised controlled trials can be designed in future to compare the intra-operative use of 5-FU versus Triamcinolone as an adjunct to surgical excision of ear keloids.

Conclusion

Single per-operative injection of triamcinolone was as effective as one intra-operative and two post-operative injections of triamcinolone in reducing recurrence with less complication rate.

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