Original Research Article

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Early outcome of surgery, triamcinolone and silicone gel combination therapy for earlobe keloid: our local experience

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ABSTRACT

Background: Earlobe keloids cause facial disfigurement, physical, emotional and psychological burden to patients, while posing an intriguing treatment challenge to the plastic surgeon. Different options of combination therapy have been used in the treatment of earlobe keloids with varied success rates.

Methods: This interventional prospective hospital-based study was carried out in Irrua Specialist Teaching Hospital, Irrua, Edo State, over a 15-month period (October 2017 to December 2018). Forty-two patients with earlobe keloids who met the inclusion criteria were serially recruited into the study. Forty-eight earlobe keloids in 41 patients had the intralesional excision biopsy, intralesional triamcinolone injection and silicone gel combination therapy. A modified Sharquie et al's scar grading system was applied pre-intervention to record the baseline scores and post-intervention to evaluate the patients' rate of response. Post treatment complications were identified, and the patients were followed up for six months.

Results: Most of the patients with earlobe keloids fell in the age group 21-30 years and the male-female ratio was 1:19.5. Multiple earlobe piercing had significant association with the development of earlobe keloids. 95.8% of treated lesions had complete response to therapy. Two (4.2%) patients had dyschromia following treatment.

Conclusions: The triple therapy combination of intralesional excision biopsy, postoperative intralesional triamcinolone injection and topical silicone gel application is a readily available, safe and efficacious treatment modality for earlobe keloids. Thus, it can be used as a first-line treatment modality.

Keywords: Earlobe keloids, Triple therapy, Intralesional excision, Triamcinolone injection, Silicone gel

INTRODUCTION

Keloids are defined as intradermal tumours resulting from abnormal response of tissue to injury in predisposed individuals. They are benign, fibrous proliferations which develop in predisposed individuals at sites of cutaneous injury, such as ear piercing, burns, surgical procedures, or even following trivial injuries like scratch. Commonly affected sites include the ear, chest and shoulder. Reloids may develop on the anterior, posterior, or on both sides of the ear lobes. They may appear as pedunculated,

sessile (mononodular, or multinodular), or may have a complex form. Keloid nodules may be superficial or have a root and be buried deep inside the earlobe tissue. The earlobe is the non-cartilaginous, pendulous inferior pole of the auricle. Its anatomic free edge, distinct shape, and lack of cartilage, makes it a common location for earring piercing. The earlobe has a high risk of keloid scar formation, especially in darker skin types. Genetic predisposition play a major role in the development of keloids, coupled with some forms of skin trauma like bruises and insect bites. The earlobe has a high risk of keloids.

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Ear piercing is the most common cause of earlobe keloids formation in predisposed individuals.² This is commonly seen when the piercing is done after age 11, especially among patients with family history of keloids.3 Ear piercing is a procedure that can be performed by nonmedical personnel in jewelry shops, stores and at homes.^{1,3} Ear piercing is the most popular form of body piercing.² Extra ear-piercing is becoming more common among young women and men because of societal quest for fashion and this has led to increase in the incidence of keloids and its attendant cosmetic problems.3 Contact allergy to nickel or other impurities in earrings have been implicated in the pathogenesis of earlobe keloid following ear piercing.² Other predisposing factors involved in keloid formation are inflammation/infection, excessive wound tension and the presence of foreign bodies.⁴

The earlobe is chosen as a model in this study because; The earlobe is the second commonly affected site of the body for keloid formation.^{5,6} The anatomical location is easily accessible, making it relatively easier to evaluate. Modifying factors like suture line tension and/or uncontrolled movement are absent or reduced to the minimum. The surgical technique of intralesional excision and simple closure adopted do not distort the anatomy of the ear.

The clinical presentation of earlobe keloid includes a localized area of itchy fleshy-coloured, elevated lesion that continuously grow larger with scar tissue.²⁻⁴ Usually, they appear as shiny, smooth, globular growths on one or both sides of the earlobe.^{2,3} Treatment of keloids is challenging for physicians because of its high recurrence rate. There are different approaches to treating this condition and no single therapy or a combination of therapies have been proven superior to the other or absolutely without a risk of recurrence when used.^{4,5} These therapies include intralesional excision, intralesional triamcinolone injection, compression therapy, silicone gel, cryotherapy, radiotherapy, flavonoids, use of omega fatty acids in cobra snake oil, intralesional interferon injection, bleomycin, 5-FU, methotrexate and laser therapy.4 This is a hospitalbased study which evaluates the early outcome of siliconebased combination triple therapy for earlobe keloids. The results gotten were compared with those reported by other studies using different modalities of triple therapy combination.

METHODS

The was an interventional prospective hospital-based study that was carried out in Irrua Specialist Teaching Hospital, Irrua, Edo State, over a 15-month period (October 2017 to December 2018). Informed consent obtained from patients and accompanying adults of patients who are minors (11-17 years) recruited for the study. The study population was drawn from patients seen in the Plastic Surgery out-patient clinics of the Irrua Specialist Teaching Hospital, Irrua, Edo State.

Table 1: The modified Sharquie scoring criteria.

Criteria	Score	Feature(s)
Colour	3	Hyperpigmentation
	2	Hyperpigmentation with areas of hypopigmentation1
	1	Pink or pale appearance
	0	Norma skin colour
Elevation	3	More than 8mm in height above the surrounding skin
	2	4-8mm in height above the surrounding skin
	1	1-3mm in height above the surrounding skin
	0	Flat or depressed scar
Consistency	3	Hard
	2	Firm
	1	Soft with some areas of firmness
	0	Soft
Itching	3	Severe itchy sensation, or constantly itchy with signs of scratching
	2	Moderate and tolerable itchy sensation
	1	Mild itchy sensation
	0	No itchy sensation.
Pain	3	Severe irritable pain
	2	Moderately irritable pain
	1	Mild pain.
	0	No pain.

The sample size for this study was calculated at a confidence level of 95% corresponding to z value of 1.96. The minimum sample size was estimated using the Cochrane formula (used for population greater than 10,000). The formula took into consideration prevalence (p); which was derived from a previous study which was 42.3%

$$N = z2pq8/d2$$

Where p =42.3% (0.423), q = 1-p (1-0.423) = 0.577 and z = 1- α /2 at 95% confidence interval is 1.96 at two tailed alpha error, d is the desired precision or deviation usually at 5% or 0.05

$$N = (Z2) x P (1 - P) / d2$$

Thus N = 375, The sample size population (N) is less than 10,000. Thus, the final sample size (nf) for the study is calculated using the following formula:

$$nf = \frac{n8}{1} + (n)/N$$

Where: nf = the desired sample size when population is less than $10,000^{\circ}$ n = the desired sample size when the population is more than $10,000^{\circ}$ N = 37 (the estimate of the

population size gotten from a previous study).⁶ Therefor nf=34. Attrition was corrected for by assuming 80% anticipated response rate. The corrected sample size (N_S) is gotten from the formula:

$$NS = \frac{N8}{\% \ anticipated \ response \ rate}$$

Thus Ns=42, Thirty-seven was the minimum number of participants required for the study but forty-two patients who met the inclusion criteria and consented to participate in the study were recruited.

Table 2: Response to treatment evaluation.

Grade	Response to Treatment	
I	No response	
II	Minimal response: Change of one score in one to three criteria, Change of one score in one to two criteria provided that one or more criterion was ranking zero before commencement of the treatment	
Ш	Moderate response: Change of one score in four criteria, Change of one score in all five criteria but not to zero	
IV	Complete response: Change of the score to zero in all criteria	

The inclusion criteria were patients age 11 years and above who presented with ear lobe keloid to the plastic surgery out-patient clinic and gave consent were recruited into this study. Patients below 11 years were excluded because it has been found that keloid is rare in individuals less than 11 years of age.² Others that were excluded were pregnant and lactating mothers, patients with diabetes mellitus, tuberculosis, uncontrolled hypertension, HIV/AIDS, patients who did not comply fully with the study protocol (such as those who introduced another modality of treatment to the study's combination therapy), patients who voluntarily withdrew from the study after consenting initially. We analysed obtained data including patient's age, gender, etiology, keloid volume, recurrence and clinical photographs. All patients included in this study were followed up for 6 months except 1 who was dropped at the 10th week following application of herbal medication to the study's treatment modality.

Procedure

Technique of excision: The intralesional excision biopsies were done under aseptic condition in an operating theatre. Skin preparation was done using 5% povidone iodine and appropriate sterile drapes applied exposing the affected earlobe. Local anaesthesia was achieved by injecting 1% xylocaine with adrenaline (1 in 200,000) into the lesion and its effect confirmed after 7 minutes. Skin incisions were made on the summit of keloid and the mass debulked using size 15 surgical scalpel blade knife. The resultant surgical wounds were closed by apposing the raised skin flaps after excising excess skin in an interrupted fashion

using prolene 4/0 sutures. The wounds were dressed with sufra tulle and 5% povidone iodine-soaked gauze. The surgical wounds were inspected on the postoperative day three and sutures were removed on the postoperative day seven.

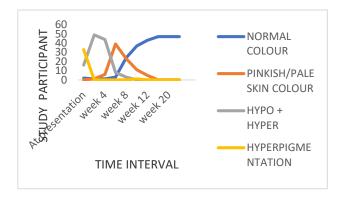


Figure 1: Change in the pattern of 48 earlobe keloidal skin colour.

Technique of injection: The intralesional triamcinolone injections were commenced on postoperative day 14. This was to allow for satisfactory healing of the wound after removal of the sutures. Methylated spirit was used to clean the site prior to injection. Using a disposable sterile 2ml syringe with a size 23G hypodermic needle, 10mg (0.25ml) triamcinolone acetonide (40mg/ml) and 0.25ml 2% xylocaine with adrenaline (1 in 100,000) solution were drawn into the same syringe. The constituted 0.5ml solution was injected into the edges of the remnant keloid tissue with adequate pressure until blanching was seen. This procedure was done fortnightly for the first three months, and then monthly for the following three months. All recruited patients had nine intralesional triamcinolone injections during the study period.

Technique of Gel (Xeragel®) application: The silicone gel application was commenced on postoperative week two. The patients were educated on how to apply a thin film of the silicone gel to the residual earlobe keloid. A thin layer was applied once a day except the days of the triamcinolone injection to allow for closure of the injection puncture site after each session.

Photographic and volumetric evaluation of the earlobe keloids: Preoperative and postoperative clinical photographs were taken using a Sony-Shot DSC-T110 16.1MP Digital Still Camera Carl Zeiss Vario-Tessar 4x Optical Zoom Lens and 3.0-inch Touchscreen Camera with fixed illumination and distance. The pre-treatment photographs were taken at presentation in the clinic while the post-treatment photographs were taken at every scheduled follow up clinic visit during the study duration. Pre- and post-treatment keloidal volumes were calculated using the length, width and height obtained with a Castroviejo calliper and cross-checked with a metallic ruler. Commonly known adverse effects of treatment were checked for. Serial weight, blood pressure (BP), fasting blood sugar (FBS), sore throat and change in menstrual patterns were recorded at presentation and every scheduled follow up visit.

Outcome measures

A modification of the scale and scoring system used by Sharquie et al which evaluated five criteria (Colour, Elevation, Consistency, Itching and Pain) with scoring from 0-3 was used in this study (Table 1). This was used to evaluate the patient's baseline and response to treatment.

Response to treatment evaluation

The evaluation of response was commenced postoperative week two and done fortnightly for the first three months, then monthly for the next three months. The responses to treatment were graded using the Sharquie et al Scoring Criteria (Table 2).⁹

Data analysis

Data obtained were subjected to statistical analysis using the International Business Machine for Statistical Package for Social Sciences (IBM SPSS) version 22 software. Data were displayed as frequency tables, percentages and graphical representations. Outcome measures were analysed using paired t test and Chi square. Confidence level of 95% was used in comparing the response of treatment and the level of significance was set at 0.05.

RESULTS

A total of 42 patients who met the inclusion criteria were recruited into the study. However, one (2.4%) was excluded from analysis. Altogether, 41 patients who had 48 earlobe keloids were analysed. There were two males (4.9%) and 39 females (95.1%) with a male to female ratio was 1:19.5.

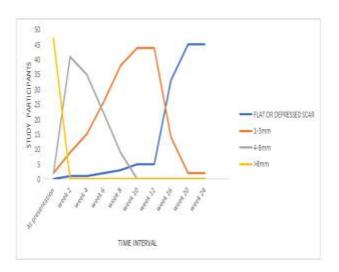


Figure 2: Change in elevation pattern of 48 earlobe keloids.

Demographical distribution

The age range of the patients recruited was 15-51 years while the mean age was 22.9 years. The largest proportion of patients 31 (75.6%) who had earlobe keloids were in the age range 21-30 years of age. Most of the patients, 26 (63.4%) had tertiary education. Family history of keloids was low, one (2.4%) in this study. One (2.4%) of the patients had keloids on another part of her body (pubic region). Forty-six (95.8%) of the earlobe had first earlobe piercing done at infancy, with no keloids but developed keloid with secondary ear piercing while two (4.2%), the male patients, developed the earlobe keloids following trauma. Most of the secondary earlobe piercing were done in the hostel, 21 (43.8%). The left earlobe was more commonly affected with a ratio of right to left earlobe keloid of 1:1.2. The commonest incubation period was 1-3months and the mean incubation period (i.e., the period between the second piercing or trauma and the appearance of earlobe keloid) was 2.3 ± 1.5 months.

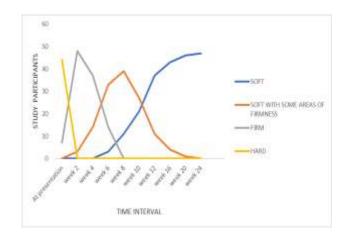


Figure 3: Change in the consistency pattern of 48 earlobe keloids.



Figure 4: Change in the itching pattern of keloid of 48 earlobe keloids.

Volume of the earlobe keloids

In the paired sample t-test for the mean pre-treatment and post-treatment earlobe keloidal volume, the p values were

0.0001 and 0.001 for the left and right earlobes respectively which was statistically significant.

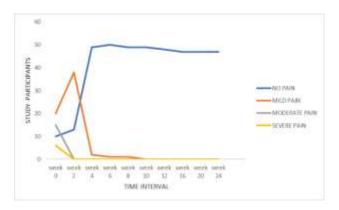


Figure 5: Change in the pain pattern of 48 earlobe keloids.

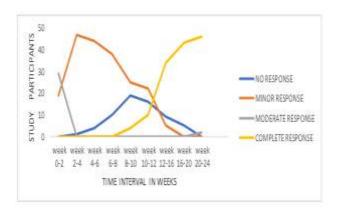


Figure 6: Time response curve showing the scored response trend among 48 earlobe keloids.



Figure 7: Male patient with bilateral earlobe keloid.

Earlobe keloidal skin colour

The appearance of keloidal skin showed a steady increase in the proportion of patients with keloidal skin approaching normal skin colour from the sixth week to plateau at about the 16th week (Figure 1).

Elevation of the earlobe keloids

The left and right earlobe keloids had same mean scar elevation; the left had a mean elevation of 16.9mm while

the mean elevation for keloids on the right earlobes was 16.3mm. Following treatment, there was a gradual increase in the proportion of patients who had flat or depressed scar from about the 12th to 20th week (Figure 2).



Figure 8: 6-month Postop appearance of bilateral earlobe keloid treated with intralesional excision biopsy, intralesional triamcinolone injection and topical silicone gel application.

Consistency pattern of the earlobe keloids

Majority of the earlobes 41 (89.6%) had hard keloid at presentation. However, there was a steady increase in the proportion of soft earlobe keloids from the fourth week. This increase plateaued at about the 18th week following treatment (Figure 3).

Itching pattern of the earlobe keloids

There was significant resolution of the earlobe itching by the 4th week, following the commencement of the post-operative intralesional triamcinolone injection and topical silicone gel application (Figure 4).

Pain pattern associated with the earlobe keloids

Mild pain, 20 (41.6%) was the most frequent at presentation. However, by the 4th week, 95.8% of the earlobes were pain free (Figure 5).

Time-response curve

The response to treatment at various time interval showed 46 (95.8%) of the earlobe keloids achieved complete response to treatment at the 24^{th} week (Figure 6). Patients of the younger age groups (11-20, 21-30) years achieved complete response compared to the older age group. This was statistically significant ($\chi 2 = 22.957$, p<0.0001).

Common adverse effects following treatment

Routine blood pressure check, weight, presence of throat pain and fasting blood sugar were done and no abnormality was recorded for any of the 41 patients. Two (4.2%) patients had skin dyschromia at the end of the 24 weeks follow up period.

DISCUSSION

The earlobe has been described as the second most frequent site of the body requiring early intervention for keloid.² This is due to the easily noticed aesthetic deformity and dragging sensation of the affected earlobe. All the patients in this study had earlobe keloid and represented 65.1% of all cases of keloidal scars seen within the study period. This prevalence of earlobe keloids is at variance with reports by Nnabuko, 31% in Enugu, Adigun et al, 42.3% in Ilorin and Oluwansanmi. 6-10 41% in Ibadan. The higher rate of earlobe keloids in this study may not be unconnected to the proximity of the study location to a tertiary academic institution. The highest incidence of earlobe keloids was seen in the age group 21-30 years. This is similar to the findings of Nnabuko in Enugu and Akaa et al in Benue. 6,11 This may be due to the fact that this age group of individuals tend to just have started gaining parental freedom. This tends to translate to being more cosmetically conscious, have higher peer pressure and are more prone to trauma.⁶ Proximity to the study location to a tertiary institution may also be a contributary factor. The female predominance is not unexpected due to the cultural practices of earlobe piercing in females. The two males in this study developed earlobe keloid following other trauma, motor vehicular crash and post flame injury. The positive family history of keloids this study was rather low (2.1%). This is at variance with findings by Nnabuko.⁶ in Enugu 73%, Oluwasanmi in Ibadan 25% and Olabanji et al in Ile-Ife 28.9%.10,12 The incubation period ranged from 1-15 months with a mean incubation period of 2.3+1.5 month. This is similar to the findings of an incubation range of period of 2-24 months with a mean incubation period of 1.1month by Nnabuko.6 The age groups 11-20 years and 21-30 years had better response to treatment. This relationship was statistically significant, p value was 0.0001. However, this was in contrast with the findings of Akaa et al in Makurdi. 11 They reported no relationship between the final response to treatment and any of the patients' demographic characteristics. This may be related to the different demographic distribution and treatment protocols used in their study. The commonest initiating factor for earlobe keloid found in this study was second earlobe piercing, seen in 46 (95.8%) of the patients. This showed a direct relationship to the predominance of keloids in female patients. Keloids following childhood earlobe piercing are uncommon. The earlobe piercing done from 11 years of age has been found to have the potential risk of keloid formation in susceptible individuals.² This has been found to coincide with the age at which an individual develops the ability to mount an exaggerated immune reaction involved in wound healing.² The keloidal lesions were almost symmetrically distributed between the right and left earlobe with a ratio of 1:1.2. This distribution did not affect the outcome of treatment to any noticeable extent. Surgical intralesional excision biopsy contributed significantly to the final outcome of this study. It reduced the size of the earlobe keloidal tissue and also relieves nerve entrapment. These in turn reduced the dose of the intralesional triamcinolone injection and amount of topical

silicone gel required postoperatively. This may have contributed to the lower adverse effects found in this study. This is in keeping with the proponents of the use of surgical excision as a major component of combination therapy for earlobe keloid. 13-15 Pruritus and pain are common features associated with earlobe keloids. 12 Histamine release by mast cells has been found to be actively growing increased in keloidal Triamcinolone injection resolves the pain and itching by its analgesic and cell membrane stabilizing properties.¹⁶ Pruritus was noted to be completely resolved in all 48 (100%) earlobe keloids following the first intralesional triamcinolone injection and topical silicone gel application.

The drastic reduction in the severity of pain and itching noted in this study may not be unconnected to the synergistic effect of debulking of the keloidal mass by the intralesional excision, the intralesional triamcinolone injection which modulates wound healing and silicone gel which further modulates scars. This study showed that triple therapy modality comprising intralesional excision biopsy, intralesional triamcinolone injection and silicone gel application was effective in the treatment of earlobe keloids. The overall complete response rate was 95.8%. This showed some similarity to the findings by Olabanji et al who reported 78.25% satisfactory outcome using the triple therapy combination comprising excision biopsy, intralesional triamcinolone injection and radiotherapy though this was a retrospective study. 12 It is similar to that reported by Coppola et al who recorded 82.7% reduction in the volume of keloids between the first and last treatments using soft tissue ultrasound for assessing the pre- and post-treatment keloidal volumes.¹⁷ This study result was at variance with the findings by Sharquie et al who reported zero complete response in their study that debulking with intralesional combined surgical triamcinolone and 5-fluorouracil (5-FU).9 This difference in response rate may be related to the type of surgery, the various sites of lesions on the body and methodology. This difference may also be due to longer follow up and technique of keloidal volume assessment used in their study. The study recorded two (4.2%) patients with dyschromia following the use of the triple therapy of intralesional excision biopsy, intralesional excision biopsy and silicone gel application. No systemic side effects were recorded over the 24 weeks follow up period. This is similar to study by Nnabuko in Enugu 0.04% and slightly variant to Abdulrasheed et al in Kaduna who reported a complication rate of 12%.^{2,6} The complications from their studies included scar widening, depigmentation, and minor wound dehiscence. Keloids of the earlobe is known to have higher recurrence rate than other anatomical region.² However, there was no recurrence noted during the 24 weeks follow up of the study. This is at variance with work by Olabanji et al in Ile-Ife who reported recurrence rate of 9.52% among the group of patients who had triple therapy combination of surgical excision, intralesional triamcinolone injection and radiotherapy, and 26.31% in another group of patients who did not have triple therapy. 12

Ogah et al in Lokoja reported a recurrence rate of 8.3% among patients who had surgical excision, intra-operative triamcinolone injection and six weeks postoperative triamcinolone injection. 18 Akaa et al reported a recurrence rate of 25.8% in a study done in Makurdi among patients who had surgical excision combined with postoperative intralesional triamcinolone injection. 11 The variance in this study compared with the other studies may be due to the shorter duration of follow up, the modalities of treatment and one study being retrospective. Tension on the suture line, wound infection, immune response and fibroblast hyperactivity are known risk factors associated with recurrence of earlobe keloids.² However, these factors were meticulously taken into consideration in this study. Following intralesional excision biopsy, healing occurred by primary intention. Silicone gel application was avoided on days intralesional triamcinolone injection was given limit the risk of infection that may predispose to recurrence. Keloid treatment is a challenge to patients and their care givers because of its risk of recurrence. There is no gold standard for treatment thus research is ongoing to offer utmost management of keloid and to prevent or minimize recurrence. Surgery alone tends to be fraught will very high rate of recurrence while use of steroids can predispose to some complications. However, the triple therapy protocol for this study carefully took all these into consideration. Thus, this technique of surgery that minimized trauma to surrounding normal tissue, low dose intralesional triamcinolone to obviate the systemic effect of steroids and topical application of silicone gel an affordable and readily available scar modulator showed good early outcome. It can be construed that triple therapy combination of intralesional excision, intralesional triamcinolone injection and topical silicone gel is effective for the management of earlobe keloid.

Limitations

The duration of the study which includes follow up is short considering the pathophysiology of keloids. The subjectivity of some measured parameters such as pain and itching were a bit difficult to obtain with certainty.

CONCLUSION

Earlobe keloids occurs commonly within the age group 21-30 years with femal predominance. The commonest presenting complaint was facial disfigurement. Progressive improvement was recorded using a triple combination therapy of with a success rate of 95.8%. The combination therapy of intralesional excision biopsy, postoperative intralesional triamcinolone injection and topical silicone gel application was found to have similar good and acceptable result during the 6-month postoperative follow-up in this study.

Recommendations

The triple therapy combination of intralesional excision biopsy, postoperative intralesional triamcinolone injection and topical silicone gel application should be used as a first line treatment modality due to its availability, safety profile and affordable cost. Improper and unsafe second earlobe piercings should be discouraged especially from around ten years, where desired, it should be done preferably health care givers under aseptic condition. A multicentre study with more patients and longer follow-up period is recommended to further validate the findings of this study.

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Conflict of interest: None declared

Ethical approval: The study was approved by the

Institutional Ethics Committee

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