Research Article

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A CLINICAL STUDY FOR THE MANAGEMENT OF EAR PINNA KELOID BY KSHARSUTRA AND AGNIKARMA

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ABSTRACT

Ear pinna keloid is a rare benign, dermal, fibro-proliferative growth characterized by excessive formation of collagen, without any malignant potential. It is one of the most challenging conditions to treat due to high relapse rate. Ksharsutra and Agnikarma are the potential therapies mentioned in Ayurveda for such conditions. Ksharsutra is used for excision, while use of Agnikarma after excision is considered to be effective in avoiding the relapse in conditions of benign outgrowths such as ear pinna keloid. In the present study 20 patients divided in two groups were studied. Group A (excision of keloid by Ksharsutra ligation; n = 10) and Group B (excision of keloid by Ksharsutra ligation followed by Agnikarma on granulation tissue; n = 10). Fisher Exact test was applied to see the risk reduction in relapse of keloid. Relative risk was 7.000 (95 % Confidence Interval: 1.043 to 46.971). This shows that there is statistically significant risk reduction for relapse of ear pinna keloid in patients treated by ksharsutra and Agnikarma as against ksharsutra alone.

Keywords: Ear pinna keloid, Ksharsutra, Agnikarma

INTRODUCTION

Ear pinna keloid is a benign, dermal, fibro proliferative growth, characterized by excessive formation of collagen, without any malignant potential. It has much more psychological impact on the patient due to cosmetic and aesthetic reasons. The term 'keloid' means 'Crab Claw' was first coined by Alibert in 1817.^{1,2} Ear pinna keloids occur in about 5-15 % of humans from manual trauma and blunt perichondrial trauma. Both sexes are affected, but the incidence is higher in women.³ The higher incidence is attributed to wearing of ornaments, ear piercing over different areas of ear pinna. As a result of such trauma patient develops swelling which is painless, circular or irregular, hard in consistency and devoid of tenderness⁴. Keloids are known to occur more frequently in black skin individuals. They show strong positive familial association and are seen more often in young age group patients. The incidence of keloids is about 15 times greater in dark skin individuals than in whites^{1,2}. Genetic associations for the development of abnormal scars have been found for HLA-B14, HLA-B21, HLA-BW16, HLA-BW35, HLA-DR5, HLA-DQW3, and blood group A. Regions of the human genome highly correlated with keloid formation in 2 pedigrees with familial keloids have been recently identified. The regions identified were in two separate, unrelated locations on the human genome, underscoring the complex and multivariable pathogenesis of this disease.⁵ Many treatment modalities have been tried worldwide for this condition which includes surgical excision, intralesional steroids, application of silicon gel or patches, radiation, pressure therapy, LASER treatment, retinoids, 5-Fluorouracil and interferon. However, none of them are foolproof with regards to complete cure and prevention of relapse as the condition is notorious for its

high relapse rate of about 50-80 %.⁶ According to Ayurveda, ear Pinna keloid can be correlated with Arbuda of Karnapali. It is described under Mansadhatu pradoshaj vyadhi.⁷ As per Ayurveda, Mansadhatu pradoshaj vyadhi (diseases of the muscular or soft tissue) are to be treated with kshar and Agnikarma in order to achieve complete cure.^{8,9} Due to frequent relapse, patients seek alternatives methods that would preferably be free of relapse. Some of the patients from our study group were referred to us, while some wanted to explore treatment at our center with complete cure in mind. We decided to design this study using Ayurvedic management for such patients with an objective to avoid relapse and provide complete cure.

MATERIALS AND METHODS

Aims and Objectives

- To study the efficacy of Ksharsutra ligation for removal of ear pinna keloid instead of surgical excision
- To study the efficacy Agnikarma after removal of ear pinna keloid to minimize the relapse.

The clinical study was conducted after approval from institutional ethics committee (approval number 3506/2011). A total of 20 patients (4 men and 16 women) were enrolled at the department of Shalakya tantra of R A Podar Ayurveda Medical College and Hospital, Mumbai, India. The inclusion criteria were: having keloid on ear pinna/ ear lobe of any size, age above 10 years, willing to give informed consent (assent of patient and parent's consent in case of minor patients). The following exclusion criteria were used: being under the age of 10 years, being pregnant or breastfeeding, having allergies to anaesthetics, or being unwilling to give informed consent.

Other conditions than ear pinna keloid like benign – preauricular cyst or sinus, papilloma, cutaneous horn, sebaceous cyst, keratoacanthoma, dermoid cyst, neurofibroma, haematoma, haemangioma etc. were excluded from study. Patients having diabetes mellitus, hypertension, bleeding disorders, tuberculosis, seropositive for HIV and Hepatitis B were excluded.

Type of study

Randomized open labeled parallel group study.

Group A: Excision of keloid was done using Ksharsutra (n = 10)

Group B: Excision of keloid was done using Ksharsutra followed by Agnikarma (n = 10)

Of the twenty patients enrolled for study fifteen had not sought any form of medical, chemical or surgical management earlier. Five of the twenty patients had keloids which were relapsed after previous surgical management. On randomization, 1 of these 5 was allotted into Group A while other 4 were kept in Group B. The patient in Group A had history of single surgical excision and relapse whereas the 4 from Group B had received previous surgical treatment on several occasions (2 had history of 2 operations and 2 others had undergone 3 operations) followed by relapse.

Preparation of Ksharsutra

Ksharsutra was prepared as per classical method mentioned by CCRAS, India.¹⁰ Surgical linen thread No.7 was used for preparation of Ksharsutra. A layer of Snuhi ksheer (latex of *Euphorbia nerifolia*) and Haridra (*Curcuma longa*) powder was applied on the thread and was allowed to get dry. Another layer of the combination was applied, similarly and was dried. This procedure was repeated for 21 times. This thread, now called as Ksharsutra, was then kept in UV chamber for maintaining its sterility.

Surgical Protocol

Under all aseptic precautions local anesthetic lignocaine 2 % with adrenaline (1:1000) was administered by infiltration in superficial skin around the base of the keloid. A superficial skin incision was taken around the base of the keloid. A sterile ksharsutra was applied and ligated tightly on the incision site¹¹. After ligation dressing with povidone-iodine was done. The patient was observed for pain, inflammation, discoloration, necrosis, if any, and also for the cutting process. The same ksharsutra was kept for three days. On the fourth day after removal of first ksharsutra a fresh sterile ksharsutra was ligated. The new ksharsutra was kept for next 3 days¹². This cycle was continued till the keloid fell off completely. Dressing with povidone-iodine was done after ligation of every ksharsutra. Patient was asked to visit on the day the keloid fell off completely. Agnikarma (~cauterization) was done on the third day of complete fall of keloid in ten patients of Group B. Agnikarma was done over new granulation tissue by ball point cautery. Follow-up: All patients were asked to give a follow up visit at the intervals of 1 month, 3 months, 6 months, 24

months and 36 months. Group B patients were additionally asked to visit at 12 months interval. A careful watch for relapse of keloid, if any, was done at the follow-up visits. The patients were being followed up till date.

RESULTS

The total number of patients in this study was 20, of which two patients were below 20 years of age (both male). Most of the patients were females (16 out of 20) of which, 14 belonged to young age-group (21-40 years of age). This is consistent with the literature on prevalence of ear pinna keloids worldwide. There were no patients from the age group of 60 and above in the study (Table 1). After Ksharsutra ligation the response in terms of complete excision of keloid varies from patient to patient and the size of keloid. In our study, the keloids of all the patients fell off completely by the 9th post-operative day (Table 2). As mentioned in the Materials and Methods, ksharsutra was changed after every 3 days. The wound after the keloid has fallen off healed on its own in all patients. The granulation tissue appeared at around fourth days after this and Group B patients underwent additional Agnikarma at this point of time. The patients were followed up at regular intervals as mentioned earlier. Most patients have completed 36 months of follow-up and there were encouraging results seen in Group B patients. The relapse rate is summarized in the Table 3. It is interesting to note that the four patients from Group B who had shown relapse with previous surgical modalities have not shown any relapse after 3 years of intervention.

Statistical analysis

Fisher's exact test was applied to the data using the In stat 3 software to see relative risk reduction. The two-sided p value was found to be 0.0198, considered significant. The row/column association is statistically significant. Relative Risk was calculated and found to be 7.000 at 95 % Confidence Interval: 1.043 to 46.971 (using Katz approximation). This shows that there is statistically significant risk reduction in relapse of ear pinna keloid by Agnikarma after ksharsutra treatment.

Odds ratio = 21.000 95 % (Confidence Interval: 1.776 to 248.25) with P value is 0.0198 considered statistically significant.
(Using the approximation of Woolf)

DISCUSSION

According to Ayurvedic literature, keloid of ear pinna can be correlated with Arbuda. Arbuda is the mass or growth that occurs at the pinna or lobule. According to Ayurvedic principles of etiopathogenesis, Arbuda is a mansa dhatu pradoshaja vyadhi (~disease having abnormal involvement of muscular and fibrous tissue) and application of Ksharsutra and Agnikarma are important treatment modalities mentioned in principles of treatment for the same. Snuhi ksheer (latex of *Euphorbia nerifolia*) is strong alkaline in nature which causes chemical cauterization. Its action on tissue begins with severe irritation and subsequent inflammation of local tissue causing local tissue necrosis.

Table 1: Age-Sex wise distribution of Patients

Age	Male	Female
10-20 years	02	00
21-40 years	00	14
41-60 years	02	02
>60 years	00	00
Total	04	16

Table 2: Number of days required for the keloid to get completely excised (Cumulative frequency)

Days	No of patients shown fall of keloid (cumulative frequency)
0	0
1	0
2	0
3	1
4	2
5	3
6	7
7	14
8	17
9	20

Table 3: Comparative effect of treatment in both the groups

Group	Relapsed	Not Relapsed
A (Ksharsutra)	07	03
B (Ksharsutra +Agnikarma)	01	09

Photo 1: Keloid Before Treatment day -0

Photo 2: During Ksharsutra ligation procedure Day-1

Photo 3: Ligated Kshar sutra Day- 3

Photo 4: Ligated Ksharsutra Day- 4

Photo 5: Fall of Keloid after Ksharsutra Day-7

Photo 6: During Agnikarma

Photo 7: During Agnikarma

Photo 8: Just After Agnikarma

Photo 9: Followup after 4 Months of Agnikarma

Photo 10: Follow up after 6 months of Agnikarma

Photo 11: Follow up after 15 months

This debris of necrosed tissues is cleared out giving way for fresh budding granulation tissue over the wound. Haridra (*Curcuma longa*) powder is antiinflammatory, antiseptic and antibacterial having wound healing activity which prevents infections and facilitates tissue growth thereby promoting healing. Ksharsutra has a controlled chemical cauterizing action on living tissue. Its action is a simultaneous combination of incision, excision, debridement, scrapping along with haemostatic, antiseptic and healing. This leads to removal of keloid mass without producing any other injury if ligated by skilled person.^{13,14} The ear pinna keloid got excised by ligating ksharsutra in all the patients. The study thus shows that ear pinna keloid can be successfully removed by application of ksharsutra. But so far as the relapse rate is considering ksharsutra application alone, does not show much merit. As mentioned by Ayurveda, Agnikarma (cauterization after removal of ear pinna keloid) is most important treatment modality. The study shows that there is statistically significant risk reduction in relapse of ear pinna keloid after doing Agnikarma after removal of keloid by ksharsutra. Agnikarma arrests overgrowth of tissues hence Agnikarma after removal of ear pinna keloid by ksharsutra reduces risk of relapse of ear pinna keloid.

CONCLUSION

From this study we can conclude that ksharsutra can be used to remove ear pinna keloid. Agnikarma done after removal of ear pinna keloid by ksharsutra considerably reduces the risk of relapse of ear pinna keloid. But so far as the relapse rate with reference to ksharsutra application alone does not show much merit.

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