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The efficacy of excision followed by intralesional 5-fluorouracil and triamcinolone acetonide versus excision followed by radiotherapy in the treatment of ear keloids: A randomized control trial[☆]

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ARTICLE INFO

Article history:

Accepted 9 February 2018

Available online xxx

Keywords:

Ear keloids

Post-excision intralesional 5-FU/TAC

Post-excision radiotherapy

ABSTRACT

Background: The ear is the common site for keloid formation especially in women after ear piercing. Surgery is the main stay of treatment in these lesions but there are large numbers of treatment failures in surgery alone.

Objective: The objective of this study was to compare the efficacy of post-excision intralesional 5-fluorouracil/triamcinolone acetonide (5-FU/TAC) and post-excision radiotherapy in the treatment of ear keloids.

Study design: A randomized controlled trial.

Setting: The study was conducted from May 2014 to January 2015 at Jinnah Burn and Reconstructive Surgery Centre, Allama Iqbal Medical College, Lahore.

Subject & methodology: After approval from the hospital ethical committee, 60 patients presented in the outpatient department fulfilling the inclusion criteria were selected and randomly assigned in two groups with the help of the random number table. Patients in group A had excision followed by intralesional 5-FU/TAC injections while patients of group B had excision followed by radiotherapy.

Patients were assessed at 6 months after completion of treatment for efficacy (no recurrence within 6 months of treatment).

Results: In our study total of 60 patients completed the study, with 30 patients in each group. 7 patients (23.34%) in Group-A and 9 patients (30%) in Group-B were males while 23 patients (76.67%) in Group-A and 21 patients (70%) in Group-B were females i.e. male to female ratio is 1:2.75. Mean age was 31.8+6.48 years. The comparison of frequency of efficacy in both groups showed that 73.33% (n=22) in Group-A and 43.33% (n=13) in Group-B had efficacy, p value was calculated as 0.01, showing a significant statistical difference.

Conclusion: Excision and intralesional 5-FU/TAC is an effective treatment for keloids on the ears.

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[☆] Paper presentation at the International Society of Burn Injuries, August, 2016 at Miami, Florida, USA.

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<https://doi.org/10.1016/j.burns.2018.02.017>

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1. Introduction

Ear keloid is a challenging problem [1]. Despite the availability of different treatment options still there is a significant number of treatment failures and variable final outcome [1-3]. Surgical excision has found a good place among its treatment options, but alone it results in 45-100% recurrence rates [2].

Radiation alone has a high recurrence rate, but has better results if used in combination with surgical excision [4]. Excision along with radiation therapy has the higher success rate i.e. 28-98% [5,6]. This wide range is due to lack of standardization in previous studies [6]. In a study by Kar Al combined surgical excision and radiation therapy and presented a recurrence rate of 71.9% (efficacy 28.1%) [5]. Narkwong et al published his results of treating 24 keloids. 15 patients completed the study and showed 87.5% efficacy with only two recurrences [7]. Use of radiation as therapeutic modality in control of benign disease merits caution especially in children and young adults [8]. Also there were early toxicity outcomes, skin redness in 54.2% and skin peeling in 24% and late toxicity outcomes being telangiectasia in 27% and permanent skin color changes in 62% in a study [9].

The use of the antineoplastic agent as treatment seems logical due to its effect on rapidly proliferating cells [10,11]. 5-Fluorouracil (5-FU) exhibit antimetabolite activity by inhibiting the DNA synthesis of cells [3,12]. It is effective treatment with rapid response and fewer side-effects, skin ulceration in 10% while telangiectasia, hypopigmentation and skin atrophy in 0% of cases in a study [12]. Intralesional 5-FU is safe with no drug toxicity when with the subcutaneous use as compared to the intravenous administration [13]. Addition of triamcinolone acetonide (TAC) helps to reduce the pain, stinging, inflammation, purpura and hyperpigmentation at injection site [14]. Also combine use of 5-FU and TAC has a synergistic effect on keloid [15].

Rationale of this randomized control trial is to assess the outcome of excision along with intralesional 5-FU/TAC and radiation in terms of efficacy and recurrence, so that it can be applied in our population as there is a convincing body of evidence that different treatments have a variable efficacy rate as mentioned. Recurrence is not only inconvenient and costly to patient but also time consuming for surgeons. Also radiation for benign diseases is controversial especially in young female adults. This study will not only delineate guidelines in management of ear keloid scars but also will be beneficial for patients with less reoccurrence and fewer side effects.

2. Materials and methods

After our hospital ethical committee approval, the parallel group, non-blinded randomized control trial was conducted at Jinnah Burn and Reconstructive Surgery Center, Lahore from May 2014 to January 2015. A total of 85 consecutive patients presented in the outpatient department of were assessed for suitability for inclusion. 60 patients meeting the inclusion criteria of age between 12-65 years of either gender were included in the study. Patients, who took any treatment in the last six months, had any history of renal or liver disease and

female with pregnancy or lactation were excluded from the study. An informed consent was obtained. Patients were divided randomly into two groups by the help of simple randomization. The computer generated the random number table was used and the holder of allocation schedule was off site. The Group A was the patients of post-excision 5-FU/TAC and group B was the patients of post-excision radiotherapy.

Sample size was calculated from wip-pepi ver: 11.15 with 80% power of test, 5% level of significance. Ratio of sample size was B:A=1. Expected efficacy was 45.7% in Group A [14] (5FU/TAC) and 87% in Group B (Surgical excision & Irradiation) [7]. The required sample size was 60 (30 in A, 30 in B).

All the patients had baseline assessment at the beginning of treatment and were recorded in Performa. All patients underwent excision of the keloid under local anesthesia.

The Group A at the time of excision received the maximum of 150mg of intralesional 5-fluorouracil [5-FU] injection in wound bed and margins with approximately 0.2ml/cm² mixed in 9:1 with TAC. Patients were followed up at a monthly interval for two consultative months and were injected 5FU/TAC with the same dose as injected per operative. If there was no recurrence after two injections then further injections were stopped. For patients who showed hypertrophy after second injection, the intralesional injections were continued at the monthly interval until the hypertrophy worsen to the point of keloid formation or became flat with complete scar resolution. The total number of injections was noted in each case.

Group B patients received radiotherapy (Electron Beam Therapy) of 10Gy in 2 fractions in two consecutive days started within 24h of excision. The treatment was targeted to the suture line and the 0.5 cm area on both sides. A small cone was used to prevent radiation to the adjacent structures.

Assessment of patients of both groups was done monthly for the first 6 months after treatment. The final assessment for efficacy was done at 6 months after completion of treatment by the researcher and data was entered in the record.

Efficacy was considered as no recurrence 6 months after the end of treatment. All the collected information was entered into S.P.S.S. version 16 and analyzed through its statistical package. Numerical variables of interest like the size of the scar were presented as mean and standard deviation. Nominal variables like efficacy (in terms of recurrence) were presented as frequency and percentage. The Chi square was used to compare the efficacy in both groups. P-value ≤ 0.05 was taken as significant. Affect modifiers age, gender, the size of the scar was dealt with stratification. The post stratification chi-square test was applied on the data.

3. Results

Total of 60 patients were enrolled after applying the inclusion and exclusion criteria and divided into two groups.

The Age ranges from 12 to 65 years in both groups. The mean age+SD were calculated in group A and B as 30.9+5.87 and 32.73+7.09years, respectively.

23.34% (n=7) in Group-A and 30% (n=9) in Group-B were males while 76.67% (n=23) in Group-A and 70% (n=21) in Group-B were females i.e. male to female ratio was 1:2.75 (Table 1).

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