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The Effectiveness of Immediate Triamcinolone Acetonide Injection after Auricular Keloid Surgery: A Prospective Randomized Controlled Trial

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Background: The earlobe and helix are common sites for keloids following ear piercing. First-line therapy involves intra-keloidal excision followed by triamcinolone acetonide (TA) injection. Yet, the optimal timing for TA injection after keloid excision remains debated. The objective of this study was to compare outcomes between immediate and delayed TA injection after auricular keloid excision.

Methods: This was a prospective, controlled trial with patients randomized into immediate or delayed groups. The Vancouver Scar Scale (VSS) and Patient and Observer Scar Assessment Scale (POSAS) were used to evaluate scar quality. The number of recurrent keloid cases was recorded, defined as a VSS height of 3, POSAS thickness greater than 5, or an increase in VSS height or POSAS thickness after keloid excision. Overall complications were recorded. A *P* value less than 0.05 was considered statistically significant.

Results: The immediate group contained 18 patients, and the delayed group had 16 patients. The mean age of patients was 25.52 years, and the mean maximum keloid diameter was 14.49 mm (7–32.5 mm). The immediate group reported a statistically significant lower recurrence rate than did the delayed group at 5 months ($P = 0.042$). No significant differences were noted between VSS and POSAS scores at 3 months, and no complications were recorded during the study.

Conclusions: Immediate TA injection is an acceptable option for auricular keloid treatment. Here, it was associated with a lower recurrence rate than with delayed injection and resulted in no complications. The immediate and delayed groups had similar outcomes for VSS and POSAS. *(Plast Reconstr Surg Glob Open 2021;9:e3729; doi: 10.1097/GOX.0000000000003729; Published online 4 August 2021.)*

INTRODUCTION

A keloid is a fibroproliferative disorder that can result from the alteration of growth factor regulation, aberrant collagen turnover, genetic abnormalities, immune dysfunction, sebum reaction, or mechanical factors. It features abnormal deposition of hyalinized collagen bundles, resulting in firm, fibrous nodules, papules, or plaques.[1]

Keloids cause disfiguration, psychological problems, and functional impairment that affect patient quality of life. The most common auricular keloid sites are the lobe and helix. Auricular keloids could result from trauma or ear piercing, with a 2.5% incidence rate.[2]

Current keloid therapeutic management has many modalities, including surgical, medical, physical, radiotherapeutic, and experimental options.[3] Intralesional triamcinolone acetonide (TA) injection is the most effective and the first-line treatment for mature keloids. TA, a synthetic corticosteroid, has been used either alone or in combination with surgery, pressure, or radiation, with varying results.

TA injection alone and in combination with lesion excision are the most common treatment options for auricular keloids.[4] The recurrence rate of an excised keloid alone is 45%–100%, whereas it is less than 50% if postoperative TA injection is included.[5–8] Intralesional TA injection could be done in a variety of ways.[9]

TA reduces collagen synthesis. It decreases X2-macroglobulins and X1-antitrypsin by promoting collagenase inhibitor activity, altering extracellular matrix components such as glycosaminoglycans, and increasing pro-inflammatory mediators, the production of β1 by human dermal fibroblasts, endogenous vascular endothelial

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growth factor, and interleukin-1 (IL-1).[10] Corticosteroids induce an increased production of β-fibroblast growth factor (β-FGF). Intralesional TA injection reduces fibroblast activity, density, and maturation.[11,12] Moreover, immediate TA injection was reported to reduce pro-α1 (I) collagen gene expression.[13] It is possible that TA, administered immediately after the excision, could prevent keloid recurrence. However, rare complications such as infection were reported following immediate TA injection.

Previous studies were inconclusive on the best timing of TA injection after keloid excision, immediate or delayed.[11,12,14] Therefore, elucidating this point was the objective of this study.[11–14]

This study aimed to compare immediate and delayed single TA injection in terms of scar quality using the Vancouver Scar Scale (VSS) and the Patient and Observer Scar Assessment Scale (POSAS) over a follow-up period of 6 months. Moreover, complications such as pain, skin atrophy, depigmentation, and telangiectasias were assessed to determine the proper TA injection timing after keloid excision.

PATIENTS AND METHODS

This prospective randomized controlled trial was conducted from September 2017 to September 2019. The ethics committee of Phramongkutklao Hospital and College of Medicine approved this study. All patients provided informed consent.

Patient Selection

The inclusion criteria were as follows: patients with auricular keloids, aged 18–65 years, with pathological tissue reports confirmed by a pathologist, and agreed to provide their informed consent for participation. The exclusion criteria were as follows: patients with a history of TA hypersensitivity or anaphylaxis, immunocompromised patients, those who underwent a previous treatment over the past year, patients using steroid or immunosuppressive drugs, and patients who refused to participate in the study. We recorded demographic data, including age, sex, body mass index, and smoking habits, and keloid-related information such as duration, maximum diameter, location, etiology, and previous treatments.

Randomization

The patients were randomly allocated to the following groups by a random numbers table:

1. Immediate group: defined as patients receiving an intraoperative injection of 0.1–0.2 mL 10 mg/mL TA into the incision after keloid excision.
2. Delayed group: defined as patients receiving 0.1–0.2 mL 10 mg/mL TA injection into the incision 1 week after the keloid excision surgery.

The total dose of TA was also decided depending on the length of suture line (0.1 mL per 1 cm).

Procedure Preparation

The surgical site was prepared under sterile conditions. The intralesional keloid excision surgery was performed under local anesthesia with 1% xylocaine HCl. The skin was closed with 6-0 nylon suture without tension and by the nontraumatizing technique (Fig. 1), and no oral antibiotic was dispensed.

Evaluation

The outcomes were recorded and evaluated by a surgeon who was blinded to the study group allocation. Images were acquired with a camera (model Rx100 mark iv with 20.1 megapixels Exmor RS CMOS Sensor and Bionz X image processor; Sony Corp., Tokyo, Japan). The focal distance was approximately 30 cm. We recorded the VSS and POSAS scores, any complications, recurrent keloid timing, and tissue pathology.

Scar Assessment

Surgical scars were evaluated by the VSS and POSAS. VSS evaluated pain, itching, pigmentation, vascularity,

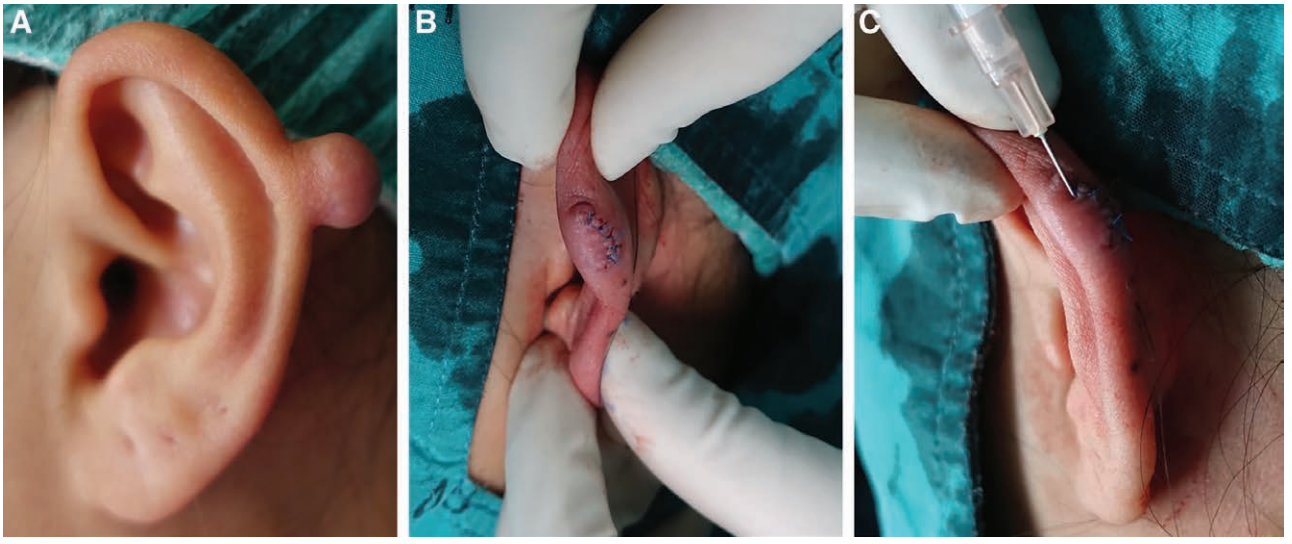

Fig. 1. Immediate TA injection after intralesional keloid excision. A, Patient with a 1.0 x 3.0-cm left helix-auricular keloid. B, Intrakeloidal excision was performed with primary intension. C, 0.1 ml 10 mg/ml TA was injected at suture line.

height, and pliability. POSAS is a reliable and valid scar assessment scale that measures scar quality from two perspectives: the patient and the clinician. The patient POSAS includes itching, pain, irregularity, color difference, stiffness, and thickness; the clinician POSAS includes vascularity, pigmentation, thickness, relief, pliability, and surface area.

Follow-up Procedure

All patients were invited to the clinic 7 days postoperatively. The surgical site was evaluated in both groups, and TA was injected in the delayed group. The sutures were removed on postoperative day 14. VSS, POSAS, and complications were recorded monthly for 6 months in both groups. A surgical scar was observed until the keloid recurred or till the end of the 6 months. Recurrent keloids were injected monthly with TA. Keloid recurrence was defined as a VSS height score of 3 or patient-POSAS thickness score of 5 or higher. Alternatively, recurrence was determined when we detected a postoperative increase in the VSS height score or POSAS thickness score. VSS and POSAS scores were not calculated after keloid recurrence.

Endpoints

The primary outcome was the total recurrence rate by the 6-month follow-up visit. The secondary outcome was complications after treatment, including infection and skin flap necrosis.

Statistical Analysis

The outcomes of this study were demographic data, VSS and POSAS scores, and complication and recurrence rates. These were compared by the Pearson chi-squared test, Fisher exact test, independent samples *t*-test, or the Mann-Whitney *U* test, as appropriate. The confidence interval for statistical data was 95%, and differences were considered statistically significant at a *P* value less than 0.05.

RESULTS

Patient Demographics

Thirty-four patients were enrolled between September 2017 and September 2019. Eighteen patients were allocated to receive an immediate TA injection, and 16 received a delayed TA injection. The patient demographics are listed in Table 1. The median age was 24.7 years (range, 18–33 years), and the study population consisted of 10 men (29.4%) and 24 women (70.6%). The keloid site distribution included the helix in 18 patients (53%), lobule in 15 patients (44%), and antihelix in one patient (3%). The mean maximum diameter was 14.48 mm (range, 7.0–32.5 mm). All keloids were located above the supra-perichondrial plane. The mean body mass index was 21.94 kg/m^2 (range 16.5–34.8 kg/m^2). The auricular keloid etiology was piercing in 32 patients (94%) and infection in 2 (6%).

VSS

The VSS scores 6 months after the surgery were similar in both groups. However, the delayed group showed significantly higher VSS height and pliability scores than the immediate group in the first 2 months.

Table 1. Demographic Data

	IG (n = 18)	DG (n =16)	*P*
Gender			0.134*
Men	3 (16.67)	7 (43.75)	
Women	15 (83.33)	9 (56.25)	
Age	20.5 (18–66)	24 (17–33)	0.616†
Body mass index	21.64 ± 3.61	23.41 ± 5.26	0.080†
Smoking			0.387*
No	16 (88.89)	12 (75.00)	
Yes	2 (11.11)	4 (25.00)	
Location			0.125*
Antihelix	0	1 (6.25)	
Helix	12 (66.67)	6 (37.50)	
Lobule	6 (33.33)	9 (56.25)	
Duration (mo)	12 (6–60)	18 (8–48)	0.446‡
Maximum diameter (mm)	14.1 (7–32.5)	12.2 (7–29)	0.523‡
Etiology			1*
Infection	1 (5.56)	1 (6.25)	
Piercing	17 (94.44)	15 (93.75)	
Previous treatment			1*
No	16 (88.89)	14 (87.50)	
Yes	2 (11.11)	2 (12.50)	

*Fisher exact test.
†Independent *t*-test.
‡Mann-Whitney U test.
$P < 0.05$ is considered significant.
DG, delayed group; IG, immediate group.

POSAS

The POSAS scores 6 months after the surgery were similar in both groups. However, the immediate group showed a significantly higher POSAS thickness score at postoperative months 2 and 3.

Recurrence Rate

Auricular keloid recurred within 6 months in four patients in the immediate group (22.2%), which is significantly less than that in the nine patients in the delayed group (56.25%; Table 2 and Fig. 2). Figure 3 shows a recurrent keloid after excision.

Complications

There were no complications such as infection, skin flap necrosis, inflection, postoperative bleeding/hematoma, skin atrophy, or telangiectasias.

DISCUSSION

Immediate TA injection after keloid excision is a safe and effective method to reduce the recurrence rate. However, surgeons often dread using it because of the potential postoperative complications. This study is the first randomized controlled trial to compare immediate and delayed TA injections after keloid excision.

A previous study reported unsatisfactory keloid treatment with a high recurrence rate.[14] Surgery and TA injection have shown varying recurrence rates (Table 3). It ranged between 50% and 100% in cases of excision alone.[15] Berman and Flores reported that recurrence following postoperative TA injection started within 7 days of excision (58.5%), and this recurrence rate was similar to excision alone (51.2%).[22] Sclafani et al

Table 2. Accumulate Number of Recurrence

Duration (mo)	No. Immediate Group	No. Delayed Group	Accumulate Number of Recurrence—IG	Accumulate Number of Recurrence—DG	*P**
1	18 (100%)	16 (100%)	—	—	
2	18 (100%)	13 (81.25%)	—	3	0.094
3	16 (88.88%)	12 (75.00%)	2	4	0.374
4	14 (77.77%)	9 (56.25%)	4	7	0.180
5	14 (77.77%)	7 (43.75%)	4	9	0.042†
6	14 (77.77%)	7 (43.75%)	4	9	0.042†

*Pearson Chi-squared test.
†Significant if $P < 0.05$.
DG, delayed group; IG, immediate group.

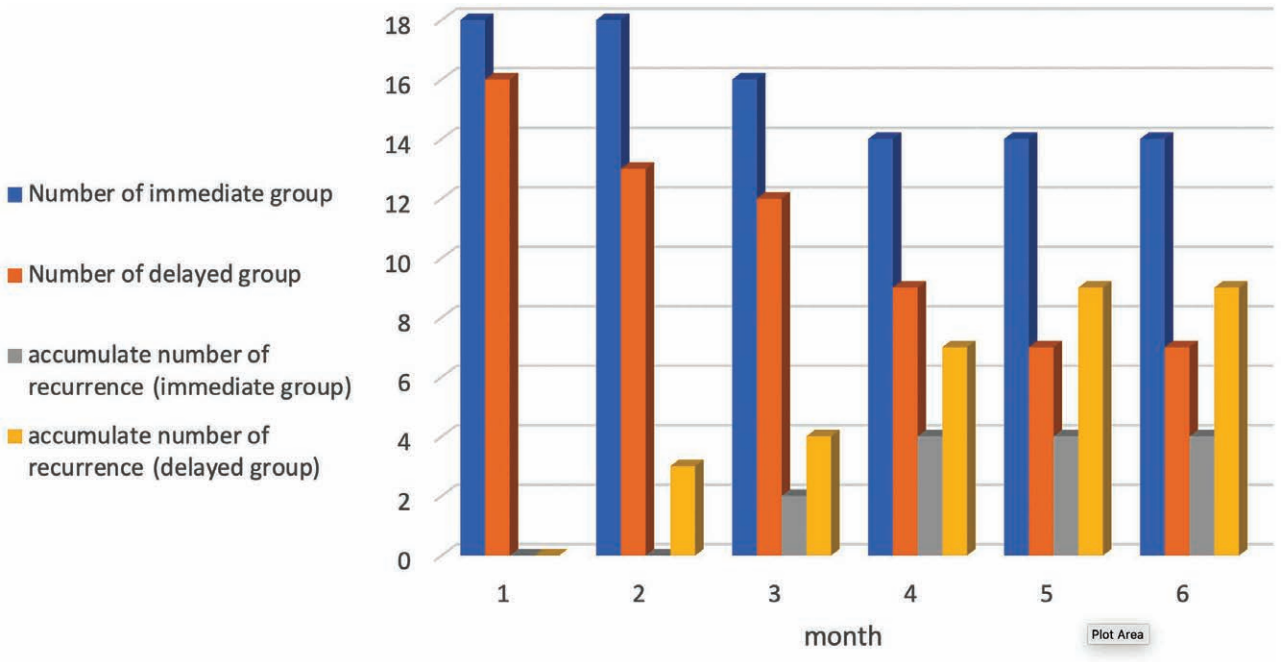

Fig. 2. Accumulated recurrence number in the immediate and delayed groups.

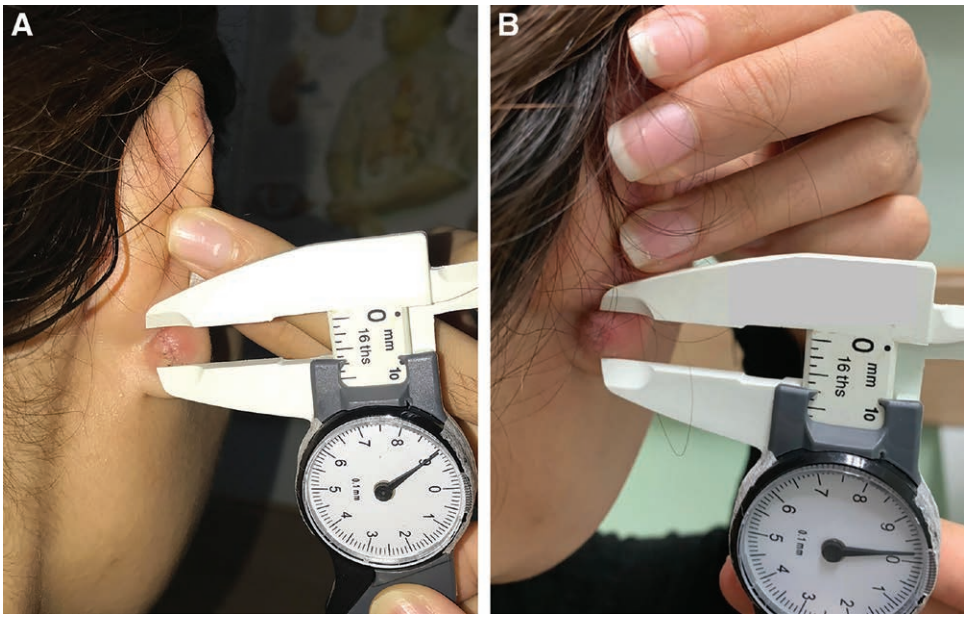

Fig. 3. A recurrent auricular keloid 4 months after excision and immediate TA injection. (A) A 2-month postoperative photograph. (B) photograph obtained 4 months postoperatively showing recurrent keloid.

Table 3. Results of the Systematic Literature Review

Study	Method	No. Keloids	Site	Treatment Regimen	Mean Number of Administered Injections	Postoperative Follow-up Duration (mo)	Recurrence Rate (%)	Results
Singleton and Gross[15]	—	54	Ear	Immediate methylprednisolone acetate 32–40 mg or TA 8 mg and continued monthly for 12 months	—	12	7%	—
Kiil[16]	Prospective trial	15	Whole body	Combined excision and immediate TA injection therapy	—	24–60	86.70%	—
Barton[17]	—	19	Ear	10–15 mg of TA injection at immediate postoperative and postoperative day 7	—	6–48	0%	—
Shons and Press[18]	—	31	Ear	0.1–0.2 mL of 40 mg/mL of TA injection at postoperative week 3 and repeated twice at 4-week intervals	—	35	3%	—
Tang[19]	Case report study	11	Whole body	Intra- and postoperative weekly steroid injection (10–30 mg Triamcinolone suspension)	—	12–36	18%	—
Salasche and Grabski[20]	A surgical technique: circular incision and plane separation of the central core of keloid	6	Ear	Immediate 5 mg/mL of TA injection and postoperative 2 week and then subsequent injections are given at 4- to 6-week interval as needed	—	>12	0%	—
Sclafani et al[21]	Randomized trial	12	Ear	0.4 mL of 40 mg/mL of TA at postoperative days 7, 21, and 35	—	19	33.30%	—
Berman and Flores[22]	Retrospective study	65	Whole body	TA group 10–40 mg/mL (started within 7days of excision)	1.4	7.5	58.50%	—
		16		IFN-α2b	—	7.9	18.70%	—
		43		Excision only	—	6.5	51.20%	—
Tan[23]	Patient-controlled comparative clinical trial	17	Whole body	4 weeks Postoperative TA injection of 0.1–0.5 mL of 40 mg/mL	—	3		16 of 17 showed 50% reduction in volume at week 12
Jung et al[24]	—	18	Ear	Preoperative intralesional TA injections were administered twice at 1-month interval: 0.1– 1.0 mL of TA (20–40 mg/mL); postoperative intralesional TA injection was started at 2 weeks time point after surgery and injection was given every 1 month for several months	5.2	18.5	16.67%	—
Srivastava et al[25]	Single-blind, randomized parallel group study	60	Whole body	TA group received intralesional TA of 40 mg/mL	—	Every 3 weeks till 24 weeks or till the keloid is resolved	—	Lowest survival curves for vascularity of VSS
				5-FU group received intralesional 5-FU of 50 mg/mL	—	Every 3 weeks till 24 weeks or till the keloid is resolved	—	Lowest survival curves for height of VSS
				TA+5-FU group received intralesional injection of a combination of TA (40 mg/mL) and 5-FU (50 mg/mL) at a ratio of 1:9	—	Every 3 weeks till 24 weeks or till the keloid is resolved	—	Short term: lowest survival curves for pliability and pigmentation of VSS

(*Continued*)

Table 3. (*Continued*)

Study	Method	No. Keloids	Site	Treatment Regimen	Mean Number of Administered Injections	Postoperative Follow-up Duration (mo)	Recurrence Rate (%)	Results
Chua et al[26]	A single blind randomized controlled trial protocol	150	Cesarean section incision	Sub-dermal injection of 2 ampule 10 mg/mL TA will be administered at a single dose	—	—	In progress	—
Mohammadi et al[27]	Retrospective study	31	Ear	First postoperative week 4–10 mg intralesional injection of TA from 20 mg/mL was administered once per month for several months	4.22	15.93	0%	—
Choi et al[28]	Single-center, retrospective, clinical study	20	Ear	Second postoperative week 0.1–0.5 mL (concentration of 10–40 mg/mL) every 4–6 weeks	3.59	24	5%	—
Zhuang et al[29]	Systemic review and meta-analysis	15	Whole body	—	—	—	—	TA was associated with significant improvement in vascularity and pliability compared with Verapamil
Our study	A randomized controlled trial	34	Ear	Immediate 10 mg/mL of TA injection	1	6	22.20%	—
				10 mg/mL of TA injection at postoperative day 7	1	6	56.25%	—

reported a recurrence rate of 33% after a delayed serial 40 mg/mL TA injection following earlobe keloid excision.[21] Chowdri et al reported a recurrence rate of 8.1% in intraoperative and serial postoperative corticosteroid injection therapy.[30] Surgical excision with postoperative intralesional TA injection is an effective auricular keloid treatment. Immediate TA injection after keloid excision in our study reduced the recurrence rate. Young et al showed that immediate TA injection after keloid excision resulted in lower pro-alpha (I) collagen transcript expression, higher production of β-fibroblast growth factor (β-FGF), lower production of transforming growth factor 1 (TGF-1) by the dermal fibroblasts, endogenous vascular endothelial growth factor, and IL-1, and thinner and less dense collagen bundles than the surgery alone group.[31,32]

TA should be used with caution because intralesional corticosteroid injections were reported to be associated with various side effects in 63% of the patients.[33] Local side effects include infection, atrophy, depigmentation, and telangiectasia. Cushing syndrome and menstrual disturbances are rare systemic complications. Ketchum et al reported that 95% of these complications result from incorrect TA injections.[34]

This study aimed to compare single-dose immediate and delayed TA injections after keloid surgery. We did not use the subsequent TA injection method to avoid disturbance of effects between doses. However, all patients received monthly TA injections after a 6-month follow-up period. Additionally, this study showed the real effectiveness of single-dose immediate and delayed of TA within 6 months. No additional records were taken after 6 months because subsequent TA injections are known to disturb the effectiveness of the first-dose TA. The recurrence rate in this study was very high because we used the VSS and POSAS scores. Moreover, we redefined recurrence for early detection, and for dual detection between physicians and patients.

Our study suggests that immediate TA injection after keloid excision results in a lower recurrence rate than delayed TA injection. Immediate TA injection after excision showed no complications. The VSS height and pliability scores were higher in the first 2 months, and the POSAS thickness score was higher in the second and third months in the immediate group. However, the VSS and POSAS scores were similar for both groups at the end of the study (Fig. 4).

This study was limited by the small number of participants. Furthermore, the follow-up period was insufficient to make definitive assertions about auricular keloid recurrence after treatment.

CONCLUSIONS

Immediate TA injection after keloid excision was a safe and effective technique for auricular keloid treatment with a follow-up of 6 months. Its advantages include a lower recurrence rate than the delayed TA injection group and no complications. VSS and POSAS scores at the final follow-up were similar in the two groups. However,

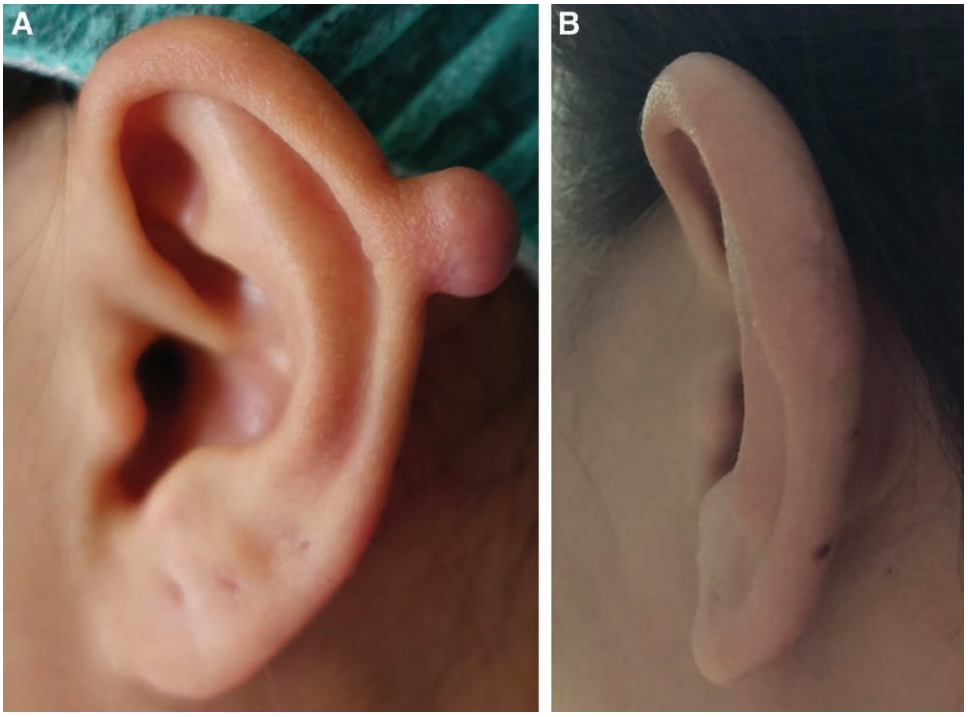

Fig. 4. A, Patient with a 1.0 x 3.0-cm keloid at left helical rim. B, A 6-month postoperative photograph.

the VSS height and pliability and the POSAS thickness scores in the immediate TA injection group were higher in the first few months.

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