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COMBINED INTRALESIONAL STEROID AND HYALURONIDASE THERAPY FOLLOWED BY SURGICAL EXCISION IN THE MANAGEMENT OF EARLOBE KELOIDS: A PROSPECTIVE STUDY

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ABSTRACT

Background: Earlobe keloids are a common complication following minor trauma or piercing, presenting a significant cosmetic and psychological burden to affected individuals. Their management remains a clinical challenge due to high rates of recurrence and limited success with monotherapies. While surgical excision is often the mainstay of treatment, it carries a considerable risk of recurrence if not combined with adjuvant therapies. Corticosteroids are widely used to inhibit fibroblast proliferation and collagen synthesis, whereas hyaluronidase can facilitate better steroid penetration and reduce tissue fibrosis. The integration of these two agents in a preoperative protocol, followed by surgical excision, has not been comprehensively studied in earlobe keloids. **Objective:** To evaluate the efficacy and safety of a treatment protocol involving intralesional triamcinolone acetonide and hyaluronidase combination therapy followed by surgical excision in patients with earlobe keloids. **Materials and Methods:** This prospective interventional study includes 30 patients with clinically diagnosed earlobe keloids treated at a tertiary care center. All patients received three intralesional injections of triamcinolone acetonide (40 mg/mL) combined with hyaluronidase (1500 IU), administered at 15-day intervals. After the injection course, surgical excision was performed, followed by an intraoperative administration of the same drug combination into the wound margins. Patients were monitored over a 24-month follow-up period for recurrence, cosmetic outcome, and complications. Outcomes were assessed using the Patient and Observer Scar Assessment Scale (POSAS) and visual analog scale (VAS) for satisfaction. **Result:** Out of 30 patients, 28 (93.3%) exhibited excellent post-treatment outcomes with no signs of keloid recurrence at two years. Two patients (6.7%) developed hypertrophic scarring, which was successfully addressed with minor scar revision. Significant improvement in POSAS and VAS scores was observed post-treatment. No serious adverse events or complications were reported during the treatment or follow-up period. **Conclusion:** The combination of intralesional triamcinolone and hyaluronidase therapy followed by surgical excision is a promising and effective protocol in the management of earlobe keloids. This multimodal approach not only minimizes recurrence but also ensures improved cosmetic outcomes and patient satisfaction. Larger, controlled studies are recommended to confirm these findings and standardize the treatment protocol.

INTRODUCTION

Keloids represent a pathological form of wound healing characterized by the excessive proliferation of fibroblasts and abnormal collagen deposition that extends beyond the boundaries of the original injury.[1] They are benign but can be disfiguring and symptomatic, often presenting with pruritus, pain, or a burning sensation. Among various anatomical locations, earlobe keloids are particularly prevalent due to the widespread cultural practice of ear piercing and the thin, pliable nature of earlobe tissue, which is more susceptible to hypertrophic scarring and keloid formation following trauma or infection.[2]

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The management of earlobe keloids poses a considerable challenge due to their high recurrence rates, which can reach up to 70–100% when surgical excision is used in isolation. A wide array of treatment modalities has been proposed and utilized, including intralesional corticosteroid injections, pressure therapy, silicone gel sheeting, laser therapy, cryotherapy, radiation, and emerging molecular approaches.[3] However, the lack of a universally accepted gold-standard treatment and the unpredictable behavior of keloids often lead to patient dissatisfaction and recurrence.

Intralesional corticosteroids, particularly triamcinolone acetonide, remain one of the most commonly used first-line therapies for keloids. They function by suppressing inflammation, reducing fibroblast proliferation, and inhibiting collagen synthesis.[4] However, when used as monotherapy, steroids are often insufficient for achieving complete regression or preventing recurrence post-excision. Moreover, repeated steroid use can lead to complications such as skin atrophy, telangiectasia, or depigmentation.[5]

In this context, hyaluronidase, an enzyme that depolymerizes hyaluronic acid in the extracellular matrix, presents a valuable adjunct. By increasing tissue permeability and breaking down intercellular barriers, hyaluronidase enhances the dispersion and penetration of co-administered drugs, thereby potentially improving the efficacy of intralesional steroids. Its antifibrotic properties and ability to reduce the viscosity of interstitial substances make it a theoretically compelling agent in combination protocols for keloid therapy.[6]

Previous studies have examined various combination of therapies, yet few have systematically investigated the sequential application of triamcinolone-hyaluronidase combination therapy followed by surgical excision, particularly in earlobe keloids.[7] The rationale behind this multimodal approach lies in first softening and reducing the vascularity and fibrous component of the keloid with injections, thus facilitating a cleaner and less traumatic excision, and subsequently reinforcing anti-keloid activity through an intraoperative injection to reduce postoperative fibroblast activation.[8]

The present study aims to address this gap by prospectively evaluating the outcomes of a structured treatment protocol that integrates three sessions of intralesional triamcinolone and hyaluronidase injections followed by surgical excision and a final intraoperative dose. The focus is on assessing the efficacy, safety, and long-term recurrence rates over a two-year follow-up period, along with patient satisfaction and cosmetic outcomes, using validated scar assessment tools.

By presenting this combined approach, the study seeks to contribute to the growing evidence base and offer clinicians a reliable, reproducible, and cost-effective method for managing one of the most aesthetically and emotionally distressing types of keloid scars.

MATERIALS AND METHODS

Study Design

This study was designed as a prospective interventional cohort study, conducted over a period of 24 months (January 2020 to December 2022) at the Department of ENT and Head neck surgery, a tertiary care academic medical center in India. Ethical approval was obtained from the Institutional Ethics Committee (IEC approval number: [insert number]), and all participants provided written informed consent prior to enrollment.

Study Population

A total of 30 patients with clinically diagnosed earlobe keloids were recruited from the outpatient Department of ENT and Head neck surgery. Patients were screened and selected based on predefined inclusion and exclusion criteria.

Inclusion Criteria

- Age between 18 and 45 years
- Presence of clinically confirmed earlobe keloid(s) of at least 6 months' duration
- Keloids resulting from piercing, minor trauma, or previous surgical procedures
- No prior treatment within the preceding 6 months
- Willingness to comply with treatment and follow-up protocol for the entire study duration

Exclusion Criteria

- Known history of hypertrophic scar formation disorders(e.g., Ehlers-Danlos syndrome)
- Patients with diabetes mellitus, active infections, autoimmune conditions, or immunosuppressive therapy.
- History of radiation therapyto the keloid site.
- Pregnant or lactating women
- Allergy or hypersensitivity to triamcinoloneor hyaluronidase

Treatment Protocol

Injection Phase (Preoperative Phase)

All patients received three intralesional injections at 15-day intervals before surgery. Each injection consisted of the following:

- Triamcinolone acetonide: 1 mL (40 mg/mL)
- Hyaluronidase: 1500 IU reconstituted in 1 mL normal saline. The two agents were mixed in a single syringe and administered using a 26-gauge needle directly into the lesion.
- Multiple linear passes were made to ensure uniform distribution of the mixture within the fibrotic tissue.

The procedure was performed under strict aseptic precautions in the minor procedure room.

Surgical Excision (Post-Injection Phase)

Approximately two weeks after the final injection, patients underwent surgical excision of the earlobe keloid. The procedure was performed under local anesthesia (2% lignocaine with adrenaline).

- Excision technique: Total keloid excision with minimal skin margin sacrifice. Care was taken to

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avoid excessive tension during closure to minimize recurrence risk.

- Intraoperative injection: Immediately after excision and before wound closure, a single intraoperative intralesional injection of triamcinolone (40 mg/mL, 1 mL) and hyaluronidase (1500 IU) was administered circumferentially into the wound margins.

Closure was performed using non-absorbable 6-0 nylon sutures, and a pressure dressing was applied. Sutures were removed after 7–10 days.

Postoperative Care and Follow-Up

Patients were advised to avoid trauma, pressure, or piercing at the excised site. Follow-up visits were scheduled as follows:

- Monthly visits for the first 6 months
- Every 3 months thereafter until 24 months

At each follow-up, clinical assessment was performed to evaluate

- **Recurrence:** Defined as any visible keloidal regrowth extending beyond the original excision site
- **Scar quality and cosmetic outcome:** Using the Patient and Observer Scar Assessment Scale (POSAS)
- **Patient satisfaction:** Assessed using a 10-point Visual Analog Scale (VAS)
- **Complications:** Including post-injection skin changes (atrophy, hypopigmentation), wound infection, delayed healing, or adverse reactions

Data Collection and Statistical Analysis

Patient demographic and clinical data were recorded in a structured proforma. Statistical analysis was performed using SPSS version 25.0

- Descriptive statistics were used for baseline characteristics, complication rates, and satisfaction scores.
- Paired t-tests were applied to compare pre-treatment and post-treatment POSAS and VAS scores.
- A p-value of <0.05was considered statistically significant.

RESULTS

A total of 30 patients completed the full treatment protocol and 24-month follow-up. The mean age was 27.4 years, with a predominance of female participants (70%), most of whom had unilateral earlobe keloids. The leading cause of keloid formation was ear piercing. All patients underwent the planned three preoperative injections, followed by standardized surgical excision with intraoperative drug administration. The recurrence rate was low, with only two cases of hypertrophic scarring, and all patients tolerated the treatment well with minimal complications. Objective and subjective outcome measures indicated significant improvement in scar quality and patient satisfaction.

Table 1: Demographic Characteristics of the Study Population (N = 30)

Variable	Value
Mean Age (years)	27.4 ± 6.3
Female	21 (70%)
Male	9 (30%)
Unilateral Keloid	22 (73.3%)
Bilateral Keloid	8 (26.7%)

This table provides a demographic overview of the study population. The cohort was mainly composed of young adult females, reflecting the typical gender distribution seen in cosmetic-related keloid formation.

Table 2: Etiology and Keloid History

Variable	Value
Etiology – Ear Piercing	26 (86.7%)
Etiology – Minor Trauma	4 (13.3%)
Mean Duration of Keloid (months)	14.2 ± 4.7
Mean Keloid Size (cm)	1.9 ± 0.5
Previous Treatment History	None (100%)

This table presents etiological factors, duration, and physical characteristics of the keloids. Ear piercing was the most common cause, and no participants had received previous treatment.

Table 3: Compliance with Injection Phase

Parameter	Value
Completed 3 pre-op injections	30 (100%)
Interval between injections	Every 15 days
Technique	26G needle, multi-pass intralesional

All patients completed the prescribed preoperative injection schedule. The injections were spaced at 15-day intervals and administered intralesionally with a fine-gauge needle.

Table 4: Surgical and Intraoperative Protocol

Parameter	Value
Surgical Excision Performed	30 (100%)
Anesthesia Used	2% lignocaine with adrenaline
Intraoperative Injection Administered	Yes (triamcinolone + hyaluronidase)

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Suture Type	6-0 nylon (non-absorbable)
Pressure Dressing Applied	Yes (all cases)

This table outlines the surgical phase of treatment. Each patient underwent excision with local anesthesia, and intraoperative injections were administered before wound closure.

Table 5: Follow-Up Compliance and Duration

Follow-Up Schedule	Patient Compliance
First 6 months	Monthly visits (100%)
6 to 24 months	Every 3 months (100%)
Total Follow-Up Completion	30 (100%)

All patients complied with follow-up visits as per protocol, ensuring consistency in monitoring and evaluation of outcomes over two years

Table 6: Keloid Recurrence and Outcome Status

Outcome	Patients (%)
Complete Resolution (No recurrence)	28 (93.3%)
Hypertrophic Scar	2 (6.7%)
Managed with Revision Surgery	2 (6.7%)

The majority of patients had complete keloid resolution. The few cases of hypertrophic scarring were managed successfully, with no recurrences of true keloid tissue.

Table 7: Minor Complications During Treatment

Complication	Patients (%)
Post-injection Pain	6 (20%)
Hypopigmentation	2 (6.7%)
Wound Infection	0 (0%)
Systemic Adverse Effects	0 (0%)

Adverse effects were minor and resolved spontaneously. There were no reports of infection or systemic complications

Table 8: Patient Satisfaction Scores (VAS)

Measure	Value
Satisfaction Scale Used	0–10 VAS
Range of Scores	6 – 10
Mean ± SD	8.7 ± 1.1

Patients reported high levels of satisfaction, as reflected by VAS scores, with most ratings falling in the upper satisfaction range

Table 9: Observer-Rated POSAS Scores

Time Point	Mean ± SD
Pre-treatment	32.5 ± 4.3
Post-treatment	10.1 ± 2.7

Significant improvement was noted in observer-assessed POSAS scores post-treatment, reflecting clinical and cosmetic benefits of the combined protocol.

Table 10: Statistical Summary of Outcomes

Comparison	Statistical Result
POSAS (Pre vs Post)	$p < 0.001$
Patient Satisfaction (VAS)	Descriptive only

Statistical testing confirmed that the improvement in scar scores was highly significant. Patient satisfaction was descriptively analyzed due to the nature of the VAS scale.

DISCUSSION

Earlobe keloids continue to pose a substantial therapeutic challenge in dermatologic and surgical practice due to their high recurrence rates, cosmetic disfigurement, and psychological burden. Despite the variety of treatment modalities available including corticosteroids, surgery, silicone sheets, cryotherapy, radiation, and laser therapy none have yielded consistently reproducible results when used in isolation.[9] The present study demonstrates that a multimodal approach combining intralesional triamcinolone and hyaluronidase injections followed by surgical excision offers a safe, effective, and minimally invasive protocol with excellent long-term out comes in the management of earlobe keloids.[10] The recurrence rate in this study was limited to 6.7%, and even these cases were not true keloids but hypertrophic scars, which were successfully managed with minor surgical revision and required no systemic therapy.[11] This recurrence rate is notably lower than rates reported in studies using monotherapies. For instance, previous study reported recurrence rates as high as 50% following surgical excision alone, emphasizing the importance of

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adjuvant therapy. Similarly, one more study highlighted that corticosteroid monotherapy, although widely used, often fails to sustain long-term remission due to its inability to fully suppress fibroblast proliferation and collagen synthesis when used alone.[12]

The use of hyaluronidase as an adjunct is one of the distinguishing aspects of this protocol. Hyaluronidase facilitates the breakdown of the extracellular matrix and enhances the diffusion of triamcinolone into fibrotic tissue.[13] The enzyme has been well-documented to increase tissue permeability, making it a valuable co-agent in scar modulation. In this study, the combination therapy resulted in visible softening and flattening of keloid tissue prior to surgical excision, making excision easier and possibly more complete.[14] The intraoperative injection of the same agents further served to modulate the wound healing response immediately after excision, targeting the initial phases of fibroblast activation.[15]

Another critical strength of this study is the strict follow-up protocol, which ensured a 100% compliance rate over a 2-year period. This level of follow-up provides robust support for the long-term efficacy of the treatment. The consistent improvement seen in POSAS observer scores and high patient satisfaction VAS ratings reflect both the clinical and cosmetic success of the approach. The mean POSAS score reduction from 32.5 to 10.1 and patient satisfaction mean of 8.7/10 are aligned with or better than outcomes reported in other multimodal protocols involving laser or pressure therapies.[16]

Complication rates were minimal and non-serious. Mild pain and transient hypopigmentation were the only adverse effects, and both resolved spontaneously. This reaffirms the safety profile of the drugs used. Notably, there were no cases of infection, wound dehiscence, or systemic side effects, which speaks to the procedural safety and reproducibility of this protocol.[17]

From a resource-utilization perspective, the protocol is cost-effective and easily implementable in outpatient surgical settings. It does not require high-end equipment, radiation exposure, or prolonged hospitalization. This makes it especially suited for resource-constrained settings where advanced therapies may not be feasible.

Despite its strengths, the study has several limitations. The lack of a control group limits the ability to directly compare this protocol against steroid monotherapy or surgery alone. A randomized controlled trial with larger sample sizes and parallel arms would strengthen the evidence and help delineate the exact contribution of hyaluronidase. Additionally, objective imaging such as ultrasound could have been used to assess scar volume and vascularity pre- and post-treatment, offering a more comprehensive evaluation of the therapeutic response.

Limitations

- Absence of a comparative control group (e.g., steroid alone or surgery alone).
- Modest sample size (N=30) from a single institution.
- Lack of objective imaging data to support clinical findings.
- Did not evaluate long-term histological changes post-treatment.
- Cosmetic outcomes, while quantitatively assessed, may carry subjective variability.

Future Considerations

- Randomized controlled trials with larger, multi-center populations.
- Longitudinal studies assessing recurrence beyond 2 years.
- Inclusion of imaging and histopathologic correlates.
- Cost-effectiveness analysis in comparison to laser and radiation therapies.
- Exploration of molecular markers (e.g., TGF-β, collagen types) to personalize therapy

CONCLUSION

This prospective study demonstrates that a multimodal treatment approach combining intralesional triamcinolone acetonide and hyaluronidase injections followed by surgical excision is a safe, effective, and reproducible strategy for managing earlobe keloids. The protocol achieved a 93.3% complete resolution rate with minimal recurrence and high levels of patient satisfaction, as evidenced by both objective scar assessments and subjective ratings. Importantly, complications were minor, and treatment was well tolerated by all participants.

The integration of hyaluronidase as an adjunct appears to significantly enhance the delivery and effectiveness of corticosteroids, contributing to improved outcomes. Furthermore, the intraoperative reinforcement with the same agents may play a critical role in modulating the post-excisional wound healing response, thereby minimizing recurrence.

Given the ease of application, cost-effectiveness, and minimal risk profile, this treatment protocol is especially suited for outpatient and resource-limited settings. However, larger, controlled trials are warranted to validate these findings, explore histopathologic correlates, and define long-term efficacy across diverse populations.

This study adds meaningful clinical evidence to the evolving field of keloid management and supports the routine use of combined pharmacological and surgical intervention for earlobe keloids.

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