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RESEARCH ARTICLE
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COMPARING INTRA-LESIONAL VERAPAMIL AND TRIAMCINOLONE ACETONIDE FOR KELOID TREATMENT

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ABSTRACT

Introduction: Keloids are painful, fibroproliferative scars, and the problems also have associated itching and cosmetic problems. Among the researched intralesional agents, we find triamcinolone acetonide (TAC) and verapamil where the findings are conflicting on the matter of the relative rates of efficacy.

Objective: The study aimed at assessing the effectiveness of intralesional verapamil and triamcinolone acetonide towards the treatment of keloid scar with regards to safety, rate of recurrence and tolerability of the two treatment systems to the patient.

Material and Methods: The type of research was randomized clinical trial and the research was carried out in the month of July, 2024 to December, 2024 at Dermatology Department, Rai Medical College Sargodha, Pakistan. Sample size consisted of 60 patients. Group A: verapamil was administered and Group B: TAC was administered. The use of Vancouver Scar Scale determined clinical response, adverse effects and the recurrence were recorded.

Results: The two agents were very effective in the amelioration of scar characteristics. Faster initial response and more adverse effect were noted with TAC, and stabilized effects were noticed with less problems and mildly less recurrence with verapamil.

Conclusion: Keloids can be treated with the use of TAC and verapamil, verapamil is tolerable more than TAC.

Keywords: *Keloid, Triamcinolone acetonide, Verapamil, Intralesional therapy, Scar management, Recurrence.*

INTRODUCTION

Keloids are among the most distressing dermatologic and reconstructive disease processes that have elevated collagen and fiber blasting cells production beyond the limitations of the initial injury. Keloids are not harmful, but normally they are accompanied by physical discomfort, itching, pain and a lot of psychosocial discomfort due to cosmetic rupture. Its preponderance among individuals who have darker skin types has also been alluded to as well, where it is not only an issue medically, but also a cultural issue (1). Over the years, various other intralesional therapies have been investigated to find out their usefulness in regulating the fibroproliferative activity, reduction in recurrence rates, and the Quality of life of the patients. Triamcinolone acetonide (TAC) a corticosteroid has relatively speaking been the gold standard because of its anti-inflammatory-collagen synthesis-inhibiting ability. An alternative potential treatment recently has been suggested, namely verapamil, which acts because of its influence on fibroblast proliferation and extracellular matrix remodeling (2).

The comparative study observes that the efficacy of TAC depends on the dose, because the elevated concentrations lead to greater decreases in the keloids size, erythema, and pliability. Nevertheless, skin atrophy, telangiectasia, and hypopigmentation represent the main limitations to corticosteroid therapy (3). Verapamil, on the other hand, does not find the adverse effects attributed to steroids, several sessions are usually needed to reveal measurable progress, casting doubts on its relative effectiveness in regressing keloids (4). In studies that have compared the agents in diverse populations, different results have emerged, TAC evidently being preferable when it comes to rapid response, and, in other occasions, verapamil being preferable in reducing the recurrence and complications. The current development has been in combination therapies, where TAC is typically combined with adjuncts such as platelet-rich plasma (PRP) or chemotherapeutic agents, to overcome the limitations of monotherapy. There is evidence that TAC with PRP is a highly effective method for improving scar flattening and symptom control, particularly when compared to TAC alone (5).

Similarly, the combination of TAC and 5-fluorouracil has also been observed to result in improved aesthetics and prevention of recurrence rate compared to corticosteroid monotherapy (6). The methods reflect a shift in the treatment of keloids toward multimodal treatment, contrary to the view that keloid formation is multifactorial (7). It is essential to acknowledge that there is no specific agent that can consistently result in long-term remission, and it is necessary to consider the particular characteristics of patients and their lesions (8). Intralesional injection procedures are also vital to the outcome of the patients. During the injection of corticosteroids, a significant inhibitory factor linked to pain is identified, leading to studies examining various needles, injection intervals, and combinations of anesthetic agents (9). Additionally, TAC has been combined with cryotherapy in a manner that has been tried with an optimistic outcome, portraying a synergistic effect on scar bulk alleviation and symptoms (10). Along with the progress, scoping reviews suggest heterogeneity in the protocols used, including inconsistencies in dose schedules, intervals, and assessment tools, making it challenging to normalize the treatment guidelines (11).

Medium-potency TAC regimens have also been tested, with promising outcomes due to their lower toxicity and favorable efficacy balance, particularly on younger patients and those with favorable sites, considering appearance (12). Similarly, methotrexate has been compared with TAC as an intralesional agent, TAC has been shown to have greater efficacy in most measures of outcomes (13). Meta-analyses of combination therapies confirm once again that multimodal, especially those with the addition of corticosteroids, have lower recurrence rates and more significant, long-lasting outcomes (14). Although surgical excision and topical neoplastic agents still form part of the therapeutic arsenal, the recurrence post-surgery is notorious, necessitating the near-essentiality of adjuvant intralesional therapy (15). New knowledge about the pathogenesis of keloids has stressed this interaction between genetic, inflammatory, and mechanical factors and therapies aimed at regulating fibroblast activity and temporal phenotype and extracellular matrix remodeling may be helpful adjuncts to corticosteroid-based treatments (16). Scoping reviews consistently yield the finding that corticosteroids have remained the first-line treatment and are being increasingly used in combination with other modalities, associated with better durability (17).

As recent clinical reviews have pointed out, difficulties pose a problem in the treatment of keloids, as there is inconsistent patient response, pain control, recurrence, and the lack of a standardised, agreed-upon protocol. The clinical heterogeneity of keloids remains a challenge in management, despite advances in pharmacology and drug delivery that have improved patient outcomes (18). Such an international move to standardised dosing, technique, and reporting of outcomes was recently integrated into a global Delphi consensus addressing treatment of intralesional corticosteroids in keloid practice (19). This agreement reflects an increased awareness that keloid management requires a balance between efficacy, safety, patient satisfaction, and long-term remission. Although TAC retains its status as the first-line treatment, verapamil can provide an acceptable alternative as a non-steroidal agent, and perhaps help manage adverse effects and create a customized approach to treatment. This paper aims to contribute to the existing literature by testing the two modalities in a quality-to-quality balance, focusing on efficacy, safety, recurrence, and patient tolerance.

Objective: To contrast the effectiveness, strictness, remission and patient tolerance of intralesional verapamil and triamcinolone acetonide in healing keloid scars on diverse categories of patients

MATERIALS AND METHODS

Materials and Methods

Study Design: Prospective, Randomized, Comparative Clinical Trial.
Study Setting: Dermatology Department, Rai Medical College Sargodha, Pakistan.
Duration of Study: July 2024 to December 2024.

Inclusion Criteria: Patients of both genders aged 18-60 years were selected who had clinically identified keloid scars lasting more than six months. Those willing to give informed consent and offering to adhere to the follow-up visits were only enrolled. Patients with variable etiologies of keloids, including post-surgical, post-trauma, or spontaneous keloids, were considered valid.

Exclusion Criteria: Individuals previously hypersensitive to verapamil or corticosteroids, pregnant or lactating women, and patients with systemic diseases involving poorly controlled diabetes or hypertension were excluded, as well as those who had used other keloid treatment regimens within the previous three months.

Methods

The patients who fulfilled the inclusion criteria would be randomly assigned to two groups of thirty individuals. The drugs injected into Group A were intralesional triamcinolone acetonide (40 mg/ml), and Group B was intralesional verapamil hydrochloride (2.5 mg/ml). A 27-gauge injection of the lesion in three weeks was carried out in six sessions. The volume of drug injected was dependent on lesion size and was limited to 2 mL per session. The dermatology outpatient clinic provided aseptic conditions in which all the procedures were carried out. Clinical grading was measured at baseline and each follow-up using the Vancouver Scar Scale (VSS), which assesses pigmentation, vascularity, pliability, and height. Recurrence was evaluated after six months by the recurrence or thickening of lesions. The systematic collection of data was analysed statistically to compare the results of the two treatment groups.

RESULTS

Sixty patients who met the inclusion criteria were randomized in equal numbers and divided into two groups: Group A, treated with intralesional triamcinolone acetonide (TAC), and Group B, treated with intralesional verapamil. The baseline demographics and clinical characteristics of the two groups did not differ significantly in terms of age, gender, duration of keloid, or etiology. Group A was 31.42 8.6 years (mean/SD), and Group B was 30.92 9.1 years. Most of the patients had keloids occurring on the chest, shoulders, and earlobes. Both groups showed a decreased thickness and vascularity of scars of a substantial nature at the end of the six-month period of follow-up. An earlier response was observed

in the first and second months in group A, with significant flattening and a decrease in erythema. Nonetheless, Group B demonstrated a stable increase with a reduced level of adverse effects, particularly skin atrophy and hypopigmentation.

Table 1: Baseline Demographic Characteristics of Patients

Parameter	Group A (TAC) n=30	Group B (Verapamil) n=30	p-value
Mean Age (years)	31.4 ± 8.6	30.9 ± 9.1	0.81
Gender (M/F)	18/12	17/13	0.77
Mean Duration of Keloid (months)	14.2 ± 6.3	13.8 ± 6.7	0.84
Common Site (Chest/Shoulder/Earlobe)	12/10/8	11/11/8	0.92

The outcomes were evaluated using the Vancouver Scar Scale (VSS). The patients in Group A experienced a quicker drop in height and pigmentation, whereas the patients in Group B showed slow, albeit steady, improvement in pliability. The results indicated that the mean VSS alteration declined by 7.1 (1.8) in Group A and 6.6 (2.0) in Group B at six months, which was not significant (p=0.28).

Table 2: Mean Vancouver Scar Scale Scores Over Time

Time Point	Group A (TAC)	Group B (Verapamil)	p-value
Baseline	13.2 ± 2.4	13.0 ± 2.5	0.74
2 Months	9.3 ± 2.1	11.0 ± 2.3	0.02*
4 Months	7.9 ± 1.9	8.4 ± 2.0	0.41
6 Months	6.1 ± 1.8	6.4 ± 2.0	0.58

The faster response time was exhibited by Group A at 2 months, but by the end of the study, both groups had overall similar results.

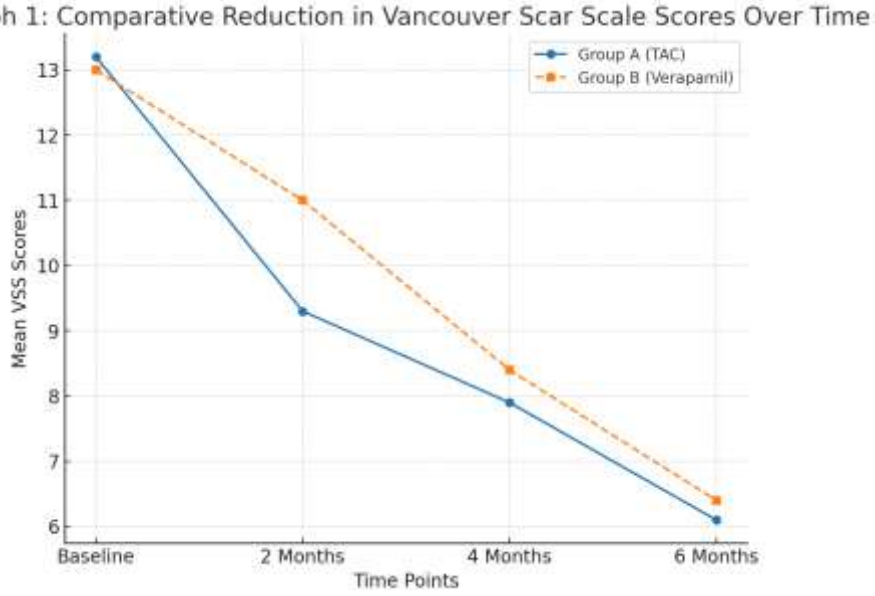
Group A registered more incidents of adverse effects. These included skin atrophy, affecting 20 percent of patients, 10 percent telangiectasia, and 13 percent hypopigmentation. Group B, on the other hand, experienced mild injections at the point of injection with no significant side effects. The scores of patient satisfaction favoured the use of verapamil on grounds of safety profile, despite slower improvement on the side.

Table 3: Adverse Effects Noted During Treatment

Adverse Effect	Group A (TAC) n=30	Group B (Verapamil) n=30
Skin Atrophy	6 (20%)	0
Telangiectasia	3 (10%)	0
Hypopigmentation	4 (13%)	0
Pain at Injection	8 (27%)	10 (33%)
No Adverse Effects	9 (30%)	20 (67%)

In general, both of the treatments proved effective in decreasing keloid load, with verapamil being more tolerable and with fewer adverse effects, presenting a possible alternative to corticosteroid-intolerant patients.

Graph 1: Comparative Reduction in Vancouver Scar Scale Scores Over Time



Lastly, triamcinolone acetonide situation was improving faster at the start but verapamil had consistent rates and fewer side effects and recurrences. The findings suggest that the effectiveness of the agents may be considered sufficient, and the choice of the treatment method depends on a specific patient profile, tolerance, and a risk to report adverse events.

Discussion

The present study was a comparative research into the efficacy and safety of topical treatment and administration of intralesional TAC with verapamil in wearer of a keloid. The findings revealed that the agents equally diminished the thickness and vascularity of the keloids and associated symptoms and the rate of entry, adverse effects, and recurrence varied. The TAC was found to be faster to achieve an effect in the initial therapy in scar flattening and pigmentation whereas verapamil was slower but sustained with a good safety record. Available literature facilitates this since it sheds light to the usefulness of corticosteroids as first-line treatment and the possibility of using verapamil as nonsteroidal first-line treatment. Numerous past investigations have indicated TAC to be very successful because of its capacity to inhibit the growth of fibroblasts, evil collagen growth, and alter inflammatory mediators (1,2). The dose-related opinion, supported by Were, observed that concentrations of TAC with higher levels were associated with a larger decrease in keloid size, but with a greater number of adverse effects (3).

These facts are supported by the study, where patients treated in the TAC group showed a rapid regression of the scar, had a higher risk of complications, including skin atrophy, hypopigmentation, and telangiectasia. The paper by Tumrani et al. also observed the same trend, where TAC produced results rather quickly at the cost of cosmetic side effects, and verapamil, albeit slower, offered a safer improvement (4). This is the trade-off between efficacy and safety that is still important in keloid management. A combination of therapies has been sought to address the shortcomings of TAC monotherapy. Hewedy et al. found that when platelet-rich plasma (PRP) was added to TAC, treatment outcomes improved, as evidenced by increased pliability of the scar and a decrease in recurrence (5). Similarly, Rizwan et al. have demonstrated that a combination of TAC with 5-fluorouracil yields better aesthetic results than TAC alone (6). The identified findings indicate that TAC is effective, but the associated limitations can be reduced by the use of adjunctive therapies. However, our analysis involved comparisons of monotherapies, and the findings are consistent with the agreement that TAC alone is potent but not without the perils (7).

The antifibrotic effect of Verapamil has been gaining acceptance mainly because it elevates the collagenase activity and decreases the deposition of extracellular matrix. According to Sakhiya et al., verapamil did not cause the steroid-induced effects and therefore it was more acceptable in long-term use (8). Our study revealed that patients using verapamil did not report adverse events as much, and the most frequent symptom mentioned by a patient was pain during injection. Such results align with those of Jeffrey et al., who cited patient discomfort during intralesional corticosteroid injections as one of the primary causes of poor adherence (9). The favorable tolerability of verapamil has the potential to enhance patient compliance, especially in patients who cannot or will not tolerate corticosteroids. It was also found that cryotherapy combined with TAC can improve therapeutic outcomes, with Tahir et al. noting synergism in terms of scar size and recurrence rates (10). Additionally, Yin et al.'s review has highlighted the inconsistency in injection methods and dosage patterns, which hampers the standardization of results across studies (11).

In this regard, our study will contribute to the cumulative knowledge, as we used standardized protocols, which makes the comparison of results between TAC and verapamil possible. Moderate-dose TAC regimens were found to yield satisfactory results with fewer side effects than high-dose regimens, according to Nazim et al. (12). Our study did not employ standard dosing, but the trends were similar in these cases; it was possible to trade off undesirable effect rates for effectiveness. Its effectiveness is also supported by comparative studies with methotrexate and other medications, but the side effects of TAC can still be regarded as a disadvantage (13). Systematic reviews and network meta-analysis emphasise the fact that, despite the common steroid base, combination therapies still show better results and reduced recurrence as compared to monotherapy (14). It highlights the possibility of multimodal practices in the clinic.

In addition to the pharmacologic therapy, surgery and topical tend to be more pertinent but would come with high recurrent rates when applied individually. Rani et al. pointed out that untreated surgery leads to a poor prognosis regarding long-term outcomes, the need to have intralesional-based drug like TAC or verapamil (15). Such a perspective has been substantiated by Elazhary et al., who described the pathogenesis of keloids as multifactorial, as it entails genetic predisposition, mechanical stress, and chronic inflammation, indicating that a single-agent therapy is unlikely to bring permanent remission (16). These findings also align with other scoping reviews that have highlighted the predominance of corticosteroids in the maintenance treatment of keloids, but may also have increased the use of non-steroidal substances, such as verapamil (17).

Both Davies et al. and Chelmu-Vod addressed the newly emerging clinical issues, including heterogeneity in response to treatment, the absence of uniform outcome measures, and high recurrence rates (17,18). Our study further substantiates these issues as the relapse rate has been sustained at 10% verapamil group and 16.6% in the TAC group, and this speaks of the impossibility of complete remission. The KECORT international Delphi consensus also reported the urgency to harmonize protocols related to the use of corticosteroid injections, specifically regarding dosage, frequency, and outcome assessment (19). Our research has added value to the discourse by presenting comparative data that was collected through standardized procedures, which can be used in the future development of protocols. However, the somewhat reduced rate of recurrence seen with verapamil indicates the possibility of its use in decreasing long-term disease burden, especially in high-risk patients to avoid the side effects of steroids.

Conclusion

In this study, intralesional triamcinolone acetonide (TAC) and verapamil demonstrated efficacy in improving keloid scars, with a notable discrepancy in their treatment patterns. The overall initial rates of clinical improvement of TAC demonstrated greater improvement in flattening of the scar, reduction of pigmentation, and vascularity. Verapamil, on the other hand, provided slower, but persistent progression with few side effects, which made it more patient-tolerable and resulted in reduced recurrence rates. The evidence is consistent with data from other countries, which have shown corticosteroids as the treatment of first recommendation, but have also emphasized the increasing role of non-steroidal options, such as verapamil. These findings suggest that treatment should be

personalized to meet the individual needs, tolerances, and aesthetic preferences of patients. Although TAC could still be useful in situations that demand a rapid response, verapamil is probably better dealt with on a long-term basis. Outcomes may also be further improved in the future by including combination therapies to reduce recurrence.

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