

Case Report

Evaluating the efficacy of intralesional verapamil over intralesional triamcinolone in management of keloid: an evidence based case report

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ABSTRACT

Author present a case of 22-year-old female with keloid due to previous trauma three years prior. Keloids are excessive fibroblast growth present in pathological scars. Therapy for keloids still remain a challenge requiring an effective intervention. While the first line has always been the use of intralesional triamcinolone, recently intralesional verapamil has also been known to reduce growth of keloids. Aim of the study was to evaluate the efficacy of both of these drug options. Literature searching was performed from three databases namely PubMed, Cochrane library and Science Direct. Findings were systematically narrowed down through inclusion and exclusion criteria into four relevant randomized controlled trials. Selected studies were critically appraised for its validity, importance, and applicability using tools from Oxford Center of Evidence-Based Medicine. Both intralesional triamcinolone and verapamil show their own benefit and risk. Triamcinolone is more effective in reducing keloid with faster improvement as seen in scar height reduction, vascularity, pigmentation and pliability. However, verapamil has fewer side effects which serve as a safer treatment option. More clinical trials in the future may be needed to obtain more conclusive result.

Keywords: Efficacy, Evidence-based, Intralesional triamcinolone, Keloid, Verapamil

INTRODUCTION

Skin trauma is inevitable, and while some wounds may heal normally, some undergo abnormal wound healing which result in hypertrophic scars or keloids.¹ Although both are due to excessive deposition of collagen in the skin, however there are several distinctive characteristics.² Hypertrophic scars do not grow beyond the boundary of wound site while keloids grow and extend into the surrounding normal skin without any spontaneous regression.^{1,3} A definitive diagnosis is made through histopathological examination where keloids present with dermal nodules and multiple thick eosinophilic collagen bundles.⁴ This is in contrary to

hypertrophic scars which present with only dermal nodules.^{2,4} In immunochemistry examination, keloids also present with increased levels of MMP-2 enzyme at the edge of collagen bundle.^{2,4}

Keloids are more common in African, Asian and Latin American ethnicities.⁵ Genetic predisposition also increases the chance of having keloids 15% higher than the general population.⁶ There are different proposed mechanisms behind keloid formation as the process is complex and not fully understood yet. Factors that contribute in keloid formation involve both systemic and local factors.^{1,2} Systemic factors are such as pregnancy and hypertension which both result in vasodilatory effect

associated with keloid aggravation.⁷ On the other hand, local factors involve delayed wound healing process and presence of skin tension.^{1,2} This explains the predisposed areas of keloids involve body parts prone to stretching such as anterior chest, shoulder, and deltoid.⁸

The management of keloid and hypertrophic scars aims to alter the abnormal cell signaling and proliferation pathway.⁹ A wide variety of therapy is currently present ranging from pressure dressings, topical agents, laser and intralesional agents.⁹ The mainstay therapy has always been intralesional corticosteroid which are thought to promote collagen degradation and inhibit fibroblast growth.¹⁰ Triamcinolone is the widely accepted corticosteroid used, however it typically requires several sessions repeated over time.⁹ In addition, there are possible side effects such as scar atrophy, pain and pigmentation changes.^{9,11} Another intralesional agent available is verapamil, a calcium channel inhibitor. Verapamil is thought to inhibit proliferation and TGF- β 1 expression in fibroblast and stimulates apoptosis, thus reducing keloid or hypertrophic scar proliferation.¹²

CASE REPORT

A 22-year-old female was brought to general clinic for routine check-up. However, patient had chief complaint of swelling in the right deltoid since two and a half year ago. Patient previously fell on to the ground, hitting the skin in the right deltoid which caused a laceration. The wound was cleansed and sutured however following the trauma a swelling had developed. It continued to extend until the current appearance as of today. The size of swelling was 7 x 5 x 2 cm (Figure 1). It is solitary, firm, circular, was not itching or painful to touch. A diagnosis of keloid was made based on clinical appearance, however due to limited facility, a histopathologic examination was not able to be done. Patient had never received treatment for the keloid. Since the drug is not cheap for her, she came to the clinic and asked if there is an effective drug to improve the appearance of keloid.



Figure 1: Presentation of keloid in the right deltoid.

Clinical question

The proposed question in this study is whether intralesional verapamil is more effective than intralesional triamcinolone as treatment of keloid.

Search strategy

The author searched PubMed, ScienceDirect and Cochrane databases for studies published from 2009 to September 2019 (Table 1 and Figure 2).

Table 1: Search strategy implemented; search conducted August 30th 2019.

Database	Search strategy	Hits	Selected articles
PubMed	Intralesional [All Fields] and ("verapamil"[MeSH Terms] or "verapamil"[All Fields]) and ("triamcinolone"[MeSH Terms] or "triamcinolone"[All Fields]) and ("keloid"[MeSH Terms] or "keloid"[All Fields])	17	3
Cochrane library	Verapamil AND triamcinolone AND keloid	10	1
Science Direct	Verapamil AND triamcinolone AND keloid	65	0

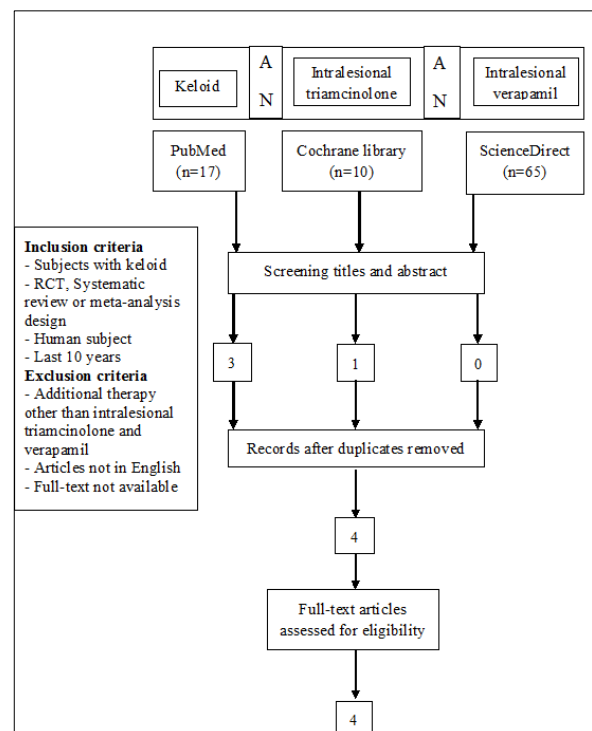


Figure 2: Flowchart search strategy conducted August 30th 2019.

DISCUSSION

Using the evidence-based medicine principles according to University of Oxford, the author appraised validity and importance of the selected studies (Table 2). The primary outcomes analyzed in all studies were components of Vancouver Scar Scale (VSS) score namely height of lesion, vascularity, pliability and pigmentation, and the difference between scores of pre-treatment and post-treatment.

Through literature searching in three databases namely PubMed, Science Direct and Cochrane there were 92 studies found. However, authors search is narrowed to only studies with high level evidence in the form of RCT or metaanalyses within the last 10 years, involving only human subject, and excluding studies which evaluate therapies other than intralesional verapamil and triamcinolone. After removing duplicates and assessing full-text articles, a total of four RCTs were selected to be further appraised (Table 3).

Critical appraisal of Saki N et al.¹³

Author assessed the Saki et al, study as valid. Patients selected were randomized using simple randomization technique. The therapy given to each scar was also randomized clearly. However, no detail of allocation concealment was described in this matter. The two groups of patient also presented with no significant different characteristics at the beginning ($p>0.05$), showing a comparable group to study.¹³ In terms of blinding process, the study was single-blinded where only patient was blinded to the treatment given.¹³ This may impact the results as it may create bias in determining the outcomes. There were no dropouts during the study.

In terms of importance aspect, it is difficult to assess as the study did not provide values of Relative Risk (RR), Adjusted Relative Risk (ARR), Relative Risk Reduction (RRR) or Number Needed to Treat (NNT). The effect of primary outcome is presented in absolute measures using

subtraction between each aspect of VSS score in week 24 compared to week 0 or start of the study.¹³ In terms of applicability analysis, this study demonstrated that it could be applied to our case. The study participants and inclusion criteria were similar to that of this case, with the same proposed clinical question. This study concluded that while both treatment modalities are safe, verapamil is not as effective as triamcinolone.¹³ However no further analysis on adverse effects were explained besides of change in pigmentation at the end of study.

Critical appraisal of Zamanian A et al.¹⁴

Study by Zamanian A et al, is valid. Patients were randomized; however, no detail was given on the randomization process. In terms of allocation, it was clearly stated that the allocation method used random numbers.¹⁴ There was no significant difference on characteristic of selected patients which were gender ($p=0.765$) and mean age distribution ($p=0.369$).¹⁴ The study was a single blind design, meaning only patients were blinded to the treatment given, which may create potential bias in the reporting process. Out of a total of 50 patients, there were no participants lost to follow up until end of study.¹⁴ There was an inequality of treatment procedure, where in groups receiving triamcinolone, lidocaine was used for diluting the drug, while in the verapamil group this was not done.¹⁴ This result gave impact towards the level of satisfaction of participants, which was found to be higher in the triamcinolone group, presumably due to lowered pain experienced due to the analgesia or sedation effect of lidocaine at the time of injection.¹⁴

The data was presented according to quantitative or categorical variables analyzed. When analyzing changes of lesion according to VSS score compared to treatment regimen given, data was provided in mean standard deviation (SD).¹⁴ In analyzing VSS score against categories of gender and age, data was provided in absolute frequencies and percentages.¹⁴ Further statistical analyses were made using Chi-square test or Fisher's exact test, t-test and Mann-Whitney U test.¹⁴

Table 2: Critical appraisal of RCT: validity, importance and applicability.

Author	Study design	Number of patients	Validity			Importance				Level of evidence*	Applicability
			Randomization	Similarity treatment and control	Blinding	Comparable treatment	Intention to treat	Clinical importance	Statistical significance*	Precision of treatment effect	
Saki N (2019)	RCT	15	+	+	+	+	+	?	+	+	II Yes
Zamanian A (2017)	RCT	50	?	-	+	+	+	+	+	+	II Yes
Abedini R (2018)	RCT	50	+	+	+	+	?	+	+	+	II Yes
Ahuja RB (2013)	RCT	40	+	+	+	+	+	+	+	+	II Yes

*Statistical significance if $p<0.05$, ? : Not stated clearly in the study

Table 3: Study characteristics of the eligible RCTs.

Study (Year)	Study design	Type of scar	No. of subject	Age (year)	Mean age of subject (years)	Average scar duration	Treatment time	Country	Dosage	Gender
Saki N (2019)	RCT single blind	Keloid less than 2 years	15	18-70	31.53	11.46 months	24 weeks	Iran	Maximum volume of verapamil (2.5 mg/mL) at each session was 1.5 cc. Maximum volume of triamcinolone (20 mg/ mL) at each session was 1.5cc	F: 14 M: 1
Zamanian A (2017)	RCT single blind	Keloids caused by different reasons: burns, trauma, surgery	50	8-60	NR	NR	12 weeks	Iran	1ml of verapamil (2.5 mg) 1ml of triamcinolone (20 mg)	NR
Abedini R (2018)	RCT observer blinded	Keloids less than 5 years	50	18-65	30.26	<5 years	18 weeks	Iran	Triamcinolone acetone 40 mg/mL, maximum total dose 20 mg/mL; Verapamil hydrochloride 0.5 mg/cm, maximum total dose 2.5 mg.	NR
Ahuja RB, (2013)	RCT observer blinded	Keloids less than 2 years	40	15-60	NR	<2 years	24 weeks	India	Triamcinolone and verapamil injection 1.5 ml were the maximum permissible injected volume of triamcinolone (concentration 40 mg/ml) and verapamil hydrochloride (concentration 2.5 mg/ml).	NR

*NR = No reference

Study showed no statistically significant difference in all four assessment of VSS scores both in triamcinolone and verapamil group.¹⁴ For the applicability analysis, this study suggested that while both treatment modalities result in similar changes, verapamil was more preferred due to less side-effect and low-cost. One case of atrophy was reported as a side effect in the triamcinolone group while no complications reported in the verapamil group.¹⁴ This study may be applicable to this case as it is feasible, the study sample characteristics were similar to patient, and the preference of patient was also assessed.

Critical appraisal of Abedini R et al.¹⁵

Study by Abedini R et al, is valid. It is a randomized observer blinded controlled trial, with the allocation method

clearly explained. The study used computer generated random sequence to determine the treatment groups.¹⁵ The two groups treated were also comparable at start, with no significant differences in regard to initial VSS scores ($p>0.05$) and lesion location ($p=0.7$).¹⁵ Subject, assessor and analyzer were blinded to treatment, however dermatologist who played role in the injection process were not blinded since the two drugs had different chemical properties which need to be carefully administered.¹⁵ There were 3 patients in the verapamil group who did not consent to continue the study and dropped out at week 18 after experiencing responsiveness of the drug.¹⁵ There was no intention to treat analysis provided.

The data outcomes were presented in mean standard deviation for continuous variables, and frequency

percentages for categorical variables. Further tests using Kaplan-Meier survival curve and logrank test were used to analyze time to complete recovery of lesion in the two groups.¹⁵ Overall, there were statistically significant different VSS scores resulting from the two groups ($p < 0.001$), with triamcinolone group showing better outcomes.¹⁵ The study also demonstrated that triamcinolone group had faster outcomes, shown by the decrease in height of lesion since week 3, while this change just began at week 18 in the verapamil group.¹⁵ Side effects such as skin atrophy, pain, and burning, were similarly reported in both groups.¹⁵ In terms of applicability, this study is applicable in this case as it matched the study characteristics, feasible, and patient's values and preferences were addressed well.

Critical appraisal of Ahuja RB et al.¹⁶

Author assessed this study as valid. The study is clearly randomized, with allocation method using computer generated random sequence.¹⁶ The initial study characteristics were not given thus making it difficult to assess whether groups were comparable at start of trial. However clear inclusion and exclusion criteria were explained. Both the trained observer and subjects were blinded to treatment, hence eliminating subjectivity of the report on assessment of VSS scales during the follow-up.¹⁶ There were no subject's loss to follow up within the 24 weeks of study.

The data outcomes were shown as mean VSS score using unpaired 2 tailed t-test, and Kaplan Meier curves for comparative survival analysis.¹⁶ Further statistical test using Wilcoxon test and log rank test were applied.¹⁶ Overall there is a statically significant change in triamcinolone group, showing a faster rate of improvement in scar height, vascularity and pliability aspect ($p < 0.00001$).¹⁶ Side effects reported were minor which were pain, telangiectasia, and skin atrophy, which was tolerated equally well in both groups.¹⁶ This study revealed that it could be applied to patient as it had similar characteristics to what was included in the study.

Overall critical appraisal

Keloid is a result of severe wound healing pathology where fibroproliferative lesions extend beyond the initial wound lesion.^{2,3} It is often triggered by an initial skin trauma, such as present in this case study. Although histopathology shows distinct features of keloid such as the arranged hyalinized collagen bundles, however clinical feature alone is sufficient to make a diagnosis.^{4,17} A reddish solid mass typical of keloid is often followed by histological findings of enlarged blood vessels associated with micro vessel regeneration and tissue hypertrophy.¹⁸ Other than clinical presentation, keloids are also strongly related with a positive family history.¹⁹ History taking of family members with tendency towards excessive scarring is significant.¹⁹ However to date there is no specific gene found to be linked to growth of

keloids, leading to presumption that possibly multiple genes contribute to keloid.²⁰ Patients with keloid may complain of pain, pruritus and psychosocial symptoms due to cosmetic disfigurement.²¹ Another important feature of keloid that distinguishes it from hypertrophic scar, is that keloid is not able to regress with time.^{7,21} Moreover, keloids typically recur following surgical excision.²¹ A study reported that keloids treated with only monotherapy of surgical excision alone, has a recurrence rate up to 100%.²¹ Hence, exploring other therapies of keloid is an important key for future study.

Guidelines on treatment of keloids according to The International Advisory Panel on Scar Management recommended use of intralesional corticosteroid since mid-1960s.^{20,22} It is used both for management of keloids and hypertrophic scars. The most common used steroid injection is Triamcinolone Acetonide (TAC).²² Mechanism of TAC on keloid involves suppressing inflammatory response by inhibiting leukocyte, monocyte and phagocytosis.²⁰ It also acts as a vasoconstrictor to limit supply of oxygen and nutrients to wound bed.²⁰ Furthermore it has an anti-mitotic feature which slows epithelialization and collagen formation thus reducing the growth of keratinocyte and fibroblast.¹¹ Intralesional TAC has been proven to cause a 50-100% regression rate, with recurrence rate of 33% after 1 year of therapy.^{11,20} A current meta-analysis also showed that intralesional TAC resulted in marked reduction in size of keloid compared to untreated control subject.¹¹

However it is worth noting that treatment with TAC is also associated with several adverse effects both local and systemically.²³ A study reported that 50% of subjects treated with TAC experienced skin atrophy, telangiectasia, and hypopigmentation, while another study did not report any side effect experienced.^{24,25} A systemic effect of Cushing's syndrome was also reported, which was found to be partly due to inadvertent injection to surrounding normal tissue.²⁶ These complications can be reduced by thoroughly adjusting the dosage, frequency and duration of TAC treatment.²⁰ Previous literatures have recommended different adjusted dosage options, but a study has proven effective that TAC concentration is within the range of 10-40 mg/mL adjusted to the site of lesion.²⁷ For keloid on trunk or extremities, initial TAC dose starts at 40 mg/mL which will then be titrated accordingly.²⁷ The safe dose range may be given every 3-4 weeks up to 6 months or more depending on improvement of lesion.^{8,20}

While corticosteroid has been used for many years, verapamil is a relatively newer emerging therapy in keloid management.¹² Intralesional verapamil was first used in 1992, and has continued to be tested in several well-designed trials, which raise the possibility of whether its efficacy is equal or even greater than that of intralesional TAC.¹² Verapamil is a L-type phenylalkylamine calcium channel blocker which plays role in hypertension, arrhythmia and angina.²⁸ However it

shares similarity to TAC, in which it inhibits cell proliferation in the pathway of fibrosis formation.²⁹ Verapamil also prevents accumulation of collagen found in keloids, through stimulating pro-collagenase synthesis.²⁹ This is due to the fact that collagen-like many other extracellular matrix macromolecules are calcium-dependent, which can be inhibited by calcium channel blockers such as verapamil.^{28,29} An open label study found that there is a significant decrease in VSS score after administration of intralesional verapamil within 8 months ($p < 0.001$) with no complaint of post-procedural pain experienced.³⁰ However, reasons why verapamil remain as second-line treatment in keloid management needs to be further discussed.

Verapamil offers few adverse effects, one which was reported was the injection-related pain requiring analgesia.^{12,20} This post injection pain may persist more than 24 hours.³⁰ However unlike TAC, verapamil does not cause other side effects such as local dermal atrophy or hypopigmentation.¹⁶ Additionally, studies reported that in verapamil group, the duration of treatment to achieve flattening of keloid took longer than TAC group.²³ Another study revealed that even with a combination of CO₂ laser and verapamil, the effect was still slower compared to TAC alone.³¹ After a 12-month observation, study reported that the recurrence rate was higher in verapamil group compared to TAC.²³

It remains a question whether intralesional verapamil is more effective than the gold standard therapy of intralesional TAC. In terms of the mechanism of action, both drugs similarly have the endpoint of increasing collagenase levels which will cause collagen degradation in keloid.²⁰ This is achieved through TAC which acts by decreasing proteinase inhibitors while verapamil increases the secretion of procollagenase.^{13,20} Vancouver Scar Scale (VSS) is a validated score to document changes in appearance of scar, which can be used to evaluate the improvement of keloids.³² The four parameters involved are vascularity, pliability, pigmentation and height of the scar. For pliability the score ranges from 0 to 5, for height and vascularity parameter the score range is 0 to 3, and for pigmentation the range is 0 to 2, giving a maximum score of 13.³²

Abedini et al, revealed that verapamil group showed no changes in vascularity and pigmentation, while only minimal change achieved in height and pliability of keloid.¹⁵ This study showed that TAC group had more complete response in all four VSS components.¹⁵ This is supported in the study by Saki et al, which showed better reduction and height and pliability parameters in the TAC group compared to verapamil group.¹³ Meanwhile, a contradicting result is shown in the study by Ahuja et al. This study demonstrated that both verapamil and TC groups achieved complete improvement, however faster rate of improvement was in TAC group ($p < 0.0001$).¹⁶ While it took 3 intralesional TAC injections to reach 0 height score, verapamil group required 5 injections to

reach the same result.¹⁶ Similarly Zamanian et al, also supported intralesional verapamil as successfully causing downward trends in the same manner as TAC in all four VSS parameters.¹⁴ Most of these studies suggested that while both drugs may effectively improve keloid according to the VSS parameters, however the effect on verapamil group took longer to show.^{14,15} However, the main downside of TAC therapy is the side effects associated, therefore making verapamil a safer option.^{14,16} The issue of recurrence of keloid growth also needs to be considered, as most of these studies did not provide longer period of observation on this subject.

CONCLUSION

In conclusion, given the properties of both drugs which share similar mechanism of action in keloids, both intralesional verapamil and TAC would generally be effective treatment. However, in regard to the shorter duration of treatment or the need for less intervals of injection, intralesional TAC would still remain more superior than verapamil. To date, it can be safe to say that intralesional verapamil offers a safer option with less adverse effects than TAC, however cost-wise there is still insufficient evidence to prove its efficacy. Further studies with larger participants need to be carried out in order to establish the issue of long-term complications or recurrence rates of both therapies. Future prospective studies may need to investigate whether both verapamil and triamcinolone can be used as a combination therapy to achieve a better improvement of keloid.

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