Original Article

Safety of Suprachoroidal Triamcinolone Acetonide Injection without Cannula Sleeve: A Modified Technique

PJO – Official Journal of Ophthalmological Society of Pakistan

Muhammad Hasnain[1], Syed Fawad Rizvi[2]
[1-2]*LRBT Eye Hospital Korangi, Karachi*

ABSTRACT

Purpose: To evaluate safety of a new technique of Suprachoroidal (SC) injection of Triamcinolone Acetonide (TA) without need of cannula sleeve.

Study Design: Quasi experimental study.

Place and Duration of Study: LRBT Korangi from July 2020 to June 2021.

Methods: Fifty eyes of forty two patients with Diabetic Macular Edema (DME) not resolved with three consecutive intravitreal injection of Bevacizumab were included. A custom made 30 gauge needle on 1cc insulin syringe without cannula sleeve was used for injection of 0.1 ml (4 mg) Triamcinolone Acetonide (TA).

Results: Mean age was 50.8±13.77 years. Mean Intraocular pressure (IOP) readings pre injection, after injection at 5 minutes, 30 minutes, 1 hour, 2 hour, 1 week, 1 month and 3 months were 12.76±3.78, 14.8±5.76, 14.5±4.98, 14.6±4.46, 14.7±4.52,14.7±7.0, 12.98±3.93 and 12.83±2.62 mm of Hg respectively. Mean Best corrected visual acuity (BCVA) (Log MAR) before injection, 1 month and 3 months after injection were 0.9±0.1, 0.6±0.2 and 0.6±0.2 respectively. Mean central macular thickness (CMT) values before injection, 1 month and 3 months after injection were 408.4±112.94, 348.67±108.94 and 330.36±105.77 µm respectively. Significant difference was observed between pre-injection IOP and post injection IOP within 2 hours but no significant difference in later readings. BCVA and CMT showed statistically significant improvement.

Conclusion: SC injection of TA without cannula sleeve is quite simple and apart from transient increase in IOP immediately after injection no significant adverse effects occur.

Key Words: Suprachoroidal injection, Triamcinolone, Diabetic macular edema, Central macular thickness, Bevacizumab.

How to Cite this Article: Hasnain M, Rizvi SF. Safety of Suprachoroidal Triamcinolone Acetonide Injection without Cannula Sleeve: A Modified Technique. 2024;40(1):55-61. **Doi: 10.36351/pjo.v40i1.1732**

Correspondence: Muhammad Hasnain
LRBT Eye Hospital Korangi, Karachi
Email: drmhasnain@yahoo.com

Received: September 04, 2023
Accepted: November 14, 2023

INTRODUCTION

Suprachoroidal injection of Triamcinolone has emerged as an alternative technique to intravitreal injection of Triamcinolone which is associated with complications like rise in IOP, cataract in phakic eyes, visually disturbing floaters, retinal tear, retinal detachment, vitreous hemorrhage and endophthalmitis.[1] Due to low solubility and sustained release property of TA, it is a promising formulation for suprachoroidal delivery.[2] Supra-choroidal space (SCS) is a potential space found between sclera and choroid. Normally SCS has nominal thickness of 35µm, helping choroid to slide against sclera during accommodation. Moreover, SCS plays a role in uveoscleral outflow of aqueous humor, which is an alternative route for its drainage.[3]

Microneedles have been developed to deliver drug into the SCS.[4] Immediately after SCS injection, the drug quickly spreads posteriorly from the scleral spur

to the macula compared to localization of the drug bolus within vitreous after intravitreal injection.[5]

Pharmacokinetic studies in animal models have demonstrated a 12-timerise in the drug concentration in retina and choroid after SC injection while only upto 3% of the drug enters anterior chamber, reducing the risk of complications like intraocular pressure (IOP) shoots, cataract formation and worsening of pre-existing glaucoma.[6] With suprachoroidal administration, TA concentration remains high in the posterior segment for the first two months but declines to levels similar to that of intravitreal delivery by the end of 3 months.[7] TA enters the systemic circulation after passing through the choriocapillaries and across the sclera.[8] The particle size of TA is critical in its ocular retention, with most particles being unable to diffuse across the sclera or taken away by choriocapillaris.[7] Of the negligible amount of TA that reaches the blood, 68% is bound to plasma proteins while unbound TA is metabolized into three less-active metabolites which are passed in urine (40%) and feces (60%).[9]

A microneedle is a hollow-bore needle with a suitable length to prevent inadvertent intravitreal injection.[10] Microneedle based injector system has been made for delivery of TA in SCS.[11] Since this injector system is not available worldwide, different custom made needles are being used for SCTA injection. Ameen Marashi used 30 gauge needle with a stopper (23 gauge sleeve) that would only let 1000 micron penetration of the needle into the sclera delivering 0.05 ml TA to reach the Suprachoroidal space with gentle pressing on the sclera.[12] Therefore there was a need to develop a microneedle with minimum resources for delivery of TA in SCS.

We describe a custom made 30 gauge needle on 1cc insulin syringe without cannula sleeve for injection of 0.1 ml (4 mg) TA.

METHODS

This was a Quasi experimental study conducted in the vitreoretinal department of LRBT Eye Hospital Korangi, Karachi from July 2020 to June 2021. Ethical Committee of the hospital approved the study. Informed written consent was taken and 50 eyes of 42 patients were included. Patients were selected through convenient sampling. Patients more than 18 years of age with Diabetic Macular Edema not resolving with three consecutive intravitreal injection of Bevacizumab, CMT of 250 microns or greater and less than 10% reduction in CMT from baseline after 3 consecutive intravitreal Injection Bevacizumab were included. CMT was calculated using Swept Source OCT (Topcon, Japan).Patients less than 18 years of age, OCT showing traction on macula, macular edema due to other causes including retinal vein occlusion and uveitis, Ocular Hypertension, Glaucoma and pregnant women were excluded. Pre-injection assessment included recording BCVA in Log MAR, IOP measurement (Goldmann Applanation Tonometry), anterior segment examination on slit lamp and posterior segment examination with dilated pupil using 90 D lens with slit lamp biomicroscopy. OCT was done to measure CMT.

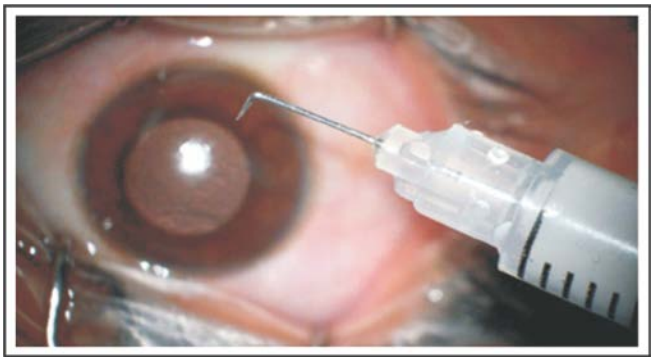
Immediately after injection, fundus examination was repeated with 90 D lens to see any intravitreal leakage of TA and arterial pulsation at optic disc. IOP was measured after 5 minutes, 30 minutes, 1 hour and 2 hour to see any IOP spike. If IOP remained elevated after 2 hour, patient was discharged on IOP lowering medication. Patients were followed after 1 week. Patients with IOP <21 mm of Hg were followed after1 month and 3 months while patients with IOP >21 mm of Hg were followed weekly till IOP became <21 mm of Hg without IOP lowering medication and thereafter at 1 month and 3 months. At each follow-up visit BCVA and IOP were recorded, anterior and posterior segment examination with dilated pupil was performed. OCT was done after 1 and 3 months to see any change in CMT.

Statistical analysis of recorded data was performed using SPSS version 25 applying repeated measure ANOVA test. A *p*-value of 0.01 was taken to check statistical significance.

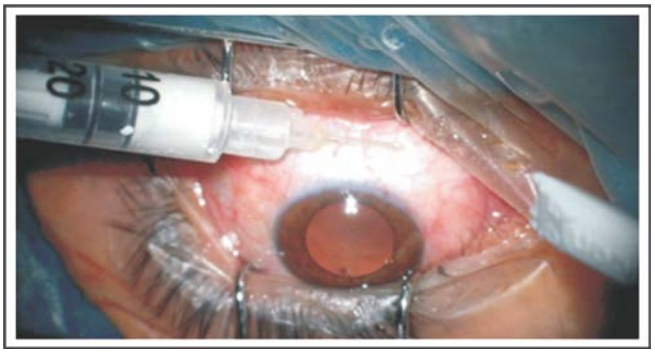
All the custom made needles require an outer sleeve which acts as a stopper to restrict the penetration of needle through choroid into the vitreous cavity. However, we designed a needle which does not need an outer sleeve. We used a 30 gauge 1cc insulin syringe for Suprachoroidal TA injection. All patients were dilated before SCTA injection. TA was filled in the syringe up-to the mark of 0.1 ml. The eyelid skin and periocular area was painted with 10% povidone iodine solution and 5% of this solution was instilled in conjunctival sac and left there for 3 minutes. The eye was draped. Caliper was used to measure 1mm tip of the needle. The tip was bent with needle holder at an angle of 90° so that distant tip end was 1mm. The distance from limbus was measured with caliper, 4mm

in phakic and 3.5mm in pseudophakic eyes. The tip of bent needle was pushed into sclera at perpendicular angle with the help of indenter or back side of trocars. Infero-nasal quadrant was chosen due to convenience, although any quadrant can be used. Once the needle was in correct place Triamcinolone was injected slowly keeping an eye on fundal glow. We waited for few seconds after injection, then took the needle out and point of entrance was pressed with corneal forceps, indenter or back side of a dialer to prevent regurgitation of Triamcinolone. Fundal glow was observed for accidental intravitreal leakage of Triamcinolone, antibiotic eye drop was instilled and eye pad was applied (Photograph 1-2).

Immediately after injection, visual acuity was checked with fingers counting and fundus examination was carried out at slit lamp to see any intravitreal leakage of TA and arterial pulsation at optic disc. IOP was measured after 5 minutes, 30 minutes, 1 hour and 2 hour to see any IOP spike. If IOP remains elevated after 2 hour then patient was discharged on IOP lowering medication.



Photograph 1: (Hasnain and Rizvi) showing 30 G needle bent at 90° with needle holder.



Photograph 2: (Hasnain and Rizvi) showing bent portion of needle inserted in inferonasal quadrant.

Complications related to the injection were noted including conjunctival hemorrhage, intravitreal leakage of TA, regurgitation of TA, IOP rise, trauma to crystalline lens, vitreous hemorrhage, retinal detachment and endophthalmitis.

RESULTS

A total of 50 eyes of 42 patients were enrolled in this study. There were 27(64.3%) males and 15 (35.7%) females. Mean age of the patients was 50.8 ± 13.77 years. Mean IOP readings pre injection, 5 minutes, 30 minutes, 1 hour and 2 hour after injection were 12.76±3.78, 14.8±5.76, 14.5±4.98, 14.6±4.46 and 14.7±4.52 mmHg respectively. Mean IOP readings at 1 week, 1 month and 3 months were 14.7 ±7.0 , 12.98±3.93 and 12.83±2.62 mm of Hg respectively.

Mean readings of IOP, CMT and BCVA at presentation, 1 month and 3 months after injection are shown in Table1.

Statistical analysis was performed using SPSS version 25 applying repeated measure ANOVA. Statistically significant difference was observed between pre-injection IOP and post-injection IOP within 2 hours (p=<0.001) but there was no statistically significant difference between pre-injection and post-injection IOP after 1 week, 1month and 3 months (p=0.027).

Bar charts 1 and 2 show post-injection IOP after 1 week and 3 months.

At 1 week, IOP rose in 2 eyes of 1 patient (4%). The patient was 23 years old female and IOP rose in each eye after SCTA in the corresponding eye. In right eye pre-injection IOP was 10 mm of Hg. IOP readings after injection at 5 minutes, 30 minutes, 1 hour and 2 hours were 15, 13, 12 and 12 mm of Hg respectively. After 1 week IOP rose to 40 mm of Hg when topical

Table 1: *IOP, CMT, BCVA at presentation, 1 month and 3 months.*

Parameters	At Presentation	1 Month	3 Months	P value
IOP (mm of Hg)	12.76 ±3.78	12.98 ±3.93	12.83 ±2.62	0.027
CMT (µm)	408.4 ± 112.94	348.67 ± 108.94	330.36 ± 105.77	<0.001
BCVA(Log MAR)	0.9 ± 0.1	0.6 ± 0.2	0.6 ± 0.2	<0.001

and systemic IOP lowering medication was started. After 2 weeks IOP was 22 mm of Hg, after 3 weeks IOP was 12 mm of Hg when IOP lowering medication was stopped. After 4 weeks IOP was 8 mm of Hg without any medication and after 3 months it was 10 mm of Hg. Same trend was observed in fellow left eye of the same patient in which pre-injection IOP was 14 mm of Hg. IOP readings after injection at 5 minutes, 30 minutes, 1 hour and 2 hours were 18, 16, 16 and 16 mm of Hg respectively. After 1 week IOP rose to 50 mm of Hg when topical and systemic IOP lowering medication was started. After 2 weeks IOP was 19 mm of Hg, after 3 weeks it was 10 mm of Hg when IOP lowering medication was stopped. After 4 weeks IOP was 10 mm of Hg without any medication and after 3 months IOP was 12 mm of Hg.

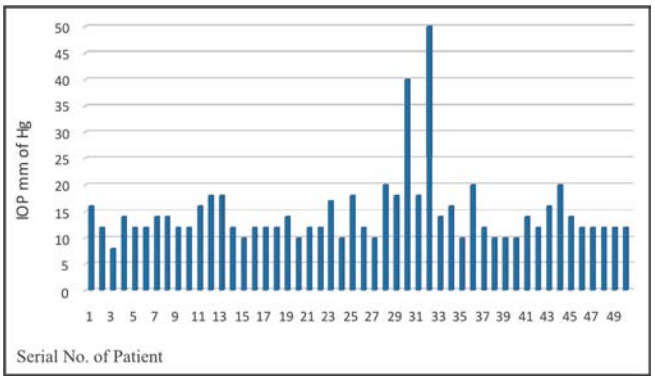


Figure 1: Bar Chart showing Post Injection IOP after One Week.

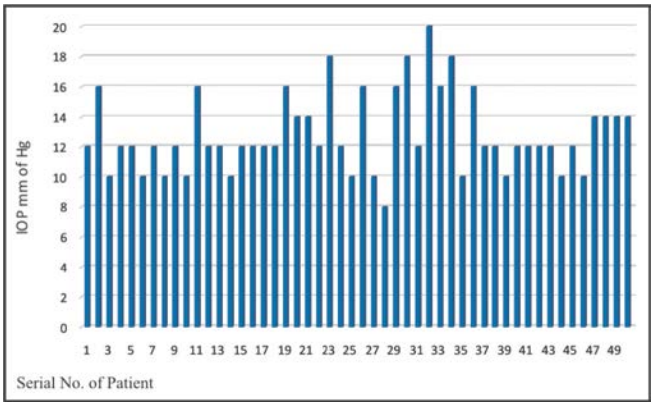


Figure 2: Bar Chart showing Post Injection IOP after Three Months.

Conjunctival hemorrhage occurred in 7 eyes (14%) while regurgitation of TA was seen in 2 eyes (4%).None of the patients got trauma to crystalline lens, intravitreal spill over, vitreous hemorrhage, retinal detachment and endophthalmitis.

DISCUSSION

Anti-VEGF treatment for DME is standard of care these days. However, clinical trials have shown that 15–20% of patients are nonresponsive to anti-VEGFs.[13] Role of intra-vitreal (IV) TA in treating DME is also well proven but studies have shown very high rate of cataract formation in phakic eyes and rise of IOP.[14]SC injection of TA is an alternative modality for treating different retinal vascular diseases.

Different animal models have demonstrated that SC drug delivery leads to significant posterior segment drug concentrations whereas only minimal amount reaches anterior chamber, contrary to IVTA, in which there is risk of cataract formation and IOP elevation.[15]Microneedle based injector system has been made for delivery of TA in SCS.[11] However, because of its limited availability customized needles have been developed for this purpose which use cannula sleeve as stopper, preventing entry of TA into vitreous. Ameen Marashi used 30 gauge needle with 23 gauge cannula sleeveasstopper,[12] Avadhesh Oli used 26 G needle with 22 G cannula sleeve as stopper[16] and Haroon Tayyab utilized 30 G needle with 24 G cannula sleeve.[17] All these techniques require custom made cannula sleeves which require considerable experience for their exact preparation besides additional cost in a setup with limited resources. In our technique we did not use any physical sleeve as stopper but instead bent the needle with needle holder to 90° to achieve stopper effect. The purpose was to make custom made needle with minimum requirement of consumables, saving time and cost. Ameen Marashi,[12] Avadesh Oli,[16] Haroon Tayyab[17] used superotemporal quadrant for injection but we used inferonasal quadrant for our convenience although any quadrant can be used.

IOP rose in 2 eyes of the same 23 years old female patient after 1 week, when IOP lowering medication was started which controlled IOP. After 3 weeks IOP lowering medication was stopped and IOP remained normal thereafter. Other studies have also shown rise of IOP after SCTA similar to our study. Haroon Tayyab described only one patient out of 24, with IOP rise from 19 to 24 mmHg at one-month after SC TA injection but returned to 16 mmHg at three months after using topical IOP lowering medication.[17] Another study reported rise of IOP in 1 patient after SCTA.[18] However AvadeshOli[16] in his study of 3 patients and Marashi et al,[6] in study of 11 eyes did not encounter rise of IOP which could be due to small sample size as

compared to our study. The rise of IOP in our cases was most probably due to TA reaching anterior chamber after SC injection. When compared to Intravitreal injection (IV) of TA, in our study IOP rose significantly in 2 eyes (4% eyes) while after Intravitreal Injection of TA LillIm has reported IOP rise in 6 of 14 (43%) treated eyes[19], Lakshmi Badrinarayanan showed IOP rise in 28% patients[20] and Pir Salim Maharen countered IOP rise in 117 (49%) patients.[21]This clearly indicates that regarding IOP rise, SC TA injection is a safer choice as compared to intravitreal TA injection.

In our study none of patient had spillage of TA into vitreous. Same has been reported by Haroon Tayyab[17]and Marashi et al,[6] which reflects safety of this technique. Conjunctival hemorrhage occurred in 7 cases (14%) and regurgitation of TA in 2 cases (4%). Conjunctival hemorrhage can be reduced by avoiding conjunctival vessels during needle insertion and using tip of indenter or back side of dialer instead of corneal forceps while removing needle from sclera. Regurgitation of TA occurs when needle has not reached SCS. If resistance is encountered while injecting TA, stop injecting, push the needle further and inject when there is no feeling of resistance while injection.

None of the patients got trauma to crystalline lens, vitreous hemorrhage, retinal detachment, TA spill over in anterior chamber and endophthalmitis. Similarly, other authors did not encounter these complications in their studies.[6,10,17] However, Junaid Hanif noted slight lenticular changes in 5 patients but did not get any vitreous and retinal complication.[22] All these studies indicate safety of SCTA like our study.

There was statistically significant difference between pre-injection CMT (408.4 ± 112.94) and post injection CMT after 1 month (348.67 ± 118.94) and 3 months (330.36 ± 105.77, P=<0.001) which showed 19.10% reduction in CMT after 3 months. Another study showed significant reduction in mean CMT, 43.9% after 1 month and 45.74% from baseline after 2 months.[6] Our study revealed 19.1% reduction in CMT after 3 months.

There was statistically significant difference between pre-injection BCVA (Log Mar) 0.9 ± 0.1 and post-injection after 3 months (0.6 ± 0.2 p=<0.001). Similar improvement in BCVA has been shown in other studies.[6,23,24] These studies emphasize positive outcome in BCVA after SC TA like our study.

Hanif Junaid carried out study on efficacy of SC TA in treating macular edema secondary to noninfectious uveitis. Pre injection IOP of 17.07±2.88 mm Hg and CMT 569.60±170.396 microns changed to IOP of 17.37±3.29 mm Hg and CMT of 208.27±37.292 respectively 3 months after injection.[22] This study also confirmed the significant reduction in CMT similar to our study.

Christopher Ryan Henry in his study on Suprachoroidal TA for non-infectious uveitis revealed baseline mean CMT 335.9 μm ± 85.00 which improved to 284.0 μm ± 76.44 at 24 week after injection (15% reduction)[9] which also showed significant reduction like our study.

Limitations of our study include a small sample size, absence of control group and short time of follow up. We recommend surgeons to use this technique as it has short learning curve and is cost effective. It can be utilized for treatment of other causes of macular edema including central vein occlusion and non-infectious uveitis.

CONCLUSION

New technique of SCTA does not require cannula sleeve, cost effective, has short learning curve and well tolerated. Apart from transient increase in IOP immediately after injection no significant adverse effects occur.

Conflict of Interest: Authors declared no conflict of interest.

Ethical Approval: The study was approved by the Institutional review board/Ethical review board (LRBT/TTEH/ERC/2459/20).

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Authors' Designation and Contribution

Muhammad Hasnain; Resident: *Concepts, Design, Literature Search, Data Acquisition, Data Analysis, Statistical Analysis, Manuscript Preparation, Manuscript Editing, Manuscript Review.*

Syed Fawad Rizvi; Consultant Ophthalmologist: *Concepts, Design, Manuscript Review.*