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Research Article

SUPRACHOROIDAL STEROID IN MACULAR EDEMA OF DIVERSE ETIOLOGIES

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A R T I C L E I N F O

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A B S T R A C T

To compare efficacy and safety of suprachoroidal injection of triamcinolone acetate (SCTA) (1 mg in 0.1 ml) in cases of macular edemas in comparison to intravitreal bevacizumab (IVB)(1.25 mg/ 0.05 ml). **Methods:** This was a interventional non randomized study conducted in the vitreoretinal department of a tertiary care hospital in Central India for a duration of 6 months. A total of 40 patients were enrolled with macular edema of diverse etilogies. Patients were given suprachoroidal triamcinolone acetate (0.1ml in 4.0ml) and intravitreal bevacizumab (0.05 in 0.1ml).Three monthly injections were given one month apart. The patients were followed for BCVA on day7,1st ,2nd and 3rd month and 1st,2nd and 3rd month for CST. **Results:** The primary endpoint was non inferiority in BCVA change and reduction in CST from baseline to 12 weeks. At 12 weeks, the SCTA group was non inferior to IVB group. The mean BCVA in SCTA on day 7,1 st month,2nd month and 3rd month were +4letters,+7 letters and 10 letters,13 letters respectively and +4.2 letters,+9 letters,+12 letters and 15 letters respectively in IVB. The mean CST also declined to 60µm, 100µm and 130µm in SCTA group and 40µm,70µm and 110µm group in IVB respectiyely. Minimal adverse effects were encountered in both the groups and were similar. **Conclusion:** Our study concluded that SCTA was non inferior to IVB in terms of functional and anatomical outcomes. All the eyes had significant anatomic improvement which was at par with intravitreal avastin with low incidence of adverse effects, thus offering a low cost and complication free alternative to anti-VEGF therapy in managing macular edema of diverse etiology.

INTRODUCTION

Injection of corticosteroids into the suprachoroidal space minimize the level of drug in the anterior parts of the globe achieving theraupetic levels in the retina.[1] This mode of drug delivery which spares the anterior segment and provides efficacy for posterior segment pathologies which minimizes the risk of cataract acceleration and IOP elevation associated with intravitreal corticosteroid delivery.[2,3,]

Intravitreal anti VEGF therapy is the accepted form of therapy for macular edemas secondary to diabetic retinopathy, retinal vein occlusion and non infectionuveitis[4,5,6]

Intravitreal steroids are second line primarily due to ocular side effects namely glaucoma and cataract.

Suprachoroidal steroid administration minimises the chances of cataract and glaucoma formation and hence offers as a safe and cost effective strategy in dealing with macular edemas of diverse etiologies.[7]

The present trial therefore aims at comparison of the suprachoroidal steroids and intravitreal avastin in macular edemas of diverse etiologies.

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The primary endpoint of this study is to compare suprachoroidal triamcinolone acetate to intravitreal bevacizumab in terms of change of BCVA and the reduction in CST from baseline to 12 weeks. The secondary endpoint is to compare the adverse effects in both the groups.

Aims & Objectives

Aim

To compare efficacy and safety of suprachoroidal injection of triamcinolone acetate (SCTA)(1 mg in 0.1 ml) in cases of macular edemas in comparison to intravitreal bevacizumab(IVB) (1.25 mg/ 0.05 ml).

Objectives

1. To study the effect of suprachoroidal injection of steroid for macular oedema based on improvement in Best Corrected Visual Acuity in terms of number of letters on ETDRS chart.
2. To study the effect of suprachoroidal injection of steroid for macular oedema based on Optical coherence characteristics mainly CentralSubfoveal Thickness.
3. To document safety of suprachoroidal steroids as compared with intravitreal anti VEGF therapy.
4.

MATERIAL AND METHODS

Study design: Interventional non randomized study
Study site: Tertiary care center, Nagpur
Study duration: 6 months
Sample size: 40 patients

Every patient underwent a comprehensive ophthalmologic examination that included the following measurement of best-corrected visual acuity (BCVA) by ETDRS chart at 4m(figure 1),intraocular pressure, slit-lamp biomicroscopy, (Topcon, Oakland, NJ, USA) dilated fundus examination with indirect of Ophthalmoscope, fluorescein angiography (Zeiss, Visuallite, Germany) and optical coherence tomography (OCT)(Topcon 3D -1,Maestro). Fluorescein angiography was done when in doubt .OCT was used to measure central subfield thickness and diagnose Macular Edema. All patients were informed of the possible adverse effects, and women of childbearing age were asked to use contraception during treatment.

After obtaining informed written consent and ethics approval, the procedure was performed in the operation theatre.

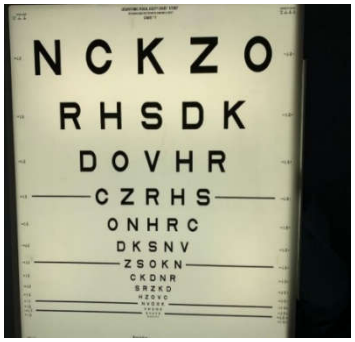

Figure 1 showing the illuminated ETDRS Chart

Inclusion Criteria

All the patients above 18 years of age coming to the Eye OPD with type 1 or type 2 diabetes milletus, non infectious uveitis, retinal vein occlusions and psuedophakic and aphakic patients with macular edema (defined as below).The baseline BCVA in SCTA and IVB was 70 to15 letters and 40 to 63 letters respectively. The baseline OCT was 250 to 300 µm for both the groups. All the patients were treatment naïve (who did not receive any form of treatment i.e.intravitreal injections or lasers, vitreo-retinal surgery)

Exclusion Criteria

- Known cases of glaucoma on or off medication(s) or patients with presenting Intraocular pressure ≥ 22 mmHg or uncontrolled glaucoma (open angle or angle closure) in the study eye
- Choroidal neovascularisation lesions secondary to age related macular degeneration surrounding the central subfield of macula.
- History of any previous ophthalmic surgeries in the study eye within 90 days of screening
- Subjects previously treated for DME cannot have been treated in the study eye with an intravitreal injection of anti-VEGF or periocular corticosteroids within 90 days prior to screening
- Subjects previously treated for DME cannot have been treated in the study eye with intraocular corticosteroids within 6 months prior to screening
- Subjects who could not complete the follow up of 3 months

CST (Central Subfield thickness) - the circular area within 1mm diameter around the foveal centre of imaging ≤ 250µ.

Procedure

The patients were randomized according to the block randomization technique in block randomization, the patients were randomized into two groups of equal sample sizes (i.e. 20 in each group). The blocks were small and balanced as one group received suprachoroidal triamcinolone acetate and the other received intravitreal bevacizumab. The number of patients in each group were similar at all times.

Group I: Patients injected with suprachoroidal triamcinolone acetate (SCTA)

Group II: Patients injected with intravitreal avastin (bevacizumab) (IVB)

Topical anaesthesia, followed by antiseptic povidone iodine was instilled and the eye was draped. Triamcinolone Acetate (0.1ml in 4.0ml) (Aurocort, Aurolab, Madhurai) (Figure 2) was administered suprachoroidally 4.0 to 4.5 mm posterior to the limbus with either a 900 mm or an 1100 mm needle(Pricon, Iscon, Jodhpur) (Figure 3). Povidone was instilled once again the eye and then the eye was patched. Monthly doses of TA were given as needed. (Figure 4a,4b,4c and 4d)

Figure 2 showing the vial of Triamcinolone acetate (aurocort)

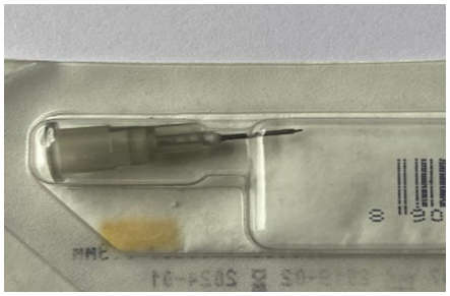

Figure 3 showing theSupra Choroidal needle of 30 G (pricon)

Topical anaesthesia, followed by antiseptic povidone iodine was instilled and the eye was draped. Avastin (0.05ml in 1ml) (Roche, Switzerland) (Figure 5)was administered intravitreally 3mm-3.5 mm (according to the lens status of the patient) posterior to the limbus with a 26 G needle. Povidone was instilled once again the eye and then the eye was patched. Monthly doses of avastin were given as needed.

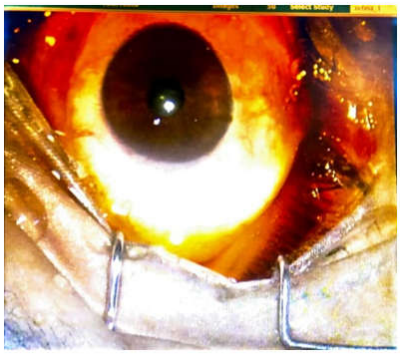

Figure 4a showing preparation of the eye and the instillation of povidone iodine solution in the conjunctival culde sac

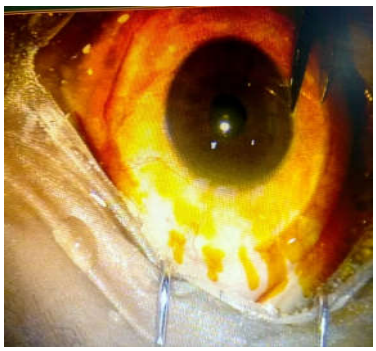

Figure 4b showing measurement with thrcastrevijocalliper at 4mm posterior to the limbus to mark the site of administrationof the drug

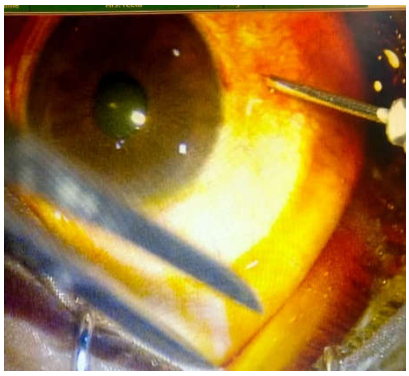

Figure 4c showing the fine bore of the suprachoroidal needle being inserted intothe suprachoroidal space at the marked site and delivery of the triamcinolone acetonide

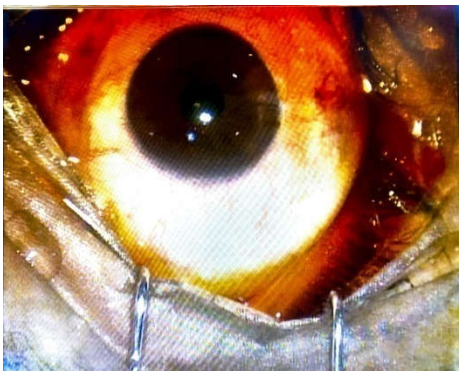

Figure 4d showing post administration instillation of povidone iodine prior to patching

An indirect ophthalmoscopy was done inmmedately after the procedure to look for any spillage of drug in vitreous cavity. The primary efficacy end point was mean BCVA change at month 3.

Figure 5 showing the vial of injection Bevacizumab (avastin)

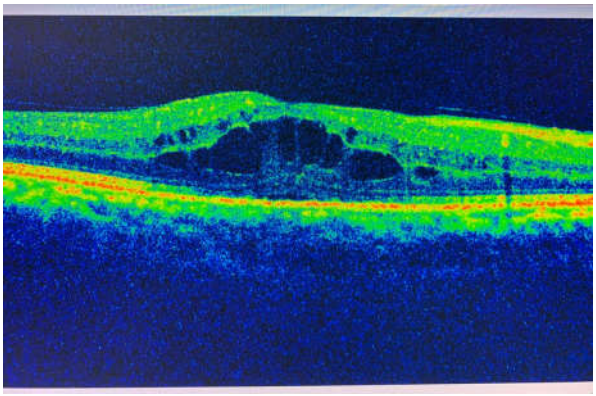

Figure 6a showing OCT image of diabetic macular edema prior to suprachoroidal triamcinolone acetonide

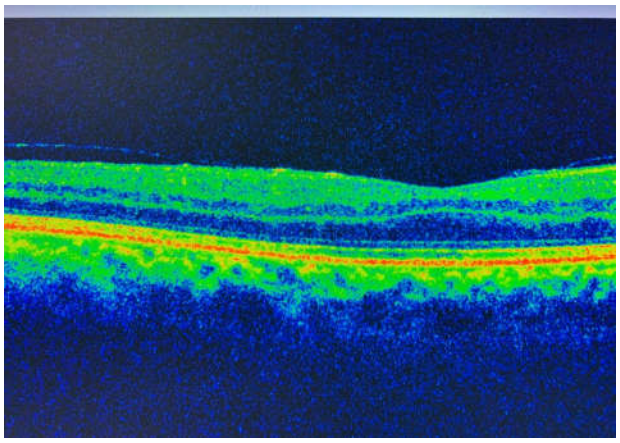

Figure 6b showing OCT image of diabetic macular edema post instillation of suprachoroidal triamcinolone acetonide

BCVA was recorded on day 1/day7/1month/2month and 3 month. OCT was done on on 1st,2nd and 3rdmonth,subsequent follow ups (Figure 6a and 6b).The mean pre and post BCVA and pre and post OCT were calculated by chi square test.A p value of 0.05 was taken statistically significant.

RESULTS

Only one eye per study subject was enrolled in the study. Total 44 subjects were included in the study, out of which 4 were excluded (3 from the Avastin group and 1 from the suprachoroidal group) due to inability to complete follow up of 3 months as per the study requirement. Hence,40 patients, 20 in each group were included in the study and the data of these cases was analysed.

Out of 40 patients, equal number of patients were divided in both genders. There was male preponderance amongst study subjects. Mean age in both groups was 59.3 years.

Diabetic macular edema was the most common etiology in both groups i.e. 14 and 15 patients followed by other diseases, including retinal vein occlusion and pseudophakic cystoid

macular edema. Both groups were identical as far as etiology was concerned.(table1)

Table 1 Etiology of Macular Edema

Etiology of Macular Edema	S/C TA	IVB
RP	00	01
CNVM	00	01
Post- cataract	02	00
Diabetic	14	15
CRVO	02	01
BRVO	02	02
Total	20	20

Both the study groups had identical mean presenting visual acuities (54 letters in SCTA group and 53 in IVB group) and mean pre injection Central Foveal Thickness (459 micron in SCTA group and 413 in IVB group). The difference was statistically insignificant, with both the determinants suggesting equal preoperative visual status between the two groups (table 2) and equal anatomical status between the two groups respectively. (table 3)

Table 2 Mean best corrected visual acuity (BCVA) at presentation

	SCTA	IVB	P value
Mean BCVA at Presentation(no. of letters on ETDRS chart)	54	53	0.95978*

* Calculated by Chi square test

Table 3 Mean Central Subfoveal Thickness (CST) at presentation

	SCTA	IVB	P value
Mean CST at presentation, as on SD OCT	459	413	0.743931*

*Calculated by Chi square test

Following 3 doses of injections in both groups and at 3 month follow up,both the study groups had identical improvement in mean visual acuity. Visual improvement in either group was non inferior to others (P value 0.9), suggesting that SCTA was non inferior to IVB in treating macular edema over a 3 months follow up(table 4).

Table 4 Mean BCVA pre and post injection

	SCTA	IVB	P value
Mean Va at Presentation	54	53	
Mean Va post injection	69	66	0.92074*

*calculated by chi square test

Similarly, there was reduction of mean CST following 3 doses of injections in both groups at 3 month follow up. This improvement in terms of reduction in CST in either group was non inferior to others (P value 0.8), suggesting that SCTA was non inferior to IVB in treating macular edema over a 3 months follow up(table 5).

Table 5 Mean CST pre and post injection

	SCTA	IVB	P value
Mean CST at presentation	459	413	
Mean CST after injection	329	303	0.8238*

*calculated by chi square test

There were minimal adverse effects in both the groups and were nearly similar.(table 6)

Table 6 Adverse effects in SCTA and IVB group

S .no	Adverse effect	SCTA	IVB
1.	Redness	2(10%)	4(20%)
2.	Subconjuctival haemorrhage	1(5%)	4(20%)
3.	Pain at the injection site	1(5%)	2(10%)
	Total	4(20%)	10(50%)

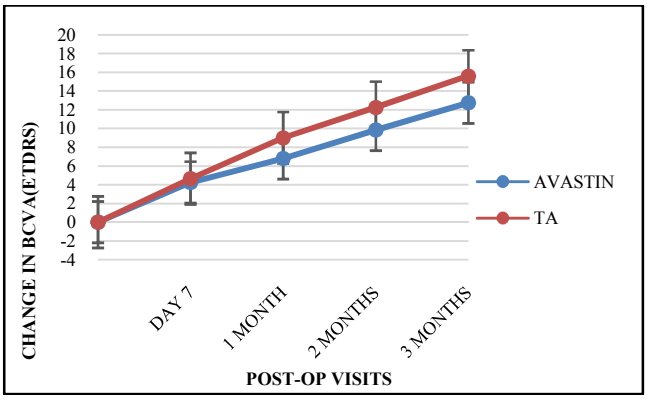

Figure 7 Mean change in Early Treatment Diabetic retinopathy Study (ETDRS) Best Corrected Visual Acuity (BCVA) in Suprachoroidal Triamcinolone Acetonide And Avastin group

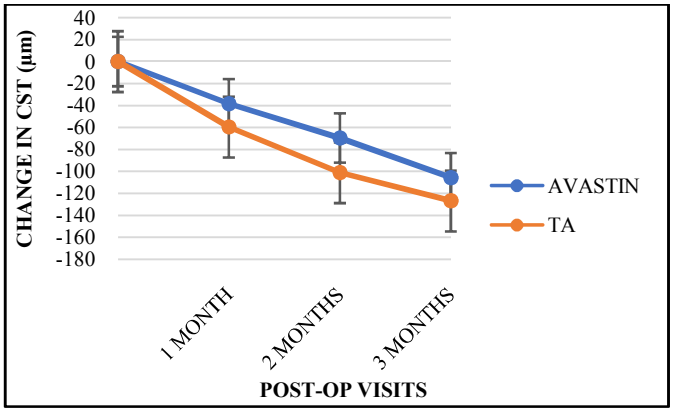

Figure 7 Mean change in Central Subfield Thickness (CST)in Suprachoroidal Triamcinolone and Avastin Group

DISCUSSION

The injection of triamcinolone acetate in the suprachoroidal space is rather a new and innovative way of treating macular edemas with different etiologies. In the HULK trial[1],they compared CLS TA alone or in combination with intravitreal aflibercept for treatment of macular edema. The patients were divided into two groups, the treatment naïve and previously treated groups. In our study, we had only treated treatment naïve patients with macular edema of diverse etiologies. We had two groups, one was injected with suprachoroidal triamcinolone acetate (SCTA) and other with intravitreal bevacizumab(IVB).

In our study, the mean changes BCVA in SCTA on day 7,1st month, 2nd month and 3rd month were +4 letters,+7 letters and 10 letters,13 letters respectively and +4.2 letters,+9 letters,+12 letters and 15 letters respectively (Figure 7).The HULK trial at 6 months had BCVA change of +5.2 letters,+8.5 letters and +1.1letters in combined, treatment naïve and previously treated populations respectively. In our study, the mean CST declined to 40µm, 70µm and 110µm group in IVB at 1st,2nd and 3rd month and 60µm,100µm and 130µm in SCTA group respectively (Figure 8). In the HULK trial, at the 6 month mean CST decreased by 91µm and 128µm to a mean CST of 331µm and 369 µm in the treatment naïve and previously treated arms respectively.

In our study, the adverse effects were seen in 4 patients of the SCTA group and 10 in IVB group like redness (2and 4), subconjunctival haemorrhage (1 and 4) and pain in injection site (1 and 2) respectively in both the groups. The Hulk trial,2 patients were with increased IOP,3 with cataract,1with local

pain at the injection site and 1 with indverent spillage of TA in inferior temporal quadrant.

In our study we did not have any patients with increased intraocular pressure. In another similar study, no rise in intraocular pressure after SCTA administration was observed but it was used to reduce macular edema in non infectious uveitis.[3]

In TANZANITE study, the safety and efficacy of SCTA with intravitreal aflibercept vs treatment of aflibercept alone was compared in RVO patients. The CST was reduced and the BCVA improved.[2] DOGWOOD study administered SCTA in macular edema of non infectious etiology, there was significant reduction in CST and improvement in BCVA.[7]

Limitations

Small sample size and different treatment groups and less follow ups.

CONCLUSION

Our study concluded that suprachoroidal administration of triamcinolone acetate was as safe as intravitreal avastin in macular edema of diverse etiologies. All the eyes had significant anatomic improvement and functional improvement which was at par with intravitreal avastinwith low incidence of adverse effects, thus offering a low cost and complication free alternative to anti-vegf therapy in managing macular edema of diverse etiology.

Bibliography

1. Patel SR, Berezovsky DE, McCarey BE, Zarnitsyn V, Edelhauser HF, Prausnitz MR. Targeted administration into the suprachoroidal space using a microneedle for drug delivery to the posterior segment of the eye. Invest Ophthalmol Vis Sci. 2012; 53:4433-41.
2. Campochiaro PA, Wykoff CC, Brown DM, Boyer DS, Barakat M, Taraborelli D, Noronha G, Tanzanite Study Group. Suprachoroidal triamcinolone acetonide for retinal vein occlusion: results of the Tanzanite Study. Ophthalmolol Retina. 2018;2:320-8.
3. Goldstein DA, Do D, Noronha G, Kissner JM, Srivastava SK, Nguyen QD. Suprachoroidal corticosteroid administration: a novel route for local treatment of noninfectious uveitis. Transl Vis Sci Technol. 2016;5:14
4. Wells JA, Glassman AR, Ayala AR, Jampol LM, Bressler NM, Bressler SB, Brucker AJ, Ferris FL, Hampton GR, Jhaveri C, Melia M. Aflibercept, bevacizumab, or ranibizumab for diabetic macular edema: two-year results from a comparative effectiveness randomized clinical trial. Ophthalmology. 2016; 123:1351-9.
5. Maturi RK, Glassman AR, Liu D, Beck RW, Bhavsar AR, Bressler NM, Jampol LM, Melia M, Punjabi OS, Salehi-Had H, Sun JK. Effect of adding dexamethasone to continued ranibizumab treatment in patients with persistent diabetic macular edema: a DRCR network phase 2 randomized clinical trial. JAMA ophthalmology. 2018;136:29-38.
6. Yeh S, KurupS, Wang R, Foster S, Noronha G, NguyenQ, DianaV. Suprachoroidal injection of triamcinolone acetonide, CLS-TA, for macular edema due to non infectioucsuveitis. Retina 00:1-9,2018.
7. Wykoff CC, Khurana RN, Lampen SI, Noronha G, Brown DM, OuWC, Sadda SR. Suprachoroidal Triamcinolone Acetonide for Diabetic Macular Edema. The HULK Trial. Ophthalmology Retina.2018; 2:874-7.

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