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Original Article

Efficacy of Formulated Posterior Subtenon Triamcinolone in Macular Edema secondary to Non–Ischemic Retinal Vein Occlusions

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ABSTRACT

Background: Retinal vein occlusion [RVO] is considered the second vascular disorder of the retina after diabetic retinopathy. Patients with RVO are at risk of the development of macular edema, which may be treated by triamcinolone.

The Aim of the work: To detect the efficacy of formulated Triamcinolone Acetonide [TA] injection in the posterior subtenon space to manage macular edema secondary to non-ischemic RVOs, either central or branch.

Patients and methods: Our study included forty-six eyes from 46 patients with non-ischemic RVO. All the eyes received a single dose of 40 mg of Triamcinolone Acetonide [TA] and VISCOAT, which is 20 mg sodium chondroitin sulfate and 15 mg sodium hyaluronate [0.5 ml] through the posterior subtenon route using NAGATA subtenon canula. Complete ophthalmic examinations were done at the baseline and after one, three, and six months of injections.

Result: The mean age of patients was 58.28±5.19 years. BCVA increased from 0.40 [0.10-0.70] at baseline to 0.75 [0.10-1.00] at the 1st ,3rd and 6th month [P < 0.001]. The median baseline OCT thickness changed from 411.50 [294.00-624.00] µm pre-injection to 265.00[187.00-614.00] µm [1st month], 265.00 [187.00-614.00] µm [3rd month], and 209.00 [178.00-531.00] m [6th month] [p<0.001]. The median IOP decreased from 13.00 [11.00-18.00] mm Hg on initial assessment to 12.00 [10.00-16.00] at the end of the study without any elevation at any point.

Conclusion: Formulated posterior subtenon triamcinolone acetonide [PSTA] is an effective treatment for macular edema secondary to Non- Ischemic RVO with minimal complications.

Keywords: Retinal vein occlusion, Posterior Subtenon, Triamcinolone, Macular edema.

INTRODUCTION

Retinal vein occlusion [RVO], retinal hemorrhage, and diabetic and hypertensive retinopathy are common vascular disorders of the retina and may cause a significant diminution of vision up to blindness. Retinal vein occlusion is considered the second vascular disorder of the retina after diabetic retinopathy [1, 2].

RVO is classified into three types depending on the level of the obstruction: When the occlusion at the posterior aspect of the optic head, it's considered Central Retinal Vein Occlusion [CRVO] and when the occlusion at any tributary, it is considered Branch Retinal Vein Occlusion [BRVO], and when the occlusion at the main bifurcation it is considered Hemi Retinal Vein Occlusion [HRVO] [2,3]. Depending on the non-perfusion of the retinal capillaries, these types have been subdivided into ischemic and non-ischemic subtypes [4].

Pathogenesis of Retinal vein occlusion may be of arterial cause; in CRVOs, it may be due to the existence of the central veins and arteries inside the adventitia of the same lamina cribrosa, resulting in compression of the veins by the neighboring stiffed arteries, In BRVOs; compression of veins at arteriovenous crossings, venous wall degenerations, and increased blood coagulability are hypothesized to be the cause. However, a new pathogenetic mechanism for venous occlusion has recently been suggested; atherosclerotic arteries may produce endothelin-1, which may spread to an adjacent vein and cause venous vasoconstriction [5]. Although the exact cause is unknown, aging, hypertension, heart disease, dyslipidemia, diabetes, smoking, and local ocular problems such as elevated intraocular pressure seem to be risk factors for venous occlusion. Patients with RVO are at risk of increased intravenous pressure, which may lead to macular edema[ME] [3].

Pathogenesis of macular edema is thought to be due to fluid exudation from the retinal vessel after losing the blood-retinal barrier, which occurred due to damage of the capillary tight junctions and secretion of vascular endothelial growth factors, which increase capillary permeability and proliferation of endothelial cells [6]. There are different treatment modalities for macular edema, such as LASER therapy, injection of anti-vascular endothelial growth factor [VEGF], and injection of triamcinolone [1].

Triamcinolone acetonide [TA] is a corticosteroid that has antiangiogenic and anti-inflammatory effects that can inhibit VEGF and other cytokines, improving best-corrected visual acuity[BCVA] and decreasing central macular thickness [CMT] [7].

The injection of intravitreal triamcinolone acetonide [IVTA] is beneficial. However, it has adverse effects such as cataracts, increased intraocular pressure [IOP], sterile pseudo endophthalmitis, and endophthalmitis [8]. To minimize these complications, we can inject the triamcinolone in the posterior sub tenon space, Which was found to be safer but less effective than IVTA [9]. To increase its efficacy, our study hypothesizes that adding sodium hyaluronate and chondroitin sulfate to triamcinolone increases its viscosity, prolonging its contact with the sclera and increasing its diffusion through the scleral barrier [10].

AIM OF THE WORK

To detect the efficacy of formulated Triamcinolone Acetonide [TA] injection in the posterior subtenon space to manage macular edema secondary to non-ischemic RVOs, either central or branch.

PATIENTS AND METHODS

1. Study populations

This prospective interventional study was done between March 2021 and March 2022 in the ophthalmology department, Al-Azhar University, Damietta, Egypt.

With a power of 95%, a sample size of 35 was calculated. Our research adhered to the principles of the Helsinki Declaration and ethical approval was obtained from the Institutional Review Board of Damietta Faculty of Medicine, Al-Azhar University. We included 46 eyes of 46 patients after taking the informed consent. Our data was protected confidentially. We recruited the patient according to the following criteria:

The Inclusion Criteria include 1] Diminution of vision due to macular edema secondary to non-ischemic retinal vein occlusions, either central or branch, 2] CMT $\geq$ 250 μ, 3] Willing to participate in the study.

The exclusion criteria include 1] Unwilling to participate in the study, 2] Ischemic RVO, 3] previous laser treatment, 4] Glaucoma, macular ischemia, cataract, vitreous hemorrhage, and neovascularization of the iris, 5] patients with previous anti VEGFs or steroid injections or any eye

surgery three months before the inclusion, 6] Cardiac co-morbidities result in significant hemodynamic changes, 7] Respiratory diseases need treatment with antibiotics, 8] Suffering from other chronic diseases as diabetes, 9]Patient with allergy from triamcinolone acetonide.

2. Data collection

Complete medical history and physical examination were done to each patient during enrollment. complete ophthalmic examinations were done before injection, including; BCVA, which was measured by Snellen's chart on a chart projector; IOP, which was measured by applanation tonometer; CMT, which was measured by spectral-domain Optical coherence tomography [OCT], and fundus examination using slit-lamp biomicroscopy with fundus non-contact VOLK +90D lens.

3. Drug preparation and route of administration

The conjunctiva was anesthetized first by Benoxinate 0.4% drops, then by a soaked microsponge in the lower fornix for five minutes. Standard sterilization by 5% povidone-iodine lid swabbing and instillation of 5% povidone-iodine in the conjunctival sac was done, and the patient was draped. After topical anesthesia and 5% povidone-iodine application, supero-temporal subconjunctival anesthesia [2% lidocaine]; a small conjunctival and Tenon's incision [7 mm posterior and supero-temporal to the limbus] was made to the bare sclera; then the patient underwent posterior subtenon [PST] injection of 40 mg TA, 20 mg sodium chondroitin sulfate and 15 mg sodium hyaluronate [0.5 ml] delivered as posterior juxtascleral injection. This suspension was mixed in a 5 ml syringe by shaking well for 2 minutes till mixing well, and no fluid level was seen.

All injections were done in the operating rooms under complete aseptic conditions. To avoid formulation reflux from the opening, we injected it using a cannula with applying pressure on the opening of the conjunctiva with a cotton tip; then, we removed the cannula very slowly and closed the conjunctiva with diathermy. Antibiotic eye drops and nonsteroidal anti-inflammatory eye drops were prescribed one week after injection.

4. Follow-up

Patients were examined at months one, three, and six after injection. The complete ophthalmic assessment was done during follow-up as those at baseline.

5. Statistical analysis

Statistical analysis was performed with SPSS statistical software, version 25 [IBM, Chicago, Illinois, USA]. The normality of the data was tested by Shapiro–Wilk test. Continuous data were expressed as mean±SD or median [percentiles] and range or interquartile range. Categorical data were expressed as numbers and percent [N [%]]. The Friedman test was used to analyze change among different periods, and the post-hoc test was further evaluated by the Wilcoxon signed-rank [WSR] test. P-value < 0.05 was considered significant.

RESULTS

Forty-six eyes from 46 patients were enrolled in our study. **Table [1]** shows the baseline parameters. The mean age of patients was 58.28±5.19 years and ranged from 50.00 to 69.00 years. Of the 46 patients, 80.4 % of patients improved without the need for further injection; nevertheless, five patients [10.9%] required re-injection in the 1st month, three patients [6.5%] re-injection needed in the 1st and 6th month, and only one patient [2.2%] required re-injection at the 3rd and 6th month.

Table [2] shows a significant difference in BCVA between the baseline and the follow-up periods after injection [1st month, 3rd month, and 6th month] according to Friedman's test [P < 0.001]. Whereas the pairwise comparison showed a significant increase in BCVA from 0.40 [0.10-0.70] at baseline to 0.75 [0.10-1.00] at the 1st,3rd, and 6th month [**Fig. 1**; P < 0.001 according to the WSR test adjusted by Bonferroni's corrections]; however, no significant difference was observed in BCVA between the 3rd month and 6th-month post-injection [P = 0.019].

Regarding OCT thickness, a significant difference was observed between the baseline and the follow-up periods after injection [1st month, 3rd month, and 6th month] [Friedman's test P < 0.001]. The median baseline OCT thickness changed from 411.50 [294.00-624.00] μm pre-injection to 265.00[187.00-614.00] μm [1st month], 265.00 [187.00-614.00] μm [3rd month], and 209.00 [178.00-531.00] m [6th month] [**Fig. 2**; P < 0.001 according to the WSR test adjusted by Bonferroni's corrections]; yet there was no significant change from the 3rd month to 6th-month post-injection [P = 0.090].

As shown in Table [3], the median of IOP was significantly decreased from 13.00 [11.00-18.00] at baseline to 12.0 [10.00-16.00] after injection [Wilcoxon signed-rank test = -2.464, P = 0.014].

Table [1]: Baseline characteristics of the patient

Variables		Outcome
Number of eyes		46
Age [years]	mean [SD]	58.28 [5.19]
BCVA [Decimal]	median [IQR] Range	0.40 [0.10-0.50] 0.10-0.70
OCT thickness [µm]	median [IQR] Range	411.50 [360.50-523.25] 294.00-624.00
IOP [mm Hg]	median [IQR] Range	13.00 [11.00-14.00] 11.00-18.00
Resistance and date of re-injection, n [%]	No re-injection 1st-month re-injection 1st and 3rd-month re-injection 3rd and 6th-month re-injection	37 [80.4%] 5 [10.9%] 3 [6.5%] 1 [2.2%]

Table [2]: Comparison of visual acuity [log MAR], OCT thickness, and IOP over follow-up periods

Variables	Baseline	1st month	3rd month	6th month	Overall P
BCVA [Decimal]	0.40 [0.10-0.70]	0.75[0.10-1.00]	0.90[0.20-1.00]	0.90[0.20-1.00]	**<0.001***
	P1	**<0.001****	**<0.001****	**<0.001****	
		P2	**<0.001****	**<0.001****	
			P3	0.019	
OCT thickness [µm]	411.50[294.00-624.00]	265.00[187.00-614.00]	216.00[187.00-465.00]	209.00 [178.00-531.00]	**<0.001***
	P1	**<0.001****	**<0.001****	**<0.001****	
		P2	**<0.001****	**<0.001****	
			P3	0.090	

Data represented as Median [Min-Max]. *Statistically significant at P<0.05 according to Friedman's test. **Statistically significant at P<0.0125 according to Wilcoxon signed-rank test adjusted by Bonferroni corrections [0.05/4=0.0125]. P1: Pairwise comparison among baseline and 1st month, 3rd month, and 6th month. P2: Pairwise comparison among 1st month and 3rd month, and 6th month. P3: Pairwise comparison between 3rd month and 6th month

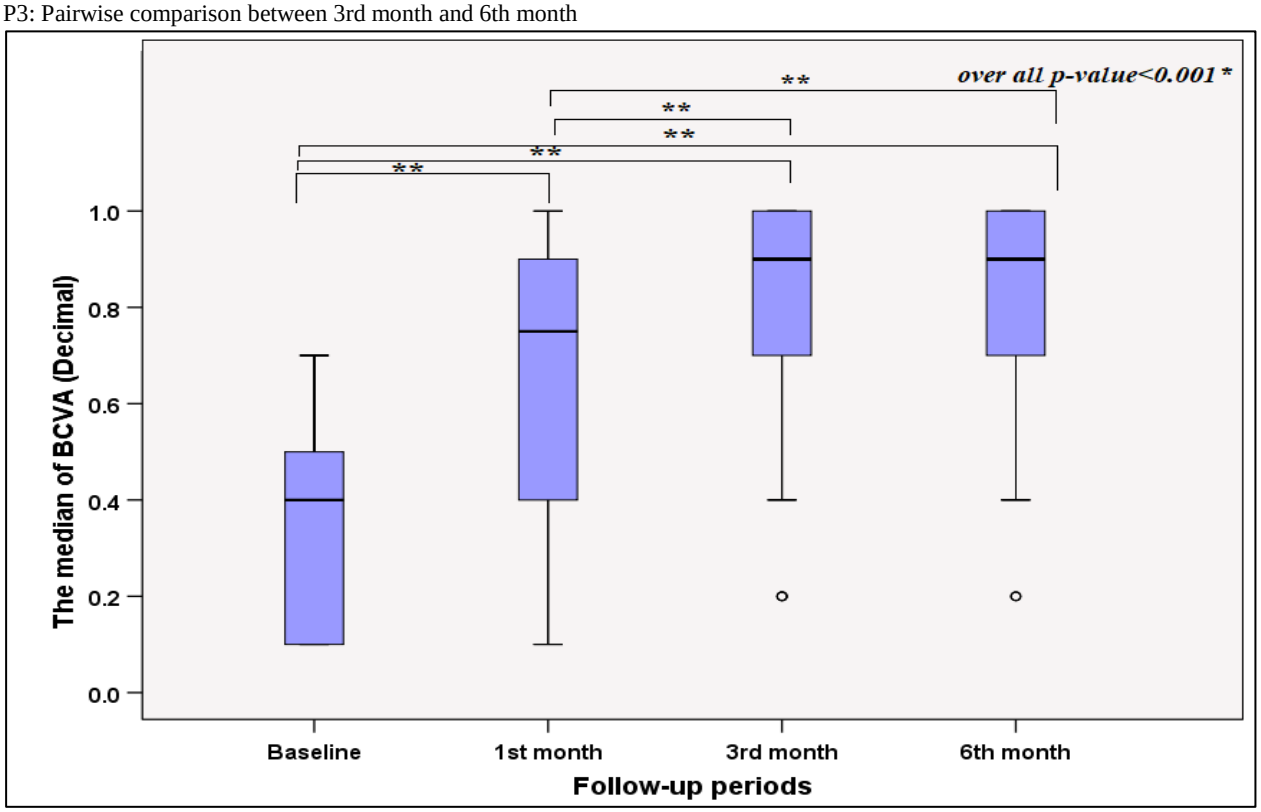

Figure [1]: Box plot showing the change in the median of BCVA IOP over the follow-up periods. The median IOP, the 25 and 75 percent quartiles [box], and the minimal and maximal IOP [whiskers] are all displayed. Outside values are marked as dots and far-out values as asterisks. *Statistically significant at P<0.05 according to Friedman's test. **Statistically significant at P<0.0125 according to Wilcoxon signed-rank test adjusted by Bonferroni corrections [0.05/4=0.0125].

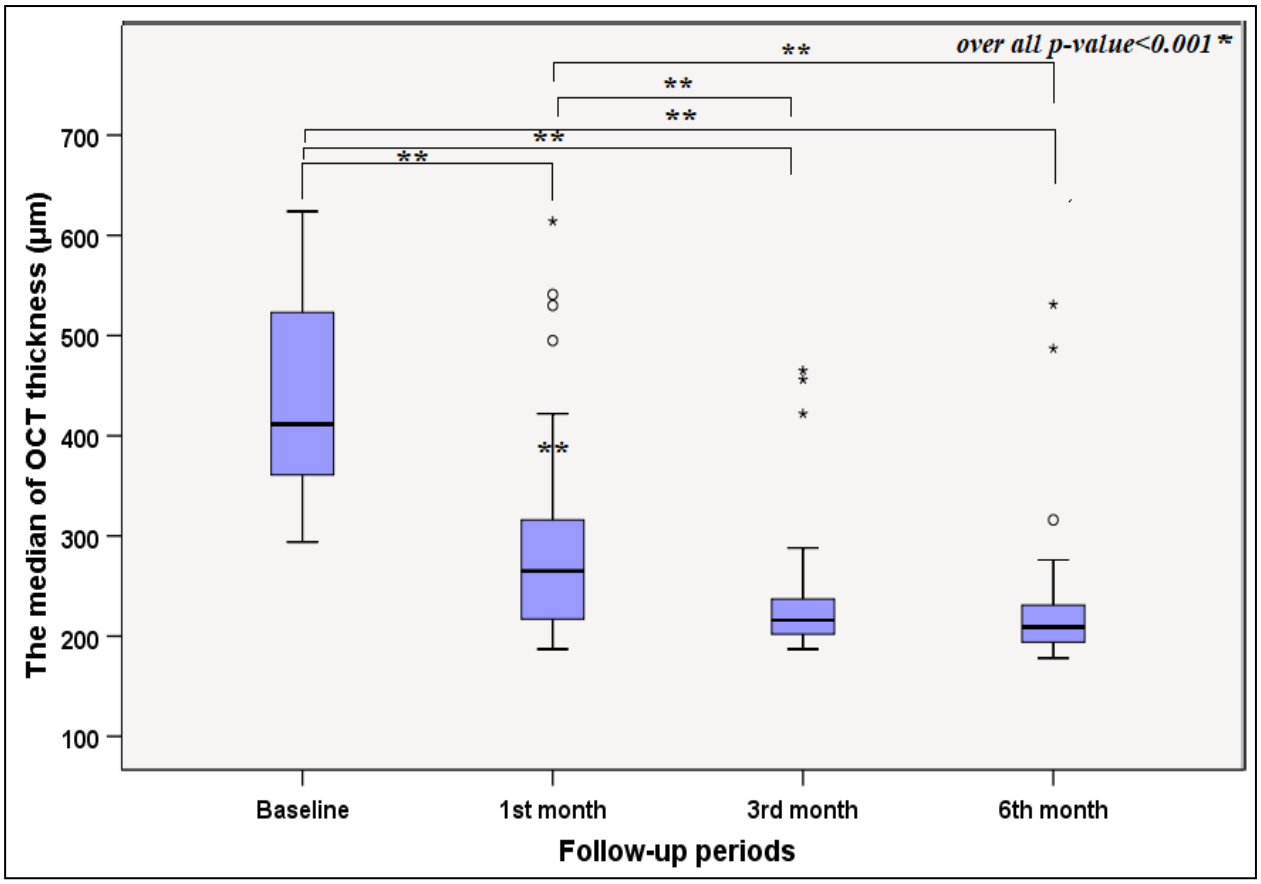

Figure [2]: Box plot showing the change in the median of OCT thickness over the follow-up periods. The median IOP, the 25 and 75 percent quartiles [box], and the minimal and maximal IOP [whiskers] are all displayed. Outside values are marked as dots and far-out values as asterisks. *Statistically significant at P<0.05 according to Friedman's test. **: Statistically significant at P<0.0125 according to Wilcoxon signed-rank test adjusted by Bonferroni corrections [0.05/4=0.0125].

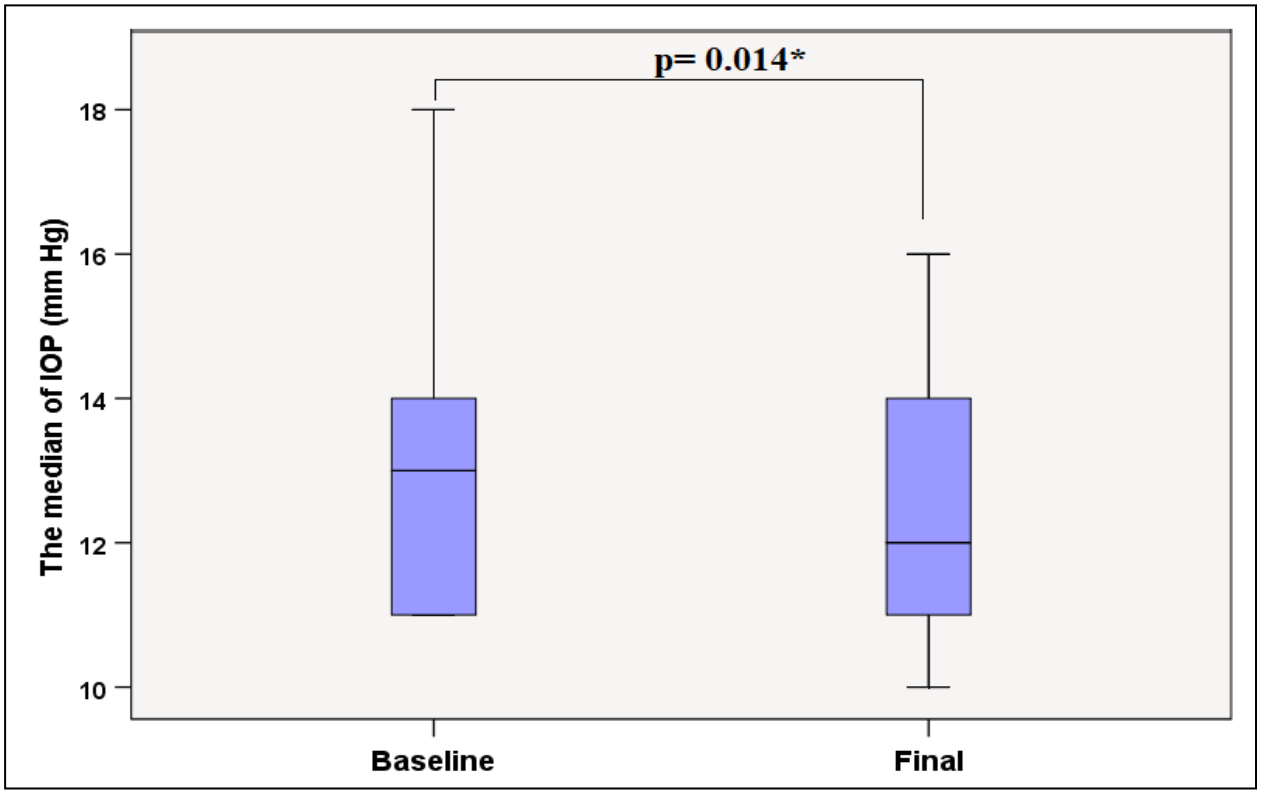

Figure [3]: Boxplot showing the change in IOP from baseline to after injection. *: Statistically significant at P<0.05 according to Wilcoxon signed-rank test.

Table [3]: Comparison of IOP after injection with PSTT

	Baseline	Final	Z	P-value
IOP (mm Hg)	13.00 (11.00-18.00)	12.0 (10.00-16.00)	**-2.464**	**0.014***

IOP: Intraocular pressure. Data represented as Median (Min-Max). Z: Wilcoxon signed-rank test. *: Statistically significant at P<0.05.

DISCUSSION

1. Summary of the main findings

Our study showed that injection of formulated TA in the posterior subtenon space is effective for treating macular edema post retinal vein occlusion in terms of reducing CMT and improving BCVA over a 6-month follow-up period without any rise in IOP. In about 80.4% of patients, the ME was effectively treated without re-injection, while in 19.6%, it was necessary. Furthermore, compared to baseline, there was a significant rise in BCVA at month 1, month 3, and month 6, but no further improvements nor worsening occurred at month 6. Likewise, OCT thickness decreased dramatically after three months and remained stable until six months following therapy. However, it showed a kind of stabilization, keeping rather good results compared to baseline. No severe elevation of IOP, which was reported in previous studies to occur with intravitreal injections of triamcinolone [11]; however, in our study, the median IOP decreased from 13.00 [11.00-18.00] mm Hg on initial assessment to 12.00 [10.00-16.00] at the end of the study without any elevation at any point.

2. Explanation of the main finding of the study

TA is a corticosteroid that has antiangiogenic and anti-inflammatory effects that can inhibit VEGF and other cytokines, which enter the pathogenesis of macular edema due to RVOs and produce changes in the diameter and perfusions of the retinal vessel, improving BCVA and decreasing CMT [7, 12, 13].

Kurt *et al*. [14] found some associations between vessel diameter, CMT, and IOP values after triamcinolone injection, suggesting that posterior subtenon TA injection causes retinal vessels constriction leading to a decrease in CMT and increase in the BCVA, which will be helpful in understanding the action mechanism of triamcinolone.

The injection of intravitreal triamcinolone acetonide [IVTA] is beneficial. However, it has adverse effects such as cataracts, increased IOP, and endophthalmitis [11]. To minimize these complications, we can inject the triamcinolone in the posterior sub tenon space, Which was found to be safer but less effective than IVTA [9]. To increase its efficacy, we added sodium hyaluronate and chondroitin sulfate, increasing the triamcinolone viscosity, prolonging its contact with the sclera, and increasing its diffusion through the scleral barrier [10].

3. Agreement and disagreement with previous studies

A prospective interventional non-comparative study by Gurram *et al*. [15] used PSTA to treat 24 eyes of 24 patients with recent-onset non-ischemic, resulting in out of the 24 eyes, 19 [79%] showed an improvement of more than five letters after a month of treatment with increased in the mean BCVA from 30.08 ± 10.16 to 40.21 ± 8.93 [p<0.05]. Additionally, all the patients exhibited a certain degree of decrease in CMT from 575.08 ± 131.55 to 282.08 ± 163.99 [p<0.05], which is in line with our findings. They concluded that PSTT is an effective treatment modality with minimal complications for ME associated with Non-Ischemic RVO.

Another study conducted by Tran *et al*. [16] examined fourteen eyes from 14 individuals with macular edema for more than three months. They demonstrated that PSTA injection is effective in the treatment of macular edema post-RVO, which agree with our findings, but they report an increase in IOP, which increased from 16.2 mm Hg at the baseline to 18.0 mm Hg after six month, which disagrees with our finding and this may be due to their small sample size and our addition of sodium hyaluronate and chondroitin sulfate.

In a recent study, Acharya *et al*. [17] examined the efficacy of PSTA injection in the treatment of ME post various retinal conditions in 60 eyes, where a significant improvement in BCVA was noted in 28 eyes [46%] at the end of the study which agrees with our result; however, they reported an increase in the IOP more than 21 mmHg in four eyes after the injection by one week, which is inconsistent with our result. Also, Elfassi *et al*. [18] showed that PSTA injection is a safe and valid alternative to the intravitreal injection for ME

management and has a comparable effect on VA and central macular thickness [CMT], mainly when IOP elevation is a concern in the intravitreal route.

In 2019, a multicenter retrospective study found that IOP elevated in 14.7% of 1252 Japanese patients [1406 eyes] after PSTA injection [19], which disagree with our study, and this may be due to their small patient age, higher IOP before injection, and large steroid dose. Similarly, Moon *et al*. [20] discovered that combining intravitreal bevacizumab with PSTA has the advantages of requiring fewer injections than intravitreal bevacizumab alone, providing better safety than intravitreal triamcinolone alone, and providing a more significant economic benefit than dexamethasone implant. Ali Ayoub *et al*. [21] also revealed that combined of sub-tenon triamcinolone with routine anti-VEGF therapy is an effective strategy for treating diabetic macular edema not only in terms of rapid and significant improvement but also in terms of reducing the number of frequent injections, this was consistent with our observation that over 80% of patients do not need re-injection.

4. Significance of our study

The study contributed to the body of evidence by demonstrating the effectiveness of Formulated PSTA in patients with ME post Non–Ischemic RVOs with fewer side effects than intravitreal injections.

5. Strength points and limitations of the study

Our study has several strength points. In our study we include a large sample size which increases our power. To the best of our knowledge, this is the first interventional study in Egyptian populations to investigate the effect of Formulated Posterior Subtenon Triamcinolone in patients with macular edema secondary to Non–Ischemic Retinal Vein Occlusions. The main limitation of our study is the absence of a comparator group.

6. Recommendations for future research and clinical practice

Multicentre trials with longer follow-ups are required to estimate this treatment's long-term safety and efficacy and to show whether the short-term benefits are only transient or may finally lead to a long-lasting improvement in vision. Moreover, comparative studies are required to compare PSTA with other formulated to present the effectiveness of sodium hyaluronate and chondroitin sulfate addition to triamcinolone more and more.

7. Authors' conclusions

So, we concluded that early injections of formulated TA effectively treat ME secondary to Non–Ischemic RVO and improve visual acuity in the 1st month, which was maintained for six months. Because of the more severe complications associated with intravitreal injections, formulated PSTA can be used a good alternative for treating diffuse ME.

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