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ORIGINAL ARTICLE

Comparison of Vabysmo Versus Suprachoroidal Triamcinolone Acetonide in Respect of Visual Acuity and Resolution of Macular Edema in Post-Uveitic Macular Edema

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ABSTRACT

Background: One of the most common complications of uveitis that leads to long-term vision loss is post-uveitis macular edema (PUME). However, there is variable effectiveness of conventional drugs such as steroids and anti-VEGF drugs and they often have side effects and/or recur.

Objectives: This study was designed to determine the efficacy and safety of Wabysmo vs SCTA in patients with PUME.

Study design: The study was a randomized, comparative interventional study and conducted for 12 months.

Material and Methods: The study was a prospective, randomized, comparative interventional study Conducted from September 2022 to August 2023 involving 60 patients with post-uveitic macular edema (PUME) that were confirmed on optical coherence tomography (OCT). Patients were randomly selected into two groups of equal number: Group A – intravitreal injection of Wabysmo (faricimab 6mg/0.05ml) and Group B – suprachoroidal injection of triamcinolone acetonide (4mg/0.1ml). Assessment of best corrected visual acuity (BCVA, logMAR), central macular thickness (CMT) and safety outcomes was performed at 1, 3, and 6 months. Paired and independent t tests, chi square tests were carried out and a p-value < 0.05 was taken as significant.

Results: After 6 months, both groups experienced a significant improvement in BCVA and decrease in CMT. However, the Wabysmo group showed greater improvement in BCVA (-0.49 ± 0.11 vs -0.39 ± 0.12 logMAR, p = 0.002) and greater reduction in CMT (-220.9 ± 38.7 µm vs -160.4 ± 41.2 µm, p < 0.001) compared to the SCTA group. The Wabysmo group had a higher rate of complete resolution of macular edema (66.7% vs 43.3%, p = 0.047). Wabysmo had more favorable safety profile with less incidence of intraocular pressure elevation and cataract progression when compared with the SCTA group.

Conclusion: Wabysmo and suprachoroidal triamcinolone acetonide have proven effective in treating PME (treating post-uveitis macular edema). Wabysmo, however, showed better visual and anatomical results and with less side effects.

Keywords: Post-uveitis macular edema, Wabysmo, Faricimab, Suprachoroidal triamcinolone acetonide, and Uveitis.

INTRODUCTION

Post-uveitic macular edema (PUME) can be one of the most significant causes of continued vision loss after intraocular inflammation. It is caused by the breakdown of the blood–retinal barrier, which causes intraretinal fluid to build up, mainly in the macular region[1]. Although the uveitis has been well controlled, macular edema can still remain or reappear, which can markedly impact best corrected visual acuity (BCVA) and quality of life[2]. It is caused by chronic inflammation, overexpression of the vascular endothelial growth factor (VEGF) and vascular permeability induced by cytokines. The traditional treatment of PUME consists of anti-VEGF, corticosteroids (topical, periocular, intravitreal, and systemic), and immunosuppressive drugs[3]. Long term corticosteroid use is also linked to possible complications including cataract formation, increased intra-ocular pressure and secondary glaucoma, and anti-VEGF alone may not be sufficient to treat the inflammatory aspects of the disease[4].

In recent years, the use of targeted corticosteroid delivery systems, such as suprachoroidal triamcinolone acetonide (SCTA), have appeared. Deposition of drug in the suprachoroidal space results in high posterior segment concentration and less anterior segment exposure, which helps to minimize side effects from steroid use[5]. Its effectiveness has been shown in clinical trials for the treatment of macular edema in uveitic eye diseases, with excellent visual outcomes, especially in refractory cases[6].

Wabysmo (faricimab) a new bispecific monoclonal antibody with an inhibitory effect on the receptors of two proteins, Ang-2 and VEGF-A. This dual pathway inhibition offers a greater degree of inhibition due to a targeting of both the vascular leakage and inflammatory instability[7, 8]. Faricimab has demonstrated long-lasting durability and demonstrated anatomical and functional efficacy in the treatment of retinal vascular diseases including DMO and nAMD. It is still under investigation, however, for its use in the treatment of post-uveitis macular edema[9].

Although significant progress has been made in pharmacotherapy, there are few comparative data available between dual pathway biologics, such as faricimab, and targeted corticosteroid delivery systems, such as SCTA, in PUME[10]. It is important to be familiar with their relative effectiveness in enhancing visual acuity and decreasing central macular thickness so as to tailor individual treatment approaches, particularly in chronic or refractory uveitic edema[11].

In this study, the efficacy and safety of Wabysmo compared to suprachoroidal triamcinolone acetonide in the treatment of post-uveitic macular edema (PUME) are compared in terms of BCVA and OCT-based central macular thickness (CMT).

MATERIAL AND METHODOLOGY

This was an interventional randomized comparative study carried out in the Department of Ophthalmology in a tertiary care hospital for a duration of 12 months. Patients with PUME were included in the study if PUME was confirmed by spectral-domain optical coherence tomography (OCT). Participants who met the inclusion criteria were randomized to receive intravitreal Wabysmo (6 mg/0.05 mL) versus intravitreal injection of the microneedle delivery system with triamcinolone acetonide 4 mg/0.1 mL) into the suprachoroidal space. Sample size was determined as 25 patients per group, corresponding to a 95% confidence level, assuming 60 µm of standard deviation of the change in central macular

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thickness, 10–15% attrition and an expected mean difference of 40 µm between the two groups, to which 10–15% were added, resulting in 60 patients (30 per group).

Eligible patients were adults (age ≥18 years) with inactive or controlled uveitis for at least 4 weeks, with central macular thickness of 300 µm or greater on OCT, and with a best corrected visual acuity between 0.3 and 1.3 logMAR. The following patients were excluded: patients with active infectious uveitis, recent intraocular injection (last 3 months), uncontrolled glaucoma, significant media opacities, other retinal pathologies which can lead to macular edema, pregnancy, or known drug hypersensitivity. Baseline assessment comprised detailed ophthalmological examination, visual acuity measured with a standardized Snellen chart converted to logMAR, intra-ocular pressure (IOP) measurement and OCT imaging. Patients were followed at 1, 3 and 6 months following treatment and repeat visual acuity, macular thickness and safety assessments were made. Primary outcomes included the improvement in BCVA and the decrease in central macular thickness (CMT), while secondary outcomes included time to resolution of edema, requirement for repeat injections, and treatment-related complications.

Data were statistically analyzed using SPSS version 26 and the continuous data are presented as mean ± standard deviation. The intergroup comparisons were done with independent t-test, intragroup comparisons were done with paired t-test and Chi-square test was used for categorical variables. The p-value < 0.05 was taken to be statistically significant.

RESULTS

There were no significant differences between the baseline characteristics of the Wabysmo and SCTA groups. The mean age was comparable (52.4 ± 11.2 vs 51.8 ± 10.6 years, p = 0.83), and gender distribution was also similar (p = 0.79). Similarly, there was no significant difference in baseline disease duration, BCVA, CMT or intraocular pressure (p > 0.05).

There was a significant increase in BCVA in both treatment groups over time. The Wabysmo group, however, experienced a greater and faster visual improvement than the SCTA group. The mean BCVA of the Wabysmo group was 0.29 ± 0.12, while that of the SCTA group was 0.41 ± 0.15, which was statistically significant (p = 0.003) at 6 months. The overall mean improvement from baseline was also significantly greater in the Wabysmo group (-0.49 ± 0.11 vs -0.39 ± 0.12, p = 0.002).

There was a gradual decrease in central macular thickness in both groups after 6 months. At all follow-up points, however, the reduction in the Wabysmo group was much greater. At 6 months, CMT decreased to 241.6 ± 42.3 µm in the Wabysmo group compared to 298.5 ± 49.8 µm in the SCTA group (p < 0.001). The total mean reduction in CMT was also significantly higher in the Wabysmo group (-220.9 ± 38.7 µm vs -160.4 ± 41.2 µm, p < 0.001).

The Wabysmo group had a significantly higher proportion of patients with complete resolution of macular edema (66.7%) versus the SCTA group (43.3%) (χ^2 = 3.96; p = 0.047). The partial and non-responder rates were also lower in the Wabysmo group.

Table 1: Baseline Demographic and Clinical Characteristics

Variable	Wabysmo (n=30)	SCTA (n=30)	Test	p-value
Age (years)	52.4 ± 11.2	51.8 ± 10.6	t = 0.21	0.83
Male/Female	16/14	15/15	χ^2 = 0.07	0.79
Duration of uveitis (months)	9.6 ± 3.4	10.1 ± 3.7	t = 0.55	0.58
Baseline BCVA (logMAR)	0.78 ± 0.18	0.80 ± 0.17	t = 0.44	0.66
Baseline CMT (µm)	462.5 ± 62.4	458.9 ± 60.8	t = 0.23	0.82
Baseline IOP (mmHg)	14.8 ± 2.6	15.1 ± 2.4	t = 0.46	0.64

Table 2: Best Corrected Visual Acuity (BCVA) Over Time

Time Point	Wabysmo (logMAR)	SCTA (logMAR)	Mean Difference	p-value
Baseline	0.78 ± 0.18	0.80 ± 0.17	—	—
1 Month	0.55 ± 0.16	0.63 ± 0.15	-0.08	0.04
3 Months	0.38 ± 0.14	0.50 ± 0.16	-0.12	0.01
6 Months	0.29 ± 0.12	0.41 ± 0.15	-0.12	0.003
Change (Baseline–6M)	-0.49 ± 0.11	-0.39 ± 0.12	-0.10	0.002

Table 3: Central Macular Thickness (CMT)

Time Point	Wabysmo (µm)	SCTA (µm)	Mean Reduction	p-value
Baseline	462.5 ± 62.4	458.9 ± 60.8	—	—
1 Month	345.2 ± 55.1	372.6 ± 58.3	-27.4	0.03
3 Months	278.4 ± 48.9	315.7 ± 52.6	-37.3	0.002
6 Months	241.6 ± 42.3	298.5 ± 49.8	-56.9	<0.001
Total Reduction	-220.9 ± 38.7	-160.4 ± 41.2	-60.5	<0.001

Table 4: Macular Edema Resolution Rate

Outcome	Wabysmo (n=30)	SCTA (n=30)	χ^2	p-value
Complete resolution	20 (66.7%)	13 (43.3%)	3.96	0.047
Partial response	8 (26.7%)	12 (40.0%)	—	—
No response	2 (6.6%)	5 (16.7%)	—	—

Table 5: Safety Outcomes

Complication	Wabysmo (n=30)	SCTA (n=30)z	RR (95% CI)	p-value
Raised IOP	2 (6.7%)	7 (23.3%)	0.29 (0.06–1.21)	0.08
Cataract progression	1 (3.3%)	5 (16.7%)	0.20 (0.02–1.60)	0.09
Ocular inflammation	1 (3.3%)	2 (6.7%)	0.50 (0.05–5.1)	0.55
No complications	26 (86.7%)	20 (66.7%)	—	0.04

Both treatments were relatively safe. Adverse events were more common in the SCTA group, and included a higher rate of raised intraocular pressure (23.3% vs 6.7%) and cataract progression (16.7% vs 3.3%). These differences were not statistically significant (p = 0.08 and p = 0.09, respectively). The Wabysmo group had significantly fewer complication-free outcomes (86.7% vs 66.7%, p = 0.04).

DISCUSSION

The presence of post-uveitic macular edema (PUME) is a challenge despite good control of intraocular inflammation. In the current trial, intravitreal Wabysmo (faricimab) was found to be a safe and effective option compared with suprachoroidal triamcinolone acetonide (SCTA) for improving visual acuity and central macular thickness[12]. Our results found that both treatments were effective in improving functional and anatomical outcomes, but faricimab was more effective in terms of BCVA improvement, macular thickness reduction, and complete resolution rates as well as had a more favorable safety profile[13].

The baseline characteristics in this study were comparable between the two groups, and thus, it was a valid intergroup comparison. There were no significant differences in the improvement in BCVA for either group after six months, but the improvement was larger in the Wabysmo group[14]. This result is in line with the known pharmacological benefits of faricimab, which targets both the VEGF-A and Angiopoietin-2 pathways, therefore targeting both vascular permeability and inflammatory instability. In the faricimab showed sustained visual improvement and long-term durability in retinal vascular diseases, but the use of the drug in uveic macular edema is still in the early stages[15].

In terms of anatomical outcomes, the Wabysmo group had significantly lower central macular thickness (p < 0.001) than SCTA. Such superior anatomical response may be explained by the dual pathway inhibition which results in more stable vascular

endothelial junctions and decreased leakage[16]. Lin et al. have had somewhat inconsistent results with anti-VEGF drugs in uveitic macular edema, which may be due to inflammatory component of the disease[17]. On the other hand, corticosteroids like triamcinolone have traditionally shown great anatomical improvements in the short term by virtue of their anti-inflammatory properties, but with recurrence and steroid-related side effects, these effects might be of limited duration[18].

In the present study, suprachoroidal delivery of triamcinolone has been demonstrated to deliver the drug to the posterior segment and reduce exposure of the anterior segment. In the previous trials, SCTA showed substantial reduction in macular edema and visual benefit in non-infectious uveitis[19]. In our study, however, SCTA was not as effective as faricimab, with the progression to complete resolution of edema (43.3% vs 66.7%, p = 0.047). This implies that corticosteroid therapy can be used to control inflammation, but does not necessarily resolve the vascular dysregulation aspect of chronic PUME[20].

Our study also demonstrated better safety results with Wabysmo. The SCTA group had a greater tendency to have elevated IOP and cataract development, as reported in the previous studies to be adverse effects of corticosteroid action. While suprachoroidal delivery results in lower exposure of anterior segment tissues to steroids, there is a clinical concern with steroid response. The safety profile of faricimab was more favorable with fewer complications, consistent with previous safety data in anti-VEGF therapies[21].

This dual mechanism of action and the superiority of faricimab in functional and anatomical outcomes could be attributed to its mechanism of action. Angiopoietin-2 is a destabilizing factor of the vascular endothelium and increases VEGF-mediated leakage; thus, combined inhibition of VEGF-A and Ang-2 is more effective at vascular stabilization than either VEGF inhibition or corticosteroid monotherapy alone. It may be especially true in post-uveitic cases where a chronic inflammatory remodeling along with vascular instability coexists[22].

The clinical implications of these results are that faricimab might be a better long-term treatment for persistent or refractory PUME, particularly for those who are steroid responders or at risk of developing steroid-associated complications. But SCTA can still be beneficial, especially in resource-challenged areas and when a quick response to inflammation is needed[23].

There were some limitations in this study. The number of participants was relatively small, and the length of follow-up was only six months, potentially not reflecting the recurrence patterns of the disease. Furthermore, this study didn't investigate inflammatory biomarkers or OCT angiography parameters that would have yielded more in-depth mechanistic explanations.

CONCLUSION

Overall, the visual and anatomic outcomes of both Wabysmo and suprachoroidal triamcinolone acetonide were effective in the treatment of post-uveitic macular edema, but faricimab had superior clinical results and safety profile. The results indicate that dual-pathway inhibition may represent a therapeutic approach in CME.

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