ISSN: 0975-833X

Available online at http://www.journalcra.com

International Journal of Current Research
Vol. 11, Issue, 01, pp.246-251, January, 2019

DOI: https://doi.org/10.24941/ijcr.33816.01.2019

INTERNATIONAL JOURNAL OF CURRENT RESEARCH

RESEARCH ARTICLE

COMPARISON OF SAFETY AND EFFICACY OF SINGLE DOSE INTRAVITREAL INJECTION OF TRIAMCINOLONE ACETONIDE 1.0 mg VERSUS DEXAMETHASONE 0.7 mg INTRAVITREAL IMPLANT IN PATIENTS WITH MACULAR EDEMA DUE TO RETINAL VEIN OCCLUSION

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ARTICLE INFO

Article History:
Received 10th October, 2018
Received in revised form
25th November, 2018
Accepted 19th December, 2018
Published online 30th January, 2019

Key Words:
Triamcinolone Acetonide, Dexamethasone, Macular Edema, Retinal Vein Occlusion.

ABSTRACT

This was a hospital based prospective, comparative study in which we compared the safety and efficacy of single intravitreal injection of triamcinolone acetonide (IVTA) (1.0 mg) and single intravitreal dexamethasone implant (IVD) (0.7 mg) in treating macular edema (ME) dueto retinal vein occlusion (RVO), including both Branch Retinal Vein Occlusion (BRVO) & Central Retinal Vein Occlusion(CRVO). 40 patients with ME having central macular thickness (CMT) >300µ on optical coherence tomography (OCT) were randomised to two groups. One group received single 1 mg IVTA and other group single 0.7 mg IVD. Log MAR best-corrected visual acuity (BCVA), CMT by OCT, intraocular pressure (IOP) by Goldmann's applanation tonometer (GAT) & cataract status were evaluated before injection and at 1, 3 and 6 months after injection. There was no significant difference in change in BCVA between IVTA and IVD groups (p=0.231).There was no significant difference in change in mean CMT between IVTA and IVD groups (p = 0.095). There was no significant difference in change in IOP between IVTA and IVD groups (p = 0.653).About, 50% patients showed cataract progression in IVTA group while in IVD group cataract progression observed in 45% of patients. Following the injection, at all stages IVD was superior in terms of vision improvement and CMT reduction. However, this superiority was not statistically significant. Progression of cataract was comparable in both the drugs.

Citation: ***Dr. Rajesh Chandra Kar, Dr. (Col) Sandeep Gupta, Dr. Amitabh Chakraborty, Dr. Sumit Kumar Singh and Dr. Debarshi Jana*****, 2019.** "Comparison of safety and efficacy of single dose intravitreal injection of triamcinolone acetonide 1.0 mg versus dexamethasone 0.7 mg intravitreal implant in patients with macular edema due to retinal vein occlusion", *International Journal of Current Research*, 11, (01), 246-251.

INTRODUCTION

Retinal vein occlusion (RVO) is the most common visually disabling disease affecting the retina after diabetic retinopathy (Shahid *et al*., 2006). Although it is more common in the middle-aged and elderly population, no age group is immune to it (Hayreh *et al*., 1994). In spite of the fact that the clinical entity of RVO has been known since 1878, its management still remains suboptimal. The pathogenesis of RVO is multifactorial with both local factors and systemic diseases being etiologically important. Known risk factors for RVO include systemic vascular disease, hypertension, diabetes mellitus, hyperlipidemia and glaucoma. Hypercoagulable states are associated with RVO. Macular edema (ME) is the main reason for decreased visual acuity in RVO. RVO causes vision loss mostly because of the development of intraretinal leakage that leads to macular edema.

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The treatment of Cystoid Macular Edema (CME) secondary to RVO has evolved considerably during the past decade. Anti-Vascular Endothelial Growth Factor (VEGF) agents have become the standard of care for ME secondary to both branch (BRVO) and central retinal vein occlusion (CRVO). Because the underlying pathophysiologic mechanism responsible for the formation of macular edema in these conditions is driven by inflammatory mediators in addition to VEGF, a considerable number of RVO patients with CME either do not respond well or become recalcitrant to anti-VEGF treatment. There are still gaps in understanding the etiology and pathogenesis of circulatory disorders of the central retinal vein and its branches. Triamcinolone and dexamethasone intravitreal implant have similar efficacy in reducing the risk of vision loss and improving the speed and incidence of visual improvement in eyes with macular oedema secondary to RVO. Triamcinolone Acetonide (TA) is a crystalline, synthetic glucocorticoid with potency approximately five times that of cortisol. Since soluble triamcinolone is washed out of the eye within 24 hours of intravitreous injection, the crystalline form is preferable.

Jonas *et al*. (2004) reported that, after intravitreal injection, triamcinolone acetonide can be detected in the aqueous humor up to 1.5 years with earlier study (Jonas, 2002; Jonas *et al*., 2001; Ladjimi *et al*., 2005) findings indicating up to 6 months. Intravitreal steroids have significant side effects like development of ocular hypertension in about 50% of eyes (Jonas, 2006; Gunnlaugsdottir, 2006; Jonas *et al*., 2005). The SCORE-CRVO study (Scott *et al*., 2009) showed that both triamcinolone (1mg & 4mg) groups were superior to observation group with respect to Visual Acuity (VA). The study also showed evidence of superior safety profile of the 1mg dose compared with the 4mg dose, particularly with respect to glaucoma and cataract, rendering the preferred dose in CRVO (Ip *et al*., 2009). In SCORE-BRVO (Scott *et al*., 2009) study, Intravitreal Triamcinolone Acetonide (IVTA) injections were not found to be associated with improved VA outcomes compared with grid photocoagulation, being the standard care. However progression of cataract was observed in some patients receiving IVTA (Avitabile *et al*., 2004; Cekiç *et al*., 2005; Chen *et al*., 2006) and endophthalmitis (Jonas, 2006),(Avitabile *et al*., 2005; Cekiç *et al*., 2005; Chen *et al*., 2006; Park *et al*., 2003; Jonas *et al*., 2006) was noticed rarely.

Dexamethasone is a potent, water-soluble corticosteroid that can be delivered to the vitreous cavity by the dexamethasone intravitreal implant. The Global Evaluation of Implantable dExamethasone in Retinal Vein Occlusion with Macular Edema (GENEVA) Trials were two Phase III trials comparing the effects of intraocular injection of Intravitreal Dexamethasone (IVD) to sham injections in patients with ME due to CRVO or BRVO (Haller *et al*., 2010). The study showed a VA improvement in patients of BRVO group receiving IVD over Sham group. However, both patient populations showed some evidence of VA improvement at earlier time points. Peak effects were at 60 days. The IVD was well tolerated, producing generally transient, moderate, and readily managable increase of Intra Ocular Pressure (IOP) in less than 16% of eyes. Haller *et al*. (2012), subgroup analysis of data from the GENEVA trial (Haller *et al*., 2010), London *et al*. (2011), Chan *et al*. (2011), Reibaldi *et al*. (Reibaldi *et al*., 2012) and Kiss, (2012) also showed evidence that the dexamethasone was one of the most recent additions to the armamentarium against ME, specifically associated with RVO. Both IVTA & IVD are currently used in ME associated in RVO, and both the drugs possess potential side effects, hence this study is proposed to compare the safety and efficacy of IVTA versus IVD for the treatment of ME associated with RVO.

MATERIAL AND METHODS

Study Design: The study was conducted at Department of Ophthalmology of Command Hospital (EC), Kolkata. Patients diagnosed as fresh case of RVO with ME, who presented to the department of Ophthalmology were included in the study. The study was done from January 2017 – June 2018. This was followed by tabulation and analysis of data. Total 40 eyes were taken (20 eyes in Group A, in which IVTA 1 mg was given & 20 eyes in Group B, in which IVD 0.7 mg was given). Randomization was done using randomly computer generated numbers. Patients were divided into two groups: Group A in which IVTA 1.0 mg was given and Group B in which IVD 0.7 mg was given. This was Prospective, clinical based, comparative study.

Inclusion criteria

- Recently diagnosed cases of RVO within 03 months of diagnosis.
- Presence of ME with CMT more than 300μm.

Exclusion Criteria

- Old cases of RVO on treatment.
- Patients with DME.
- Coexistence of visually disabling cataract and glaucoma or any other ocular disease causing diminution of VA.
- History of any previous anti-VEGF therapy.
- Active ocular infection or inflammation

Primary outcome measurement:

- To evaluate & compare the VA from baseline after giving intravitreal injection of Triamcinolone Acetonide or Dexamethasone in patients with Macular Edema due to Retinal Vein Occlusion.
- To evaluate & compare the reduction of CMT from baseline after giving intravitreal injection of Triamcinolone Acetonide or Dexamethasone in patients with Macular Edema due to Retinal Vein Occlusion.

Secondary outcome measurement

- To evaluate & compare the change in IOP from baseline after giving intravitreal injection of Triamcinolone Acetonide or Dexamethasone in patients with Macular Edema due to Retinal Vein Occlusion.
- To evaluate & compare the progression of cataract after giving intravitreal injection of Triamcinolone Acetonide or Dexamethasone in patients with Macular Edema due to Retinal Vein Occlusion.
- To evaluate & compare the incidence of Endophthalmitis after giving intravitreal injection of Triamcinolone Acetonide or Dexamethasone in patients with Macular Edema due to Retinal Vein Occlusion.

Study technique: After institutional ethical clearance and written informed consent from the patients, all selected patients underwent a complete ophthalmic examination in the Department of Ophthalmology, Command Hospital (EC), Kolkata. RVO cases with ME were diagnosed clinically based on history and measuring BCVA, detailed slit-lamp examination, central fundus examination by +90D lens, an OCT and Fundus Fluorescein angiography (FFA). Parameters evaluated for the purpose of this study were BCVA by ETDRS chart, IOP by GoldmannApplanation Tonometry (GAT) and biomicroscopic assessment of the lens status in phakic eyes, CMT by OCT measured by CirrusTM HD-OCT (Carl Zeiss Inc. MEDITEC., Dublin, CA,USA), using the macular scan pattern after dilating the pupil. Three scans were done using macular scan and a mean CMT for each individual was considered. Diagnosed cases of RVO with ME being planned for treatment by IVTA or IVD were enrolled in the study after applying exclusion criteria. Using randomly computer generated numbers, patients were divided into two groups: group A in which IVTA 1.0 mg was given and group B in which IVD 0.7 mg was given.

Intravitreal injections were given in the operation theatre, under complete sterile conditions. 1.0 mg in 0.1 ml of IVTA (Kenacort, 40 mg/ml) was administered to Group A patients and 0.7 mg in 0.1 ml of IVD (Dexamethasone Implant), was administered to Group B patients. All patients were examined the following day after each injection. Moxifloxacin 0.5% drops were prescribed four times per day for five days during post-operative period. Detailed ophthalmic evaluation was performed before injection and at 1, 3 and 6 months after treatment. BCVA was converted to LogMAR form to obtain mathematical values. Each patient underwent a CMT measurement by OCT, assessment of state of Cataract by Slit-lamp biomicroscopy and IOP measurement by GAT. Any adverse events after injection were noted and managed.

Injection technique: The injection technique was standardized. All injections were given under topical anaesthesia by applying Proparacaine (0.5%) eye drops three times at 2 minute interval. The bulbar conjunctiva and the fornices were rinsed with Betadine (5% polyvidone-iodine). After applying a sterile drape, a sterile eyelid speculum was inserted. Then, 0.7 mg IVD in 0.1ml using a disposable preloaded 30-gauge needle was injected into the vitreous cavity through the pars plana at a distance of 4.0 mm from the limbusinfero-temporally in Phakic or 3.5 mm in Pseudophakic eyes. The needle was carefully withdrawn using a sterile cotton applicator to prevent reflux. After injection topical antibiotic eyedrops :Moxifloxacin (0.5%) were given four times a day for 05 days. The injection technique and postoperative management were the same for IVTA. In this group, 1 mg IVTA (Kenacort Retard; Bristol-Myers Squibb, Paris, France) in a 0.1-ml volume using a 30-gauge needle was injected into the vitreous cavity. All patients were informed about the potential risk of endophthalmitis, retinal detachment, increased IOP and cataract progression. Written informed consent was taken from all patients before injection.

Statistical Methods: Only one eye per subject was treated. Data were collected on a MS Excel 2000 spreadsheet and analyzed using statistical software SPSS version 24.0 for Windows (SPSS, Inc., Chicago, IL, USA). Categorical variables are expressed as number of patients and percentage of patients and compared across the groups using Pearson's Chi Square test for Independence of Attributes/ Fisher's Exact Test as appropriate. Continuous variables were expressed as Mean ± Standard Deviation and compared across the 2 groups using Mann-Whitney U test. Comparison over time was done using Wilcoxon Signed Rank Test. An alpha level of 5% was taken, i.e. if any p value was less than 0.05, it was considered as significant. All statistical analyses were performed two-sided at a 0.05 level of significance. Statistical comparisons were made in sense of an exploratory data analysis, thus no correction of alpha error rate was considered.

RESULTS

A total of 20 patients (14 men, 6 women) with CME with RVO received one injection of IVTA. In IVTA group the mean age of patients was 60.55 ± 9.58 years. IVD group comprised 20 patients (15 men, 5 women) with CME where mean age of patients was 53.70 ± 14.87 years. Difference of mean age in two groups was not statistically significant (p=0.091). Both groups were age and gender matched. In IVTA group, 6 (30%) patients were female and 14 (70%) patients were male. In IVD group, 5 (25%) patients were female and 15 (75%) patients were male. Association of sex in two groups was not statistically significant (p=0.723). BCVA was converted using LogMAR value. In IVTA group, the mean BCVA pre-treatment was 1.05 ± 0.40. In IVD group, the mean BCVA pre-treatment was 0.96 ± 0.43. Difference of mean BCVA pre-treatment in two groups was not statistically significant (p=0.501). At 1, 3 & 6 months follow-up, there was no significant change in BCVA improvement between IVTA and IVD groups (p=0.231); (Table 1). Mean CMT by OCT at baseline was 496.60 ± 137.89 µ in the IVTA group and 513.60 ± 189.88 µ in the IVD group. Difference of mean CMT at baseline in two groups was not statistically significant (p=0.747). (Table 1) In IVTA group, the reduction in mean CMT at 1 month from its baseline value was statistically significant (26.00%, p value = < 0.001), while that in IVD group was also statistically significant (35.28%, p value = < 0.001).

The change in mean CMT at 3 months in IVTA (29.03%, p value = < 0.001) group was statistically significant and was also significant in IVD group (39.57%, p value = < 0.001). At 6 months the change in mean CMT in both groups was statistically significant (32.05%, p value = less than 0.001) in IVTA group while (43.46%, p value =< 0.001) in IVD group. At 1, 3 & 6 months post injection, there was no significant difference in mean CMT reduction between the IVTA and IVD groups. In IVTA group the mean IOP pre-treatment was 15.75 ± 3.10 while in IVD group the mean IOP pre-treatment was 15.85 ± 2.23. Difference of mean IOP pre-treatment in two groups was not statistically significant (p=0.9076). (Table 1). In IVTA group, IOP rise at 1 month from its baseline value was not statistically significant (15.17%, p value = 0.07), while that in IVD group was statistically significant (19.01%, p value = 0.010). The IOP rise at 3 months in IVTA (10.76%, p value = 0.070) group was not statistically significant and but was significant in IVD group (13.30%, p value = 0.010). At 6 months the IOP rise in IVTA group was not statistically significant (11.00%, p value = 0.07) while in IVD (11.12%, p value = 0.010) group was significant. In IVTA group at baseline, 8(40%) patients had no cataract, 7(35%) patients had NS1 grade cataract, 1(5%) patients had NS1+ grade cataract and 4(20%) patients had pseudophakic status (Table 2). At 06 months, 3(15%) patients had no cataract, 5(25%) patients had NS1 grade cataract, 5(25%) patients had NS1+ grade cataract, 3(15%) patients had NS2 grade cataract and 4(20%) patients had pseudophakic status. Cataract progressed in about 50% patients after IVTA injection at 06 months (Table 2). In IVD group, at baseline 12(60%) patients had no cataract, 6(30%) patients had NS1 grade cataract, 1(5%) patients had NS1+ grade cataract and 1(5%) patients had NS2 grade cataract (Table 2). At 06 months, 8(40%) patients had no cataract, 7(35%) patients had NS1 grade cataract, 4(20.0%) patients had NS1+ grade cataract, 0(0%) patients had NS2 grade cataract and 1(5%) patients had NS2+ grade cataract. In about 45% patients, cataract developed or progressed after IVD injection at 06 months (Table 3).

DISCUSSION

Retinal vein occlusion (RVO) is the second most common visually disabling disease affecting the retina after diabetic retinopathy (Shahid *et al*., 2006). Although it is more common in the middle-aged and elderly population, no age group is immune to it (Hayreh *et al*., 1994).

Table 1. Comparison of BCVA, CMT **and IOP in two groups, Pre-injection and after-injection**

		Numb er	IVTA		IVD	SD	p-value
			Mean	SD	Mean		
BCVA	Pre-treatment	20	1.05	0.40	0.96	0.43	0.50
	1 Month	20	0.72	0.28	0.57	0.40	0.18
	3 Month	20	0.67	0.27	0.58	0.28	0.31
	6 Month	20	0.61	0.20	0.52	0.28	0.23
	p-value		<0.0001		0.0006		
CMT	Pre-treatment	20	496.60	137.89	513.60	189.88	0.747
	1 Month	20	367.10	137.55	332.55	99.13	0.367
	3 Month	20	352.65	126.26	310.10	68.67	0.193
	6 Month	20	337.40	107.74	290.40	59.06	0.095
	p-value		0.0005		<0.0001		
IOP	Pre- treatment	20	15.75	3.10	15.85	2.23	0.907
	1 Month	20	18.25	4.02	19.10	3.81	0.496
	3 Month	20	17.65	2.79	17.75	3.14	0.915
	6 Month	20	17.70	2.31	17.35	2.56	0.653
	p-value		0.070		0.010		

Table 2. Progression of Cataract in IVTA group

Follow -Up	No	NS1	NS1+	NS2	PSEUDOPHAKIA	Total
Pre-treatment	8	7	1	0	4	20
%	40.0	35.0	5.0	0.0	20.0	100.0
1 Month	7	8	1	0	4	20
%	35.0	40.0	5.0	0.0	20.0	100.0
3 Month	6	5	4	1	4	20
%	30.0	25.0	20.0	5.0	20.0	100.0
6 Month	3	5	5	3	4	20
%	15.0	25.0	25.0	15.0	20.0	100.0

Table 3. Progression of Cataract in IVD Group

Follow -Up	NO CATARACT	NS 1	NS1+	NS2	NS2+	TOTAL
Pre-treatment	12	6	1	1	0	20
%	60.0	30.0	5.0	5.0	0.0	100.0
1 Month	11	7	1	1	0	20
%	55.0	35.0	5.0	5.0	0.0	100.0
3 Month	10	6	3	1	0	20
%	50.0	30.0	15.0	5.0	0.0	100.0
6 Month	8	7	4	0	1	20
%	40.0	35.0	20.0	0.0	5.0	100.0

In spite of the fact that the clinical entity of RVO has been known since 1878, its management still remains suboptimal. The pathogenesis of RVO is multifactorial with both local factors and systemic diseases being etiologically important. Known risk factors for RVO include systemic vascular disease, hypertension, diabetes mellitus, hyperlipidemia and glaucoma. Hypercoagulable states are associated with RVO. There are still gaps in understanding the aetiology and pathogenesis of circulatory disorders of the central retinal vein and its branches. ME is the main reason for decreased visual acuity in RVO. The SCORE-CRVO study (Ip, 2009) showed that both (1mg & 4mg), triamcinolone groups were superior to observation with respect to VA. In SCORE-BRVO (Scott *et al*., 2009), IVTA injections were not found to be associated with improved VA outcomes compared with grid photocoagulation, being the standard care. The GENEVA Trials showed beneficial effects of intraocular injection of 0.7mg or 0.35mg Dexamethasone implants to sham injections in patients with ME due to CRVO or BRVO (Haller, 2010). In the CRVO subgroup, the mean change from baseline BCVA letter score was 9 (0.7mg) and 10 (0.35mg) in the two IVD implant groups, significantly better than sham (0), and 29% and 33% of patients gained ≥ 15 letters in BCVA compared to 9% for sham. At 3 months, the mean change from baseline BCVA letter score was 4(0.7mg) and 6(0.35mg) in the two IVD implant groups, significantly better than sham (0), and 18% and 24% of patients gained ≥ 15 letters in BCVA compared to 10% for sham. In the BRVO subgroup, the mean change from baseline BCVA letter score was 10 (0.7mg) and 9 (0.35mg) in the two IVD implant groups, significantly better than sham (5), and 30% and 26% of patients gained ≥ 15 letters in BCVA compared to 13% for sham. At 3 months, the mean change from baseline BCVA letter score was 9 (0.7mg) and 8 (0.35mg) in the two DEX implant groups, significantly better than sham (5), and 24% and 23% of patients gained ≥ 15 letters in BCVA compared to 15% for sham. We found that Difference of mean BCVA pre-treatment in two groups was not statistically significant (p=0.501). At 1, 3 & 6 months follow-up, there was no significant change in BCVA improvement between IVTA and IVD groups. At 1, 3 & 6 months post injection, there was no significant difference in mean CMT reduction between the IVTA and IVD groups. The SCORE-CRVO study (Ip, 2009) showed that, in all 3 groups (1mg IVTA, 4mg IVTA or observation), there was a reduction of central retinal thickness from baseline to 24 months. The SCORE-BRVO (Scott *et al*., 2009) Study concluded that grid photocoagulation should remain the benchmark against which other treatments are compared in clinical trials for eyes with vision loss associated with ME secondary to BRVO. In

GENEVA trial (Haller *et al*., 2010), patients who had macular edema for a shorter period of time had a greater chance of gaining vision. London *et al*. (London *et al*., 2011) and Chan *et al*(20) also showed evidence that dexamethasone was one of the most recent additions to the armamentarium against ME, specifically associated with RVO and was intriguing for its potency, dose consistency, potential for extended duration of action, and favorable safety profile. Reibaldi *et al*. (2012) have recently advocated Dexamethasone intravitreal implant use in vitrectomized eyes with ME secondary to CRVO.

Kiss (2012) have found that for many patients with chronic macular edema from BRVO, the best choice may be the dexamethasone implant. Gregori *et al*. (2006) have found that patients with pre-existing open angle glaucoma had an IOP elevation at a higher rate than eyes without glaucoma, suggesting that this population may be at a higher risk for glaucoma surgery after intravitreal TA treatment. The GENEVA Trials showed well tolerated, producing generally transient, moderate, and readily managable increases in IOP in less than 16% of eyes in patients with ME due to CRVO or BRVO (Haller *et al*., 2010). In our study, there was no significant difference between the rise of IOP by IVTA or IVD at 1, 3 and 6 month (P= 0.496, 0.915 & 0.653 respectively) thus making both drugs equally safe on this parameter. Considerable IOP increases have been noticed with both the drugs though in IVD group the increase was significant. 02(10%) patients in each group required anti-glaucoma medications with two drugs (at 01 month) to control significant IOP rise however at 6 months IOP was reduced to baseline value. No sight threatening IOP rise was recorded in either group. In SCORE (Ip, 2009; Scott *et al*., 2009) study, IVTA injections were found to be associated with progression of cataract observed in some patients. In the elderly population of patients with RVO, intravitreal injection of TA led to clinically significant posterior subcapsular cataract and nuclear cataract in about 15 to 20 % of eyes within one year of the intravitrealinjection (Jonas, 2006). Intravitreal steroids had significant side effects like progression of cataract in some individuals (Jonas, 2006; Cekiç, 2005; Chen *et al*., 2006). Similarly in our study also, there was worsening of cataract in both the groups receiving IVTA and IVD during this 6 month follow up. 40-50% patients showed cataract progressed at 6 months of follow up. In SCORE-BRVO (Scott *et al*., 2009) & GENEVA trial (Haller *et al*., 2010), intravitreal steroids were rarely associated with endophthalmitis. No incidence of endophthalmitis occurred in any group throughout our study making IVTA & IVD equally safe in this parameter.

Conclusion

- Following the injection, at all stages IVD was superior in terms of vision improvement and CMT reduction. However, this superiority was not statistically significant.
- Both drugs remained significantly effective at 6 months after injection in terms of vision improvement and CMT reduction.
- Both drugs are comparably safe in terms of IOP rise, though in IVD group the IOP rise was statistically significant.
- Progression of cataract was comparable in both the drugs.
- Both drugs were comparably safe in terms of occurrence of endophthalmitis.

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