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ORIGINAL ARTICLE

Sustained-release intravitreal dexamethasone(Ozurdex®) implant as a surgical adjuvant in high-risk proliferative vitreoretinopathy

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Abstract

Purpose: The purpose of this study was to evaluate the efficacy of sustained-release intravitreal dexamethasone implant (Ozurdex; Allergan Inc, Irvine, CA) in prevention of proliferative vitreoretinopathy (PVR) recurrence in patients with established PVR undergoing vitrectomy.
Methods: This was double-blind, prospective, and randomized placebo-controlled trial. Eighty consecutive patients diagnosed with rhegmatogenous retinal detachment with high-risk PVR were randomized to the study and control groups (n = 40 each). Study group/adjunct group (Group 1) patients underwent vitrectomy with sustained-release intravitreal dexamethasone implant (0.7 mg). In the control group (Group 2), a similar surgery was performed without the use of dexamethasone implant. Patients were evaluated at 1 month, 3 months, and 6 months after surgery. Post-operative retinal reattachment, recurrence of PVR, best-corrected visual acuity (VA), and complications at the end of 6 months were compared between the two groups.
Results: At 6 months post-surgery, 68.7% of patients had reattached retina. Secondary outcomes were assessed by improvement in BCVA, recurrence of PVR, retinal reattachment rate, macula pucker/ERM, hypotony or increased IOP, variation in Macula edema and cataract surgery at any time. The rate of post-operative recurrent PVR was 46% and 56% in the study and control groups, but was not significant ($P > 0.05$). In addition, there was no statistically significant difference in visual outcomes between the two groups ($P > 0.05$), no significant difference in the complications rate and drug toxicity was noted between two groups. At 6 months, fewer adjunct patients had cystoid macular edema or a foveal thickness of >300 μm compared with controls ($P = 0.003$, $P = 0.031$).
Conclusions: This study fails to prove the efficacy of the intraoperative use of sustained-release intravitreal dexamethasone implant for the prevention of post-operative PVR recurrence or improvement in final VA, but it does reduce inflammation and CME. At the same time, no significant complications could be attributed to the treatment.

Introduction

Proliferative vitreoretinopathy (PVR) is an anomalous scarring process of the detached retina due to the growth and contraction of cellular membranes within the vitreous cavity and on both sides of the retinal surface. Despite improvements in the primary success rate of retinal detachment surgery,[1] PVR remains the most common cause of failure, with a reported incidence of 5.1–11.7%.[2-8] PVR is responsible for the failure of more than 75% of cases in retinal detachment surgery.[9-11] Although advances in the management of PVR have improved the anatomical success rate of surgery, multiple surgical interventions are often necessary to treat PVR and final visual results are often disappointing, with visual prognosis remaining poor.[12-15] An improved understanding of the pathophysiology of PVR has led to the use of adjunctive therapies to prevent recurrence of PVR, simplify its surgical management, and improve outcomes. Furthermore, PVR management is costly in patient time and

healthcare resources.[3] Numerous adjunctive medications have been evaluated in clinical trials,[4-12] yet no effective and safe adjunct has gained widespread acceptance. Experimentally, corticosteroids potentially can influence both the inflammatory and the proliferative components of the PVR process through a variety of modes of administration[13-15] without evidence of demonstrable retinal toxicity.[16] Clinically, intravitreal crystalline cortisone was first reported in 2000 by Jonas *et al*.[17] to be well tolerated in PVR cases undergoing vitrectomy. Previous small-scale, uncontrolled clinical studies of PVR have suggested that systemic prednisolone,[18] infused dexamethasone,[19] and intravitreal triamcinolone[20,21] may reduce the severity of PVR, although none of these studies were of sufficient power to provide a definitive answer. A slow-release preparation of corticosteroid may offer additional advantages over other agents, through sustained activity during the active phase of the PVR process.

We report the results of a further randomized prospective study on sustained-release intravitreal dexamethasone implant in improving the outcome of surgery for established high-risk PVR. The use of adjunctive medication was aimed at preventing reproliferation and, thereby, reducing the number of reoperations and potentially improving the visual outcome of surgery.

Methods

This was prospective, participant-masked, and randomized controlled clinical trial of 80 consecutive patients with PVR who underwent vitrectomy for retinal detachment. The study was approved by the Local Research Ethics Committee. The study complied at all times with the Declaration of Helsinki. Patients were randomly divided into two groups: 40 patients in the study group (Group 1) and 40 patients in the control group (Group 2). In Group 1, all 40 patients underwent surgery for PVR with the use of intraoperative sustained-release intravitreal dexamethasone implant. In Group 2, a similar surgery was performed on all 40 patients without the use of sustained-release intravitreal dexamethasone implant.

All patients aged ≥18 years with rhegmatogenous retinal detachment with high-risk PVR were included in the study. All patients had a minimum follow-up of 6 months. An updated classification of retinal detachment with PVR by the Retina Society Terminology Committee was used to classify pre-operative PVR.[22,23] A pre-operative scoring system for high-risk PVR was used, as described by Asaria *et al*.[19] If the total score was >6.33, the patient was considered at high risk for PVR and was included in the study for randomization.

The exclusion criteria were as follows: (1) Open globe injury; (2) a diagnosis of ocular hypertension on 2 or more pressure lowering medications or a definite diagnosis of glaucoma (if in the opinion of a glaucoma specialist, the patient is at high risk of visual damage from increased intraocular pressure [IOP]; (3) uncontrolled uveitis; (4) previous steroid-induced glaucoma; (5) proliferative diabetic retinopathy or vasculopathy; (6) pregnant or breastfeeding females; (7) previous known adverse reaction to Ozurdex (Allergan Inc, Irvine, CA); (8) suspected ocular/periocular infection (e.g., herpes simples virus, varicella zoster virus, mycobacterial infection, and fungal disease); (9) aphakia or patients in whom a lensectomy is planned at time of surgery; (10) pre-existing anterior chamber intraocular lens; (11) corneal opacity sufficient to impair surgical view; (12) no light perception vision; and (13) inability to give informed consent, inability to complete follow-up and unwillingness to accept randomization. There were no restrictions on the number of the previous vitreoretinal procedures.

At the time of recruitment, patients were given an information sheet with a complete and thorough explanation of the trial. On recruitment, details of medical and ophthalmic examinations were recorded. Data collected at the pre-operative clinical assessment included best-corrected visual acuity (VA), refractive status, IOP (mmHg), corneal clarity, presence of anterior segment inflammation, lens status, presence of vitreous hemorrhage, number of retinal breaks, and extent of retinal detachment (recorded in clock hours). Vitreous hemorrhage was recorded as present if a hemorrhage was observed in the vitreous base, vitreous gel, or on the retinal surface. Optical coherence tomography (OCT) examination was done for macular assessment in relevant cases. On the day of surgery, non-trial personnel randomized recruited patients to the Group 1 and Group 2 using a random permuted blocks of varying sizes. Participants were masked to their treatment and preservation of masking status was confirmed on exit. Operating surgeon was masked until the end of the surgical procedure to avoid any bias The basic steps of surgery were same for both the groups and all surgeries were performed by a single surgeon (SG). For young and uncooperative patients, general anesthesia was used; for adults, peribulbar anesthesia was used. A standard 3-port pars plana vitrectomy was performed along with the management of PVR. Elimination of traction sufficient to allow retinal reattachment was achieved by epiretinal membrane peeling or relaxing retinotomy and retinectomy. Retinopexy was applied to treat retinal breaks using endolaser and/or cryotherapy. A scleral buckle or encircling band was used in relevant cases. Silicone oil was used for internal tamponade. In patients allocated to the Group 1, on confirmation of successful retinal reattachment and completion of silicone oil exchange, the operating surgeon was asked to clinically grade the level of PVR;[23] thereafter, the surgeon was asked to inject a 0.7-mg slow-release dexamethasone implant through the final open sclerotomy port before suturing. A similar procedure was followed for the second implant administration at the time of oil removal. On confirmation that the retina remained attached after removal of oil, the surgeon was again asked to confirm the retinal status and the presence or absence of PVR. Because a variety of techniques were used to remove silicone oil, particularly if combined cataract surgery was performed, the implant was injected through a sclerotomy port (if used) or through the conventional method of delivery.[24]

After surgery, clinical data were recorded at 1 month, 3 months, and 6 months. Patient characteristics for the treatment groups were tabulated to check for any major dissimilarity at

baseline. Postoperatively, both the groups were compared for best corrected VA, retinal reattachment, recurrence of PVR, need for additional operations, and complications. The presence of cystoid macular edema (CME), epiretinal membrane (ERM), persistent submacular fluid, central foveal thickness (CFT), and macular volume were evaluated by spectral domain OCT (SDOCT).

Silicone oil removal performed 3 months after vitrectomy to allow sufficient time to test the primary outcome measured at 6 months. IOP was monitored and any additional vitreoretinal procedure except for the laser was considered reoperation. Adverse events such as elevated IOP (>24 mmHg) and cataract were considered an adverse event if they had progressed at a rate requiring surgery before the planned removal of silicone oil. The primary outcome was assessed based on proportion of patients with a stable retinal reattachment with removal of silicone oil without additional vitreoretinal procedure at 6 months. Secondary outcomes were assessed by improvement in BCVA, recurrence of PVR, retinal reattachment rate, macula pucker/ERM, hypotony or increased IOP, variation in Macula edema and cataract surgery at any time.

Results

Mean age was 29.6 ± 7.8 years and 34.2 ± 8.2 years (Adjunct: control). Majority were male (32:29) in both the groups. Ocular characteristics in both the groups are shown in Tables 1 and 2. One patient from the study group was excluded due to lensectomy and another patient was lost to follow-up. One patient lost to follow-up in the control group. At 6 months, 68.7% patients had reattached retina; 65% in adjunct and 62.8% in control group (OR, 0.89; 95% CI, 0.46–1.74; P = 0.733) [Figure 1]. There was no observed difference with respect to number of operations to achieve primary success in both the groups. Risk factors for PVR in both the groups are shown in Figure 2. The rate of post-operative recurrent PVR in the control group was 56%; in the study group, it was 46% ($P > 0.05$). Operative techniques during vitrectomy are shown in Table 3. Retinal reattachment/outcome is shown in Figure 3. Nine patients in the adjunct group and 11 patients in the control group required more than one procedure/repeat surgery for complete retinal reattachment, which was comparable. In addition, there was no statistically significant difference in visual outcomes between the two groups ($P > 0.05$). No significant difference in the complications rate and drug toxicity was noted between two groups. OCT evaluation done in the post-operative period [Figure 4] at 6 months fewer adjunct patients had CME or a foveal thickness of >300 μm compared with controls ($P = 0.003$, $P = 0.031$).

Secondary anatomic outcomes were comparable between the two groups. At 6 months, macular ERM (19:16) and rate of macular pucker surgery were comparable in both the groups. Three patients in adjunct group and four patients in the control group had second dexamethasone implant during oil removal. Mean VA at 6 months was 31.7 ETDRS letters and 39.5 letters in the adjunct and control groups. VA of ≥55 ETDRS letters was seen in 15/38 eyes in the adjunct group and 17/39 eyes in the control group.

At 6 months, fewer adjunct patients had CME or a foveal thickness of >300 μm ($P = 0.003$, $P = 0.031$). Median foveal thickness and macular volume were lower in the adjunct group (247 μm and 8.71 mm^3) compared with the control group (343 μm and 8.99 mm^3). The proportion of phakic patients in both groups

Table 1: Ocular characteristics in both the groups

Ocular characteristics	Adjunct Group (*n*=40)	Control Group (*n*=40)
ETDRS; VA, median	0	0
IOP, mean mm Hg	10.3	12.1
AC inflammation (cell count.)		
None	21	20
Mild	17	18
Moderate	1	2
Severe	1	0
Lens status		
Clear	16	18
PCIOL	16	15
Cataract	8	7
Vitreous hemorrhage		
Absent	37	38
Present	3	2

VA: Visual acuity, PCIOL: Posterior chamber intraocular lens, IOP: Intraocular pressure, ETDRS: Early treatment diabetic retinopathy study

Table 2: Previous surgeries, coexisting pathology in both the groups

Previous surgeries and coexisting pathology	Adjunct Group (*n*=40)	Control Group (*n*=40)
Laterality (right eye)	*n*=21	*n*=23
Refraction (SE) median	−0.4 (−5–0)	0 (−2.43–0)
Missing	2	1
Previous VR surgery (*n*=12 vs. *n*=17)		
None	28	23
Vitrectomy+gas	5	7
Vitrectomy+s oil	3	4
Vitrectomy+buckle	1	3
Buckle alone	3	3
Mac-off episodes, median	3	4
Coexisting ocular pathology (*n*=9 vs. *n*=6)		
Macular pathology	4	3
Amblyopia	3	2
Corneal scar	1	0
Other	1	1

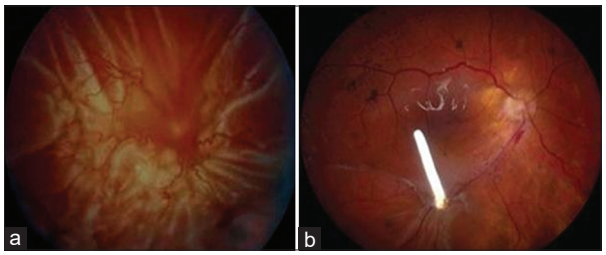

Figure 1: Pre- and post-operative photograph

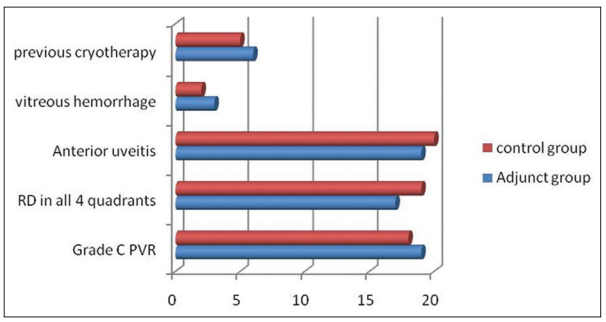

Figure 2: Risk factors for proliferative vitreoretinopathy

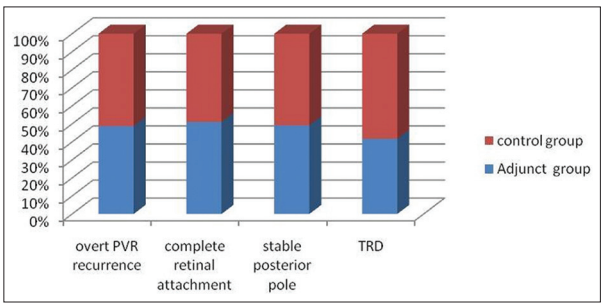

Figure 3: Retinal reattachment/outcome

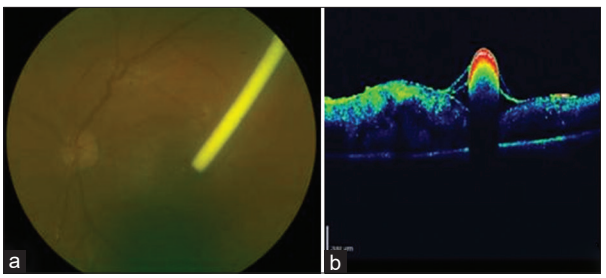

Figure 4: (a) Ozurdex over the posterior pole and (b) optical coherence tomography show hyper reflectance of the intravitreal dexamethasone implant with optical shadowing

who underwent cataract surgery in 6 months was comparable (70% vs. 68%). Hypotony incidence (14% vs. 16%) was similar in both the groups. The most common adverse event was elevated IOP. In the adjunct group, there were 31.4% eyes which had of increased IOP compared with 28.3% in the control group.

Table 3: Operative techniques during Vitrectomy

Surgical technique	Adjunct Group (n=40)	Control Group (n=40)
Lensectomy	1	0
PFCL	26	29
Retinectomy	17	19
PVR membrane peel	31	29
Segmental buckle	11	9
Encirclage	18	16
Retinopexy		
Endolaser	31	29
Cryotherapy	16	18

PFCL: Perfluorocarbon liquids, PVR: Proliferative vitreoretinopathy

Discussion

Our study showed no difference in pre-operative disease severity as evidenced by average Asaria PVR scores (Group 1 = 8.68 and Group 2 = 9.13). The slow-release dexamethasone preparation (Ozurdex), is a 6-mm implant containing 700 μg of dexamethasone in a biodegradable polymer (Novadur, Allergan, Irvine, CA). It exhibits a dual-phase response of initially high concentrations of dexamethasone in the first 2 months, followed by a period of lower concentrations sustained for up to 6 months post-injection.[25] In experimental studies, its pharmacokinetic profile was unaffected in vitrectomized eyes.[26] We found no difference in the proportion of patients achieving stable retinal reattachment with silicone oil removal without additional vitreoretinal surgical intervention at 6 months. At 6 months, 68.7% patients had reattached retina; 65% in adjunct and 62.8% in control group, which is slightly more than previously published data (49.3% vs. 43.3%, adjunct vs. control).[27]

In a study comparing the effect of 4 mg of intravitreal triamcinolone, Ahmadieh *et al.*[28] published an overall primary success rate of 81.3% in eyes with Grade C PVR undergoing vitrectomy surgery with an encircling scleral buckle. They observed no difference in the primary or secondary outcomes between the adjunct and control arms. A comparable proportion of patients achieved complete or posterior retinal reattachment and the proportion of eyes with a tractional RD or macular pucker was similar between the two study groups. Furthermore, rates of overt PVR recurrence were similar across both groups (56% vs. 46%, adjunct vs. control), which was not statistically significant. Reoperations were required in nine patients in the adjunct group and 11 patients in the control group to achieve retinal reattachment which was not significant.

In our study, despite finding no difference between retinal reattachment rates and PVR recurrence, fewer patients had CME and CFT of >300 μm at 6 months in the adjunct group compared to control group (P = 0.003, P = 0.031). Median foveal thickness and macular volume were lower in the adjunct group (247 μm and 8.71 mm^3) compared with the control group (343 μm and 8.99 mm^3). Although CME and foveal thickness

are related variables, additional factors such as ERM may affect foveal thickness. Our findings are consistent with previous reports that a slow-release dexamethasone implant may be an effective treatment for CME in vitrectomized eyes. Despite observing a difference in rates of post-operative CME, we did not observe any difference in VA at 6 months. Our visual outcomes are comparable to previous reports.

A study investigating poor visual outcomes (<20/40) after successful RD repair for PVR in 35 patients reported a 66% incidence of CME.[29] Given the lower incidence of macular edema observed in the adjunct group, one might have expected a correspondingly better visual outcome, especially when excluding eyes with limited visual potential. This observation is potentially important suggesting that retinal pathology other than macular edema such as neural retinal remodeling[30] may be the primary cause of the poor visual outcomes seen in PVR. Further studies are required to identify the cause of visual loss after RD surgery in eyes with PVR. The SD OCT imaging of eyes after fovea-involving RDs (without PVR) has correlated outer retinal abnormalities with poorer visual outcomes[31-34] and thus may serve as a target for investigation in future studies.

There were fewer cases of post-operative uveitis in the adjunct group, perhaps indicative of the additional anti-inflammatory activity of the dexamethasone. There were more episodes and a greater proportion of patients experienced at least 1 episode of elevated IOP in the adjunct group, but development of glaucoma was similar between the two groups. One of the patients in the adjunct group had implant on the fovea on first post-operative day but got dislodged with positing by 1 week without any complications. None of the patients had implant in the retrolental space or breakage of implant due to careful injection technique of the implant into the midvitreous cavity through trocar system. Dexamethasone implant can be safely injected into the vitrectomized silicone oil filled eye. Small sample size is the main limitation of our study.

Conclusions

This study fails to prove the efficacy of the intraoperative use of sustained-release intravitreal dexamethasone implant for the prevention of post-operative high-risk PVR recurrence or improvement in final VA, but it does help in reducing the CME and inflammation in high-risk PVR. At the same time, no significant complications could be attributed to the treatment.

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