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Management of ocular hypertension following intravitreal dexamethasone implant (ozurdex)

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ABSTRACT

Purpose: To evaluate the impact of intravitreal dexamethasone implantation (Ozurdex) on ocular hypertension (OHT) development and characterize its management with non-invasive or minimally-invasive modalities.
Results: Chart review was performed for patients who received Ozurdex implantation between September 2016 to September 2023. Patients were excluded if they had ever been diagnosed with neovascular glaucoma or received a different intravitreal corticosteroid prior to Ozurdex injection or 6 months afterwards. The analysis included 171 Ozurdex implants (n = 61 patients, n = 74 eyes) for analysis. Patients were followed for an average of 326 ± 45 days. The rise in IOP was greatest 2- and 3-months post-injection. OHT occurred following 40 (23.3 %) Ozurdex implants. To lower IOP, medical drops were initiated after 17 (10.0 %) implants. Selective laser trabeculoplasty was performed in 2 (1.2 %) cases. Minimally-invasive glaucoma surgeries (MIGS) were utilized in 7 (4.1 %) cases. Patients >60 years old were at increased odds of developing OHT, whereas patients treated for retinal vein occlusion were less likely to develop OHT compared to patients treated for diabetic macular edema.
Conclusion: Patient-specific characteristics, including age and treatment indication, may confer different risk for developing OHT following Ozurdex implantation. Ozurdex-induced OHT can be safely and effectively managed using a combination of medical therapy, laser trabeculoplasty, and angle-based MIGS. This study supports an increasing range of alternative approaches for addressing elevated IOP or postponing surgeries linked with higher risks.

1. Introduction

Glaucoma is a set of diseases that cause progressive optic nerve damage and subsequent visual impairment. It is the second leading cause of blindness worldwide and affects approximately 70 million individuals.[1] While its pathophysiology is not fully understood, there are a number of genetic and clinical risk factors associated with glaucoma, with the only modifiable risk factor being elevated intraocular pressure (IOP).[2] It is this elevation in IOP that contributes to optic nerve compression and damage to surrounding retinal tissue.

Intravitreal corticosteroids are a mainstay medical treatment for a number of ocular diseases. While potent, they carry several undesirable side effects, including steroid-induced ocular hypertension (OHT) and subsequently glaucoma.[3] Therefore, balancing therapeutic levels of steroids with an acceptable IOP is an active area of investigation regarding type of steroid and method of administration. One such technology is Ozurdex, an intravitreal implant that continually delivers dexamethasone into the posterior chamber of the eye over the course of months. Ozurdex is currently used to manage several diseases, including retinal vein occlusions (RVO), non-infectious posterior uveitis, and diabetic macular edema (DME).

Several studies have identified increased IOP as an adverse effect of Ozurdex, often lasting for months due to its sustained release of steroids.[4–8] In general, steroid-induced OHT is managed similarly to that of primary open angle glaucoma (POAG), and includes medical therapy and/or surgery depending on the circumstance. Steroids raise IOP by increasing the resistance to aqueous outflow at the trabecular meshwork.[9] Hence, interventions that target the trabecular meshwork such as selective laser trabeculoplasty (SLT) and angle-based, minimally-invasive glaucoma surgeries (MIGS) such as gonioscopy-assisted transluminal trabeculotomy (GATT) can be tried for steroid-induced glaucoma before traditional trabeculectomy or tube shunt implantation.[10] Compared to older intravitreal corticosteroids, such as triamcinolone or fluocinolone acetonide, Ozurdex may require less invasive

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management.[11] Nevertheless, the management of complications related to Ozurdex implantation are not well-documented, especially those that employ a variety of MIGS.

Here, we evaluated the impact of Ozurdex intravitreal dexamethasone implants on ocular hypertension (OHT) and their management at a single institution. We hypothesized that Ozurdex-associated OHT can be initially managed with non-invasive and minimally-invasive modalities without compromising safety.

2. Methods

This study was approved by the University of Chicago Institutional Review Board, and written consent was waived. A retrospective chart review was performed for all patients from September 2016–September 2023 who received Ozurdex implantation. Patients were excluded from analysis if they had ever received a diagnosis of neovascular glaucoma (NVG). Additional exclusion criteria include having previously received another type of intravitreal corticosteroid, such as fluocinolone acetonide, or within 6 months after Ozurdex injection.

Data regarding demographics, glaucoma history, best-corrected visual acuity (BCVA), IOP, medications, complications, and adjuvant treatments were collected during chart review. Patients were followed up until 12 months after Ozurdex injection. Analysis was performed as available-case analysis without imputing missing data. BCVA was recorded from Snellen charts and converted to logMAR using a published formula by Tiew et al.[12] OHT was defined as reaching an IOP of either ≥25 mm Hg or ≥10 mm Hg increase from baseline.

Multivariate logistic regression was performed to identify potential predictors of OHT. Statistical significance was set at $\alpha = 0.05$. Data analysis was completed in SAS software, version 9.4 (Cary, NC, USA). Figures were produced using the ggplot2 package, version 3.5.1, in R and RStudio software, versions 4.3.3 and 2023.12.1 (Boston, MA, USA).

3. Results

A total of 197 intravitreal Ozurdex implants were identified. After excluding eyes with a diagnosis of NVG or that received a different intravitreal corticosteroid within 6 months of Ozurdex implantation, 171 implants (n = 61 patients, n = 74 eyes) were included for analysis. The mean age was 65.8 years, with 51.4 % of patients being male (Table 1). Most patients were Black (48.6 %) or White (40.5 %). While the majority of patients had no prior glaucoma history (79.7 %), 9.5 % had primary open angle glaucoma (POAG), 5.4 % were glaucoma suspects, 2.7 % had mixed-mechanism glaucoma, 1.4 % had secondary open angle glaucoma, and 1.4 % had secondary angle-closure glaucoma. Ozurdex was indicated for patients with diabetic macular edema (54.1 %), retinal vein occlusion (39.2 %), and noninfectious uveitis (6.8 %).

Data for 74 implants (43.3 %) were collected for eyes that had never received Ozurdex, with the remaining 97 implants consisting of subsequent injections. Patients were followed for a mean of 326 ± 45 days. The rise in IOP was most prominent at 2- and 3-months post-injection (Fig. 1). Within one year, OHT had occurred after 40 (23.3 %) of injections (Fig. 2). Of the 44 patients who had repeated Ozurdex injections, 28 (63.6 %) of them did not develop OHT at any point. Medical drops were initiated following 17 (10.0 %) implants to lower IOP. Selective laser trabeculoplasty (SLT) was performed in two (1.2 %) cases. Surgical procedures were utilized in seven (4.1 %) cases: two Kahook Dual Blade goniotomies, three gonioscopy-assisted transluminal trabeculotomies (GATT), and two combined cataract surgeries with SION goniotomies. Of these minimally-invasive glaucoma surgeries (MIGS), three were intended for medication reduction (two SION goniotomies and one GATT), whereas the other four MIGS were selected for IOP reduction (two GATT and two KDB). Of the patients who received MIGS, three individuals increased the number of their glaucoma medications before ultimately proceeding with surgery. During the study period, one patient underwent 2 separate procedures, first with SLT followed by GATT two months later due to persistently elevated IOP. For patients who received MIGS, they did not require more invasive procedures, such as trabeculectomy/aqueous shunt, nor did OHT recur within the study period.

To assess factors predisposing patients to developing OHT, we performed logistic regression analysis. An age >60 years old increased the odds of developing OHT (OR 6.65, CI 1.05–41.92) (Table 2). Compared to DME, the most common indication for Ozurdex, eyes with RVO were significantly less likely to develop OHT (OR 0.07, CI 0.01–0.44) (Table 2, Fig. 3). Patients with uveitis were not significantly more likely

Table 1
Demographic and clinical characteristics of study participants.

Baseline Characteristics	Eyes ($n = 74$)
Age, mean (SD), years	64.3 (11.7)
Sex	
Female	36 (48.6 %)
Male	38 (51.4 %)
Race/Ethnicity	
American Indian	1 (1.4 %)
Asian	2 (2.7 %)
Black	36 (48.6 %)
Hispanic	2 (2.7 %)
White	30 (40.5 %)
More than one	3 (4.1 %)
History of Glaucoma	
No prior history	59 (79.7 %)
Suspect/Borderline	4 (5.4 %)
POAG	7 (9.5 %)
Mixed mechanism	2 (2.7 %)
SOAG	1 (1.4 %)
SACG	1 (1.4 %)
Indication	
DME	40 (54.1 %)
Retinal venous occlusion (CRVO/BRVO)	29 (39.2 %)
Uveitis	5 (6.8 %)

Abbreviations: POAG, Primary open angle glaucoma; SACG, Secondary angle-closure glaucoma; SOAG, Secondary open angle glaucoma; DME, Diabetic macular edema; CRVO, Central retinal vein occlusion; BRVO, Branch retinal vein occlusion.
Table 1. Demographic information, glaucoma history, and indication for intravitreal dexamethasone implant (Ozurdex) of study participants.

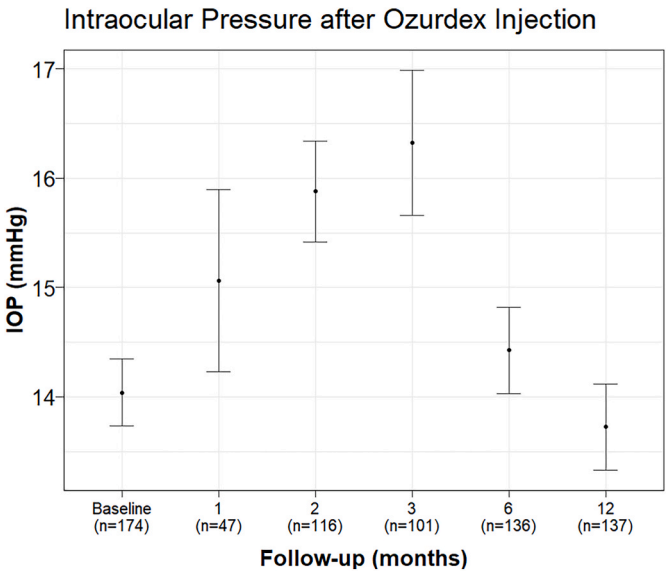

Fig. 1. Intraocular pressure after Ozurdex implantation. Time series graph of mean intraocular pressure (IOP) at baseline and in the first 12 months after intravitreal dexamethasone (Ozurdex) implant. Error bars indicate standard error of the mean for each measurement.

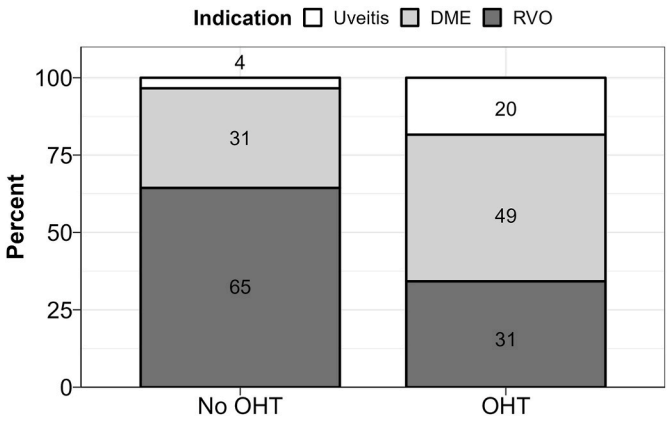

Fig. 2. Study design and outcomes. Flowchart description of study participant inclusion, development of ocular hypertension (OHT), and management following intravitreal dexamethasone (Ozurdex) implant. Abbreviations: OHT, ocular hypertension; IOP, intraocular pressure; GATT, gonioscopy-assisted transluminal trabeculotomy; KDB, Kahook dual-blade goniotomy; SLT, selective laser trabeculoplasty.

Table 2
Multivariable logistic regression model for variables on the impact of developing ocular hypertension after Ozurdex implantation.

Predictor	Odds Ratio (95 % CI)	p-value
Baseline IOP (mm Hg)	1.04 (0.77–1.14)	0.641
Age >60 years	6.65 (1.05–41.92)	0.044
Male Sex	2.09 (0.58–7.56)	0.259
RVO	0.07 (0.01–0.44)	0.004
Uveitis	2.08 (0.28–15.54)	0.473
Glaucoma History	1.38 (0.27–7.00)	0.695
Prior Ozurdex Injection	0.97 (0.28–3.32)	0.966

Abbreviations: IOP, intraocular pressure; RVO, retinal vein occlusion.
Table 2. Multivariable logistic regression model examining the relationship between patient-specific factors and new-onset ocular hypertension following intravitreal dexamethasone implant (Ozurdex).

to develop OHT than patients treated for DME. Baseline IOP, preexisting glaucoma, central corneal thickness, or prior history of Ozurdex implant did not significantly impact odds of developing OHT.

4. Discussion

Elevated IOP following Ozurdex injection is a known adverse side effect of intravitreal corticosteroids. The definition of Ozurdex-induced OHT varies in the literature. In the trial conducted by the Ozurdex GENEVA Study Group, which established Ozurdex's efficacy in treating macular edema secondary to BRVO or CRVO, investigators chose to highlight the incidence of IOP rises ≥25 mm Hg following over 6 months. Similarly, the SAFODEX study designated OHT as an IOP ≥25 mm Hg, but it also included an increase ≥10 mm Hg from baseline as an alternative criterion.[5] In other studies, Chin and colleagues defined OHT as ≥30 mm Hg or ≥10 mm Hg increase from baseline, whereas Mansoori et al. characterized OHT as >22 mm Hg or >6 mm Hg increase from baseline.[8,13]

The incidence of developing OHT in our cohort was 20.9 % over 12 months, peaking at around 2–3 months. In the literature, incidence of Ozurdex-induced OHT ranges from 9 % per the ZERO study to 27.7 % and 28.5 % per the MEAD and SAFODEX studies, respectively.[5,14,15] In the ZERO study, 342 eyes with RVO treated with Ozurdex were followed over 8 months. In the SAFODEX study, 421 eyes with predominantly RVO, DME, or uveitis were treated over a mean of 16.8 months. Generally, OHT incidence peaked at 2 months follow-up. Variations in incidence rates are likely attributable to a combination of factors, including differences in patient demographics, the distribution of Ozurdex indications, and the duration of follow-up. Nevertheless, the incidence of OHT for our study's participants fell within this reported range.

We also sought to identify risk factors for OHT development. Multivariable regression analysis showed that age >60 years old increased the risk of developing OHT. On the other hand, patients treated for RVO had decreased risk of developing OHT compared to patients treated for DME. In the SAFODEX study, the investigators identified an association between younger age and increased risk of OHT, which contrasts with our results.[5] Studies have demonstrated a bimodal distribution for steroid-induced OHT, which may help explain these disparate findings.[16–18] Additionally, the cut-offs for age groups and classification as a discrete or categorical variable can further complicate this relationship. Similarly, RVO has been associated with increased risk for OHT, whereas DME increased odds of OHT in our cohort.[5] One potential explanation for these differences could be due to uncaptured demographic characteristics – for example, data on race/-ethnicity in the SAFODEX study was not available. Study participants were located in France, whereas our study population was predominantly Black, residing in Chicago in the United States. Recent studies indicate distinct IOP responses to Ozurdex based on race/ethnicity, with Latino and South Asians having greater IOP rises compared to Whites.[6] This finding suggests that certain characteristics, including genetic background, that associate with race/ethnicity may modify the risk of developing steroid-induced OHT. For example, African Americans have shorter trabecular meshwork heights on average, which is associated with greater risk of steroid-induced OHT.[19,20] Furthermore, given that the presence and severity of diabetes correlates with OHT and glaucoma, it is unclear whether DME itself increased the risk of Ozurdex-induced OHT, or rather due to the intraocular impact of systemic hyperglycemia.[21,22] The SAFODEX study also identified patients treated for sequelae of uveitis at greater risk for developing OHT – we observed a similar trend but lacked statistical power to match this finding. Further studies are warranted to better delineate the impact of age and treatment indication for development of OHT using intravitreal dexamethasone implants.

Our study was not powered to detect whether number of previous IOP spikes was a significant risk factor for Ozurdex-induced OHT. Patients that experience IOP spikes, whether due to medications or ocular surgery, may be predisposed to Ozurdex-induced OHT, as their biology has already demonstrated a degree of trabecular incompetence. Preclinical models of glaucoma reveal an array of transcriptional and structural changes that occur following IOP elevation, suggesting repeated IOP spikes may contribute to glaucoma development in the long-term.[23] While we did not find that repeat injections significantly changed the odds of developing OHT, this result should be interpreted cautiously, as studies have reported mixed findings.[5,8,24] Considering the dose-response relationship between steroids and glaucoma, repeated Ozurdex injections warrants close monitoring and management.[25] Studies also have found that a prior history of glaucoma or glaucoma suspect was associated with an increased risk for Ozurdex-induced OHT.[26] Our patient population demonstrated a similar relationship; however, this was not statistically significant.

Treatment of Ozurdex-induced OHT is not well-characterized, especially for minimally-invasive techniques, as historically eyes refractory to medical therapy received trabeculectomy or shunt for management of steroid-induced glaucoma.[9,27] In our single-institution study, the management of Ozurdex-induced OHT included medical therapy (16.4 %), SLT (3.0 %), and minimally-invasive surgical techniques (4.5 %). Across studies in the literature, medical management was the first-line approach to manage elevated IOP. However, the choice of procedure for refractory OHT varied greatly. In the SAFODEX study, the only IOP-lowering procedure utilized was trabeculectomy. In a study by Chin et al., 3.2 % of patients required further management, which

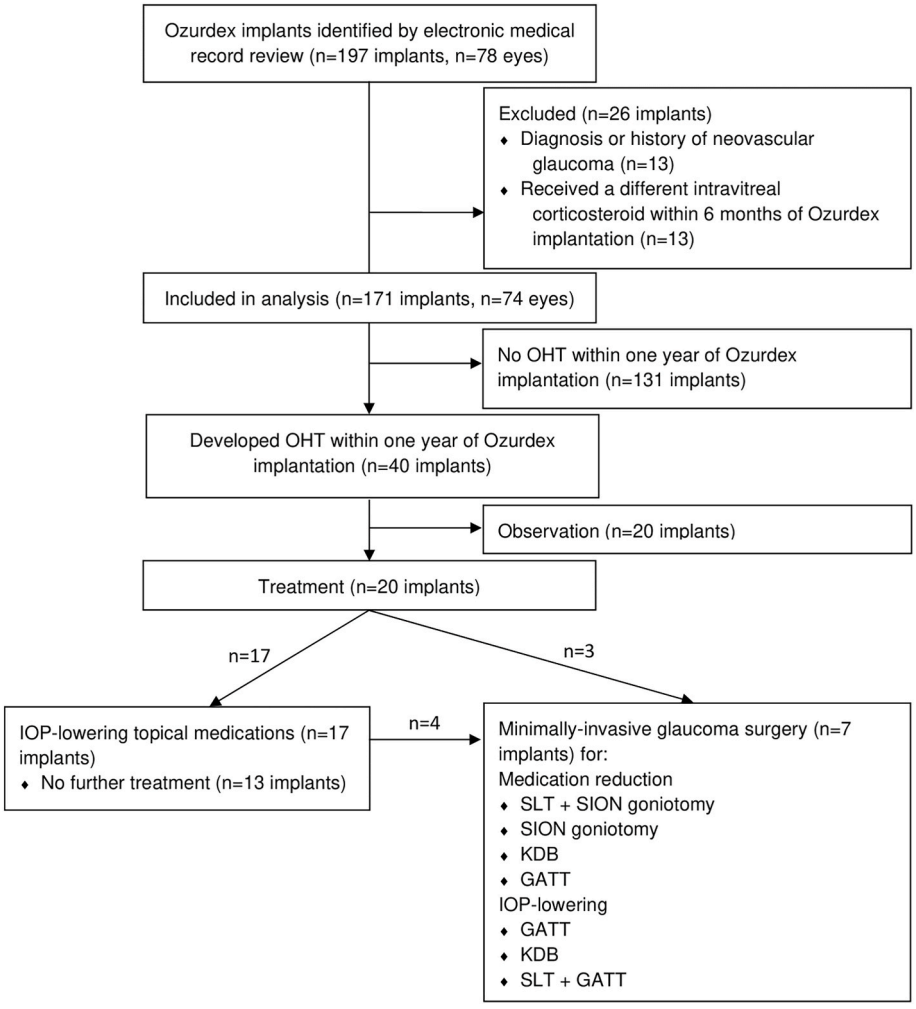

Fig. 3. Development of ocular hypertension (OHT) by Indication. Bargraphs depicting indication for intravitreal dexamethasone implant (Ozurdex), stratified by development of OHT within 1 year of implantation.

involved Trabectome surgery, glaucoma drainage device insertion, and a trans-scleral cyclophotocoagulation.[8] In the MEAD study, increased IOP for the 0.7 mg dexamethasone implant group was managed with trabeculectomy, iridotomy, and iridectomy.[28] Other options reported to manage steroid-induced OHT and glaucoma include canaloplasty and sclerectomy.[29–31] The fact that patients in this study who developed Ozurdex-induced OHT were successfully managed using laser procedures and MIGS highlights the potential safety and efficacy or less minimally invasive interventions for this adverse side effect.

This study has several main limitations. First, as a retrospective study, no standard protocol existed for monitoring patients post-Ozurdex implantation. Multiple physicians administered the intravitreal injections and followed patients at different intervals; furthermore, the study period included the COVID-19 pandemic, which significantly affected follow-up frequency. As a result, a key limitation is the possibility of non-detection of OHT. While studies suggest IOP on average peaks 2–3 months after Ozurdex implantation, a subgroup of patients will experience elevated IOP within 1–4 weeks.[4,5] In this study, most patients were not seen at the 1-month interval, which may obscure early steroid responders. Additionally, because patients were followed for 12 months, we cannot comment on long-term effectiveness of MIGS for Ozurdex-induced OHT, which may diminish with time.[32]

In conclusion, we present data that demonstrate Ozurdex-induced OHT can be safely and effectively managed with medical therapy, laser trabeculoplasty, and angle-based MIGS. Furthermore, the risk factors associated with developing OHT following Ozurdex implantation, such as older age and treatment indication, may differ between populations. Future studies should examine the relationship between successful treatment of Ozurdex-induced OHT with MIGS and underlying patient factors, such as pre-existing glaucoma. This study offers support for a growing repertoire of alternate modalities to manage intravitreal dexamethasone implant-induced OHT. These techniques have the potential to effectively manage OHT or delay interventions that are traditionally associated with greater risk.

CRediT authorship contribution statement

Jason Xiao: Writing – review & editing, Writing – original draft, Visualization, Methodology, Investigation, Formal analysis, Data curation. **Mary Qiu:** Writing – review & editing, Writing – original draft, Supervision, Methodology, Investigation, Data curation, Conceptualization.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Glossary:

IOP, intraocular pressure; OHT, ocular hypertension; POAG, primary

open angle glaucoma; SACG, secondary angle-closure glaucoma; SOAG, secondary open angle glaucoma; DME, diabetic macular edema; CRVO, central retinal vein occlusion; BRVO, branch retinal vein occlusion; MIGS, minimally-invasive glaucoma surgeries; GATT, gonioscopy-assisted transluminal trabeculotomy; SLT, selective laser trabeculoplasty.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.ajoc.2025.102274.

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