Assessment of the Real-World Safety of Intravitreal Dexamethasone Implant (Ozurdex): Novel Insights From a Comprehensive Pharmacovigilance Analysis Utilizing the FAERS Database

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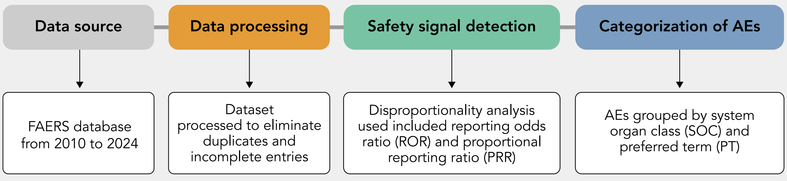
The intravitreal dexamethasone implant (Dex) is widely used for various ocular conditions, including diabetic macular edema, retinal vein occlusion, and non-infectious uveitis. Despite its efficacy, concerns remain regarding its safety profile. This study aims to analyze the adverse events (AEs) associated with Dex reported in the FDA Adverse Event Reporting System (FAERS) database from 2010 to 2024.

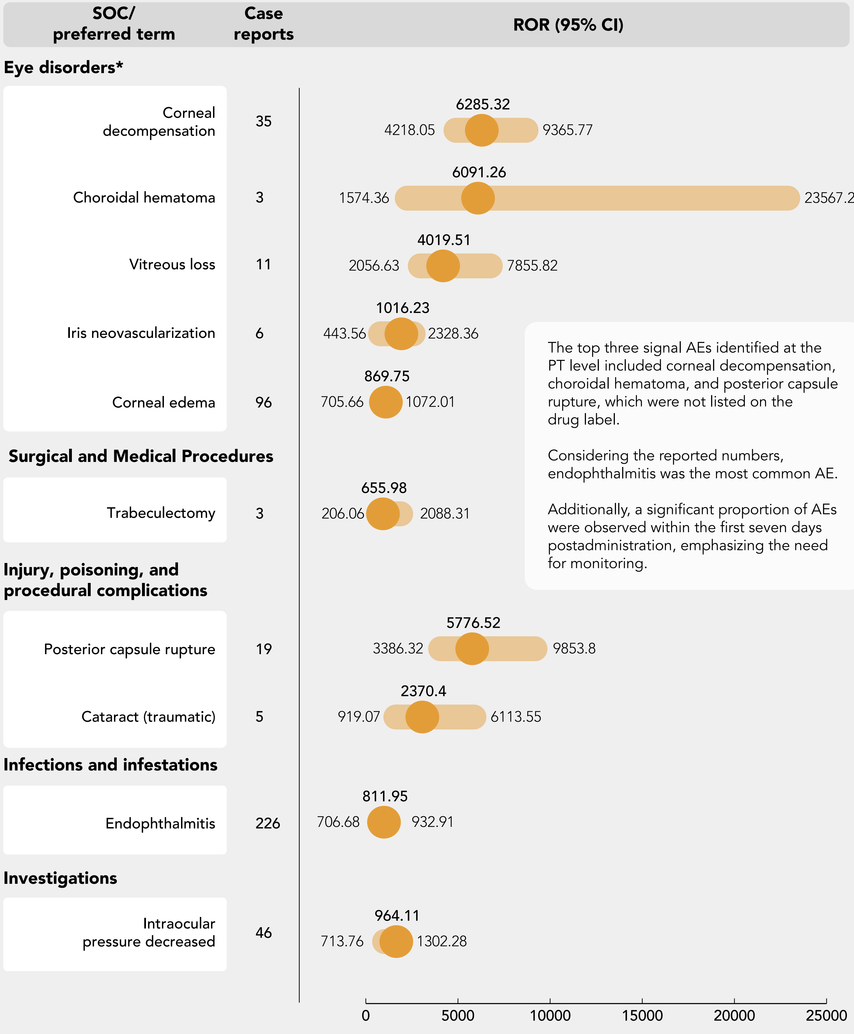
Data were extracted from FAERS, focusing on cases where Dex was the primary suspect drug



A total of 1,588 adverse event reports (AERs) were analyzed. The number and percentage of AERs each year in the FAERS database showed an overall upward trend, suggesting a growing volume of pharmacovigilance data over time.

Eye disorders were the most commonly reported SOC, with significant disproportionality signals confirming a strong association between Dex and these ocular disorders

Top ten signal strengths of reports*



The top three signal AEs identified at the PT level included corneal decompensation, choroidal hematoma, and posterior capsule rupture, which were not listed on the drug label.

Considering the reported numbers, endophthalmitis was the most common AE.

Additionally, a significant proportion of AEs were observed within the first seven days postadministration, emphasizing the need for monitoring.

* Ranked by ROR at the preferred term level and sorted by system organ class.

AE = adverse event; CI = confidence interval; PT = preferred term; ROR = reporting odds ratio; SOC = system organ class

Conclusions

While Dex remains an effective treatment option for ocular conditions, its use is associated with significant risks, particularly regarding unexpected and severe complications, such as corneal decompensation. Continuous pharmacovigilance and detailed patient monitoring are essential to mitigate these risks. Future studies should focus on prospective designs and comprehensive clinical data to better understand the safety profile of Dex.