Risk of cataract or raised intraocular pressure in patients treated with dexamethasone intravitreal implants: Results from a retrospective UK database study

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OBJECTIVE

To evaluate the real-world incidence of cataract and raised intraocular pressure associated with the use of dexamethasone implant (DEX-I), based on data from six UK secondary care eye clinics

CONCLUSIONS

- Real-world use of DEX-I was associated with lower rates of new diagnoses of cataract and raised IOP (OHT, glaucoma or use of IOP-lowering drops) compared with rates observed in published clinical trials
- The risk of raised IOP increased with the number of injections received
- 97% of patients with raised IOP were adequately controlled without requiring laser or surgical intervention
- The interval between successive DEX-I injections was not associated with the rate of development of cataract or raised IOP

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INTRODUCTION

The association between the use of intravitreal implant of dexamethasone (Ozurdex; DEX-I) and an increased risk of cataract or raised intraocular pressure (IOP) is well documented. However, data derived from clinical trial experience do not necessarily reflect the true incidence of adverse events attributable to DEX-I in a broader population. We report on the results of an analysis from UK clinical database, drawing data from a population of patients receiving DEX-I for the treatment of diabetic macular oedema (DMO), retinal vein occlusion with macular oedema (RVO+MO) or non-infectious uveitis.

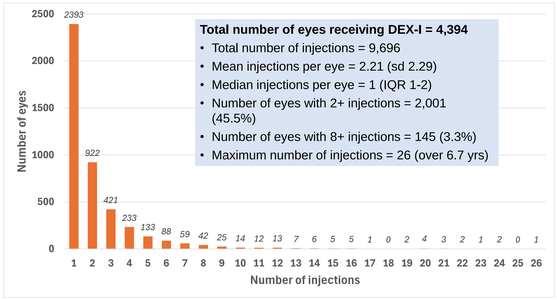
METHODS

Anonymised data was extracted using electronic patient records from six UK eye clinics using either Medisoft or Medisight software systems. Adult patients who had received one or more DEX-I for any indication over the period 2011-2024 qualified for the study. For the safety analysis presented here, data regarding cataract, raised IOP, ocular hypertension (OHT), use of IOP-lowering drops and treated glaucoma were identified for each patient. Analyses of the relationship between the time of first occurrence of a qualifying diagnoses and the exposure to and time since DEX-I implantation were carried out.

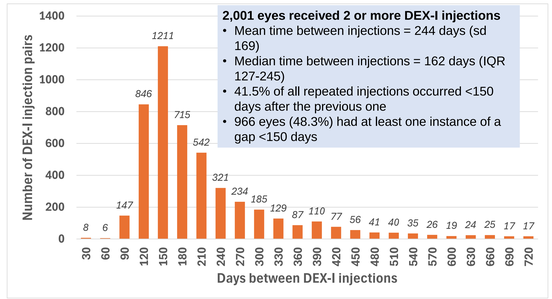
RESULTS

A total of 4,394 DEX-I treated eyes were identified in 3,942 patients, with a median follow-up of 5.88 years from the time of the first implant. The reason for treatment was RVO+MO (48.2%), DMO (47.5%) and uveitis (4.3%). At the time of first treatment, 59.2% of eyes were pseudophakic/aphakic and 39.9% were phakic. In 0.9% of eyes, lens status was not reported.

Number of DEX-I injections in the study population



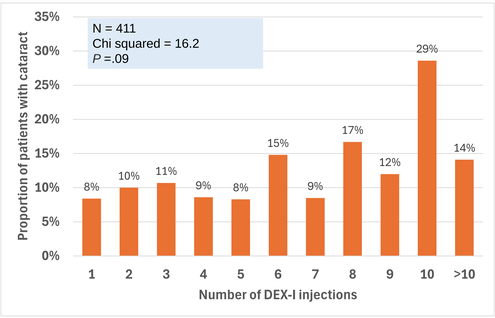
Frequency of DEX-I injections in the study population



Cataract

In 1,865 eyes that were phakic at the time of the first injection, a new cataract diagnosis was recorded in 411 eyes (22%). Mean age at diagnosis was 67.3 years. 72 diagnoses of cataract (3.8% of at-risk eyes) occurred more than one year after the first implant and less than two years after the last implant and were thus potentially attributable to DEX-I. Although the risk of cataract tended to rise in association with the number of implants administered, this trend was not statistically significant (Chi squared = 16.2; *P* =.09). Incidence of new cataract was not related to duration between injections. New cataracts were seen in 7.3% of patients with one or more treatment gaps <150 days and in 10.6% of patients with no reduced treatment gaps (*P* =.605)

Number of DEX-I injections and rate of new cataract diagnoses



Raised IOP, OHT and Glaucoma

866 eyes (19.7%) were identified as having one or more instance of an intraocular pressure >30mmHg, a new diagnosis of raised IOP, or had received specific IOP-lowering treatment >30 days following a DEX-I injection. Of these, 656 diagnoses (14.9% of at-risk eyes) were first made <180 days after the last injection and were thus potentially attributable to DEX-I. 546 eyes (83%) were treated with topical therapy, 92 (14%) underwent no active intervention, 13 (2%) were treated with selective laser trabeculoplasty while 3 (<1%) required surgical treatment (2 minimally-invasive devices + 1 trabeculectomy).

There was a significant association between the number of injections and the risk of a new OHT/glaucoma diagnosis, ranging from 8.7% of eyes with 1 DEX-I implant up to 38% of eyes that had received >10 implants (Chi squared = 215.4; *P* <.0001). New diagnoses were seen in 15.5% of patients with one or more treatment gaps <150 days and in 9.8% of patients with no reduced treatment gaps (*P* =.192)

Number of DEX-I injections and rate of IOP >30mmHg

