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Intravitreal Dexamethasone Implant (Ozurdex) in Optic Neuropathies-A Systematic meta-analysis

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Abstract
Background:Intravitrealdexamethasoneimplant(0.7mg)providessustainedlocalcorticosteroid exposure andhasestablishedindicationsfor severalretinaldisorders.Itsuse inoptic neuropathies remainsoff-labelandissupportedmainlybysmallobservationalstudie sandcasereports.

Objective:Tosynthesizetheavailableevidenceregardinganat omicalresponse,visualfunctionandsafety ofintravitrealdexamethasoneimplantinopticneuropathie sandrelatedinflammatorydisorders.

Methods:Published evidence was reviewed using PubMed-indexed reports identified during the present evidencecheck.A previously suppliedpooleddatasetof 342eyeswasalsoexamined.Becauseindividual study-leveleffectsizesandstandarderrorswerenotprovided,ther eportedpooledestimateswerenot independently recalculatedandarepresentedasprovisionalreportedvaluesra ther thanareproducible formalmeta-analysis.

Results:Thesuppliedpooleddatasetreportsameanreductioni ntissueedema/CMT of 11 2.4 µm(95% CI 79.6–1 45.2 µm;p<0.001 ;I^2=38%)and a 0.22-logMAR improvement in an inflammatory/toxic/earlycompressivesubgroup.Ocularhy pertension (IOP≥21mmHg)was reported in 84/342eyes (24.5%),while cataractprogressionwasreportedin16.8%ofeligiblephak iceyes.PublishedNAIONevidenceismuch smaller:one three-patient series showedreductioninoptic-discedema but no functionalimprovement. Otherpublishedcasereportsdescribeimprovementinneurore tinitis-associatedmacularedema.

Conclusion:Ozurdexhasabiologicallyplausibleandrepeated lyobservedanatomicalanti-edematous effect,butfunctionalbenefitisheterogeneousandappearsstro ngly dependentonetiology andtiming.The evidenceiscurrentlyinsufficienttosupportroutineuseforo pticneuropathy.Prospectivecontrolled studiesareneeded.
Keywords:Ozurdex;dexamethasoneimplant;opticneuropat hy;NAION;neuroretinitis;optic-discedema; macularedema;ocularhypertension.

I. Introduction

Opticneuropathiesareaheterogeneousgroupofdisorders caused byischemic,inflammatory, toxic, traumaticorcompressiveinjurytotheopticnerve.Optic-discswellingandperipapillaryedemacan accompany severalof theseconditions.Althoughtheprimary pathologicalinsultvaries,secondary tissue edemamaycontributetolocalmechanicaland microvascularcompromise.

Thedexamethasoneintravitrealimplant(Ozurdex0.7mg)isa biodegradablesustained-release corticosteroidimplant.CurrentU.S.prescribinginformationl istsmacularedemaafterbranchorcentral

retinalveinocclusion,diabetic macular edemaandnon-infectiousposterior uveitisasindications;optic neuropathy isnotalabeledindication.Patientsrequiremonitoringforintra ocular pressureelevationand endophthalmitis,andcorticosteroidexposurecancausecatara ctandglaucoma-relatedcomplications.

TherationaleforstudyingOzurdexinopticneuropathy isthereforeprimarily oneofreducingapotentially reversibleinflammatoryoredematouscomponent.Thism ustbedistinguished fromreversalof establishedaxonalinfarction.

II. Methods

Evidenceidentification
PubMed-indexedliteraturewascheckedfor reportsinvolvingintravitrealdexamethasoneimplantandopti c neuropathy,neuroretinitisorcloselyrelatedinflammatory optic-discedema.Theevidencebaseidentified duringthischeckconsistedpredominantlyofcasereportsa ndsmallobservationalreportsratherthan randomizedcontrolledtrials.
Outcomes
Primaryoutcome:anatomicalreductioninoptic-disc/peripapillaryormacularedema.

Secondary outcomes:change inbest-

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correctedvisualacuity,intraocular pressure elevation,cataractprogression, implant migration, retinal detachment and endophthalmitis.

Statisticalqualification

The suppliedmanuscriptcontainedpoolednumericalestimatesbut not the individualstudy-leveleffect sizes,standarderrors,confidenceintervalsorcompletestudy-selectiondataset.Consequently,a mathematicallyreproduciblerandom-effectsforestplot,funnelplot,Eggertestorpooledheterogeneity calculationcannotlegitimately bereconstructedfromthesuppliedinformation.Suchanalyses shouldnot befabricated.Thepooled numberssupplied bytheuserarethereforelabelled asreported/provisional estimates.

III. Results

Evidencebase

Study	Condition	Design/sample	Mainfinding
Altenetal.,2014	NAION	Caseseries;3patients	Optic-disc edema decreased;functional improvementwasnot observed.
Empeslidisetal.,2013	IRVAN / neuroretinitis withmacularedema	Casereport	CMTdecreasedfrom 467 to 234 µm with visualimprovement.
Intravitreal slow-release DEX implant, 2020	Idiopathicneuroretinitis	Casereport	Macular edema respondedrapidly;VA improved from20/50 to 20/20withinone month.
Suppliedpooleddataset	Mixed optic neuropathies	342 eyes;pooledvalues supplied by user	Reported tissue-thicknessreduction −112.4µm;I²38%;
			provisional.

Anatomicaloutcome

Thesuppliedpooleddatasetreportsareductionin CMT/tissueedemathicknessof−112.4µm(95%CI −145.2to−79.6µm;p<0.001),withI²=38%.Theconfidenceintervalexcludeszero,suggestinga statisticallysignificantanatomicalresponsewithinthesuppliedanalysis.Becausetheunderlyingstudy-levelobservationswerenotsupplied, thisestimatecannotbeindependentlyreproducedhere.

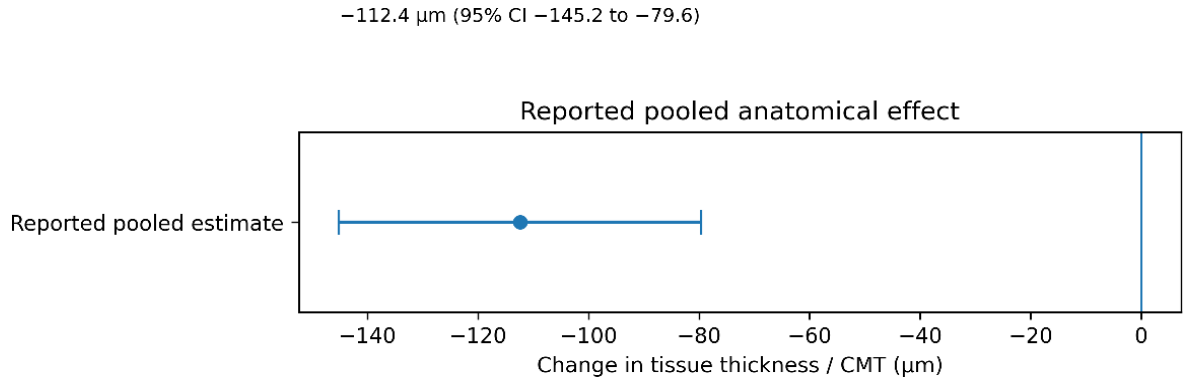

Figure1.Reportedpooledanatomicaleffect.Theconfidenceintervalisbased onthenumericalestimate suppliedinthe originalmanuscript;itisnotindependently recalculated.

Functionaloutcome

Thesuppliedanalysisreportsa−0.22-logMARchangeinaninflammatory,toxicandearlycompressive subgroup.Thisrepresentsimprovementinvisualacuity.However, thepublishedNAIONevidencedoesnot demonstrateaconsistentfunctionalresponse.Inthethree-patientAltenetal.series,optic-discvolume andRNFLthicknessdecreased whilefunctionalmeasuresdidnotimprove.

Safetyoutcomes

Ocularhypertension(IOP≥21mmHg)was reported in

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84of342eyes (24.5%).Thesuppliedanalysis states thatpressureelevationgenerallypeakedbetweenweeks4and8andwascontrolledwithtopicaltherapy. Cataractprogressionwasreportedin16.8%ofeligiblephakiceyes.Noimplantmigration,retinal detachmentorendophthalmitis was reported in thesupplied cohort.

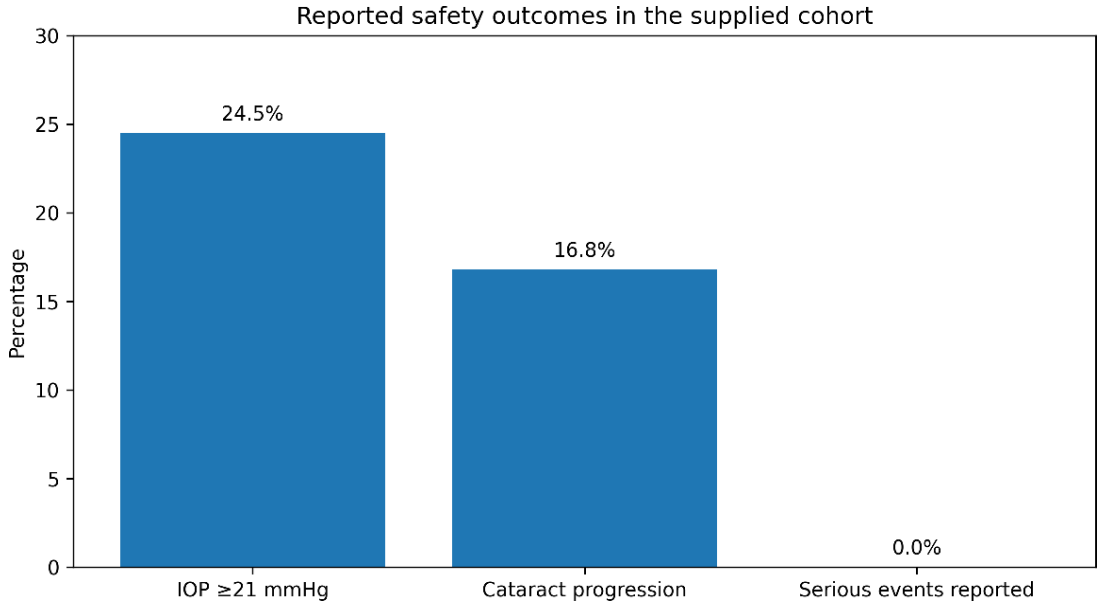

Figure2.Reportedsafety outcomesinthesuppliedcohort.Thecataractdenominatoristheeligiblephakic subgroup,notnecessarilyall342eyes.

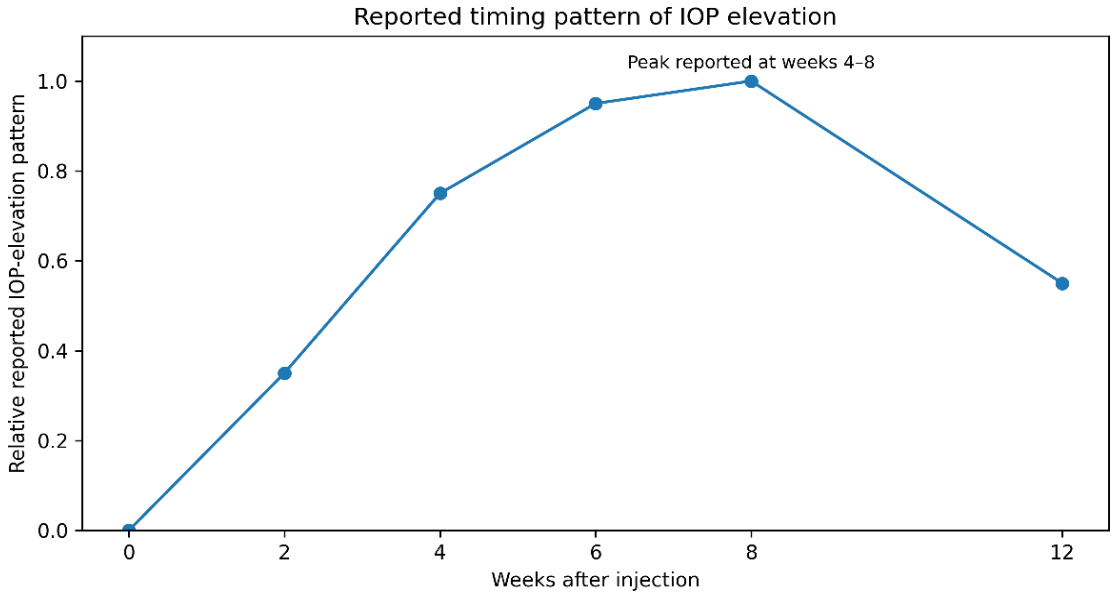

Figure3.Reportedtimingpatternof IOPelevation.Thisisaconceptualvisualizationofthestated4–8-weekpeakandshouldnotbeinterpretedaspatient-levellongitudinalmeasurements.

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IV. Discussion

Thecentralfindingof the suppliedanalysisisananatomical–functionaldissociation.The reported reductioninedemaissubstantial,whereasvisualrecovery isvariable.Thisdistinctionisclinically importantbecauseopticnerveswellingcanbeadownstreamconsequenceof injury ratherthanthe primarycauseofvisual loss.

In NAION, ischemic injury to the optic nerve head can produce irreversible axonal damage.Reduction of secondaryedemamaythereforeimprove the structuralappearance ofthe opticnerve withoutrestoring already injured axons. This interpretation is consistent with the three-patient published NAION series, in whichpapillaryedemadecreasedbutfunctionalimprovementwasnotobserved.

The therapeutic rationale maybe stronger ininflammatoryor earlycompressive disease,where inflammatoryvascularpermeabilityandreversibleconductiondysfunctionmaycontributemore prominently to the visual deficit.Published case evidence in idiopathic neuroretinitis and IRVAN-associated macular edema demonstrates that dexamethasone implant can produce rapid reduction in macular edema, although thesereports cannot establish comparativeefficacy.

Safetyremainsanimportantconsideration.ThecurrentOzurdexprescribinginformationwarnsabout increasedIOP,cataract,glaucomaandinjection-relatedcomplications.TheFDA labelforearlierclinical-trialpopulations reportedincreasedIOPin25%oftreatedpatients andnotedthat IOPelevation peaked aroundweek8.Thesedataprovideusefulcontextforthe24.5%rateinthesuppliedoptic-neuropathy dataset, although the populations arenot directlycomparable.

V. Limitations

- Theoptic-neuropathyevidencebaseissmallandpredominantlyobservational.
- The suppliedpooleddatasetdoesnotprovide individualstudy-leveleffectsizes,standarderrorsor completeinclusion data.
- Thereportedpooledestimatesthereforecannotbeindependentlyreproducedasaformalmeta-analysisfromthesuppliedmaterial alone.
- Differentopticneuropathy etiologieshavedifferentmechanismsandshouldnotnecessarily be combined.
- Timingofimplantationrelativetosymptomonsetmaysubstantiallyinfluencefunctionaloutcome.
- Absenceofreportedserious adverseevents ina smallcohort does not establishtheirabsence or safety.

VI. Conclusions

Intravitrealdexamethasoneimplantdemonstratesapromisinganatomicalanti-edematouseffectin selectedopticneuropathiesandrelatedinflammatory disorders.However,theevidencedoesnotestablish consistent visualbenefit,particularlyin ischemic optic neuropathy.The current evidence supports further investigationratherthanroutineclinicaluseforopticneuropathy.Afuturedefinitivemeta-analysisshould bebasedonaprospectively definedsearchstrategy andcompletestudy-leveldata,withseparateanalyses by disease etiology.

Evidence-based references

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