

Glaucoma-Related Adverse Events at 10 Years in the Infant Aphakia Treatment Study: A Secondary Analysis of a Randomized Clinical Trial

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IMPORTANCE: Glaucoma-related adverse events constitute serious complications of cataract removal in infancy, yet long-term data on incidence and visual outcome remain lacking.

OBJECTIVE: To identify and characterize incident cases of glaucoma and glaucoma-related adverse events (glaucoma + glaucoma suspect) among children in the Infant Aphakia Treatment Study (IATS) by the age of 10.5 years and to determine whether these diagnoses are associated with optic nerve head (ONH) and peripapillary retinal nerve fiber layer (RNFL) assessment.

DESIGN, SETTING, AND PARTICIPANTS: Analysis of a multicenter randomized clinical trial of 114 infants with unilateral congenital cataract who were aged 1 to 6 months at surgery. Data on long-term glaucoma-related status and outcomes were collected when children were 10.5 years old (July 14, 2015, to July 12, 2019) and analyzed from March 30, 2019, to August 6, 2019.

INTERVENTIONS: Participants were randomized at cataract surgery to either primary intraocular lens (IOL) , or aphakia (contact lens <http://CL>) . Standardized definitions of glaucoma and glaucoma suspect were created for IATS and applied for surveillance and diagnosis.

MAIN OUTCOMES AND MEASURES: Development of glaucoma and glaucoma + glaucoma suspect in operated-on eyes up to age 10.5 years, plus intraocular pressure, axial length, RNFL (by optical coherence tomography) , and ONH photographs.

RESULTS: In Kaplan-Meier analysis, for all study eyes combined (n = 114) , risk of glaucoma after cataract removal rose from 9% (95% CI, 5%-16%) at 1 year, to 17% (95% CI, 11%-25%) at 5 years, to 22% (95% CI, 16%-31%) at 10 years. The risk of glaucoma plus glaucoma suspect diagnosis after cataract removal rose from 12% (95% CI, 7%-20%) at 1 year, to 31% (95% CI, 24%-41%) at 5 years, to 40% (95% CI, 32%-50%) at 10 years. Risk of glaucoma and glaucoma plus glaucoma suspect diagnosis at 10 years was not significantly different between treatment groups. Eyes with glaucoma (compared with eyes with glaucoma

suspect or neither) had longer axial length but relatively preserved RNFL and similar ONH appearance and visual acuity at age 10 years.

CONCLUSIONS AND RELEVANCE: Risk of glaucoma-related adverse events continues to increase with longer follow-up of children following unilateral cataract removal in infancy and is not associated with primary IOL implantation. Development of glaucoma (or glaucoma suspect) after removal of unilateral congenital cataract was not associated with worse visual acuity outcomes at 10 years.

TRIAL REGISTRATION: ClinicalTrials.gov Identifier: NCT00212134.

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