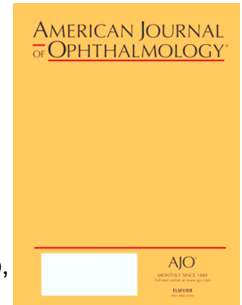


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Reporting Harm in Glaucoma Surgical Trials: Systematic Review and a Consensus
Derived New Classification System

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Abstract

Purpose: To evaluate the standards of harm reporting for glaucoma surgical trials and to develop a classification system for reporting surgical complication severity.

Design: Systematic Review and *Delphi* consensus method.

Methods: Systematic review of glaucoma surgical trials published from January 2010 until July 2017 with a quality assessment against the CONSORT *checklist for harm*. A Delphi method was employed to generate consensus (interquartile range ≤ 2) among international glaucoma experts (n=43) on severity of glaucoma surgical complications and, specifically for trabeculectomy and aqueous shunt complications, from 1 (no clinical significance) to 10 (most severe complication).

Results: 47 studies were eligible. The items of the CONSORT checklist for harm that were most frequently missing were: *use of a validated instrument to report severity* (0%), *withdrawals due to harm*, and *subgroup analyses* reported in 3 publications (6.4%). Most glaucoma experts participating in the Delphi process (80%) completed the second round, and consensus was achieved for all but one complication. The least severe complications (graded 2) were: 'transient loss of vision', 'early low intraocular pressure', 'choroidal detachment anterior to equator', 'small layered hyphema < 1 mm', and 'increased lens opacity not clinically significant'. The most severe complications (graded 10) were 'endophthalmitis' and 'permanent severe loss of vision (hand movements or worse)'.

Conclusions: Glaucoma surgical RCTs report frequency of complications but their severity is rarely reported. The quality of harm reporting is poor. We propose the use of a newly developed system of classification for assessing the severity of surgical complications based on consensus.

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