

THE LITERATURE



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Quality of Life in the Tube Versus Trabeculectomy Study

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ABSTRACT SUMMARY

This multicenter randomized clinical trial evaluated vision-specific patient-reported outcome measures in the Tube Versus Trabeculectomy (TVT) study.² The primary outcome of the TVT study was to compare the safety and efficacy of tube shunt surgery versus trabeculectomy in patients aged 18 to 85 years with medically uncontrolled glaucoma who had previous cataract and/or failed glaucoma filtering surgery. In contrast, the purpose of this study by Kotecha and colleagues was to evaluate patient-reported outcome measures to assess the effects of glaucoma surgical treatment on quality of life (QOL).

Patients with an IOP ranging from 18 to 40 mm Hg were randomized to receive either a 350-mm² Baerveldt glaucoma implant (Johnson & Johnson Vision) or trabeculectomy with mitomycin C in one eye, with neither the patient nor the provider masked to treatment assignment. Vision-specific QOL was assessed using the National Eye Institute Visual Function Questionnaire-25 (NEI VFQ-25) at baseline and annually over a 5-year follow-up period.

To assist in NEI VFQ-25 interpretation, researchers ascertained the minimal important difference, defined as the smallest perceivable difference in score that would change a patient's management, with side effects and cost aside. The investigators completed this determination by anchor-based and distribution-based methods. The anchor-based method associated a change in NEI VFQ-25 with a change in clinic status, defined as a change in visual acuity of at least 0.2 logMAR or a change in visual field mean deviation of 2 dB or more. The distribution-based approach examined the distribution of scores across the patient group and was calculated using one-third of the standard deviation method.

Baseline data were available for 202 (95.3%) patients. At baseline, there were no differences in NEI VFQ-25 scores between groups, and there were no significant changes in scores over time. In fact, there was a minimal change in scores throughout the study's duration. Although questionnaire completion remained high through 2 years of follow-up ($\geq 95\%$), it declined to 51% by the fifth year.

DISCUSSION

How may the results of this study aid in educating patients prior to glaucoma surgery?

Not only did this study find no significant difference in vision-specific QOL measures between trabeculectomy and tube shunt surgery, but it also found very little change throughout the study's duration. This may be due in part to attrition, as patients who completed 3- and 5-year postoperative surveys had a higher self-reported QOL compared with those who did not complete the questionnaire after 1 year.

The Collaborative Initial Glaucoma Treatment Study (CIGTS), which consisted of newly diagnosed glaucoma patients and is the only other multicenter randomized glaucoma clinical trial to date to report treatment intervention's impact on QOL, also found no difference in QOL scores between treatment groups. By combining the results of this study and CIGTS with the TVT study's 5-year outcomes, eye care providers may better educate patients with similar baseline characteristics on expected clinical outcomes and complications as well as patient-perceived QOL.

Which clinical outcome had the greatest effect on patient-related outcome measures?

Although this study identified no statistically significant change in QOL composite scores over time, the investigators found that NEI VFQ-25 scores were affected by certain clinical outcome measures, including change in visual acuity and visual field mean deviation. A clinically relevant change in mean deviation resulted in a smaller impact on QOL.



AT A GLANCE

- A multicenter randomized clinical trial evaluated vision-specific patient-reported outcome measures in the Tube Versus Trabeculectomy (TVT) study. Not only did the investigators find no significant difference in vision-specific quality-of-life measures between trabeculectomy and tube shunt surgery, but they also reported very little change throughout the study's 5-year duration.
- A retrospective study reviewed the outcomes of patients with open-angle glaucoma and a history of prior incisional glaucoma surgery who underwent gonioscopy-assisted transluminal trabeculectomy. Patients with prior glaucoma drainage device surgery appeared to do better than those with a history of trabeculectomy, although the results were not significant.

composite score than a change in visual acuity. With anchor-based methods, a worsening in mean deviation of 2 dB or more was associated with a median 4.4 decrease in NEI VFQ-25, whereas a loss of 0.2 logMAR or more resulted in a median 3.4 decrease. It must be noted, however, that visual field data were only available for the surgical eye, with data available for 96 patients preoperatively and 82 postoperatively.

Outcomes of Gonioscopy-Assisted Transluminal Trabeculotomy (GATT) in Eyes With Prior Incisional Glaucoma Surgery

Grover DS, Godfrey DG, Smith O, et al³

ABSTRACT SUMMARY

This retrospective study reviewed the outcomes of patients with open-angle glaucoma and a history of prior incisional glaucoma surgery who underwent gonioscopy-assisted transluminal trabeculotomy (GATT). The investigators identified 35 eyes of 35 patients. Of these, 19 had a history of trabeculectomy, 13 of glaucoma drainage device (GDD) surgery, five of endocyclophotocoagulation, and four of Trabectome (NeoMedix) surgery.

Patients either underwent GATT alone ($n = 26$) or in combination with cataract extraction and IOL implantation ($n = 9$). All patients had at least 6 months of follow-up after GATT, and primary outcomes included IOP, the number of glaucoma medications, and the surgical failure rate. Surgical failure was defined as a need for reoperation to control IOP, a postoperative IOP not lowered by at least 20% from preoperative levels by month 6, an IOP higher than 21 mm Hg after 6 months' follow-up, or an episode of IOP elevation that was refractory to medical management.

The mean preoperative IOP for all eyes was 25.7 mm Hg on 3.2 medications. At 18 months, 25 (71%) patients had follow-up data, and the mean IOP was 15.9 mm Hg on 2.3 medications ($P < .001$). By 24 months, 19 (54%) patients continued follow-up care, and there was a significant mean IOP decrease of 10.6 mm Hg, along with a reduction of 1.1 glaucoma medications.

Patients with prior GDD surgery appeared to do better than those with a history of trabeculectomy, although the results were not significant ($P = .17$). The prior GDD group had a mean IOP of 12.9 mm Hg on 2.1 medications by month 24, whereas the prior trabeculectomy group had a mean IOP of 16.7 mm Hg on 2.1 medications. The cumulative proportion of failure was 0.2 at 12 months and 0.36 at 18 months, and the cumulative proportion of reoperation was 0.2 at 12 months and 0.23 at 18 months. The failure rate was higher in patients who had undergone a trabeculectomy (37%) compared with GDD surgery (16%).

DISCUSSION

Is there an incremental response of IOP reduction with greater degrees of angle treatment?

This study suggests a larger decrease in IOP with circumferential angle treatment than prior segmental angle surgery.

Prior studies by Mosaed et al⁴ and Bussel et al⁵ have reported a mean decrease in IOP of between 7 and 8 mm Hg with a 0.8 decrease in medications 12 months after limited ab interno trabeculotomy (Trabectome) in patients with either prior trabeculectomy or GDD surgery. Grover and colleagues found a greater decrease in IOP at 12 months, with a statistically significant decrease in mean IOP of 9.4 mm Hg on 1.2 fewer medications by 12 months. These results are consistent with prior studies, which demonstrated a positive correlation between the amount of Schlemm canal treated and the IOP-lowering effect.

How may patient selection for GATT be improved?

Previous research has suggested that Schlemm canal decreases in size after successful filtration surgery, potentially from underperfusion of the meshwork and an accumulation of extracellular material, which increases outflow resistance.⁶ This study, however, suggests that the conventional outflow pathway may not be as collapsed as previously reported; Grover and colleagues described similar ease in cannulating the Schlemm canal of patients who had undergone incisional surgery as those without such a history.

In the future, an ability to assess the outflow pathway's functionality may assist surgeons with patient selection, further improving outcomes. Improving patient selection would be advantageous, as GATT is a conjunctiva-sparing, microinvasive glaucoma surgery that may save eyes from further, more invasive procedures. ■

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