What's New on the Tube?

Recent trends, updates, and controversy in aqueous shunt surgery.

BY HERBERT P. FECHTER, MD, PE

Recently, I was seeing a patient daily for a bleb leak and blebitis. Thankfully, the patient did well, but I was once again feeling discouraged about the serious long-term complications of trabeculectomy. Is this procedure the best surgical option for glaucoma? Should we surgeons be shifting our glaucoma treatment paradigm to include earlier and more frequent use of aqueous tube shunts? Which device should we use? This month's "Peer Review" column discusses recent research addressing the use of tube shunts in glaucoma. I hope that we can find some answers to these important questions.

—Barbara Smit, MD, PhD, section editor

Several recent studies are redefining glaucoma specialists' opinions on the role of aqueous shunt surgery in the spectrum of glaucoma management (Figure). This research reviews recent surgical trends, compares techniques and devices, quantifies tube-specific complications, and tries to resolve the controversy regarding when tube surgery is appropriate. Should tubes be reserved for only recalcitrant glaucoma, or can they be considered as a primary glaucoma procedure? How do tubes compare with standard trabeculectomy surgery and with each other? What are the long-term risks of an exposed tube, disturbances in motility, and corneal endothelial dysfunction? These articles provide important information for ophthalmologists to consider regarding the merits and weaknesses of aqueous shunt surgery when they are counseling patients on their surgical options.

TREND TOWARD TUBES

Trabeculectomy is still the most commonly performed incisional glaucoma procedure worldwide, but its popularity is declining in favor of aqueous shunts and other newer glaucoma surgeries. Concerns over bleb-related complications such as leaks, blebitis, hypotony, and endophthalmitis have encouraged many surgeons to seek alternate means of lowering IOP.

Initially, aqueous shunts were reserved for eyes with poor surgical prognoses with standard filtering procedures, even if wound-healing–modulation medications were used. Favorable clinical experience with aqueous shunts, however, has prompted their implantation in glaucomatous eyes with better surgical prognoses. Medicare data and surveys of glaucoma specialists document the trend toward surgeons' choosing aqueous shunts earlier and more frequently when treating moderate to advanced glaucoma.[1,2] A review of Medicare Current Procedural Terminology codes shows that the volume of trabeculectomy surgery decreased by 43%, whereas that for aqueous shunts increased by 184% between 1995 and 2004. The favorable results of studies comparing tubes to trabeculectomy surgery have further encouraged the use of aqueous shunts.

TUBE VERSUS TRABECULECTOMY STUDY: THREE-YEAR RESULTS

In 2006, a panel of glaucoma specialists reviewed the medical literature and noted that there was insufficient evidence to show that either trabeculectomy or aqueous shunts were clinically superior for the treatment of complex glaucoma.[3] In addition, the panel stated that there was inadequate evidence that any of the currently used shunting devices was clearly better than the rest.

The 3-year results from the prospective, randomized Tube Versus Trabeculectomy (TVT) Study, published in 2009, found similar IOP reductions associated with trabeculectomy using mitomycin C (MMC) and aqueous shunt surgery.[4] The tube patients achieved a mean IOP of 13 mm Hg compared with the trabeculectomy group at 13.3 mm Hg (P = .78). In fact, 62% of tube patients had an IOP of 14 mm Hg or less at the 3-year follow-up appointment.[5] Glaucoma medication usage was similar, with 1.3 medications in the tube group and 1 medication in the trabeculectomy group (P = .30). Postoperative complications occurred in 39% of the tube group compared with 60% of the trabeculectomy group, but there was no significant difference in the rate of serious complications (tube 22% vs trabeculectomy 27%). At 3 years, the cumulative probability of failure was 15.1% in the tube group compared to 30.7% in the trabeculectomy group. The differences between the TVT Study's results and

those of prior studies may be due to dissimilarities in study populations, surgical techniques, implant models, success and failure criteria, and retention during follow-up.

Despite the favorable results of tubes in the TVT Study, established practice is often difficult to change.[6] Some surgeons argue that not all trabeculectomies are created equal. They assert that the relatively high rate of complications after trabeculectomies in the TVT Study is not a universal experience and may be related to the relatively high dose of MMC used in the study (0.4 mg/mL for 4 minutes). Motility disturbances, tube erosion, and tube-related corneal decompensation are unique complications associated with tubes and may only become evident after longer-term follow-up.

Even with the shortcomings of tube shunts, the intermediate-term results of the TVT Study support the expanded use of tube shunts beyond refractory glaucomas. The study provides evidence that aqueous shunt surgery is an appropriate surgical option for patients who have undergone cataract surgery or in whom filtering surgery has failed.[7]

PRIMARY TUBE VERSUS TRABECULECTOMY STUDY

The favorable results of the TVT Study prompted the launch of another multicenter, randomized clinical trial in 2008. The Primary Tube Versus Trabeculectomy (PTVT) Study is designed to compare the long-term safety and efficacy of tube shunt surgery and trabeculectomy as a primary glaucoma surgical procedure.[8] The study enrolled patients with low-risk glaucomas such as primary open-angle glaucoma, pigmentary glaucoma, and pseudoexfoliation. None of the individuals had previously undergone incisional ocular surgery. These patients were randomized to the placement of a 350-mm^2 Baerveldt glaucoma implant (BGI; Abbott Medical Optics Inc.) or trabeculectomy with MMC (0.4 mg/mL for 2 minutes). The results of this study should provide clinicians with guidance on whether to use aqueous tube shunts as a primary glaucoma procedure.

THE AHMED VERSUS BAERVELDT COMPARISON

Researchers recently released the 1-year results of two separate studies comparing the efficacy and complications of model FP-7 of the Ahmed Glaucoma Valve (AGV; New World Medical Inc.) with model 101-350 of the BGI for the treatment of patients with refractory glaucoma. The Ahmed Baerveldt Comparison (ABC) study, involving 276 patients, found that the IOP reduction was greater with the BGI, but fewer early (AGV 43% vs BGI 58%) and serious (AGV 20% vs BGI 34%) complications were reported with the AGV.[9,10] The mean 1-year postoperative IOP of the AGV group was 15.4 mm Hg compared with 13.2 mm Hg in the BGI group (P = .007).

Figure. A well-positioned tube posterior to the Schwalbe line.

The Ahmed Versus Baerveldt (AVB) study, involving 238 patients, reported a 1-year postoperative IOP of 16.5 mm Hg in the AGV group compared with 13.6 mm Hg in the BGI group (P < .001).[11,12] The investigators also found a similar number of patients who experienced postoperative complications in the two groups (AGV 45% vs BGI 54%), but a greater number of interventions were required in the BGI group (AGV 26% vs BGI 42%). They concluded that the IOP reduction with these devices must be weighed against adverse events and that the study at 1 year does not demonstrate the clear superiority of one implant over the other.

The researchers in each study will observe patients for up to 5 years.

EXPOSURE OF AN AQUEOUS SHUNT

Tube exposure is often cited as a long-term complication of aqueous shunts. A 2010 meta-analysis of previously published articles evaluated the timing and incidence of conjunctival tube exposure reported for glaucoma drainage devices.[13] Researchers reviewed the results of 38 prior studies involving the AGV, BGI, and Molteno Implant (Molteno Ophthalmic Limited). A total of 3,105 patients and 3,255 eyes were evaluated for an average of 26 months. The overall incidence of tube exposure was 2.0%, with an average rate of exposure of 0.09% per month. The study suggests that the incidence of tube exposure does not differ between the three types of implants and can occur at any time within the first 5 years following implantation.

DISTURBANCES IN MOTILITY

Patients enrolled in the TVT Study underwent a formal motility examination during their initial screening for the study and at the 1-year follow-up visit.[14] The researchers conducted additional motility testing whenever a patient reported diplopia after the initial 3-month postoperative period. Interestingly, motility disturbances were detected in 28% of the TVT Study's patients at baseline. A new postoperative motility disturbance developed in 9.9% of

the tube patients and none of the trabeculectomy patients during the first year of follow-up. New-onset persistent diplopia was reported in 5% of the tube group and was associated with increasing age.

CHANGES IN CORNEAL ENDOTHELIAL CELLS

The health of corneal endothelial cells remains a major long-term concern for surgeons implanting aqueous tube shunts. A retrospective study of postkeratoplasty eyes that received an AGV suggested that the placement of a tube shunt may be a factor in graft failure.[15] In 2009, a prospective study evaluated the corneal thickness and endothelial cellular density in 41 patients who underwent AGV implantation for the treatment of refractory glaucoma.[16] The researchers obtained corneal specular microscopy measurements preoperatively and compared them to readings taken 1, 6, 12, 18, and 24 months after surgery as well as to results for the contralateral unoperated eye. The mean follow-up period was 19.1 months.

The average percentage decrease in corneal endothelial cell count at 24 months was 18.6% in the operated eye and just 4.2% in the control eye. The greatest decrease in cell count was found in the quadrant of the tube's insertion. The study revealed a statistically significant loss of corneal endothelial cells in the operated eye—a loss that increased with time. None of the study eyes experienced overt corneal edema or a loss of BCVA, but this may have changed with longer follow-up.

SEQUENTIAL GLAUCOMA IMPLANTS IN REFRACTORY GLAUCOMA

If the IOP remains too high after the placement of an aqueous shunt, further surgical options include a shunt revision, a cyclodestructive procedure, or the placement of a second drainage device. In 2010, a study assessed the effectiveness and complications of the sequential implantation of glaucoma drainage devices in 43 patients with refractory glaucoma.[17] The mean IOP dropped from 24.7 to 13.6 mm Hg with 32 months of follow-up. At least 75% of eyes maintained pressures below 17 mm Hg for 3 years after the placement of the second tube, with no occurrences of hypotony. The second tube reduced the IOP by an additional 44% from the preoperative level, while the mean number of medications dropped from 3.9 to 1.4. The BGI and the AGV appeared to be equally effective when used as a second drainage device.

CONCLUSION

Recent studies reflect the favorable results obtained with aqueous shunt surgery and help explain the trend away from trabeculectomy surgery. The mean postoperative IOP of eyes with the BGI was remarkably similar (13-13.6 mm Hg) in the TVT, ABC, and AVB studies. Tubes lower IOP as effectively as trabeculectomy, often with fewer complications and greater long-term survival. A head-to-head comparison between tubes revealed a lower mean IOP with the BGI when compared with the AGV. Both aqueous shunts had a similar safety profile but placed patients at risk of tube exposure, disturbed motility, and corneal endothelial failure. Many surgeons await the 5-year results of the TVT Study—as well as the initial results of the PTVT Study—to support their growing inclination to use aqueous shunts as a primary glaucoma surgery. This information should help ophthalmologists provide their patients with the safest and most effective IOP-lowering procedure. ❑

Section Editor Barbara Smit, MD, PhD, is a glaucoma consultant at the Spokane Eye Clinic and a clinical instructor at the University of Washington School of Medicine in Spokane, Washington. She acknowledged no financial interest in the products or companies mentioned herein. Dr. Smit may be reached at (509) 456-0107; bsmit@spokaneeye.com.

Herbert P. Fechter, MD, PE, is in private practice with Eye Physicians and Surgeons in Augusta, Georgia. He acknowledged no financial interest in the products or companies mentioned herein. Dr. Fechter may be reached at (706) 651-2020; fechter@pol.net.

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