

LANDMARK CLINICAL TRIAL FINDINGS TODAY: TVT



What are the current applications of the outcomes of the Tube Versus Trabeculectomy study?

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The Tube Versus Trabeculectomy (TVT) study was a multicenter, randomized clinical trial designed to compare the safety and efficacy of nonvalved tube shunt surgery to trabeculectomy with mitomycin C (MMC) in eyes with a history of cataract surgery and/or failed trabeculectomy.¹ Enrolled patients were between 18 and 85 years of age, they had previously undergone trabeculectomy and/or cataract extraction with IOL implantation, and they had uncontrolled glaucoma with IOPs ranging from 18 to 40 mm Hg on maximum tolerated medical therapy.

Patients in the TVT study were randomly assigned to receive a Baerveldt 350-mm² glaucoma implant (Johnson & Johnson Vision; n = 107) or to undergo trabeculectomy with the application of MMC 0.4 mg/mL for 4 minutes (n = 105). Surgical failure was defined as an IOP that was greater than 21 mm Hg or that was reduced by less than 20% below baseline, an IOP of 5 mm Hg or less, reoperation for glaucoma, or loss of light perception vision. After 5 years of follow-up, the TVT investigators found that tube shunt implantation had a higher rate of surgical success than trabeculectomy with MMC.

The TVT study also showed that it was more effective to implant a glaucoma drainage device to control IOP than to perform a trabeculectomy in patients

who had a history of intraocular surgery, especially trabeculectomy. Historically, the use of tube shunts had been relegated to the treatment of refractory glaucoma and patients at high risk of filtration surgery failure. However, in the past 2 decades, the rate of tube shunt surgery has increased, whereas the rate of trabeculectomy has decreased.²⁻⁴ The results of the TVT study support expanding the use of tube shunts beyond refractory glaucoma.

PTVT

After the TVT study, the Primary Tube Versus Trabeculectomy (PTVT) study was conducted to compare the safety and efficacy of trabeculectomy with MMC to that of tube shunt surgery when performed as an initial procedure in eyes without a history of incisional ocular surgery. The results of the PTVT study suggest that trabeculectomy is the more effective procedure but that tube shunt surgery has a more favorable safety profile.⁵ A greater IOP reduction was achieved with fewer medications in patients who were randomly assigned to trabeculectomy with MMC compared with patients assigned to tube shunt surgery. However, early postoperative complications and serious complications occurred more frequently after trabeculectomy than after tube shunt surgery, although the differences were not statistically significant.

FAILURE RATES

Failure rates among the TVT and PTVT study populations were recently reported in *Ophthalmology* and subdivided into tertiles based on preoperative IOP (< 21 mm Hg, 21–25 mm Hg, and > 25 mm Hg).⁶ In the TVT study, tube shunt surgery was associated with a lower rate of failure than trabeculectomy with MMC at all levels of preoperative IOP and especially when preoperative IOP was higher than 25 mm Hg. In the PTVT study, tube shunt surgery was associated with a lower rate of failure than trabeculectomy with MMC only when the preoperative IOP exceeded 25 mm Hg.

Based on these data, it can be concluded that patients with a history of cataract surgery and/or failed trabeculectomy benefitted most from tube shunt surgery when preoperative IOP was high. Surgically naïve patients benefitted the most from trabeculectomy with MMC when their preoperative IOP was low and from tube shunt surgery when preoperative IOP was higher than 25 mm Hg.

CURRENT APPLICATIONS

Glaucoma surgeons can consider how the results of the TVT and PTVT studies apply to their current patient populations and available treatment options. Ultimately, however, when choosing between trabeculectomy and tube shunt surgery for patients

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with medically uncontrolled glaucoma, the best option is typically the one with which the surgeon is most comfortable. Additionally, over time, glaucoma care has become increasingly tailored to the individual patient. It would be impossible to designate a particular procedure for all patients, given that surgical decision-making is influenced by many individual factors, including disease severity, prior eye surgery, age, phakia or pseudophakia, history of inflammation, drop tolerance, and ability to follow up. Although many glaucoma surgeons likely have an opinion on whether a tube shunt or trabeculectomy is the better choice, the most important point—and what the TVT and PTVT studies confirmed—is that both options work well.

CONCLUSION

Given the many new surgical options available for glaucoma, if the TVT study were to be repeated today,

it would almost certainly take MIGS into account. In this scenario, one potential modification would be to investigate whether the TVT study is applicable to eyes with a history of subconjunctival filtration surgery using devices such as the Xen Gel Stent (Allergan) and the Preserflo MicroShunt (Santen).

As MIGS procedures become more popular and prevalent, the need for head-to-head studies comparing these treatment options to traditional tube shunt and trabeculectomy surgeries increases. One such study, the Gold-Standard Pathway Study (GPS), is a multicenter, randomized, parallel-group, prospective, open-label clinical trial designed to evaluate the ability of the Xen Gel Stent to lower IOP and to reduce the number of topical IOP-lowering medications in patients whose glaucoma is poorly controlled on topical therapy. As more glaucoma procedures become available, further studies will be needed to determine

which approaches represent the safest and most effective means of treating glaucoma. ■

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