The Literature

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RANDOMIZED, PROSPECTIVE, COMPARATIVE TRIAL OF EX-PRESS GLAUCOMA FILTRATION DEVICE VERSUS TRABECULECTOMY (XVT STUDY)

Netland PA, Sarkisian SR Jr, Moster MR, et al[1]

ABSTRACT SUMMARY

The XVT study, conducted by Netland et al, was a randomized, prospective, comparative trial of the Ex-Press Glaucoma Filtration Device (Alcon) versus standard trabeculectomy, and it included 120 eyes of 120 subjects. In both groups, the patients were treated intraoperatively with mitomycin C and observed for 2 years. Surgical success was defined as an IOP between 5 and 18 mm Hg, with or without medication and without further glaucoma surgery.

At the 2-year follow-up visit, the success rate was 83% in the Ex-Press group and 79% in the trabeculectomy group ($P = .563$). The mean IOP was significantly reduced compared with baseline in both groups ($P < .001$), with an average IOP of 14.7 ±4.6 mm Hg and 14.6 ±7.1 mm Hg in the Ex-Press and trabeculectomy groups, respectively ($P = .927$). Visual acuity (logMAR) was significantly decreased on the first postoperative day in both groups, but it did not differ significantly compared with baseline at 1 month after Ex-Press implantation ($P = .285$) and 3 months after trabeculectomy ($P = .255$). The total number of postoperative complications was higher after trabeculectomy than after Ex-Press implantation ($P = .013$), although most of these complications were transient and self-limited. Serious complications were uncommon overall, with only one case of endophthalmitis in the trabeculectomy group.

DISCUSSION

What is the Ex-Press Glaucoma Filtration Device?

The Ex-Press is a biocompatible, stainless steel device that shunts fluid from the anterior chamber to the subconjunctival space in a manner similar to a standard trabeculectomy. It is nonvalved and compatible with magnetic resonance imaging. The device restricts flow and has a 50-µm (or 200-µm) lumen with an external diameter of 400 µm. Developed by Optonol, the Ex-Press was originally designed to be placed directly beneath the conjunctiva. Numerous complications, including erosions, extrusions of the implant, and endophthalmitis, were seen with this technique, and hence this method of implantation was abandoned.[2-9] Dahan and Carmichael modified the procedure and suggested placing the device beneath a partial-thickness scleral flap, dramatically decreasing complications.[10]

> "Patients undergoing glaucoma filtration surgery ... had fewer total complications and a quicker rate of visual recovery than those undergoing a standard trabeculectomy."

What are the advantages of using this device, and how well does it work?

The major proposed advantage of the Ex-Press is that it renders a guarded filtration procedure safer. Studies have shown a decreased incidence of hypotony, choroidal effusions, and postoperative complications with the use of this device.[1,4,11] Kanner et al investigated its efficacy for IOP reduction and reported a 94.8% success rate 3 years after implantation and a 95.6% success rate when the Ex-Press was combined with phacoemulsification.[4] A retrospective, comparative study by Maris et al compared the Ex-Press shunt to standard trabeculectomy. Although follow-up was limited, a similar IOP-lowering effect and success rate were noted between the two groups after 3 months of observation.[11]

Additional theoretical advantages of the Ex-Press include a decreased incidence of shallow anterior chambers compared to standard trabeculectomy and more uniform filtration control due to the flow-restricting property of the device. The limited nature of available data regarding the increased safety and efficacy of the Ex-Press over standard techniques makes an accurate cost-benefit analysis of the device difficult.

The XVT study provides information about the

efficacy and safety of the device. The investigators found that patients undergoing glaucoma filtration surgery with the Ex-Press had fewer total complications and a quicker rate of visual recovery compared to those undergoing a standard trabeculectomy. A large number of the complications in the trabeculectomy group were hyphema and shallow chamber/choroidal effusions, which resolved with conservative management. Serious, vision-threatening complications were uncommon in both treatment groups. Both procedures produced a significant and sustained reduction in IOP and had similar rates of success.

There is no specific unique indication for the Ex-Press. It can be used for any case in which a trabeculectomy is being performed, as long as the surgeon is comfortable with the device.

GONIOSCOPY-ASSISTED TRANSLUMINAL TRABECULOTOMY, A NOVEL AB INTERNO TRABECULOTOMY

Grover DS, Godfrey DG, Smith O, et al[12]

ABSTRACT SUMMARY

Grover et al reported on a retrospective chart review of 85 patients (age range, 24-88 years) who underwent gonioscopy-assisted transluminal trabeculotomy (GATT), a novel technique for performing a conjunctival-sparing trabeculotomy. Patients were observed for at least 6 months postoperatively. Main outcome measures included IOP, number of glaucoma medications, visual acuity, and complications that occurred either intraoperatively or postoperatively. The majority of patients (71%) included had primary open-angle glaucoma (POAG). Subjects were divided into five subgroups: POAG receiving GATT alone (n = 25), POAG with a history of cataract extraction with IOL implantation (CE/IOL) receiving GATT alone (n = 16), POAG receiving GATT combined with CE/IOL (n = 16), other form of glaucoma receiving GATT alone (n = 17), and other form of glaucoma receiving GATT combined with CE/IOL (n = 11).

Six months postoperatively, patients with POAG exhibited a mean decrease in IOP of 7.7 mm Hg (standard deviation [SD], 6.2 mm Hg), with a reduction in glaucoma medications by 0.9 (SD, 1.3). There was no statistically significant difference in the mean reduction in IOP between the three POAG patient groups. Lens status and concurrent cataract surgery did not have a significant effect on IOP among eyes undergoing GATT. The two groups of patients with other forms of glaucoma demonstrated a statistically significant mean decrease in IOP of 17.2 mm Hg (SD, 10.8 mm Hg), with a correspondingly significant mean decrease in glaucoma medications of 2.2 (SD, 1.5) 6 months postoperatively. For all groups, the 12-month data showed similar results, but there was a large drop-off in the number of follow-up patients after the 6-month visit.

> "Being able to comfortably perform intraoperative gonioscopy is the first challenge to completing an ab interno trabeculotomy."

DISCUSSION

Who are suitable candidates for GATT?

Indications for trabeculotomy have expanded over recent years, likely due to improvements in surgical technique and a low risk profile associated with the procedure. The major advance in surgical technique came with the advent of an illuminated microcatheter (Ellex iScience), which aids in the safe cannulation of Schlemm canal. Trabeculotomy can be performed in patients with various types of glaucoma, but there are a few specific instances in which it is contraindicated. Because hyphema is the most common complication, this surgery is not ideal for patients on anticoagulants (which cannot be stopped) or patients with any other bleeding disorder. The investigators also noted that patients with significant peripheral anterior synechiae, an unstable IOL, or severe endothelial compromise are not good candidates for this surgery.[12] Because there are insufficient long-term data, and because the mean IOP at 1 year was in the midteens for many of the individuals evaluated, GATT may not be well suited to patients with severe disease who require a very low IOP. More optimal candidates may be patients with mild to moderate open-angle glaucoma in whom there is a clear view of the trabecular meshwork on gonioscopy.

What are the challenges associated with this procedure?

There is a learning curve for the early adopter. Being able to comfortably perform direct intraoperative gonioscopy is the first challenge to completing an ab interno trabeculotomy. The surgeon must also be comfortable performing a small (1- to 2-mm) goniotomy and inserting the catheter into Schlemm canal. Full treatment requires 360° threading of the canal, which is not always easily accomplished. The catheter can

become kinked, or abnormalities of the canal can prevent smooth passage. The surgeon must adapt to these situations and adjust his or her technique (ie, reverse direction). Although an ab interno approach is ideal because it truly is a conjunctiva-sparing procedure, some elements of the surgery can prove challenging at first. Starting with an ab externo approach may allow surgeons new to the procedure to become comfortable with trabeculotomy and using the microcatheter. We recommend the surgeon sits temporally to spare the superior conjunctiva and still allow for future filtration or tube shunt surgery. ■

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