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Postoperative Complications in the Primary Tube Versus Trabeculectomy (PTVT) Study During 5 Years of Follow-up

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Abstract

Purpose: To describe postoperative complications encountered in the Primary Tube Versus Trabeculectomy (PTVT) Study during 5 years of follow-up.

Design: Multicenter randomized clinical trial.

Participants: 242 eyes of 242 patients with medically uncontrolled glaucoma and no previous incisional ocular surgery, including 125 patients in the tube group and 117 patients in the trabeculectomy group.

Methods: Patients were enrolled at 16 Clinical Centers and randomly assigned to treatment with a tube shunt (350-mm^2 Baerveldt glaucoma implant) or trabeculectomy with mitomycin C (MMC, 0.4 mg/ml for 2 minutes).

Main Outcome Measures: Surgical complications, reoperations for complications, visual acuity, and cataract progression.

Results: Early postoperative complications occurred in 24 patients (19%) in the tube group and 40 patients (34%) in the trabeculectomy group ($P = 0.013$). Late postoperative complications developed in 27 patients (22%) in the tube group and 32 patients (27%) in the trabeculectomy group ($P = 0.37$). Serious complications producing vision loss and/or requiring a reoperation were observed in 3 patients (2%) in the tube group and 9 patients (8%) in the trabeculectomy group ($P =$

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0.11). Cataract progression was seen in 65 patients (52%) in the tube group and 52 patients (44%) in the trabeculectomy group ($P = 0.30$). Surgical complications were not associated with a higher rate of treatment failure ($P = 0.61$), vision loss ($P = 1.00$), or cataract progression ($P = 0.77$)

Conclusions: A large number of surgical complications were observed in the PTVT Study, but most were transient and self-limited. The incidence of early postoperative complications was higher following trabeculectomy with MMC than tube shunt surgery. The rates of late postoperative complications, serious complications, and cataract progression were similar with both surgical procedures after 5 years of follow-up. Surgical complications did not increase the risk of treatment failure, vision loss, or cataract progression.

PRECIS

Early complications occurred more frequently after trabeculectomy with mitomycin C than tube shunt implantation in the PTVT Study. However, the rates of late complications, reoperations for complications, and cataract extraction were similar with both procedures.

The Primary Tube Versus Trabeculectomy (PTVT) Study is a multicenter randomized clinical trial comparing the safety and efficacy of tube shunt surgery and trabeculectomy with mitomycin C (MMC) in eyes without prior ocular surgery. Our companion article reviews the outcomes of treatment in the PTVT Study during 5 years of follow-up.[1] Trabeculectomy with MMC and tube shunt surgery produced similar intraocular pressure (IOP) reduction, but fewer glaucoma medications were required after trabeculectomy. No significant difference was observed in the rate of failure between the two procedures at 5 years. Vision loss occurred with similar frequency following tube shunt implantation and trabeculectomy with MMC.

The benefit of any glaucoma procedure in reducing IOP must be interpreted in the context of adverse events. A comparison of tube shunt implantation and trabeculectomy with MMC requires not only an assessment of efficacy, but also an evaluation of the incidence and severity of associated complications. Both procedures have their own set of complications that may occur in the early or late postoperative periods. This article describes the postoperative complications encountered during 5 years of follow-up in the PTVT Study and the management of these complications.

METHODS

The study protocol was described in detail in a previous publication.[2] The Institutional Review Board at each Clinical Center approved the study before recruitment was initiated (see Appendix for a list of Clinical Centers and Committees in the PTVT Study, available at www.aaojournal.org). Written informed consent was obtained from all subjects for both treatment and participation in the research. The study adhered to the Declaration of Helsinki and the Health Insurance Portability and Accountability Act. This study was registered at http://www.clinicaltrials.gov (NCT00666237).

Study Design

In summary, patients 18 to 85 years of age who had not undergone previous incisional ocular surgery with IOP ≥ 18 mmHg and ≤ 40 mmHg on tolerated medical therapy were eligible for the study. One eye of enrolled patients was randomized to placement of a 350-mm^2 Baerveldt glaucoma implant (Johnson & Johnson Vision, Santa Ana, CA) or trabeculectomy with MMC (0.4 mg/ml for 2 minutes). Baseline demographic and clinical information were collected for each patient. Follow-up visits were scheduled 1 day, 1 week, 1 month, 3 months, 6 months, 1 year, 18 months, 2 years, 3 years, 4 years, and 5 years after surgery. Each examination included measurement of Snellen visual acuity (VA), IOP, slit-lamp biomicroscopy, and Seidel testing. Early Treatment Diabetic Retinopathy Study (ETDRS) VA was tested at baseline and at the 1-year, 3-year, and 5-year follow-up visits. A dilated fundus examination was performed at baseline and at the 1-week, 1-month, 3-month, and annual follow-up visits. The fundus was also examined at other follow-up visits in the presence of shallowing of the anterior chamber, IOP ≤ 5 mmHg, or unexplained vision loss. Investigators provided a reason for loss of 2 or more lines of Snellen VA from baseline at follow-up visits after 3 months. Failure was defined as IOP > 21 mmHg or reduced < 20% below baseline on 2 consecutive follow-up visits after 3 months, IOP ≤ 5 mmHg on 2 consecutive follow-up visits after 3 months, additional glaucoma surgery, or loss of light perception vision. Complications that developed after additional surgery for glaucoma, complications, or cataract were censored from analysis because it could not be determined whether the new complication was related to the reoperation or original randomized surgery. The study was monitored by an independent Safety and Data Monitoring Committee.

Investigators in the PTVT Study recorded postoperative interventions and complications on standardized forms at each follow-up visit. The data forms listed several complications with designation as present or absent, and blank spaces were also included for recording complications that did not appear on the list. Investigators were asked to report any complications that were present at the scheduled follow-up visit or between study visits. The definition of a complication was not standardized. Early postoperative complications were defined as surgical complications occurring within 1 month following randomized surgical treatment, and late postoperative complications were complications developing after 1 month postoperatively. Surgical complications that developed during the first postoperative month and persisted with longer follow-up were counted only as early postoperative complications. The date and type of surgical treatment for any complications were recorded. Reoperation for a complication was defined as additional surgery requiring a return to the operating room to manage a surgical complication, such as a penetrating keratoplasty or bleb revision. Interventions performed at the slit lamp, such as bleb needling for an encapsulated bleb or reformation of a shallow anterior chamber, were not considered reoperations. Persistent diplopia, persistent corneal edema, and dysesthesia were defined as the postoperative development of these complications and their presence at the 6-month follow-up visit or thereafter. Eyes that were Seidel positive within the first month after surgery were classified as wound leaks, and those that were Seidel positive after 1 month were categorized as bleb leaks. Serious complications were defined as surgical complications that produced loss of 2 or more lines of Snellen VA and/or required reoperation to manage the complication. Cataracts were considered to have progressed if

there was loss of 2 or more Snellen lines attributed to cataract at the 6-month follow-up visit or thereafter, or if cataract surgery was performed.

Statistical Analysis

Univariate comparisons between treatment groups were made using the two-sided Student t-test, chi-square test, or Fisher's exact test. The associations of surgical complications with treatment outcome, vision loss, and cataract progression were assessed for statistical significance with the chi-square test or Fisher's exact test. Armitage's test of trend in proportions was used to assess the relationship between number of complications and these variables. A *P*-value less than 0.05 was considered statistically significant.

RESULTS

Recruitment and Surgical Treatment

A total of 242 eyes of 242 patients were enrolled in the PTVT Study, including 125 patients in the tube group and 117 patients in the trabeculectomy group. One patient who was randomized to the trabeculectomy group had laser-assisted in-situ keratomileusis in the study eye and should have been excluded because of previous incisional ocular surgery. Two patients were randomized to the trabeculectomy group but underwent placement of a tube shunt because of surgeon error. All patients were analyzed according to the treatment group to which they were assigned by randomization in an intent-to-treat analysis. None of the 3 patients who violated the study protocol had surgical complications, treatment failure, or additional ocular surgery. Operative data for the tube group and the trabeculectomy group are presented in Tables 1 and 2, respectively (available at www.aaojournal.org).

Postoperative Interventions

Postoperative interventions are listed in Table 3. Most interventions occurred in the early postoperative period and were previously reported.[3] A total of 108 interventions were undertaken in 77 patients (62%) in the tube group, and 126 interventions were performed in 77 patients (66%) in the trabeculectomy group ($P = 0.58$, chi-square test). Rip cord removal and laser suture lysis were the most common interventions in the tube group and the trabeculectomy group, respectively.

Early Postoperative Complications

Early postoperative complications developing within the first month after surgery are shown in Table 4. A total of 35 early postoperative complications were reported in 24 patients (19%) in the tube group, and 55 complications were noted in 40 patients (34%) in the trabeculectomy group ($P = 0.013$, chi-square test). Anterior chamber shallowing and choroidal effusions were the most common early postoperative complications. Among the 24 patients with a shallow or flat anterior chamber, 12 patients had associated choroidal effusions, 2 patients had wound leaks, and 1 patient had aqueous misdirection. There were 46 patients who experienced only 1 early postoperative complication. Several patients developed multiple early postoperative complications, including 11 patients with 2 complications, 6 patients with 3 complications, and 1 patient with 4 complications. Wound leak ($P = 0.002$, chi-square test) and encapsulated bleb ($P = 0.009$, chi-square

test) were early postoperative complications that were significantly more common in the trabeculectomy group compared with the tube group. No early postoperative complications occurred with significantly greater frequency in the tube group than the trabeculectomy group.

Late Postoperative Complications

Late postoperative complications occurring more than 1 month after surgery are provided in Table 5. A total of 31 late postoperative complications were seen in 27 patients (22%) in the tube group, and 36 complications were observed in 32 patients (27%) in the trabeculectomy group ($P = 0.37$, chi-square test). Encapsulated bleb was the most frequent late postoperative complication in both treatment groups. A single late postoperative complication developed in 51 patients, and 8 patients had 2 late complications. No late complications occurred with significantly higher frequency in either treatment group.

Several patients in each treatment group developed both early and late postoperative complications. During 5 years of follow-up, 66 complications were noted in 42 patients (34%) in the tube group and 91 complications were seen in 58 patients (50%) in the trabeculectomy group ($P = 0.017$, chi-square test). There were 61 patients who had 1 postoperative complication. Other patients experienced multiple postoperative complications, including 27 patients with 2 complications, 8 patients with 3 complications, 3 patients with 4 complications, and 1 patient with 6 complications.

Reoperation for Complications

Reoperations for complications are presented in Table 6. The 5-year cumulative reoperation rate for complications from Kaplan-Meier survival analysis was 3% in the tube group and 8% in the trabeculectomy group ($P = 0.059$, log-rank test adjusted for stratum). A total of 3 patients (2%) in the tube group and 9 patients (8%) in the trabeculectomy group underwent additional surgery to manage postoperative complications. Five patients in the trabeculectomy group underwent bleb revisions (i.e., surgical modification of the conjunctiva in the area of the filtering bleb), including 1 patient for anterior migration of the bleb with irregular astigmatism and 4 patients for wound leaks that failed to resolve with a bandage contact lens (2 patients) or suturing at the slit-lamp (2 patients). Trabeculectomy revision (i.e., bleb revision with surgical modification of the scleral flap) was performed in 3 patients for hypotony maculopathy, and concurrent phacoemulsification cataract extraction was performed in one of these patients. An additional patient underwent a trabeculectomy revision and anterior chamber washout for an 8-ball hyphema. Among patients with hypotony maculopathy, 1 patient had a second trabeculectomy revision for persistent hypotony and another patient subsequently had a penetrating keratoplasty in combination with phacoemulsification for persistent corneal edema and cataract. A conjunctival cyst was excised in 1 patient in the tube group, and 1 patient underwent tube revision or retraction of the tube from the anterior chamber. One patient in the tube group underwent removal of the tube shunt for exposure of the end plate. Phacoemulsification cataract extraction and endoscopic cyclophotocoagulation were performed at the time of shunt removal, and the patient was classified as a failure because of additional glaucoma surgery.

Serious Complications

Table 7 shows serious complications resulting in reoperation and/or vision loss. Serious complications were observed in 3 patients (2%) in the tube group and 9 patients (8%) in the trabeculectomy group ($P = 0.11$, chi-square test). Reoperations for complications were performed in 3 patients in the tube group and 9 patients in the trabeculectomy group. One patient in the trabeculectomy group had 2 reoperations for complications, including a trabeculectomy revision for hypotony maculopathy and a penetrating keratoplasty for persistent corneal edema. In the trabeculectomy group, loss of 2 or more Snellen lines developed because of hypotony maculopathy in 2 patients. This vision loss persisted despite trabeculectomy revision in both patients.

Vision Loss Associated with Postoperative Complications

Table 8 shows VA results in patients with and without postoperative complications. During 5 years of follow-up, Snellen VA (logMAR mean ± SD) decreased 0.20 ± 0.50 units ($P = 0.001$, paired t-test) and ETDRS VA (mean ± SD) was reduced 8 ± 21 units ($P = 0.007$, paired t-test) from baseline in patients who experienced postoperative complications. Snellen VA (logMAR mean ± SD) decreased 0.17 ± 0.41 units ($P < 0.001$, paired t-test) and ETDRS VA (mean ± SD) declined 9 ± 18 letters ($P < 0.001$, paired t-test) from baseline to 5 years in patients who did not develop postoperative complications. No significant difference in Snellen VA ($P = 0.56$, Student t-test) or ETDRS VA ($P = 0.16$, Student t-test) was seen between patients with and without complications at 5 years. The changes in Snellen VA ($P = 0.64$, Student t-test) and ETDRS VA ($P = 0.81$, Student t-test) from baseline were also similar between patients with and without complications who completed 5 years of follow-up. Loss of 2 or more Snellen lines from baseline occurred in 24 patients (31%) with complications and 36 patients (32%) without complications among patients who completed 5-year visits and/or had vision loss at last follow-up ($P = 1.00$, chi-square test). The relationship between postoperative complications and vision loss was further explored in Table 9. The presence of any postoperative complication ($P = 1.00$, chi-square test) and the number of postoperative complications ($P = 0.54$, Armitage exact test of trend in proportions) were not significantly associated with loss of 2 or more Snellen lines.

Cataract Progression

The 5-year cumulative rate of cataract extraction using Kaplan-Meier survival analysis was 56% in the tube group and 42% in the trabeculectomy group ($P = 0.21$, log-rank test adjusted for stratum). Cataract surgery was performed in 57 patients (46%) in the tube group and 44 patients (38%) in the trabeculectomy group. An additional 8 patients in each treatment group experienced loss of 2 or more lines of Snellen VA that was attributed to cataract. Cataract progression occurred in 65 patients (52%) in the tube group and 52 patients (44%) in the trabeculectomy group ($P = 0.30$, chi-square test). The risk of cataract progression relative to postoperative complications was assessed in Table 9. Cataract progression was not significantly associated with the presence of any postoperative complication ($P = 0.77$, chi-square test) or the number of postoperative complications ($P = 0.89$, Armitage exact test of trend in proportions).

Effect of Postoperative Complications on Treatment Outcome

The association of postoperative complications with treatment outcome was evaluated in Table 9. Treatment failures were pooled from the tube and trabeculectomy groups for this analysis. The presence of any postoperative complication ($P = 0.61$, chi-square test) and the number of complications ($P = 0.25$, Armitage exact test of trend in proportions) were not significantly associated with failure during 5 years of follow-up.

DISCUSSION

The PTVT Study is a multicenter randomized clinical trial comparing the safety and efficacy of tube shunt surgery and trabeculectomy with MMC in patients without previous incisional ocular surgery. The rates of early postoperative complications and overall complications during 5 years of follow-up were significantly higher in the trabeculectomy group than the tube group. Late postoperative complications and reoperations for complications occurred with similar frequency with both surgical procedures after 5 years. All surgical complications are not equal in severity. We defined serious complications as postoperative complications that produced loss of 2 or more lines of Snellen VA and/or required reoperation to manage the complication, as was done in the Tube Versus Trabeculectomy (TVT) Study[4] and Ahmed Baerveldt Comparison (ABC) Study.[5] No significant difference in the incidence of serious complications was seen after tube shunt surgery and trabeculectomy with MMC.

The rates of postoperative complications in the PTVT Study were similar to those of other multicenter randomized clinical trials involving trabeculectomy and tube shunt surgery,[4–10] as shown in Tables 10 and 11. The frequency of early postoperative complications within 1 month after trabeculectomy was 34% in the PTVT Study, 37% in TVT Study,[4] and 50% in the Collaborative Initial Glaucoma Treatment Study (CIGTS).[7] During the 5 years of follow-up, the incidence of late postoperative complications developing more than 1 month after trabeculectomy was 27% in the PTVT Study and 36% in the TVT Study.[4] The overall rate of postoperative complications after trabeculectomy was 50% at 5 years in the PTVT Study, 63% at 5 years in the TVT Study,[4] and 53.6% among patients with at least 3 months of follow-up in the Advanced Glaucoma Intervention Study (AGIS).[8] The frequency of early complications within 1 month after Baerveldt implantation was 19% in the PTVT Study and 21% in the TVT Study.[4] During 5 years of follow-up, the incidence of postoperative complications occurring more than 1 month after placement of a Baerveldt glaucoma implant was 22% in the PTVT Study and 34% in the TVT Study.[4] The overall rate of postoperative complications during 5 years of follow-up after Baerveldt implantation was 34% in the PTVT Study, 43% in the TVT Study,[4] and 69% in the AVB Study.[6] The rates of specific postoperative complications were also frequently similar across these clinical trials, despite differences in study populations and length of follow-up.[4–10] Many of the surgical complications observed in each of the clinical trials were transient and self-limited, such as choroidal effusions and anterior chamber shallowing. It is not unusual for prospective studies to generally report higher complication rates than retrospective case series. Surgical complications may be overlooked unless attention is specifically directed

toward their detection. Additionally, complications may not be documented in the medical record even when observed, especially if they are deemed to be insignificant.

The incidences of most postoperative complications in the PTVT Study were similar between treatment groups. Anterior chamber shallowing and choroidal effusions were common early postoperative complications in both the tube and trabeculectomy groups. Wound leak and encapsulated bleb were the only early complications that developed with significantly higher frequency in the trabeculectomy group compared with the tube group. Non-valved tube shunt surgery produces delayed drainage of aqueous humor to the equatorial region of the eye, but trabeculectomy results in immediate filtration of aqueous near the conjunctival incision with a greater tendency toward wound leaks in the early postoperative period. As noted in Table 11, the rate of wound leaks was higher in the PTVT Study than in CIGTS[7] or AGIS.[8] However, the Fluorouracil Filtering Surgery Study (FFSS) and TVT Study may be more appropriate clinical trials for comparison with the PTVT Study. Both studies employed the same protocol of Seidel testing at each follow-up visit,[2,9] and this method for meticulously detecting wound leaks was not used in CIGTS or AGIS. The rate of early postoperative wound leaks was 11% in the PTVT Study, 11% in the TVT Study,[4] 20% in the standard treatment group in FFSS, and 32% in the 5-fluorouracil group in FFSS.[9]

All late postoperative complications occurred with similar frequency in both treatment groups. Bleb encapsulation was the most common late postoperative complication in the tube and trabeculectomy groups. No devastating complications such as endophthalmitis or suprachoroidal hemorrhage developed during 5 years of follow-up in the PTVT Study. Although many of the differences in complication rates were not statistically different, they may be clinically relevant. For example, the occurrence of hypotony maculopathy in 3 patients in the trabeculectomy group and no patients in the tube group is not statistically significant but raises concern about a higher risk of this complication with trabeculectomy with MMC. The power of this study to detect differences in complications with low incidence rates was limited by the sample size.

It is noteworthy that the incidence of diplopia and persistent corneal edema were similar after tube shunt implantation and trabeculectomy with MMC. A cross-sectional study using a standardized questionnaire found that diplopia was more common after tube shunt surgery than trabeculectomy.[11] Restrictive strabismus after tube shunt surgery may develop because of muscle scarring or a mass effect from a large bleb.[12-15] The TVT and PTVT Studies prospectively evaluated the incidence of diplopia by asking patients about double vision preoperatively and postoperatively. The rate of new-onset diplopia in the TVT Study during 5 years of follow-up was 6% in the tube group and 2% in the trabeculectomy group.[4] The proportion of patients with diplopia in the PTVT Study was 4% in the tube group and 3% in the trabeculectomy group at 5 years. Persistent corneal edema secondary to corneal endothelial cell loss has been described after tube shunt implantation[16-22] and trabeculectomy with an adjunctive antifibrotic,[23-29] but this complication appears to be more common after tube shunt surgery. Corneal decompensation after tube shunt placement may be caused by intermittent tube-cornea touch with blinking or eye rubbing, fluid turbulence at the tube tip, or immunological factors.[21] Persistent corneal edema was the most common

late postoperative complication in the TVT Study occurring in 16% of patients in the tube group and 9% of patients in the trabeculectomy group. Even though almost twice as many patients in the tube group developed corneal edema relative to the trabeculectomy group in the TVT Study, the rates of persistent corneal edema and corneal transplantation were not statistically different between the two treatment groups. In the PTVT Study, 3% of patients in the trabeculectomy group and no patients in the tube group had persistent corneal edema at 5 years. A retrospective case-control study identified older age, history of Fuchs dystrophy or iridocorneal endothelial syndrome, postoperative complications, and greater number of prior glaucoma surgeries as risk factors for corneal decompensation after tube shunt surgery.[30] Patients in the TVT Study were approximately a decade older at enrollment than the PTVT Study, and the presence or absence of previous ocular surgery further distinguishes the two clinical trials. These differences may explain the lower incidence of corneal decompensation in the PTVT Study compared with the TVT Study.

A reduction in VA occurred in both the tube and trabeculectomy groups, but Snellen and ETDRS VA were similar between treatment groups at 5 years.[1] No significant difference in the rate of vision loss was observed between patients who did and did not experience postoperative complications. The development of any postoperative complications and the number of complications did not increase the risk of vision loss. The absence of a correlation between postoperative complications and vision loss was also seen in the TVT Study.[4]

All patients in the PTVT Study were phakic at enrollment. Cataracts were considered to have progressed if loss of 2 or more lines of Snellen VA was attributed to cataract, or if cataract surgery was performed. We did not use standardized methods for grading lens opacification, such as the Lens Opacities Classification System II[31] or the Wisconsin System.[32] Cataract progression was noted in approximately half of the patients during 5 years of follow-up in the PTVT Study, but occurred at a similar rate in the tube and trabeculectomy groups. No significant difference in the rate of cataract surgery was observed between treatment groups. Several studies have reported that glaucoma surgery is associated with a higher incidence and progression of cataract.[4-6,33-41] In AGIS, the risk of cataract formation was greater when there was at least one surgical complication, particularly marked inflammation and flat anterior chamber.[40] The presence of any postoperative complication and the number of complications were not associated with cataract progression during 5 years of follow-up in the TVT Study,[4] and these findings align with those from the PTVT Study.

Conflicting information exists about the effect of surgical complications on final treatment outcome. The presence of any postoperative complication doubled the risk of failure of trabeculectomy in AGIS.[8] However, other studies have found no significant effect of postoperative complications on trabeculectomy failure.[4,34,42] The TVT Study noted that the occurrence of any postoperative complication and the number of complications did not increase the risk of failure.[4] The PTVT Study similarly observed a lack of effect of postoperative complications on treatment outcome.

Stein et al investigated the rates of postoperative complications after glaucoma surgery among Medicare beneficiaries.[43] The rates of adverse outcomes were higher after tube shunt surgery than primary trabeculectomy or trabeculectomy with scarring. The difference in study results between the PTVT Study and Stein's study likely relates to differences in study populations and design. Data derived from Medicare claims must be interpreted cautiously because information about laterality may be missing and adverse events misattributed to the fellow eye.[43,44] Tube shunts have historically been reserved for patients who are considered to be at high risk for failure of trabeculectomy with an adjunctive antifibrotic agent, and results from the study by Stein et al may be related to differences in case severity among the glaucoma procedures that were compared. In contrast, patients who underwent tube shunt surgery and trabeculectomy with MMC in the PTVT Study had similar characteristics as a result of the randomization process, and included lower risk patients than have traditionally undergone tube shunt surgery.

Several aspects of each surgical procedure under investigation were standardized. A 350-mm^2 Baerveldt glaucoma implant was placed in the superotemporal quadrant in all patients randomized to the tube group. This implant offers a larger surface area with ease of insertion in a single quadrant, and greater IOP reduction has been observed with tube shunts with larger end plates.[6,45,46] The dosage of MMC was standardized at 0.4 mg/ml for 2 minutes in all patients in the trabeculectomy group. This was the most common dosage used by glaucoma surgeons in primary trabeculectomy in recent surveys of the American Glaucoma Society membership.[47,48] Other elements of both operations were left to the surgeon's discretion in keeping with his or her usual practice. Limbus-based and fornix-based conjunctival flaps were allowed for both trabeculectomy and tube shunt surgery. Most surgeons used a fornix-based flap when performing both procedures. A trend toward use of fornix-based flaps with diffuse MMC application in trabeculectomy has emerged in recent years.[49] This modification in surgical technique may result in lower rates of bleb-related complications, such as leaks and infection.[50] Approximately half of patients in the tube group underwent tube fenestration at the time of shunt placement, and this technique has been shown to be effective in providing early IOP reduction.[51,52]

Postoperative interventions were undertaken with similar frequency in both treatment groups. Most interventions were performed in the early postoperative period and have been previously reported.[3] Rip-cord removal and laser suture lysis were the most common interventions in the tube and trabeculectomy groups, respectively. The Baerveldt glaucoma implant is a type of non-valved tube shunt that requires temporary restriction of flow through the device until encapsulation of the end plate occurs, which is necessary to avoid hypotony in the early postoperative period. Use of an intra-luminal rip cord was the most common method for tube occlusion in the PTVT Study. Trabeculectomy is the only glaucoma procedure that allows titration of the IOP-lowering effect after surgery. Patients respond differently to glaucoma surgery, so the ability to selectively increase filtration postoperatively is a valuable feature of trabeculectomy.

This study has several limitations. There were no standard definitions or quantification of surgical complications. For example, a choroidal effusion could have represented a small, peripheral choroidal elevation or large amount of fluid in the suprachoroidal space with

central apposition. Even though the presence of postoperative complications were recorded at study and nonstudy visits, it is possible that some complications may have developed and resolved between follow-up visits resulting in an underestimation of the true incidence of postoperative complications. Patients were censored from analysis of complications after a reoperation, and this may have also produced an underestimation of complication rates. The large number of significance tests that were performed increases the probability of finding statistically significant results by chance alone. The PTVT Study was powered to detect a significant difference in failure rates between treatment groups, and complication rates were a secondary outcome measure. The study was not powered to detect significant differences in complications with a low rate of occurrence. The PTVT Study enrolled patients who met specific inclusion and exclusion criteria, and all patients randomized to the tube group received a 350-mm^2 Baerveldt glaucoma implant. The study results cannot be generalized to other patient groups or different implant types. A standard dosage of MMC was used in all trabeculectomy cases based on results from a survey of the American Glaucoma Society membership,[47] but it is unclear whether a different dosage may have altered the rate of postoperative complications or filtration failure due to fibrosis or hypotony. Many aspects of both surgical procedures were standardized, but some variation in surgical technique occurred between investigators. The patients and investigators were not masked to the randomized treatment assignment, and this is a potential source of bias.

In summary, surgical complications were common in the PTVT Study, but most were transient and self-limited. Early postoperative complications occurred more frequently after trabeculectomy with MMC than tube shunt implantation. However, the rates of late postoperative complications, serious complications, and cataract progression were similar with both surgical procedures after 5 years of follow-up. Surgical complications did not increase the risk of treatment failure, vision loss, or cataract progression.

Several minimally invasive glaucoma procedures have been introduced in recent years. Lower rates of surgical complications have been reported with these procedures compared with traditional glaucoma surgery, but they are generally less effective in decreasing IOP.[53] With the expansion of surgical options for managing glaucoma, selecting the most appropriate glaucoma operation involves balancing the risk of complications and the benefit of IOP reduction for an individual patient. Comparative studies like the PTVT Study are required to fully assess the relative efficacy and safety of the various glaucoma procedures available to surgeons. Long-term follow-up data are needed, as the cumulative risk of failure and many surgical complications increase over time.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Abbreviations/acronyms:

AGIS	Advanced Glaucoma Intervention Study
ABC	Ahmed Baerveldt Comparison
CIGTS	Collaborative Initial Glaucoma Treatment Study
ETDRS	Early Treatment Diabetic Retinopathy Study
FFSS	Fluorouracil Filtering Surgery Study
IOP	intraocular pressure
MIGS	minimally invasive glaucoma surgery
MMC	mitomycin C
PTVT	Primary Tube Versus Trabeculectomy
TVT	Tube Versus Trabeculectomy
VA	visual acuity

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Table 1.

Operative Data for the Tube Group in the PTVT Study

Conjunctival flap	
Fornix-based	110 (88)
Limbus-based	15 (12)
Method of tube occlusion	
Intraluminal rip-cord suture	84 (67)
External polyglactin ligature	41 (33)
Fenestrations	59 (47)
1	17 (29)
2	12 (20)
3	24 (41)
4	1 (2)
Number not provided	5 (8)
Patch graft	
Pericardium	61 (49)
Sclera	38 (30)
Cornea	24 (19)
Other	2 (2)

Data are presented as number (percentage)

Table 2.

Operative Data for the Trabeculectomy Group in the PTVT Study

Conjunctival flap	
Fornix-based	96 (84)
Limbus-based	19 (16)
Number of scleral flap sutures	
1	1 (1)
2	31 (27)
3	54 (47)
≥ 4	29 (25)
Tenonectomy	10 (9)
Conjunctival closure	
Single layer	93 (81)
Double layer	22 (19)

Data are presented as number (percentage)

2 patients were randomized to the trabeculectomy group but underwent tube shunt surgery, and their operative data are not included

Table 3.

Postoperative Interventions in the PTVT Study

	Tube Group (n = 125)	Trabeculectomy Group (n = 117)
Removal of rip-cord	65 (52)	—
Laser suture lysis	23 (18)	34 (29)
Removal of releasable suture	—	21 (18)
5-FU injection	0	29 (25)
MMC injection	0	2 (2)
Needling	0	23 (20)
Anterior chamber reformation	10 (8)	6 (5)
Paracentesis	7 (6)	2 (2)
Suture wound	2 (2)	3 (3)
Avastin injection	0	3 (3)
Subconjunctival steroid injection	0	1 (1)
Laser iridotomy	0	1 (1)
Laser iridoplasty	1 (1)	1 (1)
Total number of patients with postoperative interventions[*†]	77 (62)	77 (66)

5-FU = 5-fluorouracil

Data are presented as number of patients (percentage)

Interventions that occurred after a reoperation were censored

[*] Some patients had more than 1 intervention

[†] $P = 0.58$ for the difference in total number of patients with postoperative interventions between treatment groups (chi-square test)

Table 4.

Early Postoperative Complications* in the PTVT Study

	Tube Group (n = 125)	Trabeculectomy Group (n = 117)	*P*-value‡
Shallow or flat anterior chamber	12 (10)	12 (10)	1.00
Choroidal effusion	9 (7)	12 (10)	0.54
Wound leak	1 (1)	13 (11)	0.002
Hyphema	8 (6)	5 (4)	0.65
Encapsulated bleb	0	8 (7)	0.009
Hypotony maculopathy	1 (1)	3 (3)	0.57
Wound dehiscence	2 (2)	0	0.51
Aqueous misdirection	0	1 (1)	0.97
Corneal dellen	1 (1)	0	0.99
Cystoid macular edema	1 (1)	0	0.99
Suture-related infection	0	1 (1)	0.97
Suprachoroidal hemorrhage	0	0	–
Endophthalmitis/blebitis	0	0	–
Total number of patients with early postoperative complications†	24 (19)	40 (34)	0.013

Data are presented as number of patients (percentage)

Complications that developed after a reoperation were censored

*Onset ≤ 1 month

†Some patients had more than 1 complication

‡Chi-square test

Table 5.

Late Postoperative Complications* in the PTVT Study

	Tube Group (n = 125)	Trabeculectomy Group (n = 117)	*P*-value‡
Encapsulated bleb	13 (10)	18 (15)	0.33
Persistent diplopia	5 (4)	3 (3)	0.79
Shallow or flat anterior chamber	3 (2)	3 (3)	1.00
Dysesthesia	1 (1)	3 (3)	0.57
Hypotony maculopathy	0	3 (3)	0.22
Persistent corneal edema	0	3 (3)	0.22
Iritis	2 (2)	1 (1)	1.00
Choroidal effusion	2 (2)	0	0.51
Cystoid macular edema	2 (2)	0	0.51
Bleb leak	0	1 (1)	0.97
Conjunctival cyst	1 (1)	0	1.00
Anterior bleb migration with irregular astigmatism	0	1 (1)	0.97
Plate erosion	1 (1)	–	–
Tube retraction	1 (1)	–	–
Endophthalmitis/blebitis	0	0	–
Total number of patients with late postoperative complications†	27 (22)	32 (27)	0.37

Data are presented as number of patients (percentage)

Complications that developed after a reoperation were censored

*Onset > 1 month

†Some patients had more than 1 complication

‡Chi-square test

Table 6.

Reoperations for Complications in the PTVT Study

	Tube Group (n = 125)	Trabeculectomy Group (n = 117)
Bleb revision	0	5
Trabeculectomy revision	–	3
Trabeculectomy revision/phaco		1
Trabeculectomy revision/anterior chamber washout	–	1
Excision of conjunctival cyst	1	0
Penetrating keratoplasty/phaco	0	1
Removal of tube shunt/ECP/phaco	1	–
Tube revision	1	–
Total number of patients (percentage) with reoperation for complications	3 (2)	9 (8)
5-year cumulative reoperation rate for complications*	3%	8%

ECP = endoscopic cyclophotocoagulation; phaco = phacoemulsification

2 patients in the trabeculectomy group had 2 reoperations for complications

*$P = 0.059$ for difference in 5-year cumulative reoperation rate for complications between treatment groups from Kaplan-Meier analysis (log-rank test)

Table 7.

Serious Complications Associated with Reoperation and/or Vision Loss in the PTVT Study

	Tube Group (n = 125)	Trabeculectomy Group (n = 117)
Reoperation for complications*	3 (2)	9 (8)
Wound leak	0	4
Hypotony maculopathy	0	3
8-ball hyphema	0	1
Persistent corneal edema	0	1
Anterior migration of bleb with irregular astigmatism	0	1
Conjunctival cyst	1	0
Plate exposure	1	–
Tube retraction	1	–
Vision loss of ≥ 2 Snellen lines	0	2 (2)
Hypotony maculopathy	0	2
Total number of patients with serious complications†‡	3 (2)	9 (8)

Data presented as number of patients (percentage)

Complications that developed after a reoperation were censored

*1 patient in the trabeculectomy group had 2 different complications that required reoperation

†2 patients in the trabeculectomy group had both a reoperation for a complication and vision loss

‡$P = 0.11$ for the difference in serious complication rates between treatment groups (chi-square test)

Table 8.

Visual Acuity Results in the PTVT Study

	Patient with Complications			Patients without Complications			*P*-value*
	Tube Group	Trabeculectomy Group	Overall Group	Tube Group	Trabeculectomy Group	Overall Group	
ETDRS VA, mean ± SD (n)							
Baseline	72 ± 20 (41)	74 ± 19 (56)	73 ± 19 (97)	74 ± 20 (79)	73 ± 22 (59)	73 ± 21 (138)	0.89†
5 years	73 ± 26 (23)	70 ± 24 (35)	71 ± 24 (58)	67 ± 22 (51)	62 ± 30 (33)	65 ± 25 (84)	0.16†
Change	−5 ± 19 (22)	−10 ± 23 (35)	−8 ± 21 (57)	−6 ± 17 (50)	−12 ± 20 (33)	−9 ± 18 (83)	0.81†
Snellen VA, logMAR mean ± SD (n)							
Baseline	016 ± 0.33 (42)	0.21 ± 0.32 (57)	0.19 ± 0.32 (99)	0.22 ± 0.46 (83)	0.29 ± 0.65 (59)	0.25 ± 0.54 (142)	0.30†
5 years	0.30 ± 0.57 (30)	0.34 ± 0.75 (42)	0.32 ± 0.68 (72)	0.30 ± 0.53 (61)	0.50 ± 0.88 (45)	0.39 ± 0.70 (106)	0.56†
Change	0.20 ± 0.40 (30)	0.20 ± 0.56 (41)	0.20 ± 0.50 (71)	0.14 ± 0.35 (61)	0.22 ± 0.49 (45)	0.17 ± 0.41 (106)	0.64†
Loss of ≥ 2 Snellen lines, n (%)	13 (39)	11 (25)	24 (31)	18 (28)	18 (36)	36 (32)	1.00‡

ETDRS = Early Treatment Diabetic Retinopathy Study; SD = standard deviation; VA = visual acuity

**P*-value comparing the overall groups with and without complications

†Student t-test

‡Chi-square test

Table 9.

Association of Surgical Complications with Treatment Outcome, Vision Loss, and Cataract Progression in the PTVT Study

	Treatment Outcome*			Vision Loss†			Cataract Progression‡		
	Success (n = 112)	Failure (n = 87)	*P*-value	Stable vision (n = 131)	Loss of ≥ 2 Snellen lines (n = 60)	*P*-value	Stable (n = 83)	Progressed (n = 117)	*P*-value
Any postoperative complication			0.61§			1.00§			0.77§
No	67 (60)	48 (55)		78 (60)	36 (60)		47 (57)	69 (59)	
Yes	45 (40)	39 (45)		53 (40)	24 (40)		36 (43)	48 (41)	
Number of postoperative complications			0.25¶			0.54¶			0.94¶
0	67 (60)	48 (55)		78 (60)	36 (60)		47 (57)	69 (59)	
1	29 (26)	22 (25)		35 (27)	12 (20)		23 (28)	27 (23)	
2	11 (10)	11 (13)		12 (9)	7 (12)		9 (11)	13 (11)	
3	4 (4)	3 (3)		4 (3)	3 (5)		2 (3)	6 (5)	
4	1 (1)	2 (2)		1 (1)	2 (3)		1 (1)	2 (2)	
≥ 5	0 (0)	1 (1)		1 (1)	0		1 (1)	0	

Data are presented as number of patients (percentage)

*Analysis includes all patients who completed a 5-year follow-up visit and/or failed during the first 5 years of the study

†Analysis includes all patients who completed a 5-year follow-up visit and/or experienced loss of ≥ 2 Snellen lines during the first 5 years of the study

‡Analysis includes all phakic patients who completed a 5-year follow-up visit and/or had cataract progression during the first 5 years of the study

§Chi-square test

¶Armitage exact test of trend in proportions

Table 10.

Comparison of Postoperative Complication Rates After Baerveldt Implantation in Multicenter Randomized Clinical Trials

	PTVT Study (n = 125)	TVT Study (n = 107)	ABC Study (n = 133)	AVB Study (n = 114)
Shallow or flat anterior chamber	12%	11%	22%	17%
Persistent corneal edema	0%	16%	14%	12%
Choroidal effusion	9%	16%	12%	16%
Hyphema	6%	2%	18%	5%
Tube obstruction	0%	3%	14%	9%
Persistent diplopia	4%	6%	11%	2%
Chronic or recurrent iritis	2%	2%	5%	12%
Cystoid macular edema	2%	5%	7%	NR
Encapsulated bleb	10%	2%	0%	4%
Tube or plate erosion	1%	5%	2%	2%
Aqueous misdirection	0%	3%	NR	4%
Suprachoroidal hemorrhage	0%	2%	2%	3%
Vitreous hemorrhage	0%	1%	5%	NR
Phthisis bulbi	0%	0%	5%	2%
Hypotony maculopathy	1%	1%	3%	NR
Dysesthesia	1%	1%	NR	NR
Wound leak	1%	1%	NR	NR
Endophthalmitis	0%	1%	2%	0%
Retinal detachment	0%	1%	2%	0%
Overall rate/follow-up	19%/1 month 34%/5 years	21%/1 month 43% 5 years	58%/3 months 69%/1 year	69%/5 years

ABC = Ahmed Baerveldt Comparison; AVB = Ahmed Versus Baerveldt; NR = not reported; PTVT = Primary Tube Versus Trabeculectomy; TVT = Tube Versus Trabeculectomy

Complication rates reported during 5 years of follow-up

Table does not list all complications, only those reported in more than 1 study

Table 11.

Comparison of Postoperative Complication Rates After Trabeculectomy in Multicenter Randomized Clinical Trials

	PTVT Study* (n = 117)	TVT Study* (n = 105)	CIGTS† (n = 465)	AGIS‡ (n = 509)	FFSS* (n = 213)
Encapsulated bleb	22%	6%	12%	14.1%	NR
Shallow or flat anterior chamber	13%	10%	13%	15.5%	NR
Wound leak	11%	11%	6%	6.5%	20% without 5-FU 32% with 5-FU
Choroidal effusion	10%	17%	11%	7.9%	NR
AC bleeding or hyphema	4%	8%	10%	11.4%	NR
Anterior or posterior synechiae	NR	NR	5%	10.2%	NR
Persistent corneal edema	3%	9%	NR	NR	NR
Dysesthesia	3%	8%	NR	NR	NR
Hypotony maculopathy	5%	5%	NR	NR	NR
Bleb leak	1%	6%	NR	NR	2% without 5-FU 9% with 5-FU
Corneal dellen	0%	NR	4%	4.7%	NR
Suprachoroidal hemorrhage	0%	3%	0.7%	NR	5% without 5-FU 5% with 5-FU
Endophthalmitis/blebitis	0%	5%	0%	NR	0.9% without 5-FU 1.9% with 5-FU
Cystoid macular edema	0%	3%	0.2%	NR	NR
Chronic or recurrent iritis	1%	1%	NR	NR	NR
Aqueous misdirection	1%	1%	0.4%	NR	NR
Overall rate/follow-up	34%/1 month 50%/5 years	37%/1 month 63%/5 years	50%/1 month	53.6%/≥ 3 months	NR

AGIS = Advanced Glaucoma Intervention Study; CIGTS = Collaborative Initial Glaucoma Treatment Study; FFSS = Fluorouracil Filtering Surgery Study; 5-FU = 5-fluorouracil; NR = not reported; PTVT = Primary Tube Versus Trabeculectomy; TVT = Tube Versus Trabeculectomy

*Complication rates reported during 5 years of follow-up

†Complication rates reported during 1 month of follow-up

‡Complication rates reported during ≥ 3 months follow-up

Table does not list all complications, only those reported in more than 1 study