Trabectome Surgery Combined with Baerveldt Glaucoma Implantation Negates Tube Fenestration

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Abstract

Purpose: To evaluate the efficacy and survival rates of the same session ab interno trabeculectomy with trabectome and Baerveldt glaucoma implant (BT) compared to Baerveldt implant alone (B).

Method: A total of 175 eyes undergoing primary glaucoma surgery were enrolled in this retrospective comparative case series, including 60 eyes which underwent BT and 115 eyes which received B alone. Participants were identified using the procedural terminology codes, and their medical records were reviewed. The primary outcome measure was surgical success defined as 5 mmHg > IOP ≤ 21 mmHg and IOP reduction ≥ 20% from baseline, no reoperation for glaucoma, and no loss of light perception vision. Secondary outcome measures were intraocular pressure, the number of glaucoma medications, and best corrected visual acuity (BCVA).

Results: The cumulative probability of success at 1 year was 61% in BT, and 50% in B. IOP decreased significantly from 23.6±8.9 mmHg at baseline to 13.7±3.9 mmHg at the final follow up in BT (P= 0.001). The corresponding numbers for B were 23.3±7.5 and 14.2±4.5, respectively (P= 0.001). There was no significant difference in IOP at the final follow-up (P=0.56). The number of medications at baseline was comparable in both groups (2.1±1.1 in BT versus 2.4±1 in B, p=0.07). However, BT needed statistically significant fewer drops in all postoperative time intervals and used 0.9±0.9 (BT) and 1.6±1.2 eyedrops (B) at the final follow-up visit (P= 0.004). No dangerous hypertony or hypertension occurred in BT.

Conclusion: Similar rates of success and IOP reduction were observed in BT and B. Eyes who underwent trabectome surgery needed significantly fewer glaucoma medications during 1-year follow-up period while tubes did not require fenestration resulting in fewer postoperative hypotony or hypertension.

Introduction

The main surgical interventions for refractory glaucoma with low target IOP is either trabeculectomy or glaucoma drainage devices (GDD). They bypass poorly functioning physiologic outflow and drop IOP below episcleral vein pressure. Trabeculectomy is associated with high rate of annual failure and a wide range of sight-threatening complications [1–4]. Moreover, published studies indicate that glaucoma drainage devices have the same or higher success rate than trabeculectomy in the management of end-stage glaucoma with significantly better safety profile [1, 2, 5]. As such, GDDs are becoming increasingly used for wide range of refractory glaucomas and even as a primary procedure for advanced cases.

One of the most frequently implanted GDDs is Baerveldt implant (Advanced Medical Optics, Santa Ana, California, USA). In contrast to valved drainage devices such as Ahmed valve implant (AGV) (New World Medical Inc, Rancho Cucamonga, California, USA), the Baerveldt implant does not have a system to control the intraocular pressure and needs intraoperative flow restriction to provide enough time for fibrosis to develop around the plate and regulate aqueous outflow. This modification limits immediate flow postoperatively and leads to uncontrolled intraocular pressure [6]. After approximately 1 month when healing takes place around the plate, Baerveldt results in excellent IOP control [7]. Since GDDs are mostly implanted in severe cases of glaucoma with advanced optic neuropathy, this postoperative ocular hypertension may have a detrimental effect on remaining visual function. Glaucoma medications are frequently used to blunt this hypertensive phase. Repeated exposure to high concentration of preservatives especially in immediate postoperative period increase the chance of adverse side effects and hinders compliance [8, 9].

Alternatives are making fenestrations and slits anterior to the ligation or passing a suture into the lumen to allow for limited flow [10–12]. Unfortunately, these approaches have a variable effect that could be anywhere from a negligible effect on IOP to frank hypotony [11]. As a minimally invasive glaucoma surgery (MIGS), ab interno trabeculectomy (AIT) with trabectome (NeoMedix, Tustin, CA, USA) remove trabecular meshwork, the primary site of outflow resistance, and enhances outflow. The procedure results in significant and long-lasting IOP and eyedrop reduction with excellent safety profile [13].

In this study, we present our experience with same session trabectome surgery, and Baerveldt compared to Baerveldt implantation alone. We hypothesized that combining an angle procedure to enhance physiologic outflow with shunt procedure provides some IOP reduction until ligature dissolves and the Baerveldt implant starts to function.

Methods

The protocol of this study is approved by institutional review board of the University of Pittsburgh Human Subjects Research Committee. Our research adhered to the tenets of the Declaration of Helsinki and regulations of the Health Insurance Portability and Accountability Act. Patients who underwent either Baerveldt with trabectome surgery (BT) or Baerveldt implant alone (B) between 2008 and 2015 were identified using Current Procedural Terminology codes. All procedures were performed by 4 glaucoma fellowship-trained surgeons. Patients older than 18 years old with medically uncontrolled IOP were included in this study. Exclusion criteria were neovascular glaucoma, uveitic glaucoma, and history of prior ocular surgery (except uncomplicated phacoemulsification).

Data were collected from patients' electronic medical record and included basic demographic information, type of glaucoma and preoperative diagnosis, preoperative IOP and number of glaucoma medications, baseline best corrected visual acuity (BCVA), type of operation, postoperative IOP, number of medications, and BCVA.

Primary outcome measure was success defined as IOP ≤ 21 mmHg or ≥ 20% reduction of IOP from baseline at two consecutive visits, no need for further glaucoma surgery, and no loss of light perception. The secondary outcome measures were IOP, BCVA, and the number of medications.

In all cases the IOP was measured with Goldmann applanation tonometer (GAT; Haag-Streit, Konig, Switzerland) at 1 day, 1 week, 4 ±1 week, 2-4 months, 5-7 months, 8-10 months, and 11-13 months. If more than one visit was found at these intervals, the visit closest to month 6, 9, or 12 was chosen.

Surgical technique

In the case of BT, trabectome (NeoMedix, Tustin, CA, USA) surgery was performed first. Patient's' head and microscope were tilted 30˚ away from the surgeon. A temporal 1.6 mm clear corneal incision was created, and handpiece was advanced into the anterior chamber. Tip of the trabectome was engaged with trabecular meshwork at the nasal angle and advanced parallel to Schlemm's canal for 90˚ counter-clockwise followed by a 90˚ clockwise move to opposite direction for a total of 180˚ TM ablation. The handpiece was withdrawn from the anterior chamber and the incision was hydrated to seal.

Baerveldt implantation: a fornix-based conjunctival flap was created, and tenon's dissection was advanced toward the equator until enough space was created for the implant. The lateral wings of the 350 mm*mm Baerveldt implant were advanced under the superior and lateral rectus muscles. The plate was sutured to the sclera 10 mm posterior to the limbus. The tube was cut short with the bevel up to an have approximately 2-3 mm intracameral length. The tube was completely ligated near the plate junction with a 7-0 polyglactin 910 suture (coated VICRYL, Ethicon, Somerville, NJ, United States) and tested with BSS to confirm water tightness. The tube was then inserted into the anterior chamber through a tunnel created with 23-gauge needle and secured to the sclera with a 7-0 polyglactin loop stitch. In B, but not in BT, the tube portion anterior to the ligature was fenestrated with a pass of the spatulated 7-0 needle. A patch graft was used to cover the tube. The conjunctiva and Tenon's were pulled back over the shunt and sutured to the limbus.

At the conclusion of the surgery, an antibiotic (moxifloxacin) and steroid (1% prednisolone acetate) drop were applied. The antibiotic was used four times per day for one week while the steroid eye drops were used 4 times per day for one month and then tapered by one drop application per week.

Statistical analysis

All analyses were performed using SPSS software (SPSS Statistics for Windows, Version 22, Armonk, NY, IBM Corporation) To describe data, frequency, and percent, mean±SD, median, and range were used. To evaluate the baseline differences between two groups, we used ANOVA, Kruskal–Wallis, Chi-Square, and Fisher exact test.

To compare the rate of changes between two groups during the study follow-ups we used interaction analysis within a linear mixed model. To compare the results between the groups adjusted for the baseline values, we used Analysis of Covariance (ANCOVA)

The difference in IOP and number of glaucoma medications between two groups were assessed by Mann-Whitney test and independent T-test.

To demonstrate the survival of subjects in the groups, Kaplan-Meier survival plots were constructed and compared using the log-rank test. Statistical significance was set at $p < 0.05$. Success was defined as the IOP <21 mmHg and a >20% reduction from baseline with no need to further surgery.

Results

A total of 175 eyes were included in this study consisting of 60 BT and 115 B alone. Baseline patient demographics are presented in Table 1. The mean age of the study participants was 71.7±11.1 years in BT and 66.2±15.7 years in B (P= 0.016). Eighty-eight patients (50.3%) underwent phacoemulsification at the time of glaucoma surgery, 36 eyes (60.0%) in BT and 52 eyes (45.2%) in B (P=0.063). Primary open-angle glaucoma was the most common diagnosis in both groups (65.0% and 56.5% in BT and B, respectively, P=0.516) There were no significant differences between the study groups in terms of gender, preoperative intraocular pressure, baseline number of glaucoma medications, ethnicity, and type of glaucoma (Table 1).

Kaplan-Meier survival curves (Figure 1) indicated a mean duration of survival of 261.9±21.9 days in BT group and 220.28±17.5 in B group with no statistically significant difference between two groups (log rank=2.53 p= 0.11). The cumulative probability of qualified success at 3 months, 6 months, and 12 months was 74%, 64%, and 61% respectively in the BT, and 66%, 52%, and 50% in the B. In subgroup analysis, although BT combined with phacoemulsification had longer survival than B +phacoemulsification, the difference was not statistically significant. The mean survival duration was 285.5±25.8 in BT with phacoemulsification versus 225.8±25.9 in B with phacoemulsification, log Rank= 2.17, P= 0.14). Corresponding values for glaucoma surgery alone were 221±37.2 and 215.5±23.6 in BT and B group, respectively (log-Rank= 0.24, p= 0.624, Figure 1). BT combined with phacoemulsification had longer survival than BT, but the difference was not statistically significant (285.5±25.8 versus 221±37.2, Log-Rank= 1.18 P= 0.18). Corresponding values for B were 225.8±25.9 and 215.5±23.6 in B with phacoemulsification and B alone, respectively (log-Rank = 0.45, P= 0.50).

IOP was decreased significantly from 23.6±8.9 mmHg at baseline to 13.7±3.9 mmHg at final follow up in BT (P= 0.001, Figure 2). The corresponding numbers for B were 23.3±7.5 and 14.2±4.5, respectively (P= 0.001). IOP varied more in B than in BT during the early postoperative phase with 5.3% of hypotony in BT versus 13.6% hypotony in B. Overall, during the 1-year follow-up, 9 (15%) patients in BT and 30 (26.3%) patients in B group experienced hypotony, respectively, but due to the relatively low number and range of pressures, the difference was not statistically significant (P=0.08). Most of the hypotony episodes were within the first month before suture opening.

There was no significant difference in IOP at final follow-up (P=0.56). Eyes in BT experienced a 9±9.1 mmHg reduction in IOP within 1 week after the surgery compared to a 6±12.3 mmHg reduction in B (P= 0.09, Figure 2). While IOP was comparable on day one between BT with phacoemulsification and BT (20.3±11.1 mmHg versus 18.6±12.7 mmHg, P= 0.56). B with phacoemulsification had a significantly higher IOP on day 1 compared to B (25.2±16.4 versus 17.9±12.4, P=0.008).

The baseline number of glaucoma medications was 2.1±1.1 in BT and 2.4±1 in B (P=0.07, Figure 3). However, BT needed statistically significant fewer drops in all postoperative visits. At the final follow-up visit, the number of glaucoma medications was 0.6±0.9 drops in BT and 1.8±1.2 in B (p<0.005, Figure 3).

The mean BCVA at the baseline was 0.64±0.85 logMAR in BT and 0.55±0.75logMAR in B (P=0.663). Corresponding numbers for final follow-up visit was 0.72±1.07 logMAR and 0.63±0.97 logMAR, respectively (P= 0.668).

Discussion

BT and B were both effective in reducing IOP. The IOP reduction of 40% at 1-year follow-up was similar to previous reports [14–16]. While there was a trend toward greater IOP reduction following BT compared to B but the difference did not reach statistical significance. However, BT required significantly fewer medications postoperatively.

Early complications of glaucoma drainage devices include hyphema, shallow or flat anterior chamber, tube-corneal touch, corneal edema, and suprachoroidal effusion [6, 17]. These complications are caused by postoperative hypotony, which is more common in non-valved devices when the flow is not restricted and when fenestration of the tube yield excessive flow [18]. Complete ligation of the tube can prevent postoperative hypotony [19–23], but high postoperative IOPs can be dangerous to eyes with advanced glaucoma damage. Therefore, tube ligation is mostly carried out in conjunction with intraoperative longitudinal oriented 2 mm fenestrations proximal to the ligation [18]. Despite this, a postoperative hypertensive spike may develop secondary to fibrosis growth around the fenestration, malfunction of the slit valves, or insufficient fenestrations [10, 24]. Considering the limitations of fenestration, we proposed to perform trabectome surgery in the same session to prevent postoperative IOP spikes. Trabectome enhances outflow by plasma-mediated ablation of the trabecular meshwork and has a long track record of efficacy and safety in several types of glaucomas [13, 25–28].

Although trabectome is in the family of minimally invasive glaucoma surgeries and primarily proposed for mild open-angle glaucoma cases [28], recent studies suggest that it is also effective in more severe glaucomas [29]. Although the success rate of trabectome after failed trabeculectomy and tube shunt procedure support its role in the management of severe glaucoma [30, 31], many eyes at that stage cannot afford a surgical failure. The effect of trabectome is immediate and controls IOP until absorbable ligation suture dissolves, and B begins to function. In contrast to fenestration, the IOP lowering effect of trabectome also persist after the ligature suture is absorbed and has the additive effect to reduce the need for glaucoma medications. This is no small feat as nearly half of all glaucoma patients experience local and systemic side effects of glaucoma medications [32]. Adverse effects from medication are an important reason for non-adherence [33] and can also jeopardize the success of glaucoma surgery [34, 35]. Conversely, reducing eye drops can considerably improve the quality of life [36].

Since cataract and glaucoma frequently coexist, many individuals in both groups underwent cataract surgery at the same time. IOP in BT with phacoemulsification was not significantly different from BT alone, reflecting prior results that suggested an additional IOP reduction of only 0.7±0.3 mmHg when combined with trabectome surgery [37, 38]. Although phacoemulsification has been advocated as providing a trabeculoplasty-like, additional IOP reduction IOP [39], glaucomatous trabecular meshwork is often unpredictable and can result in IOP spikes [40, 41]. We observed this on day 1 in patients in B with phacoemulsification. The results of our study and previous reports on this subject show that this potentially dangerous could be prevented by the same session trabectome surgery [37]. Conversely, no severe hypotony was seen in BT that did not require tube fenestration.

There are several limitations to this study. Patients were not randomized to each treatment group. Because of the relatively small number of participants, we did not apply our past matching techniques of coarsened exact [37, 42, 43] or propensity score matching [14]. Additionally, this study was conducted at a single tertiary academic center, so the results can not easily be generalized to other practice facilities.

In summary, we found that Baerveldt implants with same session trabectome surgery significantly decreased the number of glaucoma medications and avoids both severe hypertension and hypotension, thereby negating the need for tube fenestration.

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Tables

Table 1. Baseline clinical characteristics of patients in BT and B group

			Group		
		Total	BT	B	P
Age	Mean±SD	68.1±14.5	71.7±11.1	66.2±15.7	0.016†
	Median (range)	70.5 (20.6 to 94.4)	73.7 (25.2 to 94.4)	67.8 (20.6 to 89.1)	
BCVA	Mean±SD	0.58±0.78	0.64±0.85	0.55±0.75	0.663‡
	Median (range)	0.3 (0 to 4)	0.3 (0 to 3)	0.3 (0 to 4)	
IOP	Mean±SD	23.3±8	23.6±8.9	23.2±7.5	0.731†
	Median (range)	22 (6 to 52)	21 (10 to 52)	22.5 (6 to 44)	
Medications	Mean±SD	2.3±1	2.1±1.1	2.4±1	0.076‡
	Median (range)	2 (0 to 4)	2 (0 to 4)	3 (0 to 4)	
Gender	Female	98 (56.0%)	38 (63.3%)	60 (52.2%)	
	Male	77 (44.0%)	22 (36.7%)	55 (47.8%)	0.158*
Phaco	No	87 (49.7%)	24 (40.0%)	63 (54.8%)	0.063*
	Yes	88 (50.3%)	36 (60.0%)	52 (45.2%)	
Ethnicity	White	107 (61.1%)	37 (61.7%)	70 (60.9%)	0.99**
	African American	63 (36.0%)	21 (35.0%)	42 (36.5%)	
	Other	5 (2.9%)	2 (3.3%)	3 (2.6%)	
Glaucoma	POAG	104 (59.4%)	39 (65.0%)	65 (56.5%)	
	XFG	11 (6.3%)	3 (5.0%)	8 (7.0%)	
	PACG	17 (9.7%)	7 (11.7%)	10 (8.7%)	0.516**
	PG	8 (4.6%)	3 (5.0%)	5 (4.3%)	
	Other	35 (20.0%)	8 (13.3%)	27 (23.5%)	

BCVA: best corrected visual acuity; IOP: intraocular pressure; POAG: primary open angle glaucoma; XFG: exfoliation glaucoma; PACG: primary angle closure glaucoma; PG: pigmentary glaucoma. ch† Based on t-test. ‡ Based on Mann-Whitney test. * Based on Chi-Square test.** Based on Fisher exact test.

Figures

Figure 1

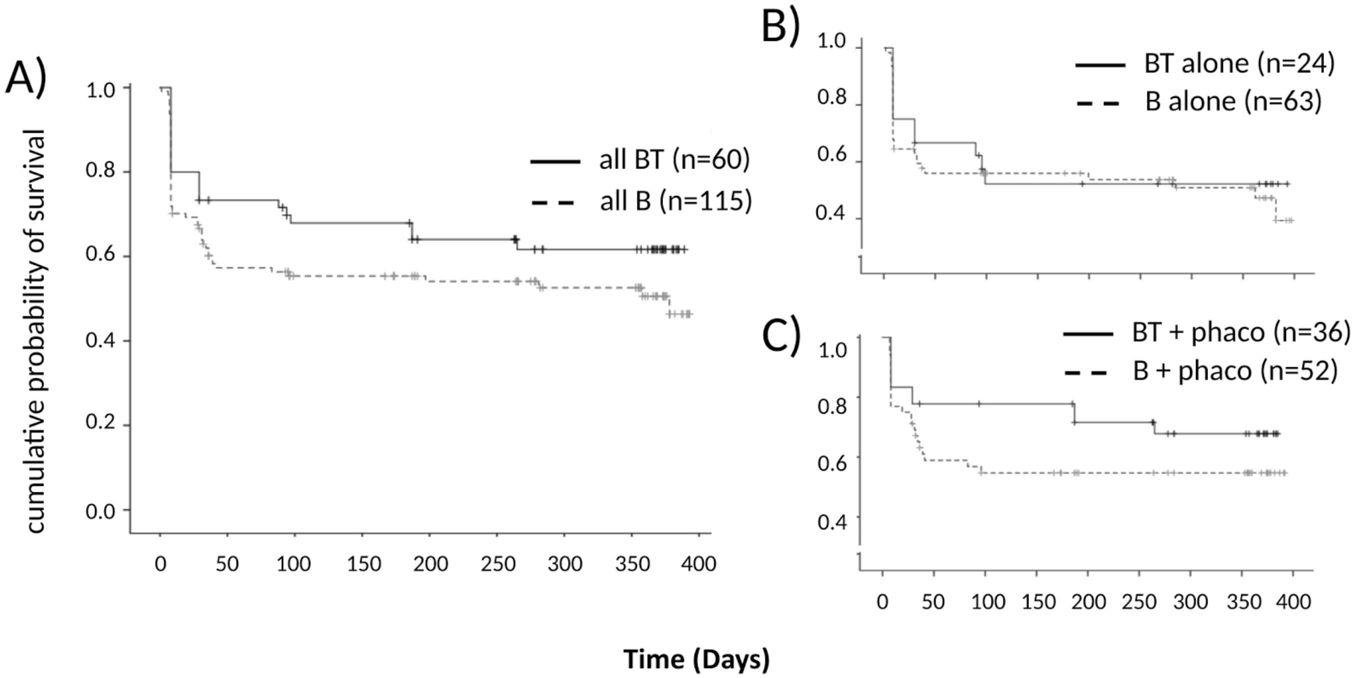

Figure 1. A) Kaplan-Meier survival plots for BT and B with success defined as a final IOP of ≤ 21 mmHg and a 20% reduction from baseline. Success rates of (BT) and B was similar in both groups. B) survival plots of BT and B for subgroup analysis separated by B) glaucoma surgery alone and C) same session phacoemulsification (lower right).

Figure 2

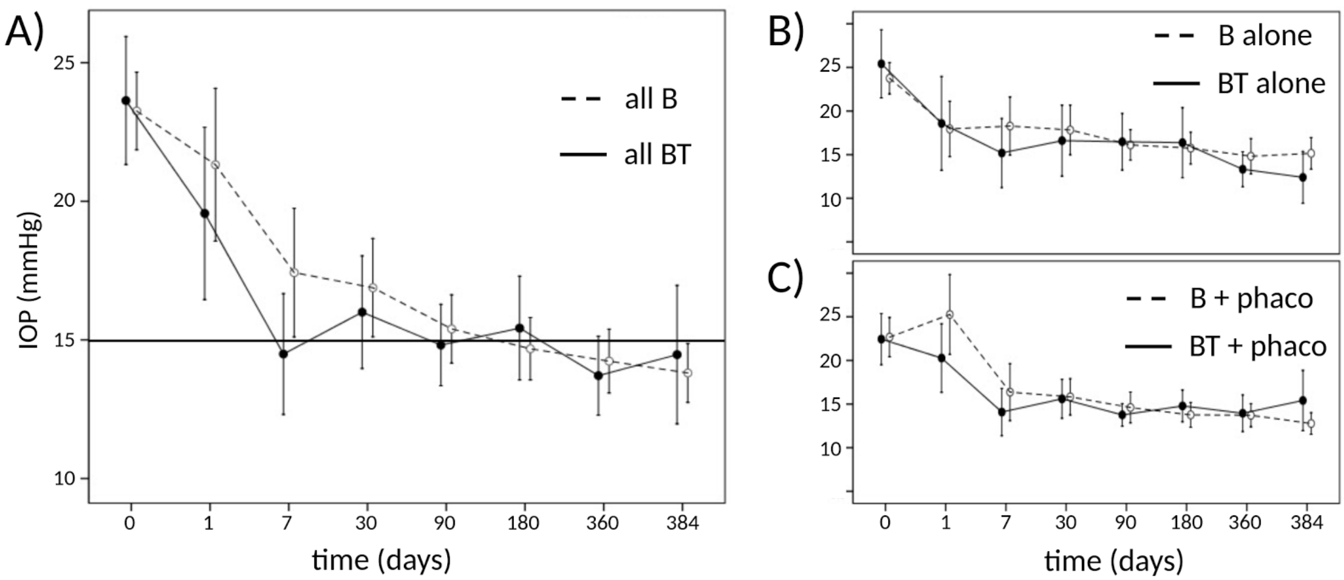

Figure 2. IOP in B and BT. A) IOP in BT was similar to B and trended towards a lower average although tubes in BT were not fenestrated and trended towards a lower average IOP. B) B and BT as stand alone procedures. C) B + phaco had a higher IOP on day 1 compared to subsequent IOPs. No such peak was seen in BT. Mean±95% confidence interval.

Figure 3

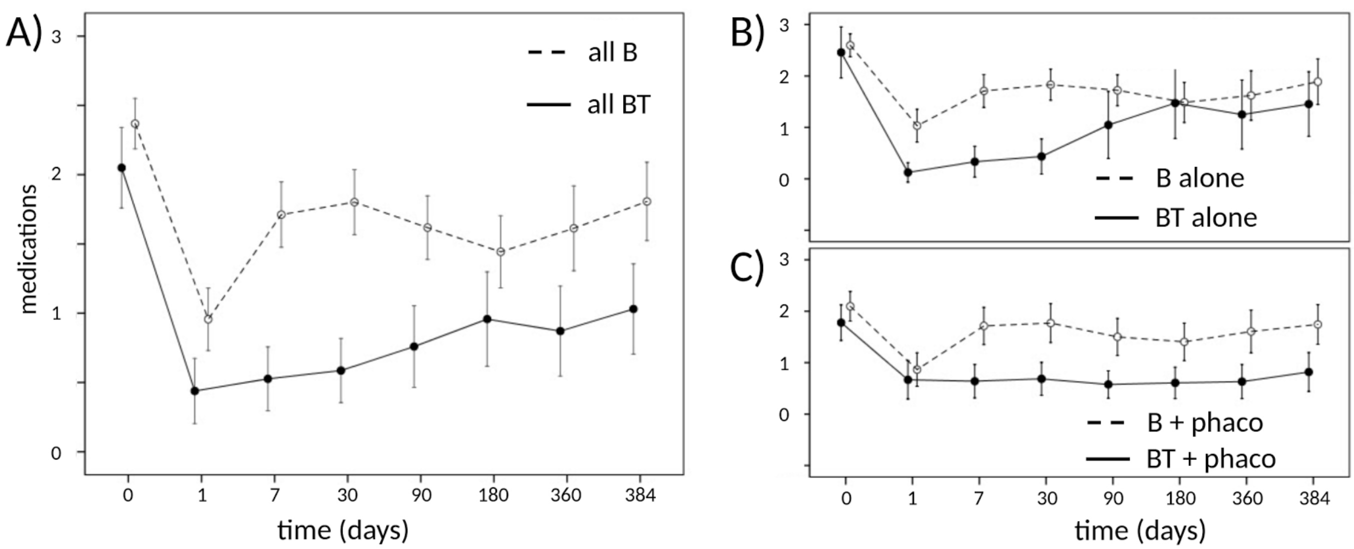

Figure 3. Preoperative and postoperative mean eyedrops for BT and B. Mean pre- and postoperative glaucoma medications for subgroup analysis separated by glaucoma surgery only (B) and same session phacoemulsification (C). Represented as mean±95% confidence Intervals.