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ARTICLE

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Gonioscopy-assisted transluminal trabeculotomy outcomes in patients with highly advanced glaucoma

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BACKGROUND/OBJECTIVES: No data regarding the outcomes of GATT in patients with highly advanced glaucoma are available. The aim of this study is to fill in this gap.

SUBJECTS/METHODS: This is a multicentre, retrospective, and case-control study including highly advanced glaucoma patients (HVF Mean Deviation, MD < −20 dB, study group–SG) and controls (CG: MD > −20 dB). Sixty eyes (31 GATT stand-alone and 29 Phaco-GATT eyes) were included in each group. The SG and CG were compared until 12 months of follow-up, and survival analyses were performed.

RESULTS: The preoperative MD was −25.95 ± 3.64 dB in the SG and −7.96 ± 5.25 dB in the CG ($p < 0.001$). Preoperative IOP was 21.5 ± 8.2 mmHg in the SG on 3.4 ± 1.4 medications, and 20.8 ± 7.3 mmHg in the CG ($p = 0.6$) on 3.0 ± 0.9 medications ($p = 0.1$). At the 12-month visit, IOP was reduced by 39.1 ± 26.6% in the SG and 36.0 ± 18.7% in the CG ($p = 0.4$), and the number of preoperative medications was reduced by 62.2 ± 33.2% in the SG and 65.5 ± 37.4% in the CG ($p = 0.6$), with 93.3% of the eyes in the SG and 90.0% of the eyes in the CG having an IOP ≤ 14 mmHg, with or without medication ($p = 0.5$). No serious adverse events were observed in any of the groups.

CONCLUSION: GATT is a safe and effective surgical option for patients with highly advanced glaucoma.

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INTRODUCTION

Intraocular pressure (IOP) reduction is the only validated method that can delay or prevent glaucoma progression [1]. The magnitude of its reduction and the final target IOP are usually determined based on glaucoma severity. In advanced glaucoma, the rate of glaucomatous progression is reduced with low IOP [2]. Additionally, peak and IOP fluctuation have been described as important predictors of progression in patients with advanced glaucoma [3, 4].

Nevertheless, a low IOP in severe glaucoma is not usually achieved with medication alone; therefore, surgery is frequently required for these patients [5]. In fact, recent strong evidence has shown that primary trabeculectomy (TRAB) may be more effective than medical treatment for preventing progression of advanced glaucoma [6, 7]. However, other surgical modalities may also be used to achieve a low IOP in patients with severe glaucoma. Recent data on minimally invasive glaucoma surgery (MIGS), especially on gonioscopy-assisted transluminal trabeculotomy (GATT), suggest its role in moderate and advanced glaucoma in selected eyes [8–14] and/or in eyes with previous incisional surgery [15–17]. Furthermore, in a recent paper by Wang and cols., GATT and TRAB had similar efficacy for the treatment of primary open-angle glaucoma (POAG) [18].

We recently published a study on 270 eyes with POAG, demonstrating that GATT is a safe and effective procedure, regardless of its preoperative severity [14]. Similar results have been reported by Aktas et al. [8] and by Dar et al. [9]. Favourable results were also observed even with hemi-GATT in moderate glaucoma and severe glaucoma [10]. Additionally, glaucoma severity was not considered as a predictor of failure for GATT in a large glaucoma cohort [19].

In the aforementioned studies, data regarding outcomes exclusively in patients with the most advanced stages of glaucoma were not available. Additionally, the results were presented based on the mean preoperative MD. The present study was designed to describe the outcomes of the GATT in patients with highly advanced glaucoma.

MATERIALS/SUBJECTS AND METHODS

This was a retrospective, multicentre, case-control study. All patients who underwent GATT (combined with cataract surgery by phacoemulsification - Phaco-GATT, or GATT stand-alone) from January 2017, with 1 year of follow-up in any of the centres of the study, were considered. The study was conducted after approval

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from the Ethical Committee of the Federal University of Goiás, Goiânia, Brazil (#4.408.795) and adhered to the tenets of the Declaration of Helsinki. The requirement for written informed consent was waived due to the retrospective nature of the study.

All patients underwent a complete ophthalmic examination preoperatively at each institution for ≤30 days before surgery. The examination included best-corrected visual acuity test, slit-lamp examination, gonioscopy with 4-mirror gonio-lens, IOP measurements with a calibrated Goldmann applanation tonometer, dilated fundoscopy, and visual field tests with the SITA Standard 24-2 test (Humphrey Systems, Dublin, CA). Data were collected preoperatively and on postoperative (PO) days 1, 7, and 30 (±7 days). Further postoperative data were collected at 3 months (±15 days), 6 months (±30 days), and 12 months (12–14 months).

The inclusion criteria were patients aged at least 18 years, a history of Phaco-GATT or GATT stand-alone procedure with 1 year of follow-up, and a reliable [20] preoperative visual field. To be included in the study, patients were required to undergo at least a hemi-GATT (180° trabeculotomy or more). The exclusion criteria were any previous corneal surgery, history of ocular trauma, or any complications in previous Phaco-GATT surgeries related to cataract extraction.

GATT was performed on all study participants and, when combined with Phaco surgery, took place afterward (surgeons: L.M., A.C.A.P., B.T., and B.M.F.). The technique begins by filling the anterior chamber with a dense ophthalmic viscoelastic device through a temporal clear-corneal incision, followed by creating an accessory incision with a 15° blade. A 5−0 Prolene suture was blunted with a hand-held cautery unit before the beginning of the surgeries. The patient's head was rotated 35° to 45° away from the surgeon, and the surgical microscope was also tilted 35° to 45° downward toward the surgeon, allowing visualisation of the nasal chamber angle through a direct goniolens. A 25 × 0.7 mm or 13 × 0.45 mm needle (according to the surgeon's preference) was inserted through the temporal incision to gently detach the trabecular meshwork, creating an entry into Schlemm's canal (SC). The blunted Prolene suture was inserted through the accessory incision, directed toward the nasal angle, and introduced into SC with the assistance of a microforceps, which was used to advance the suture circumferentially through the SC. Using the same forceps, the surgeon then gently pulled the tip of the suture from the SC through the clear-corneal temporal corneal incision, creating a 360° trabeculotomy [14, 19]. To be included in the protocol, it was necessary to undergo at least a Hemi-GATT (180° trabeculotomy or more).

The postoperative regimen consisted of moxifloxacin/dexamethasone eye drops for 4 weeks, starting every 4 h with weekly regression. The patients who underwent Phaco-GATT received a nonsteroidal anti-inflammatory drug (NSAID) eye drop every 6 h for 3 weeks. Regression of the fixed combination was performed every 5 days in patients who underwent GATT stand-alone; the administration of NSAIDs was deemed optional.

Relative success was considered if, the last recorded follow-up data indicated an IOP of 6–18 mmHg with the use of a maximum of two glaucoma medications with dose less than or equal to that used before operation. Absolute success was considered with the same IOP levels, but without any glaucoma medication. A third success criterion, named "enhanced success", was achieved if, at the last postoperative visit, an IOP ≤14 mmHg was observed, with or without the use of any glaucoma medication. In the enhanced criteria, the number of medications taken at the last postoperative visit was not considered as a possible failure condition. During the follow-up, severe complications, including corneal decompensation, loss of vision, or the need for additional glaucoma surgery, were considered failures.

Considering a difference of 2.5 mmHg in IOP to be detected between the groups with a standard deviation of 4 mmHg, a test power of 80% and an alpha error of 5%, it would be necessary to include 41 eyes in each group. All patient data were tabulated into an SPSS spreadsheet (version 22.0; SPSS Inc., Chicago, IL, USA) and reordered in ascending order based on preoperative MD. All patients with MD < −20 dB were considered to be in the study group (SG). If bilateral cases were available, only the worst eye was included in the SG. Subsequently, the remaining patients (control group, CG) were randomised and consecutively included using the website www.random.org to match an inclusion ratio of 1:1, considering the surgical modality of the SG. If both eyes from the same patient were included, the eye that was subsequently sequenced was excluded, and the next eye in the randomisation order was included. This procedure was iterated multiple times to include only one eye from each patient in the CG. The Kolmogorov-Smirnov test was used to verify the normality of the sample. The independent Student's *t*-test was used to compare continuous variables between the groups, whereas the paired Student's *t*-test was used to compare variables within each group. A Kaplan–Meier curve was used to estimate survival in each group, and the results were compared with those of the log-rank (Mantel–Cox) test. The alpha error was corrected using the Bonferroni correction for both the IOP and number of medication comparisons between the groups throughout the study. Thus, for these assessments, $p < 0.007$ and $p < 0.008$ were considered statistically significant, respectively. For all the remaining comparisons, an alpha error of 5% ($p < 0.05$) was considered significant.

RESULTS

Sixty eyes of 60 patients were included in each group (31 GATT Stand-Alone eyes and 29 Phaco-GATT eyes in both groups). Considering The demographic characteristics of the study groups are presented in Table 1. There were 48 POAG in the SG and 54 in the CG; 3 steroid-induced glaucoma in the SG and 2 in the CG; 5 juvenile glaucoma in the SG and 1 in the CG; 2 pseudophakic glaucoma in the SG and 1 in the CG; 1 with pseudoexfoliation glaucoma and 1 with post-penetrating keratoplasty glaucoma in the SG; and 2 with pigmentary glaucoma in the CG. The two groups were equivalent in terms of diagnosis ($p = 0.2$). The preoperative MD was −25.95 ± 3.64 dB (−20.04 to −34.28 dB) in the SG and −7.96 ± 5.25 dB (-0.19 to −19.46 dB) in the CG ($p < 0.001$). In all patients, a 360° GATT was performed.

The IOP and the number of medications used during the study are shown in Table 2. At the last postoperative visit, the IOP was

Table 1. Demographic characteristics of the groups.

	Age (years)[a]	Sex[b]	Eye[c]	Race[d]
Study group	61.7 ± 17.1	24 F; 36 M	29 RE; 31 LE	37 C; 23 AA
Control group	65.0 ± 11.8	25 F; 35 M	23 RE; 37 LE	45 C; 15 AA

[a]$p = 0.2$.
[b]*F* Female, *M* Male.
[c]*RE* Right Eye, *LE* Left Eye.
[d]*C* Caucasian, *AA* African American.

Table 2. IOP and number of medications during the study.

Time	Group	IOP (mmHg)	*n**	*p*	Meds	*n*	*p*
Pre-op	SG	21.5 ± 8.2	60	0.6	3.4 ± 1.4	60	0.1
	CG	20.8 ± 7.3	60		3.0 ± 0.9	60	
PO 1	SG	12.5 ± 4.7	60	0.2			
	CG	13.6 ± 6.1	60				
PO 7	SG	11.4 ± 3.6	60	0.01	1.5 ± 0.9	57	0.7
	CG	13.7 ± 5.8	59		1.5 ± 1.0	59	
PO 30	SG	11.0 ± 2.8	60	0.05	1.4 ± 0.9	58	0.8
	CG	12.4 ± 4.7	59		1.4 ± 1.0	59	
PO 3 m	SG	11.5 ± 2.9	59	0.1	1.2 ± 1.0	58	0.2
	CG	12.2 ± 2.3	58		0.9 ± 1.0	57	
PO 6 m	SG	10.9 ± 2.2	59	**0.003**	1.2 ± 1.1	57	0.1
	CG	12.4 ± 3.0	59		0.8 ± 1.1	58	
PO 12 m	SG	11.3 ± 2.6	58	0.05	1.2 ± 1.0	51	0.4
	CG	12.1 ± 1.8	58		1.0 ± 1.1	50	

SG Study group, *CG* Control group.
Bold values indicate statistical significance.

reduced by 39.1 ± 26.6% in the SG and 36.0 ± 18.7% in the CG (p = 0.4), and the number of preoperative medications was reduced by 62.2 ± 33.2% in the SG and 65.5 ± 37.4% in the CG (p = 0.6). BCVA (LogMar) improved from 2.1 ± 4.0 to 1.5 ± 3.1 at the last postoperative visit in the SG (p = 0.003) and from 0.8 ± 1.6 to 0.5 ± 1.6 in the CG (p = 0.002). The MD was available in the last postoperative visit in 37 patients from both groups, and remained stable in the SG (−26.07 ± 3.61 dB preoperatively vs. −25.49 ± 5.37 dB at 12 months, p = 0.3) and in the CG (−7.70 ± 5.29 dB preoperatively vs. 7.73 ± 5.81 dB at 12 months, p = 0.9).

New glaucoma surgery was required in two patients in the SG (one Phaco-Trabeculectomy at PO 6 m and one Ahmed tube shunt implantation at PO 30) and in three patients in the CG (one Trabeculectomy at PO 30 and another one at PO 12 m and one Micropulse Transscleral Laser at PO 12 m). Hyphaema was observed in 50% of patients in both groups, with complete resolution by postoperative day 7 in 100% of eyes in the SG and 87.5% of eyes in the CG. In one patient in the CG, surgical removal of the hyphaema was necessary. In the CG, one patient with neurotrophic keratitis was treated with artificial tears, and one patient developed an IOP spike with complete resolution after topical steroid removal. One patient in the SG developed retinal branch vein occlusion, which was noticed at the last post-operative follow-up. However, no direct relationship with the surgical procedure could be established, and this event was not considered a failure of the procedure. No further complications were observed in either group.

Relative success was achieved in 88.3% of the eyes in the SG and 91.5% of the eyes in the CG. For relative success, at 1 year, the Kaplan–Meier curve estimated a survival of the procedure in 339.2 days in the SG (95% CI: 315.2–363.1 days), compared to 343.9 days in the CG (95% CI: 321.4–366.3 days), p = 0.5, Fig. 1. Complete success was achieved in 36.5% of the eyes in the SG and 47.1% of the eyes in the CG. Considering complete success, at the last follow-up visit, the Kaplan–Meier curve estimated a survival of the procedure in 165.4 days in the SG (95% CI: 117.6–213.2 days), compared to 218.4 days in the CG (95% CI: 169.4–267.4 days), p = 0.2, Fig. 1. Enhanced success was achieved in 93.3% of the eyes in the SG and 90.0% of the eyes in the CG. Considering enhanced success, at the last follow-up visit, the Kaplan–Meier curve estimated a survival of the procedure in 355.8 days in the SG (95% CI: 340.6–371.0 days), compared to 345.3 days in the CG (95% CI 324.2–366.3 days), p = 0.5, Fig. 1. In fact, an IOP ≤ 14 mmHg, with or without the use of medication(s), was also observed in 65% of the patients from the CG in the first postoperative visit (80% in the SG, p = 0.06), in 69.4% in the CG at PO 7 (86.6% in the SG, p = 0.02), in 85.0% in the CG at PO 30 (93.3% in the SG, p = 0.2), in 87.9% in the CG at PO 3 m (93.2% in the SG, p = 0.3), in 86.6% in the CG at PO 6 m (95.0% in the SG, p = 0.1).

DISCUSSION

The goal of treating patients with advanced glaucoma is to achieve sustained and low IOP to stop or reduce disease progression rates [3]. In the Canadian Glaucoma Society Target IOP workshop, researchers suggested an IOP ≤14 mmHg as the target IOP for patients with advanced glaucoma [21]. This IOP criterion was also adopted as an initial guide in the Primary Trabeculectomy for Advanced Glaucoma Study (TAGS) [6, 7] and also here, to define the "enhanced success," regardless of the number of hypotensive medications in use. The ultimate purpose of treatment in patients with advanced glaucoma is to achieve a low and constant IOP, regardless of the use of any ocular hypotensive medication. Nevertheless, the results obtained at the 12-month visit were achieved with 1.2 ± 1.0 glaucoma medications in the SG and 1.0 ± 1.1 in the CG (p = 0.4), a greater than 60% reduction in the number of ocular hypotensive medications in both groups. The combination of low IOP with reduced number of glaucoma medications may be considered as the "enhanced goal" for any glaucoma surgery, since adherence to treatment with glaucoma medications has been reported to be poor [22]. Moreover, a high proportion of patients with glaucoma are unable to instil eye drops correctly [23], which is a major cause of nonadherence to glaucoma medications [24]. These problems are consequently raised by prescribing a high number of instillations for people with impaired vision and/or visual fields, such as in those with highly advanced glaucoma.

Trabeculectomy remains the gold-standard surgical procedure for patients with advanced glaucoma. This assumption is based on its ability to achieve a low and constant IOP over time [7]. However, it has numerous limitations, including initial and long-term safety concerns, which are mainly based on bleb-related complications, because a direct path is built from the anterior chamber to the subconjunctival/subtenon space. It is true that these problems have been vastly reduced after the technique modification by Khaw et al. [25]; however, they are still present. In

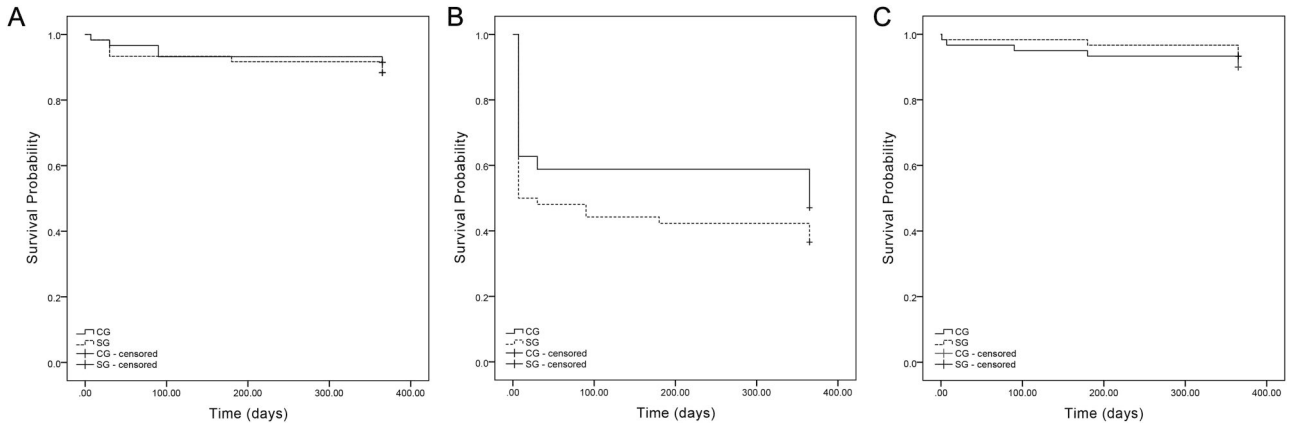

Fig. 1 Kaplan–Meier curves from both groups. A Relative success: **B** Complete success: **C** Enhanced success.

the TAGS, adverse events occurred in 38% of the participants in the trabeculectomy arm within the first 24 months of follow-up [6]. Additionally, 10.8% of patients required further intervention to manage trabeculectomy-related serious adverse events, such as a flat anterior chamber, and one patient developed endophthalmitis in this group [6].

Wang and cols. demonstrated similar ability to reduce both IOP and number of ocular hypotensive medications 12 months after surgery ($p > 0.05$ for both) and also comparable success rates at 12 months (70% in the GATT group vs. 76.5% in the TRAB group, $p = 0.559$) [18]. Ruparelia and cols. showed an overall surgical success of 71.4% for GATT and 74.3% for XEN for the management of advanced open-angle glaucoma [11]. Furthermore, GATT can be a safe and effective surgical option even in eyes with prior failed glaucoma surgeries, such as TRAB or glaucoma drainage devices [16, 17].

Thereafter, glaucoma surgeons seek alternative surgeries for selected patients with advanced glaucoma. Conjunctival-sparing procedures are desirable because trabeculectomy can eventually be performed along with other surgical options if the target IOP is not established. In this regard, favourable results have been achieved with goniotomy using the Kahook Dual Blade [12, 13]. In addition, Aktas et al. demonstrated the efficacy of GATT in patients with moderate-to-advanced glaucoma [8]. Of the 104 included patients, only 7 underwent further surgery to control IOP after 18 months [8]. Ruparelia and cols. demonstrated a 93.4% success in achieving an IOP ≤16 mmHg (with or without medications) in moderate POAG and severe POAG after Phaco-Hemi GATT [10]. Similar results were also achieved in our previous study evaluating GATT, considering only the 105 POAG advanced glaucoma eyes (MD: −20.59 ± 5.72 dB: −12.28 to −34.28 dB) with a 36.1 ± 24.3% IOP reduction to a 12-month IOP of 11.9 ± 3.0 mmHg on 1.2 ± 1.1 medications, with a relative success of 88.1% [14]. Furthermore, GATT is usually a very safe glaucoma treatment procedure, as shown in previous papers [14, 26–29], and is also demonstrated in the present study for treating patients with highly advanced glaucoma. The most common surgical complication was hyphaema, which was observed in 50% of eyes in this study, with almost all of them experiencing complete resolution within the first week postoperatively. Additionally, no serious complications were detected in the 120 eyes in this study.

In the present study, only one eye from highly advanced glaucoma patients (referred to here as preoperative MD <-20 dB) was evaluated. Including both eyes from the same patient may be a very important bias, since individual characteristics become duplicated and may strongly affect the results. Additionally, in a recent paper, binocularity was a strong predictor of failure for GATT (IRR = 4.05; $p = 0.001$) [19]. In the present study, safety and efficacy results were comparable to those observed in the treatment of patients with all levels of glaucoma severity [8–10, 14]. This is evident from previously published reports and the comparison of parameters with those of CG, in which glaucomatous eyes with different stages of the disease were included (MD: −7.96 ± 5.25 dB: −0.19, −19.46 dB) [14, 26–30]. Moreover, a high proportion of eyes achieved an IOP ≤ 14 mmHg at all time points in both groups. Considering the SG, 80% of the eyes or more achieved an IOP ≤14 mmHg from the day 1 after surgery, rising to more than 90% of the eyes from the postoperative day 30 to the end of the study, with constant IOPs (Table 2). Furthermore, SG and CG were essentially equivalent in IOP in all evaluations, with the exception of PO 6 m ($p = 0.003$), probably due to a greater number of medications used in the preoperative period in SG and at PO 6 m, despite not being statistically significant at both time points (Table 2). Since there may be some IOP spikes in the initial postoperative period, one or a combination of two glaucoma medications (with the exception of prostaglandin analogues) is maintained in all patients for 15–30 days, as a rule, even with eyes with IOP within the target, in order to prevent, or at least reduce, the risk of any IOP spike in the initial postoperative period. Additionally, the IOP results presented here were similar to the ones obtained in the TAGS study at 4 (12.4 ± 5.73 mmHg) and 12 months of follow-up (11.9 ± 4.48 mmHg) in the trabeculectomy group [6].

Large IOP fluctuation is also considered a predictive factor for glaucomatous visual field progression [3] in patients with advanced glaucoma [4]. Nouri-Mahdavi et al. analysed the predictive factors for visual field progression in the Advanced Glaucoma Intervention Study and showed that eyes with an IOP fluctuation <3 mmHg remained stable during the study, while eyes with an IOP fluctuation of ≥3 mmHg demonstrated significant progression [4]. Pyfer et al. also demonstrated reduced IOP fluctuation after MIGS [31]. Although IOP fluctuations were not directly evaluated in the present study, it was possible to assess this feature indirectly. The IOP was constant throughout the study, with low standard deviations in all measurements, with decreasing values from the first postoperative day until PO 30 and remaining approximately constant (comparison not made) until 12 months (Table 2).

The present study has some limitations, mainly related to the retrospective inclusion of patients. The decision on whether the GATT was suitable for a patient relied only on the surgeon's discretion, an important possible selection bias. It is reasonable to assume that eyes with a high risk of failure were not considered for GATT at the time of surgery choice, therefore probably artificially enhancing the results, such as eyes with very high preoperative IOP, a hypothetical but never-described predictive factor for failure. Preoperatively treated IOP may be an indication of the status of the distal portions of the outflow pathway, in contrast to the stage of the disease, as previously suggested [29], because GATT seems to be a viable option for glaucoma,

including in patients with highly advanced glaucoma. Additionally, the results presented here reflect only IOP and the number of medication behaviours after a limited follow-up period of 12 months and may not capture long-term surgical efficacy. Glaucoma is a lifetime disease, and a longer evaluation period is needed to better understand its profiles after the GATT. Moreover, no evaluation considering the progression of glaucoma was made, in addition to the MD comparison. It is true that a low and sustained IOP is the basic goal when treating patients with advanced glaucoma [1–4]. However, a more detailed glaucoma progression assessment is needed for patients undergoing GATT, especially those with advanced glaucoma. Lastly, the severity of the disease was based only on preoperative MD. Despite being a well-accepted criterion in this regard, a few other criteria could be used to define this subset of advanced glaucoma, such as eyes where the fixation is threatened, for example.

In addition to the points mentioned above, this study is the first to focus on patients with highly advanced glaucoma undergoing GATT. All patients were evaluated simultaneously, rather than over an average follow-up period, eliminating the possibility of a bias due to the use of minimal follow-up inclusion criterion. Additionally, since this was a multicentre study, results from different surgeons were evaluated together. However, prospective randomised controlled trials evaluating GATT in highly advanced glaucoma patients and also comparing GATT to trabeculectomy, as well as different glaucoma surgical modalities, are crucial in determining the viability of each surgery for patients with advanced glaucoma, including those at the most advanced stages. In conclusion, the results presented here suggest that GATT may be a viable surgical option for selected patients with highly advanced glaucoma.

SUMMARY

What was known before

- GATT is a safe and effective surgery procedure and may be a viable surgical option in patients with different levels of glaucoma severity.

What this study adds

- GATT is a safe and effective surgical procedure also for patients with highly advanced glaucoma (MD < −20 dB).
- GATT should be considered as a surgical option for selected highly advanced glaucoma patients.

DATA AVAILABILITY

The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request.

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AUTHOR CONTRIBUTIONS

All authors: substantial contributions to the conception and design of the work; acquisition and interpretation of data; revision of the manuscript; have approved all submitted versions; have agreed both to be personally accountable for the author's own contributions and to ensure that questions related to the accuracy or integrity of any part of the work, even ones in which the author was not personally involved, are appropriately investigated, resolved, and the resolution documented in the literature. Leopoldo Magacho: Writing—original draft; writing—review and editing, writing—final manuscript; analysis of data; supervision.

COMPETING INTERESTS

The authors declare no competing interests.

ADDITIONAL INFORMATION

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