The Effect of Tube Ligature on the Safety and Efficacy of Ahmed Glaucoma Valve Surgery

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Precis: In this matched case-control study, ligature of the Ahmed glaucoma valve (AGV) was associated with a reduction in the rate of postoperative complications without affecting the surgical success rate or the visual outcome following the procedure.

Purpose: The purpose of this study was to compare the safety and efficacy of AGV surgery with and without tube ligation.

Materials and Methods: This was a retrospective, matched case-control study. A review was performed of patients who underwent AGV surgery with tube ligation between June 2015 and December 2017 (ligated AGV group). Cases were matched with controls who underwent AGV surgery without tube ligation (nonligated AGV group). Data were compared on postoperative intraocular pressure (IOP), the number of glaucoma medications, surgical success rates, complications, and vision.

Results: There were 49 eyes in the ligated AGV group, and 98 eyes in the nonligated AGV group. Baseline characteristics were similar between groups except for the number of glaucoma medications (3.72 ± 0.55 in the ligated AGV group vs. 3.92 ± 0.92 in the nonligated AGV group; P = 0.01). At 18 months, IOP was 16.7 ± 6.3 mm Hg in the ligated AGV group and 17.3 ± 8.0 mm Hg in the nonligated AGV group (P = 0.76). In addition, the mean number of glaucoma medications was 2.38 ± 1.10 in the ligated AGV group and 1.68 ± 1.51 in the nonligated AGV group (P = 0.56). The overall success rate at 12 months was similar between groups (P = 0.84). The overall rate of complications was statistically lower in the ligated AGV group (28.6%) compared with the nonligated AGV group (73.5%) (P < 0.01). The mean change in logarithm of the minimum angle of resolution acuity was similar between groups (P = 0.50).

Conclusion: Tube ligation in AGV surgery may be an effective measure that reduces the rate of postoperative complications without affecting the success rate or visual outcomes of the surgery.

Key Words: glaucoma, tube ligation, Ahmed glaucoma valve, hypotony (J Glaucoma 2020;29:1173–1178)

Implantation of the Ahmed glaucoma valve (AGV) (New World Medical Inc., Rancho Cucamonga, CA) is a common surgical option for the management of glaucoma refractory to medical treatment.1 Since its approval by the Food and Drug Administration in 1993, it has become particularly useful in cases of failed trabeculectomy.2 The main advantage of the AGV, compared with nonvalved glaucoma drainage devices, is that it contains a unidirectional flow restricting valve mechanism designed to prevent the occurrence of postoperative hypotony from excessive filtration.3 Clinical studies have demonstrated that the AGV has a lower rate of hypotony when compared with nonvalved glaucoma drainage devices.4 However, hypotony remains a potential complication that was reported following AGV implantation, especially in the early postoperative period.5–7 Furthermore, shallowing of the anterior chamber following AGV implantation has been reported in 15% of cases in the Ahmed Versus Baerveldt (AVB) study4 and in 19% of cases in the Ahmed Baerveldt Comparison (ABC) study.8

Modifications to the standard surgical technique of AGV implantation have been attempted to prevent postoperative hypotony.9,10 Kee9 described a technique where the tube, along with a 6-0 prolene suture utilized as a stent, is partially ligated with an 8-0 vicryl suture. This technique was performed in 16 patients and only 1 developed hypotony postoperatively. Another technique described by Lee et al10 includes complete ligature of the tube along with 3 strands of an 8-0 nylon suture that are positioned adjacent to the tube serving as stents. The strands are exposed through the conjunctiva to facilitate their removal postoperatively. In the same report, they investigated outcomes of AGV implantation using the proposed technique and the rate of hypotony in their study was 8.4%.

There is limited literature on the effect of ligation on the rate of complications following AGV surgery. Furthermore, it is unknown whether or not the success rate in ligated patients differs from their nonligated counterparts. To the best of our knowledge, all previous reports on ligating the AGV have been either noncomparative10 or small series with short postoperative follow-up.9 Therefore, our objective was to compare the safety and efficacy of AGV surgery with and without tube ligation in patients with glaucoma refractory to medical treatment.

MATERIALS AND METHODS

Study Design

After obtaining approval from the institutional review board at our hospital, a matched case-control study was performed to evaluate the effect of ligation on postoperative intraocular pressure (IOP) and safety. A retrospective chart review was performed of all patients who underwent AGV surgery from June 2015 to December 2017. All patients who underwent AGV implantation with tube ligature for glaucoma were included (ligated AGV group). Patients were excluded if their postoperative follow-up was <6 months. Patients with a past history of previous glaucoma surgery were not excluded. All cases were matched with controls

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who underwent AGV surgery without tube ligation (nonligated AGV group). Matching was based on age (within a 30% range) and glaucoma diagnosis. Controls were sequentially selected from the surgical records of patients undergoing AGV within the defined period of inclusion. For calculating sample size, we assumed that the rate of hypotony in eyes undergoing AGV surgery is 8.4%. The rate of hypotony with ligation was assumed to be 0.1%. To achieve a 95% confidence interval and 80% power with a 1:2 ratio of cases to controls, the required sample size was 49 cases and 98 controls.

Data Collection
Preoperative data were collected on age, sex, specific glaucoma diagnosis, number of antiglaucoma medications, previous glaucoma surgeries, visual acuity, IOP, slit-lamp findings, and fundus examination. Surgical details included the method of tube ligation, site of tube placement, and intraoperative complications. Postoperative data were collected on visual acuity, IOP, slit-lamp findings, fundus examination, number of glaucoma medications, surgical complications, and the need for further surgical intervention. Data were collected from visits that were within 7 postoperative intervals: visit 1 (0 to 5 d), visit 2 (6 to 30 d), visit 3 (1 to 2 mo), visit 4 (month 3 ± 1), visit 5 (month 6 ± 2), visit 6 (month 12 ± 4), and visit 7 (month 18 ± 4). If a patient had > 2 visits within the same interval data on IOP and number of medications were collected from only one of them. However, complications and further surgical interventions were always included even if they had occurred outside the study intervals.

Surgical Technique
All surgical procedures were performed by either a glaucoma consultant or a fellow under direct supervision. The implantation of AGV was performed following a standard surgical technique. A fornix-based conjunctival flap was created in the desired quadrant for implantation. This was followed by fixation of the plate at a distance of 8 mm posterior to the limbus. The tube was then trimmed to an appropriate length and inserted into the anterior segment through a scleral tunnel that was created with a 23 G needle. The tube was then secured to the sclera 2 mm posterior to the insertion point. Subsequently, donor pericardial tissue (Tutoplast; IOP Inc., Costa Mesa, CA) was used to cover the insertion point. Subsequently, donor pericardial tissue (Tutoplast; IOP Inc., Costa Mesa, CA) was used to cover the exposed subconjunctival aspect of the tube. The conjunctiva was then sutured to the limbus in a watertight manner.

Two different tube ligation techniques were used based on surgical preference, patient age, and the likelihood of patient cooperation for laser suture lysis. The ligation was performed by either a polypropylene (9-0) or a polyglactin (7-0) suture. Then, complete occlusion was confirmed by attempting to flush balanced salt solution through the tube with a 30 G cannula before proceeding with tube insertion. In cases ligated with polyglactin, the suture was positioned on the subconjunctival segment of the tube and left to absorb during the early postoperative period. Alternatively, in cases ligated with polypropylene, the suture was placed near the tube tip so that it lies on the intracamerical segment of the tube making it visible inside the anterior chamber. If ligature removal was required postoperatively it was performed by direct laser suture lysis as the occluding suture was visible under slit-lamp examination.

Postoperatively, the patients were prescribed topical antibiotic drops for 1 week along with topical steroid drops on a tapering regimen spanning over a period of 6 weeks.

Statistical Analysis
Complete success was defined as IOP within a range of 5 to 21 mm Hg at all the visits after the first 3 months without the use of glaucoma medications, without the need for additional glaucoma surgery, and no significant visual loss (> 2 lines). Qualified success allowed IOP to be out of the target range in nonconsecutive visits, the use of glaucoma medications, and surgical revisions (not an additional glaucoma procedure). Failure was defined as IOP out of the target range (5 to 21 mm Hg) at any 2 consecutive visits (as per the previously determined postoperative intervals) after the first 3 months, an additional glaucoma procedure, or the occurrence of severe visual loss related to surgery [eg, endophthalmitis, suprachoroidal hemorrhage (SCH), or phthisis bulbi].

Statistical analysis was performed using R (RStudio, version 1.1.463 Mac; RStudio Inc., Boston, MA). Descriptive analysis was performed for both groups in which categorical data were presented as frequencies and percentages and continuous variables were presented as mean ± SD. Visual acuity was converted to logarithm of the minimum angle of resolution for statistical analysis. Between-group comparison was performed by using the t test for continuous variables and the χ2 test for categorical variables. A Kaplan-Meier survival curve was used to plot the success rates for both groups. The groups were then compared with the log-rank test. A P-value < 0.05 was considered statistically significant.

RESULTS
A total of 147 eyes were included in this study. There were 49 cases in the ligated AGV group and 98 cases in the nonligated AGV group. Table 1 presents the baseline characteristics of the study population. There was no statistical difference between groups regarding age, sex, preoperative IOP, baseline visual acuity, the number of previous glaucoma surgeries, and the number of previous ocular surgeries. Patients in the nonligated AGV group used a significantly higher number of preoperative glaucoma medications compared with the ligated AGV group (P < 0.01).

The number of cases that had polypropylene ligation was 15 (30.6%), whereas the remainder of cases underwent tube ligation with polyglactin. The mean time from surgery until suture lysis in the polypropylene subgroup was 29.9 ± 28.75 days (ranging from 2 to 103 d).

Figure 1 presents the mean IOP at baseline and at each postoperative interval in both groups. At the last postoperative interval, there was a statistically significant decline in mean IOP in the ligated AGV group (from 32.9 ± 9.5 to 16.7 ± 6.3 mm Hg, P < 0.01) and the nonligated group (from 34.3 ± 8.3 to 17.3 ± 8.0 mm Hg, P < 0.01). At visit 1 (0 to 5 d), the ligated AGV group had a higher mean IOP compared with the nonligated AGV group (21.3 ± 11.0 vs. 13.8 ± 8.6 mm Hg, respectively; P < 0.01). From visit 2 (6 to 30 d) onwards, the mean IOP was similar between groups (P > 0.05). Furthermore, the number of patients that had an IOP level that is equal to or more than baseline during the first 3 visits was 17 (34.7%) in the ligated AGV group compared with 12 (12.2%) in the nonligated AGV group (P < 0.01).
The mean number of glaucoma medications used was higher in the ligated AGV group compared with the nonligated group throughout all postoperative visits (Fig. 2). The difference between both groups was statistically significant from visit 1 (0 to 5 d) (1.39 ± 1.53 vs. 0.11 ± 0.60 medication, \( P < 0.01 \)) to visit 5 (month 6 ± 2) (2.06 ± 1.23 vs. 1.59 ± 1.40 medication, \( P = 0.04 \)). From visit 6 (month 12 ± 4) onwards, the difference in the mean number of glaucoma medications between groups was not statistically significant (\( P > 0.05 \)).

Figure 3 presents the Kaplan-Meier survival analysis for surgical success in both groups. At 12 months, the overall success rate was 83.2% in the ligated AGV group and 81.2% in the nonligated AGV group (\( P = 0.84 \)). Furthermore, the rate of complete success was 14.3% in the ligated AGV group and 29.6% in the nonligated AGV group (\( P = 0.06 \)).

Six patients (12.2%) in the ligated AGV group and 15 patients (15.3%) in the nonligated AGV group required surgical revision (\( P = 0.80 \)). In the nonligated AGV group, 4 patients (4.1%) required revision for hypotony-related complications (ie, flat anterior chamber, choroidal effusion) compared with 1 patient (2.0%) in the ligated AGV group. Table 2 outlines the surgical revisions required in both groups.

Postoperative complications in both groups are outlined in Table 3. The overall rate of complications was higher in the nonligated AGV group compared with the ligated AGV group (28.6% vs. 73.5%, \( P < 0.01 \)). Hypotony (defined as IOP ≤ 5 mm Hg) occurred in 11 eyes (11.2%) in the nonligated AGV group and only in 1 eye in the ligated AGV group.

There was no statistically significant difference in visual outcome between groups (Table 4). The mean change in logarithm of the minimum angle of resolution acuity between baseline and last visit was 0.05 ± 0.44 in the ligated AGV group and −0.01 ± 0.55 in the nonligated AGV group (\( P = 0.50 \)). Loss of >2 lines of Snellen visual acuity occurred in 7 (14.3%) patients (4.1%) required revision for hypotony-related complications (ie, flat anterior chamber, choroidal effusion) compared with 1 patient (2.0%) in the ligated AGV group. Table 2 outlines the surgical revisions required in both groups. *Statistically significant difference between both groups at this visit (\( P < 0.05 \)).

FIGURE 1. Comparison of mean intraocular pressure (IOP) between ligated and nonligated Ahmed glaucoma valve (AGV) groups during the follow-up period. *Statistically significant difference between both groups at this visit (\( P < 0.05 \)).

FIGURE 2. Comparison of the mean number of glaucoma medications between ligated and nonligated Ahmed glaucoma valve (AGV) groups during the follow-up period. *Statistically significant difference between both groups at this visit (\( P < 0.05 \)).

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patients in the ligated AGV group and 17 (17.3%) patients in the nonligated AGV group (P = 0.64).

**DISCUSSION**

This study compares the outcomes of ligated AGV surgery against nonligated AGV cases using a matched case-control design with intermediate postoperative follow-up. A large proportion of the study population had complex subtypes of glaucoma that were recalcitrant to medical treatment and some of the patients had failed before glaucoma surgery. Compared with patients with primary glaucoma undergoing their first procedure, these patients are considered at high risk for developing postoperative complications.

The findings of our study suggest that tube ligation was an effective modification to the standard AGV surgical technique in reducing the rate of postoperative complications. The overall rate of complications in the nonligated AGV group was 73%, which is slightly higher than, but comparable to, the reported rate in both the AVB and ABC clinical trials (63% and 43%, respectively). However, the ligated AGV group in our study had a much lower complication rate (28%).

**TABLE 3. Postoperative Complications in Ligated and Nonligated AGV Groups***

| Complications                  | Ligated AGV | Nonligated AGV | P‡  |
|-------------------------------|-------------|----------------|-----|
| Non–tube-related              | 9 (18.4)    | 65 (66.3)      | <0.01|
| Shallow AC                    | 0 (0.0)     | 8 (8.2)        |     |
| Choroidal effusion            | 2 (4.1)     | 6 (6.1)        |     |
| Corneal edema                 | 0 (0.0)     | 3 (3.1)        |     |
| Hyphema                       | 2 (4.1)     | 20 (20.4)      |     |
| Cataract progression†         | 2 (11.8)    | 7 (16.3)       |     |
| Aquous misdirection           | 0 (0.0)     | 1 (1.0)        |     |
| Choroidal hemorrhage          | 2 (4.1)     | 3 (3.1)        |     |
| Retinal detachment            | 0 (0.0)     | 3 (3.1)        |     |
| Endophthalmitis               | 0 (0.0)     | 1 (1.0)        |     |
| Early hypotony (< 3 mo)       | 0 (0.0)     | 8 (8.2)        |     |
| Late hypotony (> 3 mo)        | 1 (2.0)     | 3 (3.1)        |     |
| Encapsulation                 | 0 (0.0)     | 2 (2.0)        |     |
| Tube-related                  | 5 (10.2)    | 7 (7.1)        | 0.74 |
| Tube obstruction              | 2 (4.1)     | 4 (4.1)        |     |
| Tube malpositioning          | 2 (4.1)     | 1 (1.0)        |     |
| Tube erosion                  | 1 (2.0)     | 2 (2.0)        |     |
| Total                         | 14 (28.6)   | 72 (73.5)      | <0.01|

*Some patients had >1 complication.
†Percentage corrected to phakic patients.
‡Pearson χ² test.

**TABLE 4. Comparison of the Visual Outcome Between Ligated and Nonligated AGV Groups***

|                          | Ligated AGV | Nonligated AGV | P*  |
|--------------------------|-------------|----------------|-----|
| Baseline VA              |             |                |     |
| 20/100 or better         | 18 (36.7)   | 29 (29.6)      |     |
| <20/100 and ≥20/400      | 8 (16.3)    | 24 (24.5)      |     |
| CF or worse              | 23 (46.9)   | 45 (45.9)      |     |
| Final VA                 |             |                | 0.11|
| 20/100 or better         | 20 (40.8)   | 24 (24.5)      |     |
| <20/100 and ≥20/400      | 9 (18.4)    | 27 (27.6)      |     |
| CF or worse              | 20 (40.8)   | 47 (48.0)      |     |

*Pearson χ² test.

AC indicates anterior chamber; AGV, Ahmed glaucoma valve.
complications. For example, there was 1 patient in the ligated AGV group with an IOP of 4 mm Hg at 4 months postoperatively. In this particular case, glaucoma was secondary to intermediate uveitis and the late onset of hypotony (occurring after 3 mo) was most likely due to impaired aqueous production and not related to increased drainage through the device. Furthermore, there were 2 cases of choroidal effusion in the ligated AGV group. The first case was the same patient who had uveitic glaucoma and late-onset hypotony, and placement of another ligation suture was required to increase the IOP and resorb the choroidal effusion. The second patient developed choroidal effusion 2 weeks after surgery with a recorded IOP of 12 mm Hg, and in his case, the effusion resolved with conservative management and did not require surgical drainage. It is not unusual to encounter choroidal effusion following glaucoma surgery despite normal IOP. Hence, although ligating the tube reduces the risk of early postoperative hypotony, it does not eliminate the chance of choroidal effusion.

Postoperative SCH is another complication that has been linked to early postoperative hypotony following glaucoma surgery. However, in our study, the rate of SCH was not lower with tube ligation (4% in the ligated AGV group vs. 3% in the nonligated AGV group). A possible explanation of this finding is the history of cyclodestruction before AGV surgery. Both patients in the ligated AGV group who developed SCH had a history of prior cyclophotocoagulation (CPC). One patient underwent CPC twice and the other underwent CPC 3 times. Two patients who developed SCH in the nonligated AGV group did not have a history of prior CPC and the third case had undergone only one session of cyclodestruction before tube surgery.

Another striking difference between both groups is the occurrence of postoperative hyphema at a higher rate in the nonligated AGV group (20% vs. 2% in the ligated AGV group). Patients with neovascular glaucoma comprised 18% of our study population, and these patients have a propensity to bleed from iris neovessels postoperatively. A high postoperative IOP in the ligated AGV group might have been a protective factor that provided a tamponading effect against iris neovessels reducing the chances of bleeding.

The rate of complications in the nonligated AGV group in our study demonstrates that hypotony can occur despite the presence of a valve-like mechanism. Possible explanations of hypotony following AGV surgery include ciliary body shutdown thereby reducing aqueous production,9 leakage from the area surrounding the tube,16 and dysfunctional valve mechanism.

A reduced rate of complications with tube ligation comes at the expense of having to manage high IOP in the postoperative period. In our study, the mean IOP at the first postoperative interval (0 to 5 d) in the ligated AGV group was 21.3 ± 11.0 mm Hg. The high postoperative IOP can be managed with glaucoma medications in the early postoperative period or by removal and/or dissolution of the ligating suture. However, close monitoring of IOP is required in patients with severe glaucoma and advanced visual field loss. Preventing elevated IOP in the immediate postoperative period after glaucoma surgery is as important as preventing hypotony.

The relatively high IOP level with tube ligature is temporary and it is controlled soon after surgery with the use of topical medications. In our study, a difference in mean IOP between groups was observed during the first month only. At visit 3 (1 to 2 mo), both the ligated and nonligated AGV groups had comparable mean IOP (17.3 ± 5.6 vs. 17.9 ± 8.1 mm Hg, respectively; P = 0.56). Furthermore, tube ligation did not affect the long-term IOP level following the early postoperative period, as the mean IOP was comparable between both groups throughout the remainder of the follow-up period. A notable difference between both groups is the need for a higher number of glaucoma medications in the ligated AGV group. Despite the fact that some nonligated AGV cases in our study also required glaucoma medications in the early postoperative period, coinciding with the occurrence of the hypertensive phase, the difference between both groups remained significant for the entire duration of the first year. Following that period, the use of glaucoma medications was comparable between groups. At visit 6 (month 12 ± 4), the mean number of glaucoma medications in the ligated AGV group was 2.0 ± 1.10 compared with 1.86 ± 1.51 in the nonligated AGV group.

In a randomized clinical trial, Pakravan et al17 reported that the initiation of aqueous suppressive therapy after AGV surgery increases the success rate at 1 year. They hypothesized that reducing the amount of aqueous outflow through the tube by early initiation of aqueous suppressants reduces the number of inflammatory mediators reaching the plate and thereby producing a thinner capsule surrounding the drainage device leading to improved long-term outflow facility. In our study, we expected that ligating the AGV would produce a higher success rate through the same mechanism, limiting the plate-aqueous contact in the early postoperative period; however, our results failed to prove this finding.

Both ligated and nonligated AGV groups had similar surgical success rates at 12 months (83% vs. 81%, respectively) and thereafter. The success rates from our study are comparable to the 1-year success rate of the ABC study (83%),15 but are slightly higher than the rate reported in the 1-year outcomes of the AVB trial (58%).18 The reason for this difference is that the AVB study had a more strict definition of success with the upper IOP limit being 18 mm Hg as compared with 21 mm Hg in our study. It is important to note that patients in our study differ from those in both the ABC and AVB studies, as we included patients from all age groups and we had a higher number of patients who had prior cyclodestruction.

Our study has some limitations including the retrospective design. A prospective, randomized trial to test our hypothesis was not possible, because after observing the reduction in the complication rate with the first few cases of tube ligature most surgeons started to ligate AGVs in all high-risk cases at our institute. Another limitation is that the data were collected from multiple surgeons with different techniques of AGV ligation. Last, the intermediate-term follow-up does not address the long-term effects of ligation on the efficacy of AGV surgery.

In conclusion, our study shows that in high-risk patients with glaucoma that is recalcitrant to medical therapy, undergoing AGV surgery with tube ligation can reduce the rate of postoperative complications without affecting the intermediate-term surgical success rate. When compared with nonligated controls, ligated cases have a higher mean IOP in the early postoperative period and require more glaucoma medications during the period of follow-up. Future randomized clinical trials with a longer period of follow-up are required to further consolidate the findings of the current study and explore the long-term effects of ligation on the efficacy of AGV surgery.
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