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A Modified Tube Ligation Method during Ahmed Valve Implant Surgery

윤일석¹, 이마빈², 안재홍¹

Iluk Yun, MD¹, Marvin Lee, MD², Jaehong Ahn, MD, PhD¹

아주대학교 의과대학 안과학교실¹, 공안과의원²

¹Department of Ophthalmology, Ajou University School of Medicine, Suwon, Korea

²Kong Eye Clinic, Seoul, Korea

Purpose: To investigate the efficacy of a modified tube ligation method to prevent early postoperative hypotony during Ahmed glaucoma valve (AGV) implant surgery.

Methods: In this study, 38 eyes of 38 patients who underwent AGV implantation were observed for at least 6 months after the surgery. After priming the valve, the tube was ligated using a temporary 6-0 Prolene intraluminal stent and an 8-0 Vicryl ligature. Intracameral injection of viscoelastics was performed at the end of the surgery if the anterior chamber became shallow during the procedures. Hypotony was defined as IOP < 6 mmHg.

Results: Early postoperative hypotony developed in 5 of 38 (13.2%) eyes and lasted for a mean 6.8 ± 3.8 (1–12) days. No patient required a surgical intervention related to the hypotony. IOP was > 21 mmHg in four (10.5%) eyes on the first postoperative day.

Conclusions: The modified tube ligation method, combining partial ligation of the tube and selective intraoperative viscoelastic injection, can reduce complications and interventions related to early postoperative hypotony after AGV implantation.

Key words: Glaucoma, Implant surgery, Hypotony

Introduction

Glaucoma drainage implants are generally used to control intraocular pressure (IOP) in refractory glaucoma that is not responding to maximal tolerable medical therapy or in eyes for which filtration surgery failed.¹ These devices function by allowing the aqueous humor to flow freely through a tube in the anterior chamber toward a reservoir body implanted in subconjunctival space.² The Ahmed glaucoma valve (AGV; New World Medical Inc., Rancho Cucamonga, CA, USA) is a valved shunt device that is de-

signed to restrict excessive aqueous flow. The AGV has a one-way valve mechanism that opens when IOP > 8 mmHg, thereby reducing the risk of early postoperative hypotony.³⁻⁵ Although the AGV has a tendency to lower the incidence of postoperative hypotony versus valveless glaucoma drainage devices, postoperative hypotony and related complications remain clinical problems following AGV implant surgery.^{3,6-8} Partial ligation of the tube during AGV implant surgery is reportedly an effective method to prevent early postoperative hypotony.⁹⁻¹¹ Also, intracameral injection of viscoelastics has been used to reform the anterior chamber when postoperative hypotony is associated with a shallow anterior chamber.¹⁰ It is possible that the preventative effect of partial tube ligation against early hypotony can be potentiated by intracameral injection of viscoelastics. However, viscoelastic materials in the anterior chamber can also induce significant IOP elevation when a tube is partially ligated because of the increased resistance to fluid flow from the

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Corresponding Author: Jaehong Ahn, MD, PhD

Department of Ophthalmology, Ajou University School of Medicine,
#206 World cup-ro, Yeongtong-gu, Suwon 16499, Korea

Tel: 82-31-219-5260, Fax: 82-31-219-5259

E-mail: chrisahn@ajou.ac.kr

anterior chamber, through the narrower passage created by the partial ligation. In this study, we developed a modified tube ligation method that combines a partial ligation with selective viscoelastic injection during AGV implant surgery, and investigated its efficacy and complications related to hypotony in the early postoperative period.

Materials and Methods

Retrospective medical chart reviews were carried out for glaucoma patients who underwent first AGV implant surgery by a single surgeon between March 2012 and March 2015 at Ajou University Hospital, Korea. This study was approved by the institutional review board of Ajou University Hospital as a retrospective chart review study (AJIRB-MED-MDB-15-326) and adhered to the guidelines of the Declaration of Helsinki.

If both eyes received AGV implant surgery, only the first operated eye was included. Patients who received other ocular surgeries simultaneously, such as cataract surgery or pars plana vitrectomy, were excluded because these procedures might have influenced the early postoperative IOP. We collected data including patient demographics, visual acuity, IOP, glaucoma diagnosis, and number of glaucoma medications used. Postoperative data, including IOP, visual acuity, glaucoma medications, and postoperative complications, were collected over at least 6 months. Of the 46 eyes of 45 patients who underwent AGV implants surgery using the modified partial ligation method, eight eyes of eight patients were excluded: three underwent combined procedures with phacoemulsification surgery, two were excluded because intraoperative IOP records were missing, the second eye was excluded in the one patient who received AGV implant surgery in both eyes, one was excluded because of a simultaneous combined procedure with pars plana vitrectomy, and one was excluded because a partially ligated suture was removed during surgery.

The FP-7 model of the Ahmed valve (New World Medical Inc.) was used in this study. After administering retrobulbar or subconjunctival anesthesia, a fornix-based conjunctival flap was made between the superior rectus and lateral rectus

Figure 1. Partial ligation of the tube with 6-0 polypropylene (Prolene) as a stent. Ligation of the tube and the Prolene stent was performed with 8-0 Vicryl at the proximal site of the tube and the Prolene stent was withdrawn.

muscles. Next, 0.04% mitomycin-C (MMC)-soaked Weck-cel sponges (Medtronic, Minneapolis, MN, USA) were applied over the sub-Tenon's space for 5 min. The Weck-cel sponges were removed and the area was irrigated with balanced salt solution (BSS). The AGV was flushed with BSS to prime the valve mechanism. Next, a 6-0 polypropylene (Prolene; Ethicon Ltd., UK) stent was inserted into the lumen of the tube. Both the silicone tube and the Prolene were ligated with 8-0 polyglactin (Vicryl; Ethicon Ltd.) at the proximal site of the tube for possible laser suture lysis in the future (the ligation site was not covered by a scleral allograft). Next, the Prolene stent was removed from the tube (Fig. 1). The tube was irrigated with BSS again to confirm that the tube was not completely occluded. The plate of the AGV was placed 8 mm posterior to the limbus and fixed to the sclera with 7-0 Prolene. An entrance site to the anterior chamber was made with a 23-gauge needle between 1.0 and 1.5 mm posterior to the limbus. The tube tip was inserted through the entrance site and placed into the anterior chamber, parallel to the iris plane. After the tube had been inserted, the entry site was checked for leakage using a Weck-cel sponge; no case of leakage was observed. A 4 × 4-mm scleral allograft was used to cover the silicone tube.

IOP was measured with a tonometer (Tono-pen; Reichert, NY, USA) 3 min after the anterior chamber had been inflated with BSS solution. The conjunctiva and Tenon's capsule were closed with 10-0 nylon. When the anterior chamber depth became shallow during wound closure, viscoelastics (hyaluronic acid eye; sodium hyaluronate 1.5%, KUKJE, Korea) were injected into the anterior chamber at the end of the surgery. After the surgery, topical 0.5% moxifloxacin (Vigamox; Alcon, TX, USA) and 1% prednisolone acetate (Pred Forte; Allergan, Irvine, CA, USA) were started and tapered over 2 months. All patients were followed at postoperative day 1, every week until 1 month, and every month after 1 month. Hypotony was defined as an IOP < 6 mmHg on any single visit during the postoperative period.

Statistical analyses were carried out using the SAS software (ver. 9.4, SAS for Windows; SAS Institute Inc., Cary, NC, USA). Statistical analyses, including the Wilcoxon signed rank test, were performed to compare the preoperative and postoperative IOPs.

Results

In total, 38 eyes of 38 patients were included in the study. The mean age of the patients was 58.3 ± 12.3 years at the time of surgery. The mean postoperative follow-up period was 13.7 ± 8.0 months. The most common cause of glaucoma surgery was neovascular glaucoma (44.7%), followed by open angle glaucoma (26.3%) with failed trabeculectomy or pseudophakia. Intracameral viscoelastic injections was performed in 20 eyes during surgery because the anterior chamber became shallow during wound closure (Table 1).

The mean preoperative IOP was 32.2 ± 8.9 mmHg. The mean IOP was significantly lower at postoperative day 1 (13.3 ± 6.8 mmHg) and this was maintained until 6 months (13.3 ± 3.3 mmHg) after the surgery. The number of anti-glaucoma medications was also significantly reduced at all follow-up visits until 6 months. No anti-glaucoma medication was used until 3 weeks after the surgery and then use increased gradually (Table 2).

Five of 38 (13.2%) eyes experienced early postoperative hypotony. One eye without viscoelastic injection exhibited

Table 1. Characteristics of patients

Age (years)	
Mean $\pm$ SD	58.3 $\pm$ 12.3
Range	27-80
Sex (n, %)	
Female	10 (26.3)
Male	28 (73.7)
Eye (n, %)	
Right	19 (50)
Left	19 (50)
Lens status (n, %)	
Phakic	13 (34.2)
Pseudophakic	25 (65.8)
Diagnosis (n, %)	
Neovascular glaucoma	17 (44.7)
Open angle glaucoma	10 (26.3)
Uveitic glaucoma	4 (10.5)
Angle closure glaucoma	2 (5.3)
Miscellaneous	5 (13.2)
Previous glaucoma surgery (n, %)	
No	28 (70)
Yes	12 (30)
Intraoperative Intracameral viscoelastics injection (n, %)	
No	18 (52.6)
Yes	20 (47.4)
Follow up period (months)	
Mean $\pm$ SD	13.7 $\pm$ 8.0
Range	6-31
Preoperative intraocular pressure (mean $\pm$ SD, mmHg)	32.2 $\pm$ 8.9
Number of preoperative medications (mean $\pm$ SD)	3.7 $\pm$ 0.5

Values are presented as mean $\pm$ SD or n (%) unless otherwise indicated.

hypotony at postoperative day 1 and recovered spontaneously on the next day. In the other four eyes with viscoelastic injection, hypotony occurred between 1 week and 2 weeks after the surgery. In those four eyes, IOP increased gradually to > 5 mmHg after 8.3 (7–12) days with no surgical intervention. No hypotony-related complications, such as choroidal detachments or a shallow anterior chamber, were noted in those eyes.

Table 2. Intraocular pressure (IOP) and number of medications before and after the surgery

	IOP (mmHg)	No. of Medications
Preoperative	32.2 ± 8.9	3.7 ± 0.5
First day	13.3 ± 6.8 ($p < 0.01$)*	0.0 ± 0.1 ($p < 0.01$)*
First week	10.3 ± 5.1 ($p < 0.01$)*	0.0 ± 0.0 ($p < 0.01$)*
Second week	11.1 ± 3.3 ($p < 0.01$)*	0.0 ± 0.0 ($p < 0.01$)*
Third week	12.0 ± 3.1 ($p < 0.01$)*	0.0 ± 0.0 ($p < 0.01$)*
First month	13.7 ± 5.0 ($p < 0.01$)*	0.1 ± 0.4 ($p < 0.01$)*
Third month	13.8 ± 3.6 ($p < 0.01$)*	1.2 ± 1.2 ($p < 0.01$)*
Sixth month	13.3 ± 3.3 ($p < 0.01$)*	1.7 ± 1.1 ($p < 0.01$)*

Values are presented as mean ± SD unless otherwise indicated.

*Wilcoxon signed rank tests: Comparison between preoperative and postoperative data.

IOP was > 21 mmHg on postoperative day 1 in 3 (7.8%) eyes. Two were injected with intraoperative viscoelastics. In the first, IOP (26 mmHg) normalized by the next day after treatment with 250 mg oral acetazolamide. In the second, IOP was 40 mmHg at the first postoperative day but after digital massage, IOP decreased to 13 mmHg without additional anti-glaucoma medications. The third case (secondary glaucoma due to ocular trauma), which was not injected with viscoelastics, exhibited an exudative membrane around the tube tip at postoperative day 1 and IOP was 30 mmHg. This was a trabeculectomized and pseudophakic eye with a partial iris defect due to a previous perforated laceration of the cornea. Although the tube tip was irrigated with BSS, IOP did not decrease, so diode laser suture lysis (50 µm, 450 mW, 0.05 s) of the partial ligature was performed at 1 week after the surgery. IOP recovered to 10 mmHg immediately and was maintained during follow up.

Hyphema was observed in five (13.1%) eyes, one of which needed chamber irrigation on the first postoperative day because a blood clot blocked the AGV tube tip. One eye with viscoelastic injection (2.6%) exhibited mild choroidal effusion on postoperative day 7. The eye was not defined as hypotonic because IOP was maintained between 6 and 9 mmHg until the choroidal effusion was resolved. Conservative management, including topical atropine 1%, was performed for 3 weeks and the choroidal effusion resolved spontaneously.

Discussion

Incomplete occlusion of the tube and high outflow of aqueous fluid are two reasons for early hypotony in glaucoma drainage device implantation before the reservoir plate becomes encapsulated.¹² Taglia et al.¹³ reported that the occurrence of hypotony-related complications with the Ahmed valve was 31%. Coleman et al.³ reported that hypotony was observed in 22% of patients after Ahmed valve implantation. In *in vitro* experiments, the Ahmed and Krupin implants functioned as flow restriction devices or regulators, rather than as valves that truly opened and closed in response to pressure changes after immersion in fluid.¹⁴

Kee⁹ was the first to suggest partial ligation during AGV surgery. A partial ligation of the silicone tube of the AGV with a 6-0 Prolene stent and 8-0 Vicryl ligature could decrease early postoperative hypotony and its surgical complications, compared with a non-ligated AGV. Lee et al.¹¹ also reported that the partial ligation method prevented a shallow anterior chamber and its complications after AGV surgery. In these previous reports, stents were placed outside and beside the tube and were ligated with the tube. To avoid direct contact between the ligature and the stent, in our ligation method we locate a stent inside the tube and remove it after the ligation procedure has been completed. Kee et al.⁹ and Lee et al.¹¹ reported 6.3% (1/16 eyes) and 8.4% (8/95 eyes) incidences of postoperative hypotony in the partial ligation group, respectively, so early postoperative hypotony was still not completely prevented. Using our method, we observed a 13.2% (5/38 eyes) rate of hypotony during the early postoperative period. Apart from the differences in the ligation methods, the slightly higher incidence of hypotony in our study may be related to differences in the material properties of the AGV (S2 model in previous studies and FP7 here) because the silicone plate tended to have more postoperative hypotony (statistically insignificant).¹⁵⁻¹⁷ However, it seems that partial ligation methods can reduce hypotony-related complications. In this and previous reports using partial ligation in AGV surgery, hypotony-related complications did not require surgical interventions. Additionally, hypotony developed in only 1 of

38 (2.6%) eyes at postoperative day 1 in our study and four eyes developed hypotony between 1 and 2 weeks after the surgery. The duration of hypotony may be reduced because the wound healing process begins before hypotony develops which may decrease hypotony-related complications.

It has been reported that no hypotony was developed in the eyes with closing pressure measured prior to implantation ≥ 7 mmHg.¹⁸ However, it is difficult to measure the opening and closing pressure of the valve during surgery. Instead of measuring valve pressures, we examined chamber depth by microscopy after tube insertion and injected viscoelastics into the anterior chamber selectively. Because we confirmed no wound leakage around the tube, we assumed that shallowing of the anterior chamber during wound closure were caused by over-filtration with low valve closing pressure even after partial ligation. Viscoelastics have been used to reform a shallow anterior chamber after glaucoma surgery, such as trabeculectomy and glaucoma drainage device implantation.^{10,19} The intracameral viscoelastics stay in front of the lumen narrowed by ligation or the valve at which flow dynamics are thought to be changed, and would delay or prevent hypotony by restricting the flow of chamber fluid temporarily, until it is washed out.^{19,20} The material properties of viscoelastics are also important factors influencing the flow through the tube and valve mechanism. The molecular weight of the viscoelastics used in our study was 2.5×10^6 Da, whereas those of Healon (sodium hyaluronate 1.4%, Abbott Medical Optics, Inc. Abbott Park, IL, USA) and Healon GV (sodium hyaluronate 1.4%, Abbott Medical Optics, Inc.) are $2.5\text{--}3.8 \times 10^6$ Da and 5×10^6 Da, respectively.²¹ Thus, the physical properties of the viscoelastic substance used in our study (1.5% hyaluronic acid) might be similar to Healon, although resting and dynamic viscosities were not provided by the manufacturer.

Our findings have some limitations because the study was not a prospective, randomized, and case-controlled study performed in the limited number of patients. Further investigation is needed to validate this method, comparing it with other ligation and non-ligation methods.

In conclusion, a modified partial-ligation method combining partial ligation of the tube and selective viscoelastic in-

jection effectively reduced hypotony and its complications in AGV implant surgery. Although this method did not exhibit improved performance in decreasing the occurrence of hypotony compared with previous partial ligation methods, it did delay hypotony developing time and reduced hypotony-related complications.

Conflicts of Interests

All authors certify that they have NO affiliations with or involvement in any organization or entity with any financial interest (such as honoraria; educational grants; participation in speakers' bureaus; membership, employment, consultancies, stock ownership, or other equity interest; and expert testimony or patent-licensing arrangements), or non-financial interest (such as personal or professional relationships, affiliations, knowledge or beliefs) in the subject matter or materials discussed in this manuscript.

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