

The efficacy of viscocanalostomy for uncontrollable primary open-angle glaucoma in a developing country

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Purpose: To evaluate the safety and efficacy of viscocanalostomy in the management of medically uncontrollable primary open-angle glaucoma (POAG) in a developing country. **Materials and Methods:** This is a prospective, non-randomized case series of 14 consecutive eyes with medically uncontrollable POAG, all subjected to viscocanalostomy. The main outcome measure was success rate based on the intraocular pressure (IOP) level achieved post-operatively. The procedure was considered a complete success if IOP was less than 21 mmHg without any anti-glaucoma medication. Qualified success was defined as IOP of less than 21 mmHg with anti-glaucoma medication. All patients had a regular follow-up of at least 12 months. **Results:** IOP was reduced from a mean baseline value of 27.9 ± 7.3 mmHg (range: 21-40 mmHg) to a mean final value of 16.0 ± 2.7 mmHg (range: 13-22 mmHg), which was statistically highly significant ($P < 0.005$). The mean number of pre-operative anti-glaucoma medications was 3.0 ± 0.4 (range: 2-4), which was reduced significantly ($P < 0.0001$) to 0.3 ± 0.6 (range: 0-2) at the last follow-up visit. One year post-operatively, complete success was achieved in 71% and qualified success was observed in 21.4% of patients, summing up to an overall success rate of 92.4%. There were no major complications in any of the patients. **Conclusion:** Viscocanalostomy could be performed effectively and safely for control of POAG in developing countries.

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Viscocanalostomy is a non-penetrating procedure for uncontrolled primary open-angle glaucoma (POAG). Classic trabeculectomy, with or without anti-metabolites, has documented complications, many of which are attributed to the filtering bleb.^[1-5] Viscocanalostomy can relieve outflow obstruction by creating a trabecular–Descemet window that removes the inner wall of Schlemm’s canal and the juxtacanalicular tissue.^[5,6] Viscocanalostomy is associated with a good success rate and with less complications than penetrating filtering surgery.^[2] There are many reports on the success rate and complications of non-penetrating glaucoma surgery. However, regarding the more sophisticated procedures in this type of surgery, most of the currently available literature originates in developed countries. This study was conducted to determine the surgical outcome of this procedure in a developing country.

Materials and Methods

Fourteen eyes of 13 consecutive patients with uncontrolled POAG, despite maximally tolerated medical therapy, underwent viscocanalostomy at the Ophthalmology Department of the Islamic Azad University of Medicine, between February 2005 and August 2007. All surgeries were performed by one surgeon (KM). The surgeon was a general

ophthalmologist, with a surgical experience of 20 years. However, the reported cases are the first, independent surgical experience of the surgeon with viscocanalostomy. Glaucoma diagnosis was based on intraocular pressure (IOP) (more than 21 mmHg), optic nerve head cupping, visual field defects, and gonioscopy. The diagnosis was confirmed independently by two of the authors (KM and LS). Inclusion criteria included a diagnosis of POAG and inadequate IOP control (i.e., IOP > 21 mmHg), despite maximal tolerable medical treatment. Exclusion criteria included any evidence of angle-closure on gonioscopy, post-traumatic glaucoma, neovascular glaucoma, and other secondary or developmental types of glaucoma, or any previous intraocular operation. In addition, patients with advanced glaucoma, as defined by a vertical cupping of the optic nerve head of more than 0.6 or a severe visual field defect on standard automated perimetry, were excluded. The research project was in compliance with the tenets of the Declaration of Helsinki and approved by the Ethical Committee of the Islamic Azad University. All subjects gave written informed consent prior to enrollment in the study. Extra charge was not obtained neither from the patients nor from the third-party payers.

All patients were phakic and viscocanalostomy was performed as described previously.^[5,6] In summary, after creating a large superior, fornix-based peritomy, a limbal-based half-thickness scleral flap (5×5 mm) was made and extended 1.5 mm forward into the clear cornea. Then, a deep, smaller scleral flap (approximately 4×4 mm) was prepared below the superficial flap. Subsequently, Schlemm’s canal was unroofed, and the fibrotic tissue was simultaneously removed from the bottom of the canal. The dissection was continued into the cornea, exposing the anterior trabecular meshwork and Descemet membrane, such that a corneal window was created. Using viscocanalostomy cannulation, high-viscosity sodium hyaluronate (Healon GV; Abbott Medical Optic Inc., Santa Ana,

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CA, USA) was injected into the cut ends of Schlemm's canal on both sides once the Schlemm's canal had been de-roofed and the trabecular–Descemet window had been created. The deep flap was excised and the superficial flap was sutured using four or five separate 10-0 nylon sutures. Healon GV was injected under the flap and the conjunctival flap was sutured with two separate 10-0 nylon sutures.

Standard post-operative therapy consisted of 0.5% topical chloramphenicol, four times a day for 1 week, and betamethasone every 6 h for 15 days. Patients had regular follow-up visits, in which the visual acuity and surgical wound appearance were assessed, and IOP was determined by Goldmann applanation tonometry. The optic nerve was examined using a 90 D lens at the slit lamp. In addition, the number of anti-glaucoma medications and complications were recorded at each visit. Complete success was defined as an IOP less than 21 mmHg without anti-glaucoma medication. Qualified success was defined as an IOP of less than 21 mmHg with one or more anti-glaucoma medication(s). Regardless of level of IOP, loss of light perception, or the need for additional surgery, was considered as surgical failure.

For statistical analysis, a paired *t*-test and Fisher's exact test were used, employing statistical package for the social sciences (SPSS) for Windows version 11.5 software (SPSS Inc., Chicago, IL, USA). Statistical significance was set at $P < 0.05$ level.

Results

The study was performed on 14 eyes (six right eyes and eight left eyes) of 13 Iranian patients, with a mean age of 68 years (range: 44-75 years). Nine patients (69.2%) were female.

The mean pre-operative IOP was 27.9 ± 7.3 mmHg (range: 21-40 mmHg). The mean IOPs at 1 day, 1 month, 3 months, 6 months, and 1 year post-operative dates were 10.7 ± 6.2 mmHg (61.6% IOP reduction), 19.1 ± 3.1 mmHg (31.5% IOP reduction), 15.7 ± 3.3 mmHg (43.7% IOP reduction), 17.8 ± 5.6 mmHg (36.2% IOP reduction), and 16.0 ± 2.7 mmHg (42.6% IOP reduction), respectively [Fig. 1]. IOP ranged between 13 mmHg and 22 mmHg at the last visit, and the IOP reduction was statistically significant at all time intervals ($P < 0.005$). The mean number of pre-operative anti-glaucoma medications was 3.0 ± 0.4 (range: 2-4)

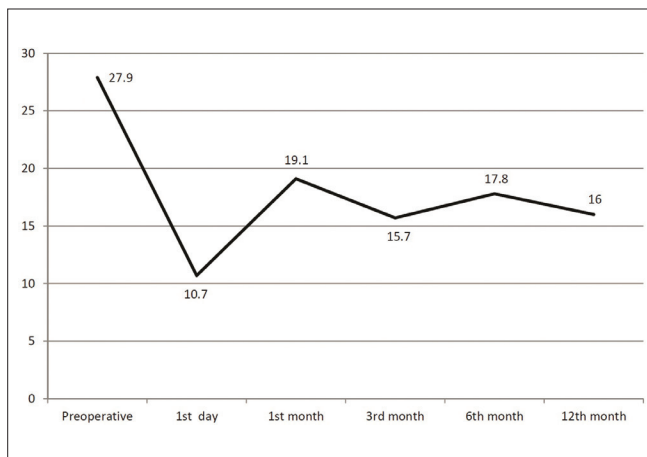


Figure 1: Intraocular pressure following viscocanalostomy in 14 glaucomatous patients with primary open-angle glaucoma

and the mean number of post-operative medications was 0.3 ± 0.6 (range: 0-2 medications) ($P < 0.0001$).

At the 1-year follow-up visit, complete or qualified success was achieved in 71% or 21.4% of patients, respectively. Despite using three topical anti-glaucoma medications, one patient failed to achieve adequate IOP control, and his initial procedure was considered to have failed. A conventional trabeculectomy surgery with mitomycin-C application was performed in this single case.

No major intraoperative or post-operative complications were observed. Microscopic hyphema was observed in 14.3% of patients, which was conservatively managed and disappeared spontaneously in 1 week. Small ruptures (micro-perforations) of the Descemet membrane were seen in two patients (14.3%). In one case, Descemet membrane detachment (approximately 30-40% of the total membrane area) was seen at the first post-operative day, without any other complications such as Descemet perforation. In this case, the cornea remained clear during the detachment phase, and gradual and spontaneous reattachment occurred nearly after 4 weeks without any surgical intervention. Bleb formation was encountered in two patients; however, 1 year following surgery, the unintentionally formed bleb remained functional in only one patient. No shallow or flat anterior chamber, induced cataract, long-term hypotony, or choroidal detachment was seen in any patient during the one-year follow-up period. Neither laser goniotomy nor bleb revision was performed in any of the patients.

Discussion

Non-penetrating glaucoma surgery is gaining increasing interest because it may reduce the incidence of many surgical complications associated with classic trabeculectomy, such as excessive filtration resulting in a flat anterior chamber, choroidal detachment, long-term hypotony with accompanied maculopathy, and intraoperative and post-operative bleeding.^[6-9] Here, we found that after 1 year, viscocanalostomy surgery significantly reduced the IOP by 42.6% compared to pre-operative levels, with an overall success rate of 92.4% at 1 year. IOP was reduced to high teens in most patients and this would be acceptable regarding the moderate nature of glaucomatous damage in our patients.

Using the same technique in an African population, Stegmann and associates previously reported overall and complete success rates of 89.0% and 82.7%, respectively.^[5] In a study of 67 eyes, Sunaric-Megevand and associates reported complete success rates of 68%, 60%, and 59%, and overall success rates (including qualified successes) of 88%, 90%, and 88%, at one, two, and three post-operative years, respectively.^[6] Wishart *et al.* reported complete success rates of 76% for POAG patients undergoing phacoviscocanalostomy and 67% for POAG patients undergoing viscocanalostomy alone. IOP was reduced by an average of 29.9% and 40%, respectively, following these operations. Among patients with pseudoexfoliative glaucoma, complete success rates following combined phacoviscocanalostomy and viscocanalostomy alone were 95% and 63%, respectively. In the combined group, IOP was reduced by an average of 42.5% and in viscocanalostomy group, IOP was reduced by 51%.^[7,8]

In our study, intraoperative complications included

microscopic hyphema and Descemet membrane microperforation. Descemet detachment was also observed on the first post-operative day in one patient. Although not observed at the time of surgery, this detachment is believed to have occurred during Healon GV injection under the scleral flap. This detachment occurred in the absence of other complications such as Descemet rupture, hyphema, or corneal intrastromal hematoma. The cornea remained clear during the detachment phase, despite the relatively long duration (almost 4 weeks) of the detachment. According to some reports, Descemet detachment can occur together with other complications, such as corneal hematoma or edema, and often requires surgical intervention.^[9,10] In our case, reattachment occurred gradually over 4 weeks, without requiring surgical or special medical intervention. We are not sure about the mechanism by which the cornea remained transparent until reattachment occurred. It is possible that the hyperosmotic property of Healon induced corneal dehydration and clearance.

Penetrating glaucoma surgery with conjunctival bleb formation carries a potential risk for post-operative infection, particularly in thin-walled, cystic blebs.^[11,12] Bleb formation occurred in two cases, with only one case maintaining a bleb after 1 year. Long-term hypotony and bleb-associated complications were not seen in any case. No serious complications were noted during the follow-up period, and the microscopic hyphema resolved quickly without complications. One eye demonstrated post-operative hypotony, but the IOP reached a normal level after 1 week post-operatively, and remained stable thereafter. Descemet microperforations were seen in two eyes, but no serious long-term consequences to this complication were noted during the follow-up period.

Our study had several potential limitations: first, we included only glaucomatous cases with moderate damage, while most patients in developing countries present with advanced glaucoma. We excluded advanced glaucoma cases, because the target pressure in these patients should be in low teens and the result of visco canalostomy in our hands was not necessarily good. Second, we had no control group in our study to compare surgical results. Third, we had a limited sample size. However, with current sample size, we reached statistical significance for primary outcome measure and these recent limitations are acceptable regarding the nature of study as a prospective case series. Obviously, prospective randomized clinical trials with higher sample size are warranted to further investigate the matter.

In conclusion, reporting from a developing country, visco canalostomy appears to be a safe and effective surgical

procedure. A larger number of patients and a longer follow-up period are warranted for the further evaluation of this relatively novel procedure in developing countries. In addition, comparing the future surgical cases of the same surgeon would show the learning curve of visco canalostomy more precisely. However, we believe that the high success rate and low complication rate in these initial 14 cases are highly encouraging to suggest popularization of non-penetrating glaucoma procedures in developing countries.

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