

CANALOPLASTY: 2-YEAR CLINICAL RESULTS

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INTRODUCTION

Trabeculectomy is still the gold standard of the glaucoma surgery, involving a surgically formed pathway for aqueous humor between the anterior chamber and the subconjunctival space to lower intraocular pressure (IOP). Although this procedure has a long-standing proven ability to lower IOP, numerous intra- and postoperative complications have been reported: hypotony, blebitis/endophthalmitis, hyphema, suprachoroidal hemorrhage or effusions, encapsulation of the bleb with resultant transient IOP elevation, loss of visual acuity and increased risk of cataract formation.(1)

The need for superior glaucoma surgical procedures has been motivated by the goal of achieving long term IOP control in the safest possible manner. Canaloplasty uses the natural outflow system to reduce IOP and targets the main source of outflow resistance which is the juxtacanalicular connective tissue region of trabecular meshwork and the inner wall of Schlemm's canal.(2)

Restoring the natural trabeculocanalicular outflow system is made by circumferentially catheterizing and dilating Schlemm's canal using a flexible microcatheter. The placement of an intracanalicular tension suture within Schlemm's canal distends the trabecular meshwork inward, stenting the canal open.(3)

The study presented in this paper evaluates the 2-year postsurgical safety and efficacy of canaloplasty (circumferential dilation and placement of a tension suture in Schlemm's canal).

MATERIALS AND METHODS

The study comprised 15 eyes from 13 patients with primitive open-angle glaucoma (POAG) or exfoliative glaucoma (PEXG) who underwent canaloplasty in Ophthalmology Department of the County Hospital of Piatra Neamț, between September 2012 and August 2014. All surgeries were done by the same surgeon. All the patients were able to understand and provided an informed consent for the procedure. Patient demographic data are shown in table no. 1.

Table no. 1. Patient demographic data

Parameter	Value
Patients / eyes(n)	13/15
Age in years	
mean ± SD	76.38±3.885
range	70 - 85
Sex n (%)	
Female	6 (46.15)
Male	7 (53.84)
Glaucoma diagnosis n (%)	
POAG	7 (53.84)
PEXG	6 (46.15)
Eyes with previous ocular surgery n (%)	
Cataract	5 (33.33)
Argon laser trabeculoplasty	1 (6.66)

Two patients were operated on both eyes. Inclusion criteria were open angle glaucoma, primitive or secondary; exclusion criteria were any form of angle closure glaucoma and congenital glaucoma. Eyes that previously underwent surgery not interfering with circumferential catheterization of Schlemm's canal (cataract surgery) were not excluded from the study. One patient has had argon laser trabeculoplasty in the eye scheduled for canaloplasty. A complete ophthalmologic examination was performed preoperatively including IOP measurement by applanation tonometry, visual acuity, gonioscopy, anterior and posterior slit lamp biomicroscopy and visual field examination whenever visual acuity was adequate for this procedure.

Surgical technique

All surgeries were performed according to the technique described by Scharioth, using the microcatheter Glaucolight from DORC.(4) After superior limbal peritomy, a superficial scleral flap of 5x5 mm, 1/3 of scleral thickness is dissected up to clear cornea. There is no bipolar cautery use in order to maintain the integrity of collector system and to avoid

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Article received on 16.03.2017 and accepted for publication on 31.05.2017

ACTA MEDICA TRANSILVANICA June 2017;22(2):75-77

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scleral collagen shrinkage that might make more difficult the final suture of the flap. A deep scleral flap is then fashioned, 0.5 mm inside the first, of adequate thickness and keeping constant the level of dissection (figure no. 1). With anterior dissection of this second flap the Schlemm's canal is unroofed. A paracentesis is made before creation of the trabeculo-descemet window, in order to reduce the IOP. The dissection of the deep flap is continued anteriorly fashioning the trabeculo-descemet window.

Figure no. 1. Dissection of the deep scleral flap



After the excision of the deep scleral flap the microcatheter Glaucolight from DORC was introduced into the Schlemm's canal, the entire 360° circumference (figure no. 2). A 9:0 polypropylene suture was tied at the exteriorized end of the catheter and introduced in the canal during the catheter withdrawal. The suture was tied under tension in the canal using a slip knot. After placement of high viscosity sodium hyaluronate in the scleral lake, the superficial scleral flap was sutured with 5 absorbable sutures (Vicryl 8:0). Anterior chamber was refilled with BSS and conjunctiva repositioned and sutured with 2 absorbable sutures.

Figure no. 2. Illuminated microcatheter through the Schlemm's canal



Postoperative management

Immediately after surgery 40 mg gentamicin and 2 mg dexamethasone were injected subconjunctivally in all patients. Postoperatively, the patients received a combination of antibiotic and steroid, eye drops during the day and ointment at night, which was tapered according to the degree of intraocular inflammation. Antiglaucomatous medication was discontinued after the procedure and recommenced according to IOP measurements if necessary. Postoperatively, patients were examined at day 1 and then at 1,6,12, 18 and 24 months. At each visit, a full ocular examination was performed including Goldmann applanation tonometry, slit lamp biomicroscopy, gonioscopy and mydriatic funduscopy.

Statistical methods

Student's t tests were used to compare IOP results at different time points with preoperative IOP. Results with $p < 0.05$

were considered significant.

RESULTS

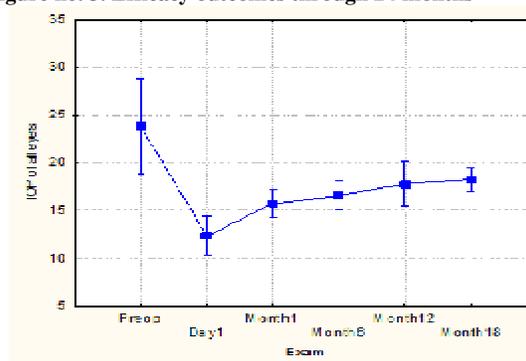
The study group included patients who met the inclusion and exclusion criteria and provided consent for long term follow up. In the study group, 7 (53.84%) patients had primitive open angle glaucoma and 8 (61.53%) pseudoexfoliative glaucoma (PEXG). Previous surgical procedures were cataract surgery in 5 patients (38.46%) an argon laser trabeculoplasty in a tertiary center for pseudoexfoliative glaucoma in one patient. The outcomes of the study are presented in table no. 2.

Table no. 2. Outcomes after 24 months

Exam	No. of eyes	Mean IOP (mmHg) ± SD	Mean meds(n) ± SD	t value	df	p value
Preoperative	15	23.867 ± 8.927	2.53 ± 0.990			
Day 1	15	12.333 ± 3.754	0	4.612	28	0.000
Month 1	15	15.733 ± 2.658	0	3.382	28	0.002
Month 6	14	16.571 ± 2.593	0	2.941	27	0.007
Month 12	14	17.786 ± 4.136	0	2.324	27	0.028
Month 18	9	18.222 ± 1.641	0	1.862	22	0.076
Month 24	4	17.750 ± 2.062	0.5 ±	1.334	17	0.200

All the patients attended the 1-month visit, 12 patients/14 eyes (93.33%) were evaluated at 6 and 12 months, 9 patients/9 eyes (60%) were evaluated at 18 months and 4 patients/4 eyes (26.66%) at 24 months. The mean preoperative IOP was at baseline 23.867 ± 8.927 mm Hg. Mean IOP was 12.333 ± 3.754 mm Hg at day 1, 15.733 ± 2.658 mm Hg at month 1, 16.571 ± 2.593 mm Hg at month 6, 17.786 ± 4.136 mm Hg at month 12, 18.222 ± 1.641 mm Hg at month 18, and 17.750 ± 2.062 mm Hg at month 24. Mean IOP was reduced at all time points compared with baseline: mean reduction was 48.32% at day 1; 34.07% at month 1; 30.55% at month 6; 25.48% at month 12; 23.63% at month 18 and 25.60% at month 24. This reduction was statistically significant at day 1, months 1, 6 and 12. Figure no. 3 shows mean IOP values through 24 months.

Figure no. 3. Efficacy outcomes through 24 months



There was no need of antiglaucomatous medication at any time point for any patient, except month 24 when 1 patient restarted Ganfort for his operated eye in which IOP was 30 mm Hg. There were no intraoperative complications. During the postoperative follow-up, 4 eyes had hyphema at day 1 and 2 eyes were found with peripheral supero-nasal Descemet membrane detachment with intracorneal migration of the

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prolene suture at 1 month. Postoperative hyphema cleared spontaneously with no effects on visual acuity and the detachment of Descemet membrane remained stable and did not affect visual acuity.

DISCUSSIONS

There are three pathological processes in open angle glaucoma: reduced outflow into Schlemm's canal, collapse of the canal and closure of the collector channels.(5) Schlemm's canal surgery with canal dilation and tensioning is the only glaucoma procedure that corrects all three. The canaloplasty procedure was designed to enhance the outflow of aqueous humor by dilating Schlemm's canal, establishing circumferential flow, and stretching out the TM.(6) It is the first procedure designed to treat the entire Schlemm's canal. There are a few studies in the literature dealing with long term results of canaloplasty. Grieshaber et al in 2010 studied the safety and effectiveness of canaloplasty (360-degree viscodilation and tensioning of Schlemm's canal) in black African patients with primary open-angle glaucoma (POAG). The mean follow-up time was 30.6 ± 8.4 months. They concluded that canaloplasty produced a sustained long-term reduction of IOP in black African patients with POAG independent of preoperative IOP. As a bleb-independent procedure, canaloplasty may be an alternative to classic filtering surgery, in particular in patients with enhanced wound healing and scar formation.(7) In a comparative case-series Koerber investigated 30 eyes of 15 adult patients with bilateral POAG who had canaloplasty performed in one eye and viscocanalostomy performed in the contralateral eye. With a follow-up period of 18 months, both the canaloplasty and viscocanalostomy groups showed statistically significant reduction in mean IOP and number of supplemental medications as compared with preoperative values. He concluded that canaloplasty and viscocanalostomy were safe and effective in the surgical management of open-angle glaucoma. Both procedures demonstrated excellent safety profiles.(8) Grieshaber et al assessed in 2011 the safety and efficacy of canaloplasty (360-degree viscodilation and tensioning of Schlemm's canal) in whites with open-angle glaucoma. They made a prospective study on 32 patients who underwent primary canaloplasty with a follow-up time of more than 1 year. Postoperative IOP levels were in the low-to-mid-teens. They considered canaloplasty a safe procedure but with its own profile of complications.(9) Lewis et al designed a multicenter prospective trial providing that canaloplasty safely and effectively lowers IOP with persistent control of IOP through a 3 year postoperative period.(3) The present study comprises a 2-year evaluation that addresses the longevity of this surgical procedure, its safety and efficacy, a key consideration in the surgical management of a chronic disease. Postoperative IOP reduction was important with complete surgical success (IOP below 21 mm Hg without medication) in 100% cases at any time point during the follow-up period. Canaloplasty did not necessitate the close postoperative follow up that is often required after trabeculectomy. Being a bleb-independent procedure, early postoperative care did not include bleb massage or suture release to enhance flow. So, one can speak about canaloplasty as a more cost effective procedure with less resource utilization and greater convenience for the patient and surgeon. One of the early postoperative complications was hyphema, which is not uncommon after canaloplasty, due to IOP decrease to less than episcleral venous pressure. Postcanaloplasty Descemet membrane detachment is not a rare event. Predisposing factors that can lead to this complication include a recent episode of corneal edema, hypotony, previous ocular surgery, corneal scarring and anatomic predisposition.(10) Injecting high viscosity viscosurgical material into Schlemm's canal might cause Descemet membrane detachment, rupture of trabecular meshwork with cheese-wiring

of the polypropylene suture, or opening of the suprachoroidal space and detachment of the ciliary body.(11) There are several limitations of this study: it is not randomized, although it is prospective and there are many remaining questions regarding the proper degree of the suture tension, the long term effect of the suture in the Schlemm's canal and its consequent microscopic changes in outflow system morphology. Additional studies including a greater number of patients are recommended.

CONCLUSIONS

Canaloplasty safely and effectively lowered IOP with persistent control throughout the entire follow-up period, and without significant early and late postoperative complications. This prospective study comes in agreement with the report of G.Scharioth published in 2013 according to which canaloplasty is the only new procedure with the potential to replace trabeculectomy as the gold standard for treatment of moderate to advanced glaucoma.(12)

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