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"ANTI-GLAUCOMA IMPLANT A3": SURGICAL TECHNIQUE AND THE LONG TERM FOLLOW-UP RESULTS

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✧ ***The goal of our work*** was to study the safety profile and effectiveness of a domestically manufactured shunting device for the treatment of advanced stage primary open-angle glaucoma. This article describes the surgical technique of "Anti-Glaucoma Implant A3" implantation, as well as long term follow-up results obtained from 19 patients (20 eyes). ***Materials and methods.*** The devices were implanted in 19 patients (20 eyes) with advanced stage primary open-angle glaucoma. The diagnosis was made based on collected medical history, results of objective and instrumental test findings. All patients included in the study underwent a standard ophthalmologic examination, including: automatic refractometry, best-corrected visual acuity (BCVA) assessment, automated static perimetry, biomicroscopy of the anterior segment, indirect ophthalmoscopy with an aspheric lens, gonioscopy. Optical coherence tomography (OCT) was used to assess retinal nerve fiber layer (RNFL) thickness. ***Conclusion.*** Intraocular pressure (IOP) lowering surgical procedures using an anti-glaucoma shunting device are non-inferior by their effectiveness to trabeculectomy, and have lower complication rate.

✧ ***Keywords:*** glaucoma; drainage; ophthalmic surgery; intraocular pressure; surgical treatment; intraocular pressure lowering surgical procedures; shunting devices.

ДРЕНАЖНОЕ УСТРОЙСТВО «ИМПЛАНТАТ АНТИГЛАУКОМНЫЙ А3»: ОПЕРАЦИОННАЯ ТЕХНИКА И ОПЫТ ПРИМЕНЕНИЯ

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✧ ***Целью*** нашей работы было изучение профиля безопасности и эффективности шунтирующего устройства отечественного производства в лечении далекозашедшей стадии первичной открытоугольной глаукомы. В статье приведена хирургическая техника имплантации устройства «Имплант антиглаукомный А3», а также отдалённые результаты, полученные в ходе наблюдения за 19 пациентами (20 глаз). ***Материалы и методы.*** Устройства были имплантированы 19 пациентам (20 глаз) с далекозашедшей стадией открытоугольной глаукомы. Диагноз поставлен на основании данных анамнеза, результатов объективных и инструментальных обследований. Всем пациентам проводили стандартное офтальмологическое обследование, включающее: авторефрактометрию, визометрию, статистическую компьютерную периметрию, биомикроскопию переднего отрезка глазного яблока, офтальмоскопию с асферической линзой, гониоскопию. Для оценки толщины слоя нервных волокон диска зрительного нерва выполняли оптическую когерентную томографию. ***Выводы.*** Гипотензивные вмешательства с применением антиглаукомного дренажа не уступают по эффективности трабекулэктомии, при этом наблюдается меньшее количество осложнений.

✧ ***Ключевые слова:*** глаукома; дренаж; офтальмохирургия; внутриглазное давление; оперативное лечение; гипотензивные вмешательства; шунтирующие устройства.

INTRODUCTION

Over the past 20 years, possible surgical treatments for glaucoma have expanded significantly due to the appearance of various intraocular devices implanted to reduce intraocular pressure (IOP) and stabilize the glaucoma process [1]. Despite the abundance of minimally invasive glaucoma surgery techniques, most of them are indicated for use only at the initial stages of the disease [2]. Trabeculectomy (the gold standard of antihypertensive interventions) and implantation of tubular shunts still remain the most effective methods of reducing IOP in developed and advanced stages of glaucoma. In our situation, the use of foreign-manufactured devices is limited due to their high cost. In this article, we share the experience of using a domestic tubular drainage device.

"The Antiglaucoma implant A3" drainage device is manufactured by Reper-NN (Nizhny Novgorod). The shunt was developed by the Tambov Interbranch Scientific and Technical Complex together with the Department of Eye Diseases of Privolzhsky Research Medical University in Nizhny Novgorod under the supervision of Professor I.G. Smetankin, MD, Ph.D. The device, made of a transparent acrylic series polymer, is a 3.2 mm long square tube with an inner lumen diameter of 200 microns. The distal end of the shunt has a true bias and an auxiliary port with a diameter of 0.1 mm. At the proximal end, there is a support element for fixing the implant under the scleral flap. This drainage device configuration has been used since 2014.

SURGICAL TECHNIQUE FOR DRAINAGE DEVICE IMPLANTATION

Under local anesthesia, a conjunctival flap is formed, with the base to the limb, and a part of the Tenon's capsule is excised. After hemostasis, a superficial trapezoidal flap is cut out to one-third of the scleral thickness of $4 \times 4 \times 3$ mm in size from the base to the limb. In the meridional direction, an intrascleral canal is formed that extends 1.5 mm beyond the superficial scleral flap borders. At the 3 (or 9) o'clock position, an anterior chamber paracentesis is performed with a lancet-shaped knife, and cohesive viscoelastic is injected to maintain the anterior chamber volume and prevent postoperative hypotension. Next, paracentesis is performed with a 22 G needle in the gray area of the surgical limb, under a superficial scleral flap, and the drainage device is implanted. The superficial scleral flap is fixed with two interrupted sutures (8.0 silk). A continuous suture is placed on the conjunctiva.

The use of special reusable tweezers, with branches that have recesses following the shape of the proximal end of the shunt, is recommended for implanting the "Antiglaucoma implant A3" drainage device. In patients with high IOP, before drainage device implantation, it is advisable to perform a posterior sclerectomy to prevent cilio-choroidal detachment.

MATERIALS AND METHODS

The "Antiglaucoma implant A3" device was implanted in 19 patients (20 eyes) with advanced stages of open-angle glaucoma. The diagnosis was made based on history and the results of physical and instrumental examinations.

Pre-admission, the patients were examined by a general practitioner, dentist, otolaryngologist, and endocrinologist, and the required therapy was prescribed. During their stay in the hospital, patients received advice and recommendations from relevant specialists, as needed. Two weeks before hospitalization, the patients underwent a standard preoperative examination, which included a general clinical blood test, a general urinalysis, a biochemical blood test (glucose, bilirubin, ALT, AST, prothrombin, blood type and Rh factor, creatinine, urea, and amylase), and blood tests for infectious disease markers (viral hepatitis, syphilis, and HIV). All patients underwent a standard ophthalmological examination, which included autorefractometry, visual acuity examination, static automated perimetry, biomicroscopy of the eyeball's anterior segment, ophthalmoscopy with an aspherical lens, and gonioscopy. Optical coherence tomography (OCT) of the optic nerve head (ONH) was performed to assess the thickness of the nerve fiber layer of the ONH.

To assess changes during the postoperative period, we also performed visual acuity examination, refractometry, biomicroscopy with an aspherical lens +60D, tonometry, perimetry, and OCT of the ONH. IOP was measured using a non-contact ICare tonometer. The results, obtained using the method of non-contact Icare tonometry and Goldman applanation tonometry, correlated with data from previous studies.

Perimetry is an important, affordable method for diagnosing glaucoma and progression of the glaucoma process. In our study, it was performed using the Perigraph Perikom automated static perimeter. This is a modern, Russian sphere perimeter with a personal computer that meets European standards. This device identifies changes in the visual

field characteristic of glaucoma, namely arched and paracentral scotomas, expansion of the blind spot, nasal step, and sectoranopia. Since Perikom is a suprathreshold tool, its capabilities are insufficient for the early diagnosis of glaucoma; however, the device's sensitivity did not affect this study's results because the patients had advanced stages of the disease.

Currently, OCT, which is based on the principle of light interference, has been used widely to diagnose glaucoma and monitor changes in the ONH. Modern spectral OCT tomographs use the principles of Fourier spectral analysis, which enables the identification of clinically significant pathology that cannot be diagnosed by ophthalmoscopy. OCT identifies and analyzes morphological changes in the retina and nerve fiber layer and their thickness, as well as ONH characteristics, by numerous parameters. Using the Heidelberg Spectralis HRA-OCT tomograph, it is possible to obtain an optical axial resolution of 7 microns and a digital resolution depth of 3.5 microns. This device performs 40,000 A-scans with high resolution, and thanks to its TruTrack function, it is possible to track eyeball movements and determine the scan line in the position obtained in the reference image.

The follow-up period for patients in this study was six to 36 months (mean 22.8 $\pm$ 9.65 months). The study included 12 men and seven women. The patients' ages ranged from 42 to 88 years. The average value was 68.35 $\pm$ 14.79 years. Three patients in our sample were of working age.

Ten patients had undergone cataract surgery by phacoemulsification with IOL (intraocular lens) implantation (PE $\pm$ IOL) before this procedure. In the others, one case of immature cataract was detected, and initial, age-related cataracts were registered in nine eyes. In seven eyes with cataracts, a combined PE $\pm$ IOL intervention was performed, and a drainage device was implanted. In the case of combined surgery for cataract and glaucoma, phacoemulsification was performed through a corneal tunnel and access for drainage implantation was made separately, taking the presence of previous antihypertensive procedures into account.

At the time of admission, all patients received conservative antihypertensive therapy. Most of them were at the maximum instillation mode and used three different drugs. The average number of instilled medications was 2.7 $\pm$ 0.47. At different times before the surgical treatment, three patients underwent laser trabeculoplasty. Most patients (13 eyes) had previously undergone antihypertensive surgeries. The average visual acuity without correction at the time of admission was 0.2 $\pm$ 0.1, whereas it was 0.3 $\pm$ 0.1 with correction. The average IOP at the time of admission was 24 $\pm$ 5.7 mm Hg. Three patients had a high degree of myopia.

In six patients (seven eyes), the IOP level was within the statistically average norm and did not exceed 21 mmHg; however, according to the examination data (perimetry, and OCT of ONH over time), their glaucoma process was not stabilized. Taking into account the stage of the disease, these IOP values did not correspond to the target level. In eight patients, IOP was moderately increased and ranged from 22 to 28 mmHg. High IOP indicators exceeding 29 mmHg were identified in five cases.

RESULTS AND DISCUSSION

Analysis of the IOP value changes over time showed that, at the time of discharge from the hospital (on the days 3–5), hypotension was present in 18 of 20 cases. The IOP did not exceed 4 mmHg in nine cases. The IOP was within normal limits in only two cases. There were no cases of ophthalmic hypertension. The average IOP at the time of discharge was 4.7 $\pm$ 3.2 mmHg.

Six months after surgery, 18 patients showed normalization of IOP. In two eyes out of 20, an increase in IOP was noted, which was reduced by instillations of antihypertensive drops.

After 12 months, in 50% of the cases (nine eyes), IOP remained normotonic without the use of antihypertensive drugs. In eight patients, the IOP level was normalized with a single antihypertensive drug. In two patients, the pressure increased moderately (IOP did not exceed 26 mmHg). In these cases, compensation was achieved after performing diode laser trans-scleral cyclocoagulation (DLTC).

Eighteen months after surgery, eight patients maintained normal IOP values, not exceeding 21 mmHg. In four patients, the pressure remained within the statistically average norm with the use of one antihypertensive drug. Two drugs (or one combined) were prescribed for four patients to achieve their target IOP. In one case, DLTC was performed with subsequent stabilization of the IOP and the rejection of antihypertensive therapy.

At the end of the second year of follow-up, the IOP in five cases was normal without the use of antihypertensive drugs. One antihypertensive drug was prescribed to one patient to normalize IOP. In five cases, the pressure was normalized using two

drugs (Fig. 1). In the third year of follow-up, the IOP remained within the target values in four out of five patients. In one case, to stabilize the IOP values, a second DLTC was performed, which led to the normalization of intraocular pressure.

In the long term after surgery, visual acuity worsened in four cases. Three of them were due to cataract progression. Phacoemulsification was performed in these patients, which improved their visual acuity. In one case, visual impairment was associated with the progression of glaucoma. During follow-up, this patient underwent DLTC twice, which stabilized the process. In most cases, drainage device implantation not only preserved visual function, but also improved it to some extent (Fig. 2).

The statistical analysis of visual acuity changes over time excluded cases of phacoemulsification after drainage device implantation.

Analysis of the changes in glaucoma over time, according to the OCT data of the ONH, showed progressive loss of the nerve fiber layer in one case. By automated perimetry, negative changes were not recorded during the first year of follow-up. In the postoperative period, a partial 2 mm hyphema was detected in two patients, and one patient had corneal edema with folds in the optical zone. Three patients from the sample underwent needling with the injection of a gel implant containing sodium hyaluronate into the filtering bleb to prevent excessive scarring.

According to foreign and Russian literature, trabeculectomy is still the gold standard of antiglaucoma surgery. In modern ophthalmology, most antihypertensive surgeries are performed using antimetabolites and cytostatics, which are not approved for use in our country. Previous studies reported that the incidence of pronounced ocular hypotension ranged from 0% to 38% after trabeculectomy (C. Jonescu-Cuypers, et al., S. Cillino et al.) [3, 4]. According to randomized clinical trials, pronounced hypotension developed in approximately 16.7% of cases [5], and hyphema was detected in an average of 23.5% of cases during the early postoperative period [6]. Excessive scarring of the filtering bleb occurred in 9% of the cases where cytostatics or antimetabolites were not used. According to previous clinical studies, the frequency of cataract progression due to antihypertensive surgeries ranged from 0 [7] to 35% [8] with a mean of 16.1% (Table 1).

Our results and the data obtained from the literature regarding trabeculectomy are presented in Table 2.

The effectiveness of antihypertensive procedure with antiglaucoma drainage was not inferior to the results of trabeculectomy and had fewer complica-

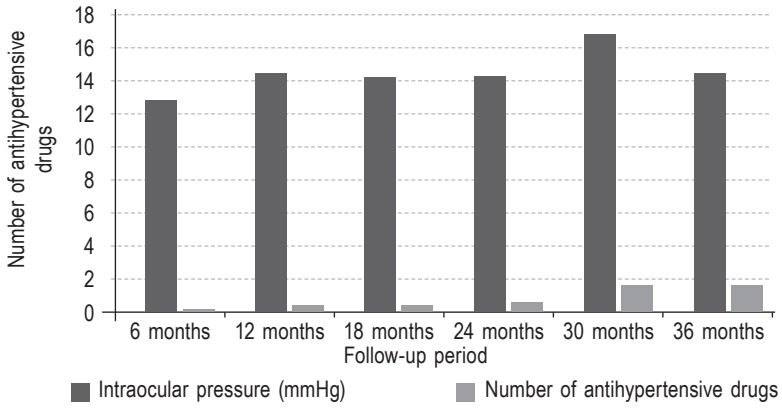

Fig. 1. Dynamics of IOP level and of the number of intraocular pressure lowering medications

Рис. 1. Динамика уровня внутриглазного давления и количества гипотензивных препаратов

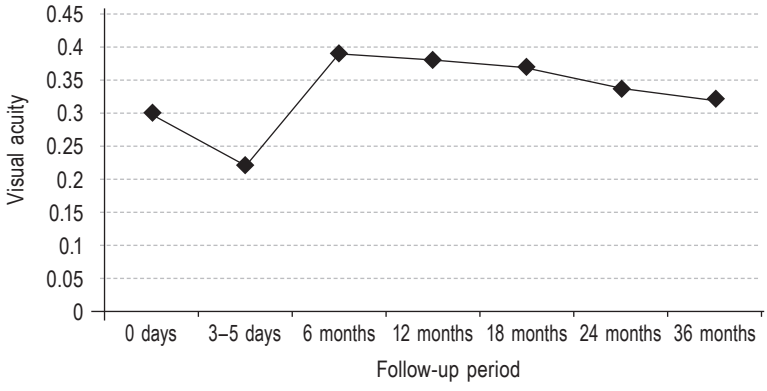

Fig. 2. BCVA dynamics

Рис. 2. Динамика остроты зрения

Table 1 / Таблица 1

Indices of complication prevalence in different glaucoma surgery methods
Показатели частоты осложнений при различных методиках хирургического лечения глаукомы

Type of complication	Trabeculectomy, %	Drainage implantation, %
Hypotension	16.7	–
Ciliochoroidal detachment	20.8	–
Hyphaema	23.5	10
Cystic filtering bleb	13	15
Cataract progression	16.1	–

Table 2 / Таблица 2

Comparison of the intraocular pressure level and the number of intraocular pressure lowering medications used
Сравнение показателей уровня внутриглазного давления и количества применяемых гипотензивных препаратов

Author	Year	Number of eyes	Follow-up period (months)	Preoperative IOP	Postoperative IOP	Number of antihypertensive drugs before surgery	Number of antihypertensive drugs after surgery
Luke et al.	2002	30	12	27 ± 7.0	15 ± 4.3	2.5	0.6
Cillino et al.	2004	33	24	32.1 ± 3	14 ± 1.1	2.3	0.7
Our study		20	23	24.05 ± 5.763	14.125 ± 3.775	2.7 ± 0.47	0.7

tions. The drainage device, made of an acrylic-based polymer, did not cause an inflammatory reaction following implantation.

The disadvantages of the considered drainage device include the product's fragility. Two shunts were split during fixation with tweezers, may be due to incorrect positioning of the proximal end between the branches. Currently, an injector for easy implantation of the drainage device is under development.

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