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Clinical Experience with Ex-Press Mini Glaucoma Shunt Implantation

Morena Gavrić, Nikica Gabrić, Jurica Jagić and Ana Čović

University Eye Hospital »Svjetlost«, Zagreb, Croatia

A B S T R A C T

In this prospective study we wanted to report our experience and to evaluate the effiacacy and safety of Ex-press Mini-Glaucoma Shunt implantation under a superficial scleral flap, as a newly and improved surgical technology in a treatment of POAG(Primary open-angle glaucoma) and refractory glaucoma. 44 eyes (35 patients) underwent an implantation of Ex-Press Mini Glaucoma Shunt. We had 21 patiens with POAG (60%) and 14 patients with PEXG-pseudoexfoliation glaucoma (40%). The follow-up period was 8.62+7.48 months (range 2–22 months). Main outcome measures included postoperative IOP control, postoperative medications and early postoperative complications. The IOP was measured in the following postoperative time-points of 1 day, 1 week, 1, 3, 6, 9 and 12 months. The mean IOP values 1 year postoperatively were reduced for 52.8% compared to preoperative values and the use of medications were reduced for 77%. We had complications like postoperative hypotony (3.5%), choroidal ablation (7%), intraocular hemorrhage (3.5%) and postoperative shunt closure (3.5%). The Ex PRESS Mini Glaucoma Shunt implanted under a superficial scleral flap is relatively safe and effective surgical procedure and provides satisfactory IOP control and medication reduction. However, device related complications remain still a problem.

Abbreviations: POAG – Primary open-angle glaucoma, PEXG – Pseudoexfoliation glaucoma, IOP – Intraocular pressure

***Key words**: Ex-Press Mini Glaucoma Shunt, glaucoma*

Introduction

Glaucoma is the second cause of blindness in the world[1]. It is defined as a group of diseases that are characterized by the common feature of progressive optic neuropathies (the open –angle glaucoma) or feature of occludable angle drainage in the anterior chamber (the closed-angle glaucoma). The innermost cases of these patients have the open-angle glaucoma (OAG). The therapy of these type of glaucoma can be medical with antiglaucomatous eye drops or surgerical treatment. As the step between two therapies, laser treatment can be used (Argon laser trabeculoplasty or Selective laser trabeculoplasty)[2–5].

Glaucoma filtration surgery is usually performed on patients who have uncontrolled intraoculare pressure despite of all medical treatment or failed laser trabeculoplasty.

In novel time, in a surgical treatment of open angle glaucoma (OAG), an implant named Ex-press Mini-Glaucoma Shunt is used[6].

It is well known surgical technique and worlwide available for almost a decade. The new developments in ophtalmic surgery are primarly focused on smaller incisions and effective control of IOP and therefore less complications associated with trabeculectomies or traditional glaucoma drainage implants[7].

In this prospective study we wanted to report our experience and to evaluate the effiacacy and safety of Ex-press Mini-Glaucoma Shunt implantation under a superficial scleral flap, as a newly and improved surgical technology in a treatment of POAG and refractory glaucoma.

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Materials and Methods

We prospectively analysied 44 eyes who underwent to Ex-PRESS Mini Glaucoma Shunt implantation under a superficial scleral flap. We studied 34 patients: 16 males (47.71%) and 19 females (54.28%). We had 21 patiens with POAG (60%) and 14 patients with PEXG-pseudoexfoliation glaucoma (40%). Patients were excluded if they had angle closure glaucoma, normal tension glaucoma, secondary glaucoma, uveitis or cataract. Also they were excluded if they had previous ocular surgery other than filtering surgery or uncomplicated cataract surgery. The follow-up period was 8. 62+7.48 months (range 2–22 months). The mean age of the studied population was 63.68+7.69 years. The primary outcome measures were mean IOP, postoperative medication use and early postoperative complications and those were evaluated and calculated in comparision to preoperative outcomes. The IOP was measured in the following postoperative time--points of 1 day, 1 week, 1, 3, 6, 9 and 12 months. All patients received the same ophthalmic examination preoperatively and at intervals postoperatively. All operations were done by the same surgeon and under same sugical procedure.

Results

One year postoperatively, mean IOP in all patients decreased from 31.15±6.28 to 14.70±4.74 mmHg ($p<0.001$). (Figure 1.). Mean number of medications was reduced from 3.1±0.70 preoperatively to 0.70±0.79 postoperatively. The successful procedure was defined as those in which postoperative IOP was > 5mmHg or <18 mmHg without the use of antiglaucoma medications. A review of the early postoperative complications related to Ex-Press Mini Glaucoma Shunt revealed 1 case of hypotony (IOP <5 mmHg – 3.5%), 2 cases of hypotony with choroidal detachment (7%), 1 case of excesive intraocular haemorrhage 24 hours postoperatively (3.5%) and 1 one case of postoperative shunt closure (3.5%) which was successfully solved by needling revision procedures.

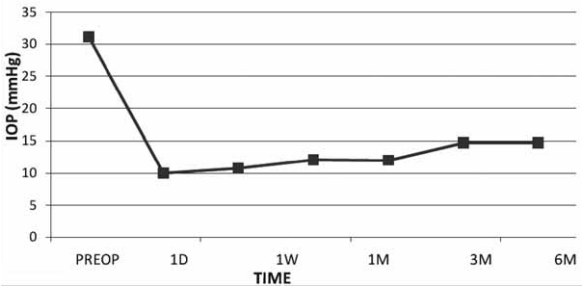

Fig. 1. Reduction of the mean IOP after Ex-Press Mini Glaucoma Shunt implantation during following time-points postoperatively. (p≤0,05, student t-test).*

Discussion

The open-angle glaucoma is a progressive optic neuropathy resulting in a loss of retinal ganglion cells and therefore a progressive damage of a visual field[8]. The primary goal of glaucoma treatment is reducing intraocular pressure by means of medications or surgical options[9]. Traditional glaucoma surgery treatment as trabeculectomy has been related to many complications [10]. The novel and alternative procedure is implantation of the Ex-press mini glaucoma shunt under scleral flap[11–13]. The device is a small stainless steel, nonvalvuled flow-restricting device developed as less invasive surgical procedure. As we noticed before, today the expresss mini glaucoma shunt is recomended as the first surgical option, as well as the second surgical option in cases when the clasic trabeculoplasty did not give expected results.

Several studies investigated the efficacy and safety of Ex-press mini glaucoma shunt compared to standard trabeculectomy. All of them demonstrated significant higher success rates compared to standard procedure to lower intraocular pressure in the treatment of open-angle glaucoma, fewer prescriptions for IOP medications, higher responder rates and also showed significant longer time without need for medications. However, Ex--Press device is not without complications such as early hypotony, but it ensures greater predictability with less complications in general, like inflammation, hypotony and also provides more rapid visual recovery. It well known that the Ex-Press also has a wider range of indications than trabeculectomy. In our study the mean IOP values and the number of medications for all patients were significantly decreased from the preoperative measures at all intervals. The mean IOP values 1 year postoperatively were reduced for 52.8% compared to preoperative values and the use of medications were reduced for 77% what is in accordance with so far published studies[10–13]. We had complications like postoperative hypotony (3.5%), choroidal ablation (7%), excessive intraocular hemorrhage (3.5%) and postoperative shunt closure (3.5%). None of the patient developed a conjuctival erosion. All early postoperative complications were successfully resolved.

In conclusion, our study showed that Ex-Press Mini Glaucoma shunt implantation under partial thickness scleral flap is safe and effective procedure in a treatment of an open-angle glaucoma and refractery glaucoma what confirmed the results presented in previous studies[10–13].

This promising and relatively new device provides satisfactory IOP control, medication reduction, higher responder rates and low rate of device related complications.

However, on the basis of review of the publised literature and studies, the longer follow up period is needed to summarized all advanteges and disadvantages of this novel glaucoma surgical technique.

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M. Gavrić

University Eye Hospital »Svjetlost«, Heinzelova 39, 10 000 Zagreb, Croatia
e-mail: morena.gavric@svjetlost.hr

KLINIČKO ISKUSTVO SA »EX-PRESS MINI GLAUCOMA SHUNT«

SAŽETAK

U ovoj prospektivnoj studiji smo htjeli prikazati naša iskustva sa Ex- Press Mini Glaucoma Shunt-om kao i evaluirati učinkovitost i sigurnost ove nove i poboljšane kirurške tehnike u tretmanu primarnog glaukoma otvorenog kuta i refraktivnog glaukoma. 44 oka su podvrgnuta ovom kirurškom postupku. Imali smo 21 pacijenta s dijagnozom primarnog glaukoma otvorenog kuta te 14 pacijenata s dijagnozom pseudoeksfolijativnog glaukoma. Vremenski period praćenja pacijenata je bio 8,62+7,48 mjeseci (raspon 2–22 mjeseci). Glavna postoperativna mjerenja su bili IOT (intraokularni tlak), potreba za medikamentoznom terapijom te rane postoperativne komplikacije. IOT je mjeren u periodima od 1 dana, 1 tjedna te 1, 3, 6, 9 i 12 mjeseci nakon operacije. Srednja vrijednost IOT se nakon 1 godine smanjila za 52,8% u odnosu na preoperativne vrijednosti,dok se potreba za medikacijom smanjila za čak 77% što je u skladu s dosada objavljenim studijama. Od ranih postoperativnih komplikacija imali smo 1 pacijenta s postoperativnom hipotonijom (3,5%), 2 pacijenta s ablacijom žilnice (7%), 1 pacijenta s intraokularnim krvarenjem (3,5%) te 1 pacijenta s postoperativnom obstrukcijom shunt-a (3,5%). Na osnovu navedenih podataka možemo zaključiti da je implantacija Ex-Press Mini Glaucoma Shunt-a ispod skleralnog flap-a sigurna i učinkovita kirurška metoda koja pruža zadovoljavajuću kontrolu IOT-a te smanjenu potrebu za medikacijom postoperativno, kao i nisku stopu ranih postoperativnih komplikacija povezanih sa implantacijom samog shunt-a.