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Profile and variability of intraocular pressure after the EX-PRESS device implant

Perfil e variabilidade da pressão intraocular após implante do dispositivo EX-PRESS

Rodrigo Egidio da Silva[1,2] https://orcid.org/0000-0002-8072-4767
Juliana de Lima Jácomo[3] https://orcid.org/0000-0003-1971-3695
Lara Ribeiro Vilela[3] https://orcid.org/0000-0003-1971-3695
Antônio Wilson Soares de Oliveira[2] https://orcid.org/0000-0001-6728-5934
Francisco Wellington Rodrigues[1,2] https://orcid.org/0000-0002-7995-0273

Abstract

Objective: *The EX-PRESS device is a surgical alternative for the treatment of POAG. To describe the IOP behavior before and after the implantation of the EX-PRESS, the pharmacological treatment used in the pre and postoperative period and the complications in the first year of the postoperative period.* ***Methods:*** *A quantitative descriptive study with review of electronic medical records of a private ophthalmological reference hospital in Goiânia (GO) from 2013 to 2018. Sample composed of 8 eyes with POAG subjected to the EX-PRESS implant. We observed the variables: gender, age, operated eye, antiglaucomatous medications used, pre and postoperative intraocular pressure, and possible complications.* ***Results:*** *In the preoperative period, all eyes used antiglaucomatous drops, 75% used 3 or more different classes simultaneously. After 12 months of EX-PRESS, only 12.5% used three or more eye drops and 37.5% did not use any eye drops. On average, IOP varied from 18.63mmHg (SD 9.38) in the preoperative period to 14.50mmHg (SD 4.14) at 12 months postoperatively. Complications were: ocular hypotension, ocular hypertension; thinning of the conjunctival blister, cystic blister obstruction of the EX-PRESS. We resolved all coplications.* ***Conclusion:*** *The efficacy of EX-PRESS in IOP reduction was verified in the study. Concomitantly, there was a considerable decrease in anti-glaucomatous medications, and few associated complications.*

Keywords: *Glaucoma drainage implants; Glaucoma; Intraocular pressure; Drug therapy; Postoperative complications; Prosthesis implantation/methods.*

Resumo

Objetivo: O dispositivo EX-PRESS é uma alternativa cirúrgica para o tratamento do GPAA. Descrever o comportamento da PIO antes e após a implantação do EX-PRESS, o tratamento farmacológico utilizado no período pré e pós-operatório e as complicações no primeiro ano do pós-operatório. **Métodos:** Estudo descritivo quantitativo com revisão de prontuários eletrônicos de um hospital particular de referência oftalmológica de Goiânia (GO) no período de 2013 a 2018. Amostra composta por 8 olhos com GPAA submetidos ao implante de EX-PRESS. Foram observadas variáveis: sexo, idade, olho operado, medicações antiglaucomatosas usadas, pressão intraocular pré e pós-operatória, e possíveis complicações. **Resultados:** No pré-operatório, todos os olhos usavam colírios antiglaucomatosos, 75% faziam uso simultâneo de 3 ou mais classes diferentes. Após 12 meses do EX-PRESS, apenas 12,5% usavam três ou mais colírios e 37,5% não usavam nenhum colírio. Em média, as PIO variaram de 18,63 (DP 9,38) mmHg no pré-operatório para 14,50 (DP 4,14) mmHg em 12 meses do pós-operatório. As complicações foram: hipotensão ocular, hipertensão ocular,afinamento de bolha conjuntival, bolha cística, obstrução parcial do EX-PRESS. **Conclusão:** A eficácia do EX-PRESS na redução da PIO foi verificada na amostra desse estudo. Concomitantemente, constatou-se diminuição considerável de medicações anti-glaucomatosas, e poucas complicações associadas.

Descritores: Implantes para drenagem de glaucoma; Glaucoma; Pressão intraocular; Tratamento farmacológico; Complicações pós-operatórias; Implantação de prótese/métodos

[1] Hospital VER, Goiânia, GO, Brazil.
[2] Pontifícia Universidade Católica de Goiás, Goiânia, GO, Brazil.
[3] Curso Acadêmcio de Medicina, Pontifícia Universidade Católica de Goiás, Goiânia, GO, Brazil.
Research developed by:
Pontifícia Universidade Católica de Goiás – Goiânia, GO, Brazil.
Hospital VER – excelência em oftalmologia, Goiânia, GO, Brazil.

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Introduction

In 2010, WHO named glaucoma as the second leading cause of blindness in the world (8%), behind the cataract (51%), and the leading cause of irreversible blindness.[1] More recent epidemiologies estimate that 64.3 million people worldwide have glaucoma in 2013, with projections of 76 million for 2020 and 111.8 million for 2040.[2] In Brazil, epidemiological data are scarce. The lastest studies describe a prevalence of 2% to 3% in the population over 40 years old.[3]

The most common form, Primary Open Angle Glaucoma (POAG), is defined by the European Glaucoma Society as a chronic and progressive optic neuropathy with morphological changes in the retinal and optic nerve fiber layers, in the absence of congenital or another ocular disease,[4] IOP is the most important and potentially modifiable risk factor that can positively affect the natural history of the disease, which is why it is the most studied and the basis of treatment.[5,6]

Drugs and surgical procedures have the primary goal of reducing IOP to avoid degeneration of the optic nerve[6-8] and preserving the patient's visual acuity to the same level as it was at the time of diagnosis. It is assumed that the determination of the target IOP should be, whenever possible, individualized.(8,9)

Trabeculectomy is the most commonly used surgical procedure in POAG and has remained the gold standard since its inception in 1968.[7] However, with the intense technological development in the field of ophthalmic microsurgery, innovative alternatives have emerged, such as the EX-PRESS mini glaucoma shunt (excessive pressure regulating shunt system) drainage device .[10-12]

EX-PRESS was approved in Europe in 1999, by the FDA in 2002[12] and in Brazil, by the National Agency of Sanitary Surveillance (ANVISA), in April 2011 (nº. record: 80153480152).[13] The officially recommended technique is the insertion of the device under a partial-thickness scleral flap.[10,12,14] The mechanism of action of EX-PRESS, similar to trabeculectomy, is based on the deviation of the aqueous humor from the anterior chamber to the subconjunctival space, forming a filter bag. Thus, there is the reduction of IOP.

The advantages provided by the EX-PRESS include rapid learning curve, lower postoperative intraocular pressures, less inflammation (since there is no tissue removal), predictable outcomes related to consistent lumen size and controlled flow, and fewer postoperative complications.[12]

Since its launch in the market, several studies have compared EX-PRESS to other treatments dedicated to the treatment of glaucoma, especially with risks and complications. Current data show that devices such as the EX-PRESS, implanted under a scleral flap, have a better early postoperative safety profile when compared to trabeculectomy, and the effectiveness in reducing IOP by both methods is maintained.[15-17]

In view of well-established advantages, we consider it relevant to observe in detail the drainage effect of the EX-PRESS in IOP. When tracing the pressure variation profile, we will have data that will contribute to the precise evaluation of the stability and effectiveness of the device. In a population with high miscegenation such as in Brazil and the reduced concentration of studies in this segment, the parameters found in this study could be used to optimize the therapeutic choice for POAG, as well as to develop strategies to achieve better results with EX-PRESS.

Methods

This is a quantitative descriptive study done through a review of electronic medical records of a private ophthalmological hospital in Goiânia (GO) from 2013 to 2018. It was approved by the Research Ethics Committee (CEP) of the Pontifical Catholic University of Goiás (PUC-GO).

The study has a sample of 8 eyes with a diagnosis of POAG. Inclusion criteria were patients over 18 years of age, IOP above 22mmHg, minimum use of two classes of antiglaucomatous medication, excavations greater than 0.7 with loss of neuronal rhyme, open angle confirmed, loss of visual field using Anderson criteria.[18 -20] We excluded from the sample selection patients under 18 years old, charts with incomplete data, users of contact lens and/or patients with closed angle glaucoma.

All patients were assessed to IOP through the Topcon computerized tonometer CT-80 Japan pneumatic tonometer For this preliminary study, the IOP measurement was chosen by the pneumatic tonometer, where the mean IOP was used after 3 isolated measurements in each operated eye. The following variables were observed: sex, age, operated eye, antiglaucomatous medications used, intraocular pressure and complications during the first year postoperatively. All patients underwent a complete ophthalmologic examination. The patients submitted to the EX-PRESS implant were treated by the same surgeon and the same surgical technique with the differential in the preparation of the scleral flap and the use or not of the antifibrotic agent depending on the case.[10]

Description of the technique: performed peribulbar anesthesia. Made a fornix based conjunctival flap. Hemostasis with bipolar cautery. Depending on the case, antifibrotic was applied. Rectangular scleral patch of approximately 4 mm. Temporal paracentesis through the cornea temporal region. The scleral flap is lifted and the center of the "blue line" adjacent to the clear cornea corresponding to the location of the trabecular meshwork is identified. A 26-gauge needle is inserted through the center of the "blue line" into the anterior chamber at an angle parallel to the plane of the iris.[10] The needle is withdrawn. The needle should not be moved sideways to prevent the formation of aqueous flow around the implant. The EX-PRESS shunt is preloaded on an injector. A metal rod is installed in the lumen of the shunt, which is connected to the end of the injector.[10]

When placing the shunt in the anterior chamber through the ostium created with the needle, the angle used to make the ostium is the same as the angle with the shunt.[10] The shunt is inserted until the end of the wound, leveling the plaque with the scleral bed. After this, an area is pressed in the axis of the injector, which retracts the metal rod in the lumen of the bypass, thus allowing the lumen of the shunt to be released from the injector.[10]

The scleral flap is then sutured in place with 10-0 nylon thread. A minimum of three sutures are required, and the number of sutures depends on the aqueous humor flow generated by injecting a balanced solution through the temporal paracentesis in the anterior chamber. Finally, the conjunctiva is closed with the nylon suture 10-0.[10] In our study, after closure of the planes, the surgeons tested via paracentesis the elevation of the bubble.

After the data were collected, they were transcribed into spreadsheets in Microsoft Excel® software. Subsequently, the quantitative variables were described by means of proportions and measures of central tendency and dispersion.

Results

The mean age of the patients was 54.63, with a maximum age of 73 and a minimum of 32 years, with a predominantly female gender (75%). Of the operated eyes, 62.5% were on the left eye (Table 1).

Table 1
Characteristics of operated eyes

Variables	Eyes, n (%)
Age (years), mean (SD)	54.63, (16.03)
Interval (years)	32-73
Gender, n (%)	
Male	2 (25)
Female	6 (75)
Eye operated, n (%)	
Right	3 (37.5)
Left	5 (62.5)

All eyes were treated with antiglaucomatous eye drops prior to surgical treatment, of which 75% made simultaneous use of 3 or more different classes of these eye drops. After 12 months of EX-PRESS, only 12.5% used three or more eye drops and 37.5% did not undergo any antiglaucomatous pharmacological treatment (Figure 1).

On average, intraocular pressures ranged from 18.63mmHg (SD 9.38) in the preoperative period to 13.88mmHg (SD 8.03) in seven days, 15.75mmHg (SD 3.93) in 30 days and 14.50mmHg (SD 4.14) at 12 months postoperatively. There was a mean reduction of 4.13mmHg (SD 10.22) in the IOP variation before EX-PRESS up to one year after the implant target IOP with medication in 75% of cases (Figure 2).

Postoperative complications are described in Table 2 Ocular hypotension (IOP <10mmHg) occurred in 62.5% of the eyes, and ocular hypertension (IOP = 22mmHg), conjunctival bladder thinning, cystic blistering and partial obstruction of the EX-PRESS occurred, each one of them, in 11% of the eyes. In the face of persistent increases in IOP, ocular massage, needlework, and antiglaucomatous eye drops were introduced. The thinning of the conjunctival bubble and cystic blister, were resolved with conjunctival regrowth and excision of the bubble, respectively. The partial obstruction of the EX-PRESS, which occurred after 15 days of implantation, had spontaneous resolution without the need for surgical repositioning.

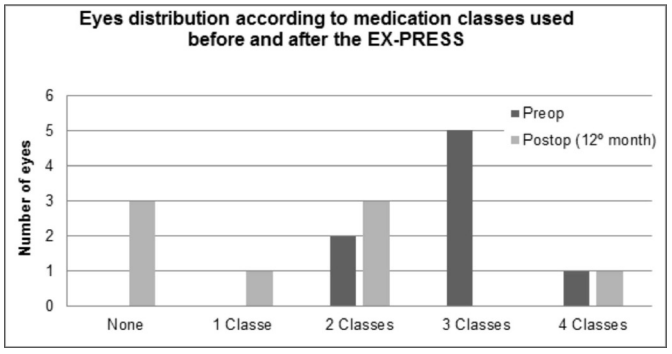

Figure 1: Eyes distributed according to the number of classes of antiglaucomatous eye drops used before EX-PRESS and in the 12th month of implantation.

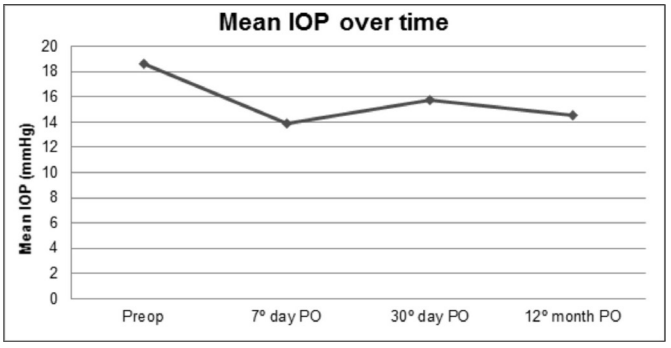

Figure 2: Mean IOP change from immediate preoperative up to 1 year after EX-PRESS.

Table 2
Post-OP Complications and interventions

Complications	Cases n (%)
Hypotension (≤10mmHg)	5(62.5)
Hypertension (≥22mmHg)	1 (12.5)
Conjunctival bladder thinning	1 (12.5)
Cystic blister	1 (12.5)
Partial Obstruction of EX-PRESS	1 (12.5)
Post operative interventions	
Conjunctival coating	1 (25)
Excision of the cystic blister	1 (25)
Massage	1 (25)
Needle	1 (25)

Post-OP: postoperative; n: absolute number of complications in relation to total number of eyes / n: absolute number of interventions

Discussion

In this study, we describe the IOP variation, measured with the pneumatic tonometer, of eyes submitted to the surgical treatment of glaucoma with EX-PRESS, correlating with pharmacological treatment, postoperative complications and variables of age, gender and side of the operated eye.

The present study identified that the majority of patients undergoing EX-PRESS implantation surgery were approximately 54 years old. The III Consensus on Primary Open Angle Glaucoma (POAG), published by the Brazilian Society of Glaucoma, says that age is directly proportional to the prevalence of POAG.[21-23] The American Academy of Ophthalmology provides us with the same epidemiological pattern, including the incidence of POAG.[24] The European Glaucoma Society, in 2014, reaffirms that there is an increase in POAG with increasing age and that there is a higher prevalence of POAG in Caribbean-Africans and Latinos compared to Caucasians.[4] Therefore, the data collected in this research match the data present in national and international literature.

Regarding gender, it was evidenced that the predominant sample of this study was of women. It is estimated that in the world there will be 79.6 million people with POAG in 2020, with the female gender corresponding to 55% of the cases.[21,25] In studies evaluating glaucoma, there is no consensus among the genus predominantly associated with POAG. Some studies have shown that males are more likely to have POAG than females,[26-30] as in the study by Kim et al.[30]. This study suggests that hormonal

factors may be associated with the protection of the female gender to the development of POAG, since the endogenous estrogen produced until menopause[30,31] and the use of exogenous hormone therapy after menopause[30,32] were considered protective factors. However, in some studies there was a quantitative predominance of the female groups[33-35] when compared with the male groups,[36] corroborating with the sample of our study.

Before the surgical treatment, a pharmacological approach is suggested as the first choice. In the study sample, all eyes were treated with eye drops prior to implantation. At that time, most were simultaneously using 3 or more different classes of drugs. After 12 months of the EX-PRESS implant, there was a significant reduction in the use of eye drops, in about 87.5% of the cases. In a Dutch study,[37] published by De Jong et al., it was shown that, compared to trabeculectomy, patients undergoing EX-PRESS were less likely to use medications, and if necessary, fewer medications were prescribed to maintain IOP in normotensive eyes. Thus, the financial resources needed to maintain the controlled IOP were lower.[37] De Jong et al. also showed in a French study that the cost of medication after surgery is lower when the patient is submitted to the EX-PRESS procedure.[38] These studies show that, as in our study, there was less need for drug treatment after implantation of the EX-PRESS, resulting in reduction of expenses to maintain an appropriate IOP and, consequently, a better financial benefit to the patient.

The results of the studies cited above, as well as those of our work, are consistent with what is described in the literature. Dahan et al. [39] implanted the drainage device in 23 eyes and observed a reduction of the number of eyes under pharmacological treatment, initially 14 and after one year only 2 eyes needed the eye drops. EX-PRESS makes it possible not only to stop using the topical drug, but also to reduce the number of drug classes necessary to control IOP, as can be seen in the study by Lankaranian et al.,[40] where in a sample of 100 eyes submitted to the EX-PRESS there was a reduction in the average amount of medicine in use, dropping from 2.7 ± 1.1 in the preoperative period to 0.7 ± 1.1.

In our study, mean intraocular pressure was approximately 18.63mmHg preoperatively, 13.88mmHg at 7 days, 15.75mmHg at 30 days and 14.5mmHg at 12 months postoperatively. That is, the IOP before EX-PRESS up to one year after the implant reduced on average 22.17% (4.5 mmHg). The literature reports that there is low IOP variation during the recent postoperative period, as well as the data collected in our study.[41]

This variation of IOP is consistent with the international literature, as stated in the article published by Liu et al.[42] Twenty-four eyes were studied and the mean IOP was 10.2 ± 2.8 mmHg seven days after device placement, 13.1 ± 2.7 mmHg at 30 days and 14.0 ± 3.6 mmHg in 12 months, and all patients in this study had follow-up for at least one year, as well as in our study. However, in the study by Liu et al. the efficacy and safety of the implantation of the EX-PRESS together with the phacoemulsification in the POAG were evaluated,[42] which may have generated interference in the results of the study, since the efficacy and safety were not evaluated only with the implementation of the EX- PRESS.

Similar data were found by Mariotti et al.[43] In this study, 248 eyes treated with the EX-PRESS implant were included. Most of the eyes were submitted only to the implantation of EX-PRESS, and the rest had surgery combined with cataract extraction. After that, the results of both groups were grouped, showing that the mean preoperative IOP decreased from 27.63 ± 8.26 mmHg (n = 248) to 13.80 ± 2.83 mmHg (n = 238) in 12 months.

Since its launch in the market, several studies have compared EX-PRESS to other treatments for glaucoma, especially with risks and complications. Standard treatment with trabeculectomy may present postoperative complications, such as excessive filtration, shallow or flat anterior chamber, hypotonia, suprachoroidal hemorrhage, maculopathy, and choroidal detachment.[44-47] Several studies have described this device as safer compared to trabeculectomy,[15-17] however the EX-PRESS does not exempt the surgical treatment of complications. Our study corroborates with such safety of the device implanted under a scleral flap that the complications found have maintained a pattern of low incidence. The most frequent complication was ocular hypotension (IOP <10mmHg), which occurred in 62.5% of the eyes in the immediate postoperative period, all of which resolved spontaneously without any sequelae. Among comparative studies, both Hong et al. and Seider et al., with samples of 100 and 93 eyes respectively, found lower rates of early postoperative hypotonia and choroidal detachment in the EX-PRESS group.[23,48] Similarly, three other studies[24,49,50] reported fewer episodes of postoperative hypotension in patients treated with EX-PRESS.

In the aforementioned studies, it was also evidenced that the patients had lower rates of hyphema and postoperative visits, and presented a faster recovery of vision when compared to the patients submitted to trabeculectomy. In our sample, hyphema did not occur in any of the eyes, and the postoperative IOP reached values of hypertension (IOP = 22mmHg) in only 12.5% of the cases. This information agrees with data from the comparative studies cited, in which the mean IOP achieved was equivalent[23,48,49] in both treatments or even lower[34] in the eyes with EX-PRESS, a parameter that is directly related to the success of the treatment. What could justify the effectiveness of the drainage device compared to trabeculectomy would be the technique itself does not require iridectomy, which induces minimal inflammation, and consequently, fewer early postoperative complications and less need for the use of hypotonic postoperative medications.[21] In addition, greater control of aqueous humor flow through consistent lumen size of EX-PRESS tends to result in fewer complications, unlike trabeculectomy, where performing at different sizes could directly interfere with the intensity of the drainage.[39] This reality became a rule after the use of the device implantation technique under a scleral flap. Proven to be more effective and safe than those initially used for EX-PRESS implantation, this was the technique used in the eyes of our study.

This study presents some limitations, among them, the non-comparison between two methods of IOP measurement and the reduced number of eyes in the studied group. A possible justification for the low use of EX-PRESS in Brazil is because of its high cost in a developing country. The authors would like to point out that trabeculectomy remains the gold standard for the control of ocular hypertension. The EX-PRESS would be another possible resource, in specific cases, in the control of IOP in the fight against this important and impacting disease called glaucoma. A suggestion for future studies would be the development of prospective, double-blind, multicentric studies comparing trabeculectomy with EX-PRESS in the Brazilian population.

Conclusion

Progressively, the EX-PRESS glaucoma filtration device gained more importance in the surgical field for the treatment of glaucoma. The results of our study, in agreement with the

international literature, revealed that the implantation of the EX-PRESS device is effective in reducing the IOP in patients with POAG, both in the short and medium term. Therefore, the reduced number of side effects to the eyeball and the low rate of intercurrences associated with the procedure reduces the risks of the implant. At the same time, it was observed that there was a considerable decrease in the use of anti-glaucomatous medications for the control of IOP, reducing financial expenses in the treatment of POAG and improving the patient's quality of life.

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Corresponding author:
Francisco W. Rodrigues
Av. Americano do Brasil, n°260, Goiânia (GO), Brazil.
Zip code: 74180-110
E-mail: verfco.med@gmail.com