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Clinical and epidemiological profile of patients with hypertensive peak after Ahmed glaucoma valve implant

Perfil clínico-epidemiológico de pacientes com pico hipertensivo após implante de válvula de Ahmed

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Abstract

Objective: *To report the clinical epidemiological profile of patients who presented the hypertensive peak after VAT and to indicate possible associated risk factors.* ***Methods:*** *A retrospective, observational and descriptive study (review of medical records of patients assisted in the IBOPC) from 2014 to 2016.* ***Results:*** *We analyzed 40 patients with glaucoma submitted to Ahmed Glaucoma Valve implant. The most common preoperative diagnosis was secondary glaucoma, with the most frequent corneal penetrating post-transplant indication. 95% of the surgeries were of isolated tube implantation. 56% of patients had previous anti-glaucomatous surgery. 46% needed a posterior surgical procedure to manage postoperative complications, and the most frequent was atalamia (9.7%). IOP preoperatively = 28.6 ± 12.20mmHg, with use of 3.41 medications. At 3 weeks the mean IOP increased to 16mmHg, with use of 0.42 medications. After 3 months of surgery the mean IOP was 16.5mmHg, with use of 1.86 of medications. After 6 months of follow-up the mean IOP decreased (16.4 ± 6.74 mmHg), with 2.23 ± 1.45 medications. The mean of the AV (Snellen) was 20/100p in the preoperative period and 20/200 after the 6th month of surgery. Fourteen patients fulfilled the criteria for HP, of which 6 obtained HP resolution. Of the patients who developed HP, 78.4% started to elevate IOP between the 2nd and 4th postoperative week. Six (14.6%) patients had complete surgical success, partial in 36.6% and bankruptcy in 31%.* **Conclusion:** *The hypertensive phase may occur in part of the patients after the initial weeks of the surgical procedure. The knowledge of this phenomenon, the previous preparation of the surgeon, the regular monitoring of the patient and the control of IOP with the use of medications are determinant in the resolution of this complication.*

Keywords: *Glaucoma; Glaucoma drainage implants; Intraocular pressure; Postoperative complications*

Resumo

Objetivo: Relatar perfil clínico epidemiológico de pacientes que apresentaram o pico hipertensivo após o IVA e apontar possíveis fatores de risco associados. **Métodos:** Estudo retrospectivo, observacional e descritivo (revisão de prontuário de pacientes assistidos no IBOPC) de 2014 a 2016. **Resultados:** Foram analisados 40 pacientes com glaucoma submetidos à implante de válvula de Ahmed. O diagnóstico pré-operatório mais comum foi glaucoma secundário, sendo a indicação pós-transplante penetrante de córnea a mais frequente. 95% das cirurgias foi de implante de tubo isolado. 56% dos pacientes tinham cirurgia anti- glaucomatosa prévia. 46% necessitaram de procedimento cirúrgico posterior para manejo de complicações pós-operatórias, sendo que a mais frequente foi atalamia (9,7%). PIO média no pré-operatório = 28,6 ± 12.20mmHg, com uso de 3,41 medicações. Com 3 semanas a PIO média aumentou para 16mmHg, com uso de 0,42 medicações. Após 3 meses de cirurgia a PIO média estava em 16.5mmHg, com uso de 1,86 de medicações. Após 6 meses de seguimento a PIO média reduziu (16,4 ± 6.74mmHg), com 2,23 ± 1.45 medicações. A média da AV (Snellen) foi de 20/100p no pré-operatório e de 20/200 após 6° mês de cirurgia. Catorze pacientes preencheram os critérios para a FH, destes 6 obtiveram resolução da FH. Dos pacientes que desenvolveram a FH, 78,4% iniciaram a elevação da PIO entre a 2ª e 4ª semana de pós-operatório. Seis (14,6%) pacientes obtiveram sucesso cirúrgico completo, parcial em 36,6% e falência 31%. **Conclusão:** A fase hipertensiva pode ocorrer em parte dos pacientes após as semanas iniciais do procedimento cirúrgico. O conhecimento deste fenômeno, o preparo prévio do cirurgião, o acompanhamento regular do paciente e o controle da PIO com o uso de medicações são determinantes na resolução desta complicação.

Descritores: Glaucoma; Implante de drenagem de glaucoma; Pressão intraocular; Complicações pós operatórias

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Introduction

Currently, conventional surgical treatment for glaucoma consists of non-penetrating trabeculectomy or sclerectomy with mitomycin, which are a good option for patients without adequate control of intraocular pressure (IOP) with drug or laser therapy.[1] In cases of refractory glaucoma, where there is previous failure of conventional surgery and specific conditions limiting its performance, implantation of drainage devices represents a useful alternative for pressure control.[2,3] In some situations, the implant may be the initial therapeutic option, but this decision will depend on the individual evaluation of each patient.

Among the currently available implants, the most used ones in Brazil are Ahmed, Molteno and Susanna.[4] The Ahmed valve implant (AVI) model FP-7 comprises silicone and a single tube and plate. It is characterized as restrictive due to having an inherent valve mechanism creating a Venturi effect, and unidirectional flow of aqueous to open at pressures of 8 mmHg, which in theory reduces the chances of immediate postoperative hypotonia.[5,6]

The efficiency in reducing IOP by the drainage implant is already documented.[2] Despite this, many factors influence the final pressure control, including the type of implant, surgical technique, postoperative follow-up, and individual characteristics of each patient, such as inflammatory reaction and current pathological process. In the first few days after surgery a considerable decrease in IOP is expected, since the aqueous flow is free and there is still no fibrous capsule formation around the episcleral plaque. However, after the first few weeks postoperatively, some patients present high blood pressure levels, with the need of medications. This phenomenon is described as hypertensive phase,[5,7] and despite several reports in studies, little is known about the risk factors and characteristics of the postoperative period favoring its occurrence. Thus, the objective of the present study is to report the clinical epidemiological profile of patients presenting the hypertensive peak after the AVI, and thus point out possible associated risk factors.

Methods

A retrospective, observational and descriptive study will be carried out by reviewing medical records of patients treated at Hospital Humberto Castro Lima, Salvador, Bahia, from January 2014 to January 2016. Inclusion criteria: patients with glaucoma who underwent AVI; age from 03 to 80 years. Exclusion criteria: absence of postoperative follow-up up to 6 months; procedures combined with AVI, such as vitrectomy and penetrating keratoplasty, except cataract extraction. The data will be analyzed anonymously and the results presented in aggregate form, not allowing the identification of the participants of the research. Because it is a non-interventional study, there will be no further risks to the welfare of the patients.

Data to be analyzed: age, gender; laterality of the eye; previous diagnosis of glaucoma; number of anti-glaucomatous surgeries prior to implant; best corrected visual acuity (BCVA) through the Snellen Table before and after the 6th AVI month; IOP values in the preoperative period, after surgery on the 1st day, 1st, 2nd and 3rd weeks, 1st, 3rd and 6th months after AVI; average preoperative medication and 6 months after the implant; complications associated with the implant until the 6th month; type of surgery performed; crystalline condition; and need for reoperation.

The hypertensive phase (HP) will be defined as: IOP > 21 mmHg during the first 3 months after surgery, with or without medication, after reduction of IOP < 22 mmHg during the first postoperative week, and absence of complications such as tube obstruction, valve malfunction, and positioning failure. The resolution of HP will be considered in cases of IOP < 22 mmHg with: (1) IOP reduction of 3 mmHg or more with the same number of medications or less; or (2) reduction of at least one medication with change in IOP < 3 mmHg. The surgical success will be defined as IOP > 5 mmHg and < 22 mmHg with (relative success) or no (complete success) use of anti-glaucomatous medications, without additional glaucoma surgery or serious complications. Hypotonia will be considered when IOP ≤ 5 mmHg in two consecutive visits.

The quantitative variables will be expressed through their averages and standard deviation, the qualitative variables will be expressed by their absolute and relative frequencies. The q-square test will be used for the qualitative variables, and for the quantitative variables the t-student test will be used for paired samples. Statistically significant results will be the analyzes with $p < 0.05$.

Description of the surgical technique

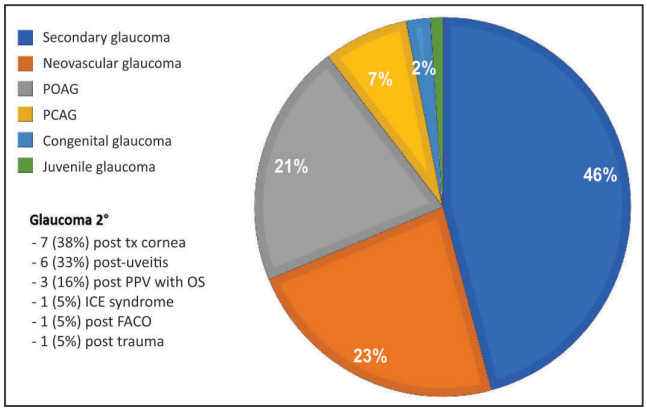
It begins with local anesthesia through retrobulbar block; traction suture (6-0 wire) in the cornea to expose the area where the implant will be made; limbic base peritomy with subconjunctival dissection and insertion of the implant in the upper temporal quadrant between the straight muscles; plate sutured to the sclera, 8-10 mm from limbus; access to the anterior chamber through a 23 gauge needle parallel to the iris plane and viscoelastic injection; bevelling at the tip of the tube 2.5 mm from the limbus; insertion of the tube into the anterior chamber and confection of U-suture midway to the point of entry of the tube and the episcleral plaque; suture patch of sclera over the tube securing its anterior part with two stiches of vicryl 7-0; suture of the conjunctiva and Tenom with vicryl 8-0.

Results

The final sample of the study had 40 patients and 41 eyes, being 27 right eyes and 14 left eyes. The patients' age ranged from 3 to 87 years, of which 24 (58.5%) were men and 17 (41.5%) were women. The average age was 53.8 ± 20 years. The most common preoperative diagnosis was of secondary glaucoma, identified in 18 (44%) patients, and within this group the penetrating corneal transplant was the most frequent one (38% of the total). Regarding the rest, 9 (22%) patients had neovascular glaucoma; 8 (20%) had primary open-angle glaucoma; 3 (7%) had primary closed-angle glaucoma; 2 (11%) cases of congenital glaucoma, and 1 (5%) cases of juvenile glaucoma (Figure 1).

Most of the surgeries were of isolated tube implant (95%), and only 2 patients (5%) were associated to phacoemulsification and intraocular lens implant. Of the total, 23 patients (56%) had previous anti-glaucomatous surgery, 11 of whom already had 2 or more surgeries. Thus, 18 patients (44%) underwent valve surgery as the first procedure for the treatment of glaucoma. Regarding previous cataract surgery, 21 (51%) patients were phakic, 18 (44%) were pseudophakic, and 2 (5%) were aphakic. 19 (46%) patients required a subsequent surgical procedure for the management of postoperative complications associated to the implant or

failure to control the IOP. Table 1 summarizes the main clinical-epidemiological characteristics of the patients under study.



POAG: primary open-angle glaucoma; PCAG: primary closed-angle glaucoma

Figure 1: Pre-operative Diagnosis for Ahmed Valve Implant

Table 1
Clinical-epidemiological characteristics

Age	
Average ± SD	53.8 ± 20.0
Variation	3 – 87
Gender n (%)	
Male	24 (58.5)
Female	17 (41.5)
Eye n (%)	
Right	27 (65.9)
Left	14 (34.1)
Crystalline n (%)	
Phakic	21 (51.2)
Pseudophakic	18 (43.9)
Aphakic	2 (4.9)
Previous surgeries n (%)	
None	18 (43.9)
One	12 (29.3)
Two	4 (9.8)
Three	5 (12.2)
Four	2 (4.9)
Type of surgery n (%)	
Only Ahmed valve implant	39 (95.1)
Phacoemulsification + Ahmed valve implant	2 (4.9)
Need for reoperation n (%)	
Yes	19 (46.3)
No	21 (51.2)

SD: standard deviation

Table 2 shows the complication rates associated to the implant procedure. The most frequent complication was atalamia, with 4 (9.7%) cases described. There were 3 (7.3%) cases of choroidal detachment, and 3 (7.3%) cases of blister encystment. Other less frequent complications are listed in Table 2.

The average preoperative IOP was 28.6 ± 12.20mmHg, with an average use of 3.41 ± 1.11 medications; and in the last review after 6 months of follow-up the average IOP reduced to 16.4 ± 6.74 mmHg with 2.23 ± 1.45 medications. On the 1st day after surgery the average IOP was 10.3 ± 6.20 mmHg without the use of medications. At 03 weeks the average IOP increased to 16 ± 6.57 mmHg with use of 0.42 ± 0.83 medications. After 3 months of surgery the average IOP was 16.5 ± 5.0mmHg with 1.86 ± 1.49 of medications. Table 3 and figure 2 show the variation of IOP and the use of medications in the period. The average VA with Snellen table was 20/100p in the preoperative period and 20/200 6 months after surgery.

Table 2
Postoperative complications up to 6 months after Ahmed valve implant

Complication	Nº affected eyes	(%)
Atalamia	4	9.7
Choroidal detachment	3	7.3
Blister encystmen	3	7.3
Tube exposure	2	4.8
Touch corneal endothelial tube	2	4.8
Retinal detachment	1	2.4
Exposure of scleral flap	1	2.4
Iritis	1	2.4
Touch iris tube	1	2.4
Exposure of tube plate	1	2.4
Infection	1	2.4
No complications	24	58.5

Table 3
IOP variation during the pre and postoperative periods of the Ahmed valve implant

	IOP value (average ± SD)	Nº medications (average ± SD)
Properative	28.6 ± 12.20	3.41 ± 1.11
1st POD	10.3 ± 6.20	0.03 ± 0.16
7th POD	9.7 ± 4.02	0.11 ± 0.51
14th POD	14.8 ± 9.3	0.09 ± 0.52
21st POD	16.0 ± 6.57	0.42 ± 0.83
30th POD	16.9 ± 6.95	0.94 ± 1.11
90th POD	16.5 ± 5.0	1.86 ± 1.49
Late Post-operative (6th month)	16.4 ± 6.74	2.23 ± 1.45

IOP: intraocular pressure; POD: postoperative day; SD: standard deviation

A total of 14 (34%) patients met the criteria for the hypertensive phase (HP), 6 (14.6%) of whom could not be assessed due to lack of data or because they had IOP above 21 mmHg in the first week. Of the 14 patients described, 6 (42.8%) had the HP treated, with the IOP returning to acceptable levels. Most of the patients who developed HP started to increase IOP between the 2nd and 4th postoperative week, accounting for 78.4% of the total. Regarding the outcome of the patients, a complete surgical success was considered in 6 (14.6%) patients, partial in 15 (36.6%) patients, and failure with need for new surgery in 14 (31%) patients. Again, 6 (14.6%) patients were not included in this evaluation due to lack of data (Table 4).

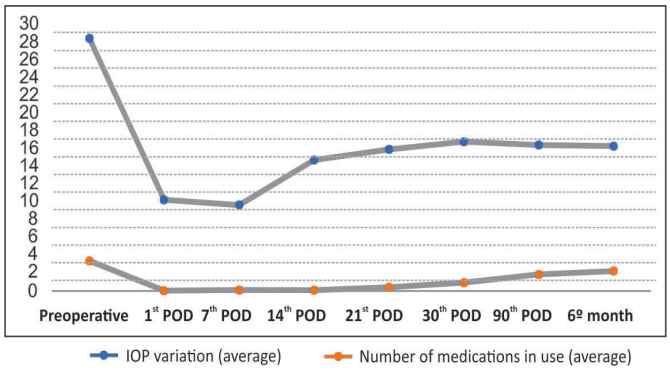


Figure 2: Variation of average intraocular pressure versus average number of antiglaucomatous medications in use.

Table 4
Evaluation of the incidence and percentage of resolution of the hypertensive phase

	Number of patients (%)
HP	
Yes	14 (34.1)
No	21 (51.2)
Not applicable	3 (7.3)
Incomplete data	3 (7.0)
PH resolution	
Yes	6 (42.8)
No	7 (50.0)
Incomplete data	1 (7.1)
Surgical success	
Relative	15 (36.6)
Complete	6 (14.6)
Failure	14 (34.1)
Incomplete data	6 (14.6)

HP: hypertensive phase; Relative Surgical Success: IOP > 5 mmHg and < 22 mmHg with the use of anti-glaucomatous medications; Complete surgical success: IOP > 5 mmHg and < 22 mmHg without the use of anti-glaucomatous medications.

Discussion

HP is an unwanted complication in the postoperative of drainage device implant, and its knowledge leads to better clinical conduction and resolution of cases. In order to better define the profile of the patient who developed HP, the sample analysis showed no predilection by gender (7 men and 7 women), the average age was 49.7 ± 17.3 years. Several previous studies describe the clinical-epidemiological profile of patients undergoing drainage implant surgery, but they barely describe the gender and age characteristics of the subgroup of patients who presented the hypertensive phase. The most frequent indication for tube implant was secondary glaucoma (with the majority resulting from cases after corneal transplantation), followed by neovascular glaucoma. These two diagnoses were also described by Ayyala et al. as the main ones for indication of drainage implant in their study,[5] and corroborated in the study by Moreno et al.[8] The average preoperative IOP was 25 mmHg ± 7.4, and the average number of medications before surgery was 3.8, similar to that already described in other studies.[9,10] All variables described above were submitted to analysis, but none were statistically significant, and it was not possible to identify predictive factors for the development of HP after Ahmed valve implant.

The present study revealed a rate of 34% hypertensive phase occurrence, a value below that reported in the literature, ranging from 50.7% to 82%.[5,7,9] This may be justified for some reasons, especially the use of the drainage device silicone model, which produces a lower tissue inflammatory response and greater plate stability than polypropylene models, in addition to avoiding micro movements in the implant area. [11] An HP resolution rate of 42.8% was observed, which is close to that reported by Ayyala et al. who observed the return of IOP to normal values in 52% of the patients, without the need for additional procedures.[5]

In the present study, HPoccurred from the 2nd week until the 4th week, when the formation of a fibrous cap began around the device plate, with intense edema and congestion, leading to worse IOP control.[10] Mahdavi et al. [7] observed a similar result to that mentioned, with the onset of HP after the 5th week ± 2.8 weeks. Despite this, a considerable reduction in the average preoperative IOP value was observed from 28.6 ± 12.2 mmHg to 16.4 ± 6.74 mmHg after the 6th postoperative month. This result agrees with that observed in other studies: reduction from 30.5 ± 10.5 to 16.5 ± 7.4 in Mahdavi et al. [7] 27.53 ± 7.48 to 15.29 ± 4.37 in Borges et al. [14]

Regarding visual acuity, there was no significant difference between the pre and postoperative values, with only 1 case (4.1%) of evolution to no light perception, which is in agreement with Ayyala et al, where vision loss was observed in 5.9% of the patients. [5]

A relative success rate of 36.6%, absolute of 14.6%, and failure in 31% of patients, with the need for a new surgical procedure was verified. Thus, the final success rate was 51.2%, which is below the values reported by other studies.[12,13] El Afritt[12] reported relative success of 69.23%, and absolute of 33.33%. It should be remembered, however, that the present study was conducted in a public medical residency service, with patients of low-income class and poor adherence to the postoperative treatment, besides a significant absence in postoperative reviews. This limitation may justify the presence of higher rates of complications and a lower rate of surgical success.

The search for factors to increase the risk of the hypertensive phase should be stimulated in order to avoid such complication in the postoperative period of the drainage implant. The patients submitted to this type of procedure have advanced glaucoma and greater risks with IOP increase. In this study the demographic variables and preoperative characteristics were evaluated in relation to the development of HP. It is believed that the preoperative IOP value is related to a greater chance of IOP elevation after implant, but a reduction of the sample due to insufficient data in 6 patients (14% of the total), which could not be submitted to analysis of the occurrence of HP, limited the statistical analysis.

Conclusion

Drainage device implant is an important resource in the treatment of refractory glaucoma. One should be aware of the implications of using different implant models as well as their constitution. The hypertensive phase may occur in part of the patients after the initial weeks of the surgical procedure. The knowledge of this phenomenon, previous training of the surgeon, regular monitoring of the patient, and control of IOP with the use of medications are determinant in the resolution of this complication.

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