ORIGINAL ARTICLE

Trabeculectomy profile in an ophthalmological reference service in Ceará: quantitative retrospective study

Perfil da trabeculectomia em um serviço de referência oftalmológica no Ceará: estudo retrospectivo quantitativo

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ABSTRACT

Objective: To know the profile of trabeculectomy, in addition to the success rate in controlling intraocular pressure in patients with glaucoma.

Methods: A retrospective, observational study, with medical records of patients with glaucoma, followed up at an ophthalmological reference center, who underwent trabeculectomy from January 1, 2016 to May 31, 2017, by a single experienced surgeon. The success rate was considered with an intraocular pressure < 21 mmHg, for high intraocular pressure glaucoma, and a reduction of at least 20% for normal intraocular pressure glaucoma.

Results: We analyzed 160 eyes, among which the majority (63.1%) were female, and 46.25% were aged between 61 and 80 years. There was a predominance of primary open-angle glaucoma in 67.3% of cases, and most were in an advanced stage (91.9%). After performing trabeculectomy, in 39.4% of the eyes, interventions were required at some point in the postoperative period; however, when comparing the groups that presented, or not, these procedures, the evolution of intraocular pressure showed no statistically significant difference. The postoperative period follow-up showed that the intraocular pressure remained below 21 mmHg and with reductions greater than 40% of the baseline intraocular pressure value.

Conclusion: The success rate of trabeculectomy exceeded 90%, with a small rate of complications, noting that trabeculectomy is a safe procedure with significant success in the glaucoma control in the state of Ceará.

RESUMO

Objetivo: Conhecer o perfil da trabeculectomia e a taxa de sucesso no controle da pressão intraocular em pacientes com glaucoma.

Métodos: Estudo retrospectivo, do tipo observacional, com prontuários de portadores de glaucoma de um centro de referência oftalmológica que realizaram a trabeculectomia de 1° de janeiro de 2016 a 31 de maio de 2017, por um único cirurgião experiente. A taxa de sucesso foi considerada como uma pressão intraocular < 21 mmHg, para glaucoma de pressão intraocular elevada, e uma redução de pelo menos 20% para glaucoma de pressão intraocular normal.

Resultados: Foram analisados 160 olhos, entre os quais a maioria pertencia ao sexo feminino, e 46,25% estavam na faixa etária de 61 a 80 anos. Houve predominância do glaucoma primário de ângulo aberto (67,3% dos casos), e a maioria estava em estágio avançado (91,9%). Após a realização da trabeculectomia, em 39,4% dos olhos foram necessárias intervenções em algum momento do pós-operatório. Contudo, ao comparar os grupos que apresentaram ou não esses procedimentos, a evolução da pressão intraocular não apresentou diferença estatisticamente significativa. No pós-operatório, a pressão intraocular manteve-se abaixo de 21 mmHg e com reduções superiores a 40% do valor da pressão intraocular basal.

Conclusão: A taxa de sucesso da trabeculectomia ultrapassou 90%, com pequeno índice de complicações, constatando que a trabeculectomia é um procedimento seguro e com relevante sucesso no controle do glaucoma no estado do Ceará.

Keywords:

Glaucoma; Intraocular pressure; Trabeculectomy; Postoperative complications; Postoperative period; Aftercare

Descritores:

Glaucoma; Pressão intraocular; Trabeculectomia; Complicações pós-operatórias; Período pósoperatório; Assistência ao convalescente

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INTRODUCTION

Glaucoma is a public health issue and one of the leading causes of permanent vision loss in Brazil and around the world.^(1,2) An increase in intraocular pressure (IOP) exceeding 21 mmHg is a primary risk factor for this illness. Cases with IOP within the normal range, on the other hand, can occur.^(2,3)

Despite the advancement of less invasive treatments and devices, generally known as "minimally invasive glaucoma surgery", trabeculectomy (TREC) remains the most performed surgery for glaucoma control. Trabeculectomy is an antiglaucomatous surgery in which a fistula allows for connection between the intraocular and the extraocular regions. This surgery is also called filtering, because the aqueous humor is redirected to the subtenonian region, where it will be absorbed, reaching the venous circulation.⁽²⁾

A series of precautions should be taken after performing TREC, motivated by dynamic postoperative (PO) procedures, such as modulation of healing corticoids, needling with mitomycin C (MMC), prophylaxis of fistula infection, and evaluation of excessive leakage of the filter ampulla, to avoid complications such as atalamia, choroidal detachment, and endophthalmitis, making this surgery more efficient for IOP control.^(4,5) Therefore, this study aimed to know the profile of TRE, in addition to the success rate in controlling IOP in patients with glaucoma.

METHODS

The research followed the ethical principles of the Declaration of Helsinki and was approved by the Ethics Committee, via *Plataforma Brasil* (CAAE 88274418.3.0000.5049). This was a retrospective observational study with medical records of glaucoma patients followed at *Fundação Leiria de Andrade* (FLA), a referral glaucoma center that serves patients from all over the state of Ceará, in Brazil. Medical records of patients who underwent the TREC surgical in the period from January 1, 2016, to May 31, 2017, by a single experienced surgeon, were analyzed.

The surgical technique used was peribulbar block with 6mL of anesthetic solution (2/3 bupivacaine 0.75% with 1/3 lidocaine 2% and hyaluronidase); a partial-thickness 7-0 Vicryl corneal traction suture was placed superiorly, and the eye was pulled down; conjunctival dissection of the fornix base and vessel cauterization were performed; a 3 x 3 mm limbal-based scleral flap was performed; MMC at 0.4 mg/mL (two small cotton swabs soaked and applied for three minutes subconjunctival and one swab for one

minute under the scleral flap) was applied followed by local lavage with 10 mL of balanced salt solution; temporal paracentesis was performed; corneal-trabecular resection with 1 mm punch; peripheral iridectomy with Vannas; the scleral flap with Nylon 10-0 (one stitch in each loose end of the flap) was sutured; anterior chamber was remade with a balanced solution and filtration through the flap was tested, with suture adjustment; conjunctival suture with Vicryl 7-0 (one stitch in each end, anchored to the cornea) and the filter ampulla was tested for suture adjustment. In the PO, the patients were using the following eye drops: moxifloxacin hydrochloride 5.45 mg/mL (6/6 hours for 1 week), prednisolone acetate 1% (1/1 hour for 3 days, then 3/3 hours with weekly weaning) and atropine 1% (8/8 hours for 1 week).

Regarding the transconjunctival needling technique, performed by the same surgeon, the subconjunctival application of 0.4 mL of MMC 0.2 mg/mL and lidocaine 2% solution with epinephrine was used, to then undo the episcleral adhesions and cut all scleral flap sutures, with a 26 G needle, aiming to reestablish the aqueous humor flow through the fistula.

Inclusion criteria were age over 18 years; having follow-up in the FLA, regardless of duration and stage of the disease, and having undergone TREC in the period evaluated, by a single surgeon. Patients who did not undergo PO follow-up at FLA were excluded from the sample. As some patients had surgery on both eyes, each eye was analyzed separately.

The variables analyzed were gender, age group, the existence of previous eye surgery, type of glaucoma, stage of disease, number of hypotensive eye drops used before TREC, and their drug class; existence of PO surgical interventions, and the evolution of IOP (on the 1st, 7th, 30th, 90th, 180th, 270th, 365th, 540th, and 730th PO).

An analysis of the epidemiological profile and a correlation of the IOP temporal analysis with the presence or absence of PO interventions was performed. For the calculation of the TREC success rate, we adopted the definition of Landers et al., who considered the achievement of an IOP of less than 21 mmHg a success for high IOP glaucoma, or a reduction of at least 20% in baseline IOP for normal pressure glaucoma.⁽⁶⁾ The relative risk (RR) of PO complications was also calculated based on the number of antiglaucomatous eye drops used before TREC, age group, and type of glaucoma.

Quantitative data are presented as mean ± standard error, while qualitative data are represented by absolute numbers or percentages. For descriptive and statistical analysis, tables, and graphs, were plotted in Excel Microsoft Office (New York, NY, United States) and GraphPad Prism software version 5.0 (GraphPad Software, San Diego, CA, United States). One way analysis of variance (Anova) multiple comparisons test, followed by Dunn's test, for quantitative comparisons, Chi-squared test and Fisher's exact test for qualitative analyses were used. Values showed a statistically significant difference when p < 0.0001 and/or < 0.05.

RESULTS

A total of 160 eyes were analyzed, among which the majority (63.1%) belonged to the female gender, and 46.25% were in the age group of 61 to 80 years. No statistical differences were observed between the two most prevalent age groups (p = 0.644; T-test).

Regarding the history of eye surgeries, in 23.75% of the eyes, procedures were performed, namely: phacoemulsi-fication (FACO) was the most found (57.9%), followed by corneal transplantation (7.9%).

When evaluating the types of glaucoma, the highest prevalence of primary open-angle glaucoma (POAG) was observed, representing 67.32% of cases, followed by primary angle closure glaucoma (PACG) with 15.68%.

There were no cases in early stages, and most eyes were in advanced stages (p < 0.001; T-test), representing a female and a male involvement of 96.8 and 93%, respectively.

Regarding the eye drops used, 95% were using antiglaucomatous eye drops before TREC, which varied in number and drug classes. Of the eyes using eye drops, more than 80% used two or three drugs, and only 1.3% used a combination of five drugs. The beta-blocker, prostaglandin, carbonic anhydrase inhibitor, and alpha-agonist drug classes were prescribed in more than 20% of eyes each, while the cholinergic class was present in only 0.4% of prescriptions.

Concerning the procedures required in the PO period of TREC, because of complications, a total of 63 eyes (39.4%) were approached, some with more than one procedure in the same eye, and most procedures required needling (50.7%).

Postoperative complications were divided into two groups: Group A (n = 44) represented by interventions involving the control of subconjunctival fibrosis (needling and surgical bleb revision), and Group B (n = 21) procedures to prevent ocular hypotony, probably due to insufficient wound healing (conjunctival suture, scleral flap suture, and anterior chamber reconstruction).

Comparing the PO complications in Groups A and B, it is possible to relate the RR of the number of eye drops previously used for glaucoma and age groups. Statistically significant RR values were obtained for the use of two and three eye drops and age groups between 20 and 80 years (sample were not enough for other variables). Therefore, there was a greater tendency for complications in Group A among users of two hypotensive eye drops and age range 20 to 60 years; and a greater risk for Group B in users of three eye drops and age range from 61 to 80 years (Table 1).

Table 1. Relative risk for postoperative complications for thenumber of eye drops, age group, and type of glaucoma, withrespective 95% confidence interval

	Group A (n)	Group B (n)	RR (95%CI)	p-value
Number of eye drops				
1	4	1	0.60 (0.1-3.6)	1.00
2	10	15	4.00 (1.8-8.9)	0.0002*
3	25	5	0.36 (0.15-0.8)	0.0169*
4	4	0	0	0.296
5	0	0	-	-
Age group				
<20	0	0	-	-
20-40	2	5	2.58 (1.4-4.8)	0.03*
41-60	10	10	2.04 (1.04-4.0)	0.04*
61-80	28	6	0.36 (0.2-0.8)	0.008*
>80	4	0	0	0.296
Type of glaucoma				
POAG	37	11	0.64 (0.3-1.3)	0.217
PACG	7	4	1.15 (0.48-2.7)	0.74

Group A: needling and surgical revision; Group B: conjunctival suture, scleral flap suture, and anterior chamber reconstruction.

Fisher's exact test and Chi-squared test were used.

n = total eyes (some with more than one procedure in the same eye). Reference group to RR = Group B. * $p_{<0.05\%}$

RR: relative risk; 95%Cl: 95% confidence intervals; POAG: primary open-angle glaucoma; PACG: primary angle closure glaucoma.

Regarding the evolution of IOP, a significant decrease in IOP was observed compared to measurements before TREC, so all patients had IOP values below 21 mmHg at the end of follow-up (Table 2). Comparing the IOP of the patients who underwent some surgical intervention in the PO versus those who did not, it was not possible to observe a significant difference between these groups (Figure 1A). Considering the types of complications (Groups A and B), lower IOP values were observed in Group B, statistically significant for the 30th PO (Figure 1B).

The eyes submitted to needling mostly improved IOP after this intervention (Figure 2) and comparing these eyes with those without interventions in the PO, a statistical difference was observed on the 7th, 30th, and 90th PO, showing lower IOP values in the group without interventions (Table 3).

Table 2. Decrease in mean intraocular pressu	re for each posto	perative time point	compared to mean	intraocular pres	sure before
trabeculectomy					

Time (days)	Before	1 st	7 th	30 th	90 th	180 th	270 th	365 th	540 th	730 th
Mean IOP, %	24.23	10.83	10.10	11.70	11.71	12.25	13.03	12.69	13.09	10.91
IOP decrease, %	100	55.29	58.34	51.70	51.67	49.43	46.24	47.64	45.99	54.98

IOP: intraocular pressure



Figure 1. (A) Graph with the mean intraocular pressure (in mmHg), \pm the standard error, for each time the patient was divided into two groups (those undergoing some intervention post-trabeculectomy and eyes that had no interventions in the postoperative). The lower table describes the mean intraocular pressure values for each group. b = p < 0.05, one way analysis of variance (7th postoperative without interventions vs 30th and 270th postoperative with intervention). a = p < 0.001, one way analysis of variance (intraocular pressure post-trabeculectomy versus intraocular pressure before). (B) Graph representing the mean intraocular pressure (intraocular pressure in mmHg), ± the standard error for each time the patient (submitted to the intervention in the postoperative) was divided into two groups (Group A: needling and surgical revision; and Group B: conjunctival suture, scleral flap suture, and anterior chamber reconstruction). The lower table describes the mean intraocular pressure values for each group. b = p < 0.05; one way analysis of variance (30th postoperative Group A versus 30th postoperative Group B). a = p < 0.001; one way analysis of variance (intraocular pressure post-trabeculectomy versus intraocular pressure before).

By calculating the ratio of the total number of eyes with IOP less than 21 mmHg to the total number of eyes with IOP documented, the success rates of 95.04%, 95.14%, 93.42%, 92.15%, 95.65%, 100% at 3-, 6-, 9-, 12-, 18-, and 24-months PO, respectively, were obtained.



IOP: intraocular pressure

Figure 2. Graph demonstrates the change in intraocular pressure after needling over time. The mean intraocular pressure value reduced from 25.09 mmHg (standard deviation of 10.42; range of 12.0 to 60.0; median of 24.0 mmHg) preoperatively to 14.45 mmHg (standard deviation of 5.41; range of 9 to 30; median of 13 mmHg) at the 270th postoperative (Wilcoxon signed-rank test; p < 0.001). Points that are located to the right of the straight line indicate that the intraocular pressure improved after the procedure.

Table 3. Intraocular pressure follow-up data for patients undergoing trabeculectomy, comparing eyes submitted to needling with those without postoperative intervention

		w	ith need	lling	No interventions				
РО	n	IOP ↑	$IOP\downarrow$	$IOP_{m} \pm SEM$	n	IOP ↑	$IOP\downarrow$	$IOP_{m} \pm SEM$	p-value
1 st	34	30	2	13.9 ± 0.5	80	20	2	9.9 ± 1.1	0.35
7 th	32	34	4	13.8 ± 0.5	88	24	0	9.5 ± 1.1	0.002*
30 th	33	28	7	16.9 ± 0.3	93	20	2	10.6 ± 1.2	0.001*
90 th	34	26	6	14.4 ± 0.5	64	30	5	11.4 ± 0.9	0.03*
180 th	29	34	5	15.0 ± 0.5	57	22	2	11.5 ± 1.1	0.13
270 th	22	30	9	14.5 ± 0.6	39	20	6	12.1 ± 1.2	0.27
365 th	18	28	7	15.1 ± 0.9	26	22	1	11.9 ± 1.3	0.08
540 th	6	18	10	13.2 ± 2.9	11	40	5	14.9 ± 1.2	0.68
730 th	2	18	10	14.0 ± 2.4	06	17	2	10.2 ± 4.0	0.33

PO: postoperative day; IOP: intraocular pressure; IOP, , mean intraocular pressure; SEM: standard error of the mean.

 \uparrow = maximum; \downarrow = minimum.

* p < 0.05 with needling versus without interventions (Chi-squared test)

DISCUSSION

The age factor was consistent with the global literature, as glaucoma affects individuals over 40 years of age,⁽⁷⁾ and older subjects in the more advanced stages of the disease,⁽⁸⁾ with a predominance of cases in the age range from 61 to 80, similar to the study conducted in São Paulo, Brazil, which found a mean age of 62.8 \pm 11.5 years,^(9,10) and in the Amazon, where it was also evident that most

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patients with glaucoma were over 40 years old (mean, 63.5 years). $^{\scriptscriptstyle (11)}$

The literature highlights factors that that could explain the gender discrepancy in glaucoma, such as eyes with shorter axial length and shallower anterior chamber in women.^(7,12) Endocrine disparities between men and women have also been described as a possible risk factor for glaucoma, including hormone levels and replacement therapy, oral contraceptive use, and menopause.⁽⁷⁾ Gender was not found to be a significant risk factor in several population-based investigations,⁽¹³⁻¹⁵⁾ but another important epidemiological survey conducted in Australia showed that the prevalence of glaucoma was higher in females,⁽¹⁶⁾ correlating with the current study (63.1%). Others, on the other hand, have shown a higher incidence in men.^(16,17)

Regarding the type of glaucoma, there was an agreement with the literature, since POAG was the most prevalent.^(1,2) We observed a higher rate of glaucoma in advanced stages (91.9%), which was in accordance with the indications for TREC present in international consensus guidelines, confirming the indication of fistulizing surgery in advanced stages refractory to drug treatment.^(4,6,18)

Considering the hypotensive eye drops that 95% of patients used before TREC, in terms of quantity, most used two to three drugs, corroborating the studies that show that polymedication is a common practice in the treatment of glaucoma as the condition becomes advanced.^(18,19) In relation to the pharmacological class, beta-blockers were formerly the most frequently used.^(20,21) However, in the 1990s, the use of prostaglandin analogs increased, consequently decreasing the use of beta-blockers.^(21,22) In a study on the pharmacoepidemiology of glaucoma in Brazil, prostaglandin analogues and polymedication were found to be the most prevalent.⁽¹⁹⁾ However, other studies carried out in this country showed the beta-blocker as the most used, and a combination of one or two drugs in the management of the disease,^(18,23) which agreed with our results. Another relevant data was the amount considered high, in relation to the literature,^(22,23) of users of carbonic anhydrase inhibitors, in relation to those of beta-blockers, perhaps justified by the older population in this study, who may have comorbidities that invalidate the use of beta-blockers, such as heart disease, lung disease or depression, or even by the tachyphylaxis, more frequent with beta-blockers.^(21,22)

Regarding the amount of eye surgery previous to TREC, the present study showed a rate of 23.5%, similar to data already published,^(1,6) but different from other studies with a higher⁽²⁴⁾ or lower rate,^(25,26) perhaps influenced

by the age of the selected population, or by the prospective design of those studies, mainly in view of performing FACO. $^{\scriptscriptstyle (1,6,24,26)}$

We obtained a total of 39.04% of interventions in the PO, a value close to that found in some studies that had an average of 42,9%,⁽²⁶⁻²⁹⁾ but high, if compared to another that found values lower than 20%.⁽²⁵⁾ Considering the type of intervention, there was a predominance of needling (50.7%), meeting the scientific evidence of increased subconjunctival fibrosis in the region of the scleral flap, making it necessary to reorder the surgery with needling, to undo the fibrotic beams, and application of MMC, thus prolonging the useful life of the filter bleb.^(4,24,30-32) Another relevant factor was the high number of glaucomatous eye drops used before TREC, knowing that this prolonged use induces subclinical inflammation and increases the bleb healing process, resulting in fistula closure.^(33,34)

Despite the importance of using MMC during TREC, this drug has side effects, such as avascular bleb formation and suture dehiscence, making reintervention with a new conjunctival suture necessary, avoiding hypotony and intraocular infection.^(5,6,24) In this study, these complications ranged from 5.5 to 20.5%. Considering the technique employed in the application of MMC and its concentration of 0.4 mg/mL, higher rates of leakage of the bleb and atalamia were expected,⁽³⁵⁻³⁷⁾ but we found a lower frequency, with increased subconjunctival fibrosis prevailing as the main complication. And, when compared to studies in which learning surgeons were evaluated, (1,5,29) it is evident that the surgeon's experience factor could influence the development of complications of this type (surgeon expertise at the time of the TREC, such as use of punch and management of sutures for optimal filtration rate, avoiding early hypotony),^(34,38,39) more than the time or concentration of MMC.

This study compared the complications of the PO, dividing them into groups A (with greater fibrosis), and B (poor healing or suture dehiscence), showing a greater tendency for complications of Group A among users of two hypotensive eye drops and with an age range of 20 to 60 years, a fact that corroborates the literature, since there was greater fibrosis in younger patients.^(4,6,8,29) We observed a higher risk for Group B, among users of three eye drops preoperatively, unlike what was found in the literature, in which the use of two or more antiglaucomatous eye drops would be correlated with increased fibrosis in the PO.^(6,29,33,34) On the other hand, we found the age range of 61 to 80 years as having a greater tendency to hypotony, perhaps by continuous and prolonged use of the high

amount of eye drops with benzalkonium chloride preservative, which, by its accumulative and inflammatory effect on conjunctival tissue, could have triggered apoptosis and destruction of Tenon's capsule, consequently leading to a higher prevalence of suture dehiscence, avascular blebs and hypotonia in the elderly.^(4,27) Furthermore, lower IOP values were seen in Group B, statistically significant at the 30th PO, something expected for being composed of eyes with greater leakage of the bleb.

Most eyes submitted to needling improved IOP after this intervention, and in relation to those who did not undergo interventions in the PO, we observed a statistical difference on the 7th, 30th, and 90th PO, showing lower IOP values in the group without interventions. These results corroborate those in the literature, which demonstrated the success of needling as a procedure to decrease IOP, reestablishing fistula filtration; however, it is necessary to repeat this manipulation with the application of MMC, considering the increased risk of fibrosis in these eyes;⁽³²⁾ thus, justifying this higher IOP than in the eyes not submitted to interventions.

As for the evolution of IOP, we obtained a significant decrease after TREC (reduction remained above 45% compared to baseline IOP for each PO moment), corroborating other studies that have demonstrated the effectiveness of this antiglaucomatous surgery in glaucoma control, remaining as the procedure of choice by most surgeons of this pathology. ^(1,4,6,28) The high success rate (over 90% of patients acquired IOP less than 21 mmHg) was not in accordance with the literature, as most studies showed rates around $60\%^{(25,29,40)}$ to $80\%.^{(28,34)}$ Perhaps, this difference was due to the study type, retrospective with analysis of medical records, which leads to information bias, considering a large number of records with missing data regarding the analyzed parameters, especially when it comes to longer follow-up.

Moreover, when analyzing the evolution of IOP and comparing the presence or absence of surgical interventions in the PO, there was no significant difference between groups, although we observed lower IOP values in eyes that did not undergo manipulation in the PO. This fact corroborated the studies that showed a higher IOP in the eyes that underwent manipulations after TREC, having a correlation with the greater stimulus to fibrosis by local manipulation, even with the use of subconjunctival MMC in the needling.^(32,35,39)

Importantly, a careful PO is fundamental for the TREC success, demonstrated in this study, and in the world literature, as a well-established, relatively effective, and safe technique, subject to complications, but which, if

resolved in a timely manner, culminates in lasting results in the control of glaucoma. $^{\scriptscriptstyle (24,30,39)}$

The study had limitations related mainly to the lack of information in medical records, besides the loss of follow-up by many patients, especially after 270 days of follow-up, making data collection difficult and favoring the occurrence of information bias, thus reducing the quality and validity of data analysis.

CONCLUSION

The success rate of trabeculectomy exceeded 90%, with a small rate of complications, noting that trabeculectomy is a safe procedure with significant success in the glaucoma control.

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