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Effectiveness of trabeculectomy plus trabeculotomy in the reduction of intraocular pressure in patients with primary congenital glaucoma

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Abstract

Objective: *To evaluate the effectiveness of trabeculectomy trabeculotomy in the reduction of intraocular pressure in patients with primary congenital glaucoma.* **Material and methods:** *A pre-experimental before and after study was conducted with several measurements after; patients with intraocular pressure ≥ 21 mmHg were included, of both sexes, and children under six years, which had the trabeculotomy trabeculectomy. Success was defined as the reduction of intraocular pressure < 21 mmHg within three months after the procedure. For the descriptive analysis, medians with ranges and quartiles 25 and 75 were used. For the inferential analysis, we conducted a visual graphic and analysis of variance for repeated measures of Friedman. A value of p < 0.05 was considered as significant. The software used was SPSSv15.* **Results:** *16 eyes were included with intraocular pressure 27.75 mmHg (23-40), vertical and horizontal corneal diameter of 14 mm (12-16), who had undergone trabeculectomy with mitomycin C trabeculectomy; at three months after surgery the intraocular pressure was 12.5 mmHg (8.5-23) (p <0.001) and no changes were observed in the corneal diameters. An eye with a flat anterior chamber was observed as an adverse effect. Thirteen eyes required topical hypotensors to achieve the target intraocular pressure.* **Conclusions:** *The treatment with trabeculectomy trabeculotomy in primary congenital glaucoma is effective in the reduction of the intraocular pressure.* (Gac Med Mex. 2015;151:669-73)

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Background

Childhood glaucoma comprises a heterogeneous group of conditions resulting from a structural defect in acqueous outflow known as primary glaucoma; or a disease that, associated with this anomaly, shows iridodysgenesis, irido-corneal dysgenesis or some other systemic disease, such as Sturge-Weber or neurofibromatosis, which is known as secondary glaucoma[1]. Primary congenital glaucoma (PCG) is an uncommon disease, but it is the most common form of infantile glaucoma, with a frequency of one case per 10,000 births, a number that increases in populations with high incidence of consanguinity. Presentation of the disease is bilateral in up to 70% of cases, frequently asymmetric, although observations suggest that in 25-30% of cases it can be unilateral[2]. In addition, this type of glaucoma causes

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total blindness in 0.01-0.04% of cases, and usually it is more difficult to manage than other types of glaucoma on the first year of life[3]. In 60% of the patients, the diagnosis is made within the first 6 months of life, and it can be generally established with clinical signs and symptoms, including intraocular pressure (IOP), corneal diameter and optic nerve evaluation. The classical triad of this disease is: epiphora, photophobia and blepharospasm, but there can be other signs, such as opacity, corneal diameter increase, Haab striae and red eye[4].

The recommended treatment for this condition is surgical, which is designed to eliminate acqueous humor outflow resistance created by iridocorneal angle abnormalities. Goniotomy, one of the procedures described for this condition, has the need for a transparent cornea as limitation. Trabeculotomy is also used; as in goniotomy, in the case of trabeculotomy, sometimes it is necessary to perform more than one procedure to reduce IOP, and complications such as hyphema and traumatic cataract can occur[14]. The trabeculotomy plus trabeculectomy combined technique was first described by Nicolás Belmonte in 1979 and has been used as primary treatment or in treatment-refractory cases[20]. It has the advantage that it can be used even with corneal opacity, in addition to creating two acqueous outflow ways. Other intervention that can be performed is placement of a valve implant, which is generally reserved for most advanced or treatment-refractory cases. In the present study, the effectiveness of the trabeculotomy plus trabeculectomy combined treatment was assessed in the control of IOP in patients with CPG.

Design

A pre-experimental before-and-after study design with several post-procedure mesurements was used, and patients diagnosed with CPG with ≥ 21 mmHg IOP, from both sexes and younger than six years, who underwent trabeculotomy with trabeculectomy, were included. Success was defined as IOP reduction (dependent variable) < 21 mmHg within 3 months after the procedure. For descriptive analysis, medians with ranges and 25th and 75th quartiles were used. For inferential analysis, a graphic visual analysis and the analysis of variance (ANOVA) for Friedman's repeated measures were performed. A p-value < 0.05 was considered to be significant. Version 15.0 of the SPSS sofware was used. The study was carried out at the Ophthalmology Department of the High-Specialty Medical Unit N^{o} 25 of Monterrey, in Nuevo León. Prior to its conduction, the study was authorized by the Ethics Committee of the hospital where it was carried out; in addition, informed consent was requested from both parents or legal guardians of the minors.

To calculate the sample minimum size, the formula to compare two mean continuous variables was used with an IOP prior to the trabeculotomy plus trabeculectomy of 27 ± 6 mmHg; i.e, an expected difference of 6 mmHg before and after the procedure or intervention, i.e., the surgery (22%), with an α-value of 0.05 and a β-error of 0.20, which yielded a number of eyes to include of 14. The sampling technique used was convenience-non-probabilistic, and for descriptive analysis, absolute frequencies and percentages were used, as well as means or medians with standard deviations or ranges. For inferential analysis, a graphic analysis was performed and the ANOVA for Friedman's repeated measures was used. A p-value < 0.005 was considered to be significant; and the statistical package SPSS version 15.0 was used for calculations.

An exploration was performed under anesthesia at the moment prior to the trabeculotomy plus trabeculectomy, where the following was examined: previous IOP by means of the Schiotz tonometer, corneal diameters measurement and biomicroscopy to assess corneal transparency. The surgery was subsequently performed: a corneal bridal suture with 7-0 vicryl was placed in order to facilitate exposure of the upper conjunctiva. A limbus-based conjunctival flap was then created onto the upper limbus (at 1 or 11 o'clock). A rectangular flap with an approximate size of 2 x 3 mm was then dissecated towards the limbus, into half or two thirds of scleral thickness. Mitomycin C was applied in a cotton swab, which was placed beneath the flap for 2 min; subsequently, the area was rinsed with 30 cc of physiological saline.

Using high magnification, a radial incision was carefully performed on the underlying sclera, tearing with the blunt end of a slit knife. The incision was made on the transition zone between the blue cornea (trabecular band) and the scleral tissue, where Schlemm's canal is located. The canal is identified when a reflux of acqueous humor is observed as coming from the incision, occasionally mixed with blood. The Vannas scissors were introduced at the incision level in the exposed canal, seccioning it 1 mm at each side. The double trabeculotome, right and left, was then inserted into the incision and its advancement without resistance into the canal lumen was checked. A controlled rotation was then applied towards the anterior chamber, thereby crossing the internal side of Schlemm's canal, breaking the trabecular mesh and the angle's

embrionary tissue. In a similar way, the trabeculotome was introduced through the other end of the incision. Schlemm's canal internal wall was sectioned in an extension of about 120°. A small portion of tissue was then excised from the corneo-scleral bed, with an approximate size of 1 x 2 mm, including some trabecular mesh and a portion of Schlemann's canal (trabeculectomy), followed by a peripheral iridectomy. The scleral flap was repositioned and sutured onto the corners with 10-0 nylon interrupted stitches. The conjunctiva was closed using 7-0 vicryl simple sutures; at the end, antibiotic drops were applied and an occlusive dressing was placed.

The next day after the procedure, the patient was assessed at the outpatient clinic for corneal transparency and bi-digital IOP; in addition, topical antibiotic and antiinflammatory was started, and next reviews under anesthsia were scheduled at 1 month and 3 months after the first surgery. In the following 2 explorations under anesthesia, IOP was assessed again with the Schiotz tonometer, as well as corneal transparency and diameter.

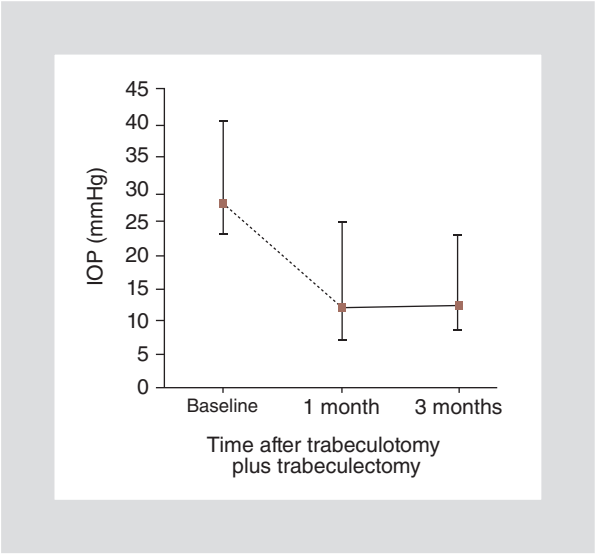

Figure 1. *IOP in 16 eyes with PCG with measurements prior to trabeculotomy plus trabeculectomy and 1 and 3 months later. Values are presented as medians (minimum-maximum).*

Results

Sixteen eyes from 10 patients of the Ophthalmology Department of the High Specialty Unit N° 25 with the diagnosis of PCG and intraocular pressures higher than 21 mmHg, who underwent trabeculotomy plus trabeculectomy, were included. Four patients (40%) were of the male sex and 6 (60%) of the female sex, with median age of 2 years (range: 1-6); six of them had bilateral disease.

Median IOP prior to trabeculectomy was 27.7 mmHg (23-40); at 1 month of the surgical procedure, it was 12 mmHg (7-25), and at 3 months, 12.5 mmHg (8.5-23) ($p < 0.001$).

With regard to vertical (p 0.223) and horizontal (p 0.368) corneal diameters, a median of 14 mm (12-16) was observed for all 3 measurements. All patients were applied mitomycin C during the surgical procedure and only one adverse effect occurred: a shallow chamber secondary to overfiltrating surgery, which required closure of the trabeculectomy flap. The use of coadjuvant hypotensive agents was necessary after surgery in order to achieve the IOP goal in 13 eyes (Fig. 1).

Discussion

PCG is a condition characterized by an alteration of the iridocorneal angle that difficults aqueous humor outflow, which results in IOP increase and, therefore, vision is affected by changes produced to the optical nerve, as well as in corneal transparency and eye globe size[3]. The classical symptom triad PCG presents with is comprised by photophobia, epiphora and lacrimation; the observed signs are: corneal opacity, increased corneal diameter, optic nerve with wide excavations and IOP increase. PCG is characterized for requiring surgical treatment, with several procedure options, such as goniotomy, a procedure that is performed when the cornea is transparent, which is a condition not present in most patients, since IOP increase causes corneal opacity, thus making iridocorneal angle visualization impossible[5]. Trabeculotomy is also performed in patients with this disease and has the advantage that it can be performed in spite of corneal opacity; however, being a blind procedure, Schlemm's canal might not be correctly canalized or the tissue could cover the surgical area again. In addition, more than one surgery is often necessary in order to stabilize IOP. Thus, trabeculotomy plus trabeculectomy surgery was implemented, since by performing two procedures in one without the need for a clear cornea, favorable results are more likely to be attained[10].

In this prospective research work, 16 eyes were accepted, with a 3-month follow-up. In the study by Mullaney, which is retrospective, a total of 100 eyes were included, from 1991 to 1996, with a mean follow-up of 304 days. Campos-Mollo[11] conducted a similar study

Table 1. IOP and vertical and horizontal corneal diameters prior to trabeculotomy plus trabeculectomy and 1 and 3 months later in 16 eyes with PCG

Patient No.	IOP (mmHg)			Vertical corneal diameter (mm)			Horizontal corneal diameter (mm)		
	Before	1 month	3 months	Before	1 month	3 months	Before	1 month	3 months
1	23	12	10	14	14	14	13	13	13
2	24	11	10	14	14	14	13	13	13
3	37	12	11	15	15	15	14	14	14
4	24	8	10	16	16	16	15	15	15
5	34	10	8.5	15	15	15	15	15	15
6	30.5	13	14	15	15	15	16	16	16
7	27.5	12	13	15	15	15	14	14	14
8	24	18	22	13	13	13	13	14	14
9	26	12	12	13	13	13	14	14	14
10	32	10	13	13	13	13	13	13	13
11	30	10	15	14	14	14	14	14	14
12	25	7	11	14	14	14	15	15	15
13	32	12	13	12	12	12	12	12	12
14	40	12	12	12	12	13	13	13	13
15	28	25	23	14	15	15	14	14	14
16	26	13	14	13	13	13	14	14	14

where trabeculotomy plus trabeculectomy was used as initial surgical procedure; it was a retrospective study of 22 eyes with a mean follow-up of 8.5 years[23].

The primary endpoint of this study were the changes in IOP after trabeculotomy plus trabeculectomy surgery; at 3 months' follow up, a median of 12.5 mmHg (8.5-23) was observed, a figure slightly higher than that found by Campos-Mollo, Moral-Cazalla and Belmonte-Martínez in their study, where they had a 8.9-year follow-up with a mean of 10.89 ± 4 mmHg. Campos et al. considered IOP higher than 21 mmHg to be a surgical failure, a situation that occurred in 4 (18%) out of 22 studied eyes and which underwent a second trabeculectomy; conversely, in our study, 2 (12.5%) of 16 studied eyes continued with figures higher than 21 mmHg, which prompted the placement of an Ahmed valve to each one of them[21].

In the present study, when corneal diameter progression was assessed, no changes were observed in vertical or horizontal diameter, with a median of 14 mm (12-16). In the aforementioned study by Campos et al., neither was an increase in corneal diameter observed, and very similar figures of 13.4 mm (12-15) were found. In the study by Beerman et al., preoperative corneal diameter mean in the group undergoing trabeculotomy plus trabeculectomy was found to be 13.6 mm ± 1, and that of corneal diameter at 6 months was 13.46 mm ± 0.93, and in the group undergoing trabeculectomy with mitomycin C, preoperative diameter was 13.53 mm ± 1.1 and, 6 months after surgery, it was 13.46 mm ± 1.1[18].

Mandal et al. studied patients with advanced PCG who underwent trabeculotomy plus trabeculectomy; the use of postoperative topical ocular hypotensive agents was required in 11 out of 157 assessed eyes[15], in contrast with findings in our study, where 13 of 16 observed patients required at least one topical hypotensive agent to reach the IOP goal.

Here, only a shallow chamber secondary to overfiltrating surgery was observed as an adverse event; in this patient, closure of the trabeculectomy flap was required in order to improve IOP. Conversely, in the study by Mandal, 4 patients had shallow anterior chamber, with re-intervention being required only in 4 cases. In the study by Beerman, in the group that underwent

Table 2. IOP and vertical and horizontal corneal diameters prior to trabeculotomy plus trabeculectomy and 1 and 3 months later in 16 eyes with PCG. The values are presented as medians (mínmum-maximum)

	Prior	1 month	3 months	p
IOP (mmHg)	27.7 (23-40)	12 (7-25)	12.5 (8.5-23)	< 0.001
Vertical corneal diameter (mm)	14 (12-16)	14 (12-16)	14 (12-16)	0.223
Horizontal corneal diameter (mm)	14 (12-16)	14 (12-16)	14 (12-16)	0.368

trabeculotomy plus trabeculectomy in one eye, flat bleb occurred as an adverse event, shallow anterior chamber in 2 eyes and hyphema in other 2[18].

This investigation was carried out with 16 eyes from 10 PCG-diagnosed patients who underwent an exploration under preoperative anesthesia, where IOP was assessed using a Schiotz tonometer and vertical and horizontal diameter was measured; subsequently, trabeculotomy plus trabeculectomy surgery was carried out, and the patients were assessed the next day to rule out any adverse events. In addition, they were examined, again under anesthesia, 1 month and 3 months after surgery to check IOP and corneal diameters, with a significant improvement found in patients treated this way. Only in two eyes was a second hypotensive procedure required; in both cases, an Ahmed valve was placed and in one there was an adverse effect, shallow chamber associated with surgical overfiltration, thereby undergoing closure of the trabeculectomy scleral flap, which stabilized IOP. With regard to corneal diameters, no modifications were observed in the corneal diameter length. However, longer follow-up with a larger number of patients should be considered for future research, as well as conducting a randomized trial (Tables 1 and 2).

Conclusions

In the present study, the effectiveness of trabeculotomy plus trabeculectomy was assessed in the decrease of IOP in this type of patients, by means of 3 measurements that were carried out during an exploration under anesthesia prior to surgery, and 1 month and 3 months later. In conclusion, this study suggests that trabeculotomy plus trabeculectomy is effective in the reduction of IOP in patients with PCG and, therefore, there is no progression in vertical and horizontal corneal diameters after the procedure. However, both the number of patients included and the follow-up were short, and there was no control group.

References

1. Skuta GL, Cantor LB, Weiss JS. Pediatric Ophthalmology and Strabismus. Singapur: American Academy of Ophtalmology; 2011.
2. Chakrabarti D, Mandal AK. Poster presented in Asia ARVO. 2009. Presenting symptoms and signs in Indian children with primary developmental glaucomas; p. 213 [abstract 47].
3. Alfadhli S, Behbehani A, Elshafey A, Abdelmoaty S, Al-Awadi S. Molecular and clinical evaluation of the primay congenital glaucoma in Kuwait. Am J Ophthalmol. 2006;141(3):512-6.
4. Kanski JJ. Oftalmologia clínica. Barcelona: Elsevier; 2009.
5. Douglas GR. Assessing and Treating Glaucoma in Children of the Developing World. EE.UU.: Orbis International; 2009.
6. Mandal AK, Chakrabarti D. Update on congenital glaucoma. Indian J Ophthalmol. 2011;59 Suppl:S148-57.
7. Mandal AK, Chakrabati B. Primary combined trabeculotomy-trabeculectomy for developmental glaucomas. Journal of Current Glaucoma Practice. May-August 2010;4 (2):91-96.
8. Mandal AK. The pediatric glaucomas. Filadelfia: Elsevier; 2006.
9. Hoskins HD Jr, Hetherington J Jr, Magee SD, Naykhin R, Migliazzo CV. Clinical experience with timolol in childhood glaucoma. Arch Ophthalmol. 1985;103(8):1163-5.
10. Enyedi LB, Freedman SF, Buckley EG. The effectiveness of latanoprost for the treatment of pediatric glaucoma. J AAPOS. 1999;3(1):33-9.
11. Campos-Mollo E, Moral-Cazalla R, Belmonte-Martínez J. Combined trabeculotomy-trabeculectomy as the initial surgical procedure of primary developmental glaucoma. Arch Soc Esp Oftalmol. 2008 Aug;83(8): 479-85.
12. Mullaney PB, Selleck C, Al-Awad A, Al-Mesfer S, Zwaan J. Combined trabeculectomy and trabeculotomy as an initial procedure in uncomplicated congenital glaucoma. Arch Ophthalmol. 1999;117(4):457-60.
13. Bowman RJ, Cope J, Nischal KK. Ocular and systemic side-effects of brimonidine 0.2% eye drops (Alphagan) in children. Eye (Lond). 2004;18(1):24-6.
14. Russell-Eggitt IM, Rice NS, Jay B, Wyse RK. Relapse following goniotomy for congenital glacuomadue to trabecular dysgenesis. Eye (Lond). 1992;6 (Pt 2):197-200.
15. Mandal AK, Prasad K, Naduvilath TJ. Surgical results and complications of mitomicyn C augmented trabeculectomy in refractory developmental glaucoma. Ophtalmic Surg Lasers. 1999;30(6):473-80.
16. O' Connor G. Combined trabeculotomy-trabeculectomy for congenital glaucoma. Br J Ophthalmol. 1994;78(10):735.
17. Anderson DR. Trabeculotomy compared to goniotomy for glaucoma in children. Ophthalmology. 1983;90(7):805-6.
18. Reddy BPK, Dada T, Sihota R, Panda A. Comparative evaluation of trabeculotomy-trabeculectomy with mitomicyn c vs trabeculectomy with mitomicyn c for primary congenital glaucoma. Journal of Current Glaucoma Practice. 2011;5(1):15-9.
19. Beck AD, Wilson WR, Lynch MG, Lynn MJ, Noe R. Trabeculectomy with adjunctive mitomycin C in pediatric glaucomas. Am J Ophthalmol. 1998;126(5):648-57.
20. Fulcher T, Chan J, Lanigan B, Bowell R, O'Keefe M. Long-term follow-up of primary trabeculectomy for infantile glaucoma. Br J Ophthalmol. 1996;80(6):499-502.
21. Belmonte N, Ladislao-Pérez J. Trabeculo-trabeculectomía. Arch Soc Esp Oftalmol. 1979; 39:610-4.
22. Elder MJ. Combined trabeculotomy-trabeculectomy compared with primary trabeculectomy for congenital glaucoma. Br J Ophthalmol. 1994; 78(10):745-8.
23. Mullaney PB, Selleck C, Al-Awad A, Al-Mesfer S, Zwaan J. Combined trabeculectomy and trabeculotomy as an initial procedure in uncomplicated congenital glaucoma. Arch Ophthalmol. 1999;117(4):457-60.
24. Morales J, Al Shahwan S, Al Odhayb S, Al Jadaan I, Edward DP. Current surgical options for the management of pediatric glaucoma. J Ophthalmol. 2013;2013:763735.