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Original Article

LONG TERM EVALUATION OF PRIMARY CONGENITAL GLAUCOMA MANAGEMENT IN SOHAG UNIVERSITY HOSPITAL

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Abstract

Aim and objectives: *The purpose of the study is evaluation of efficacy of management of the cases of primary congenital glaucoma (PCG) in ophthalmology department at Sohag University Hospital.* ***Patients and methods:*** *A retrospective, case series study was conducted on 87 patients of primary congenital glaucoma and managed by combined trabeculeclectomy and trabecultomy with mitomycin and Ologen (CTTMO) evaluated postoperatively after 1, 3, 6 months 1, 2, 3, 5 years. Regarding the introcular pressure (IOP), transverse corneal diameter (TCD) and complications.* ***Results;*** *Preoperative IOP was 31.28±5.575 mmHg, then was measured on follow up after 1, 3, and 6 months post operatively and it was 11.35±5.562, 12.693±7.0528, and 12.626±6.1290 respectively****,*** *IOP was further followed up for 1, 2, 3, and 5 years post operatively and it was 12.137± 6.4846, 13.00±7.231, 15.08±7.933, and 14.65±6.863 respectively* ***Conclusion;*** *In our department the procedure performed for treating congenital glaucoma; combined trabeculectomy_trabeculotomy with mitomycin and Ologen (CTTMO) achieved a high success rate (93.6% at the 1st year of follow up and 84.6% at the end of 5th year of follow up)*

Keywords: *Primary congenital glaucoma, Combined trabeculectomy trabeculotomy, Mitomycin*

1. Introduction

The most common form of childhood glaucoma is primary congenital glaucoma (PCG) [1]. PCG results in elevated intraocular pressure due to genetically defined anomalies in the trabecular meshwork and anterior chamber angle in the absence of additional eye and systemic developmental issues [2]. The predominant symptoms, including epiphora, photophobia and blepharospasm, are linked to elevated IOP. These symptoms are brought on by the eye's rapid expansion, which results in buphthalmos, or "ox eye" in Greek, enlargement of the cornea, horizontal or oblique breaks in the Descemet membrane (Haab-striae), corneal enlargement, and corneal edoema and opacification [2]. More than two third of cases of PCG are bilateral [3] Genetic consanguinity is a great risk factor. Parents of PCG patients should be aware that the hazard of a second toddler with PCG is small but real [4]. Lowering and managing the IOP as well as treating secondary problems such amblyopia and refractive alterations are the goals of PCG therapy [5]. The remedy is surgical basically and the medical therapy used as an addition

to surgery. The imperative motive of all surgical operations is to remove the barrier to aqueous out flow induced by the anatomical defect in the anterior chamber angle [6]. Angle surgery including; goniotomy, trabeculectomy enhanced with mitomycin C (MMC) and implant surgery, is the mainstay [7]. The antimetabolite mitomycin C (MMC) is administered in the trabeculectomy procedure to prevent extensive postoperative scarring [8]. With the advantage of being removed in cases of hypotonia and the filtration blebs being flat and vascularized without raising the risk of hypotony, infection, or leaking bleb, Ologen is a flexible, biodegradable collagen matrix of animal origin [9]. Children with PCG have alternative variable prognosis [4]. It is influenced by a number of variables, including the severity and timing of the surgery. The prognosis is worse and the failure rate is higher the sooner in life the disease manifests itself [10]. The efficacy of the management mainly measured by the maintenance of low IOP after surgery, our study is aiming to evaluate long term efficacy of the cases with primary congenital glaucoma treated at Sohag Ophthalmology dept.

2. Patients and Methods

The study is a retrospective, case series study was conducted on 87 patients of primary congenital glaucoma and manged by combined trabeculeclectomy and trabecultomy with mitomycin and Ologen (CTTMO). Informed concent was taken from parents of these children. Approval from the Health Research Ethics Committee in Sohag faculty of medicine.

2.1. *Inclusion criteria*

In this study, the children with PCG operated after 3 months of age, then, it was completed the follow up period 5 years.

2.2. *Exclusion Criteria*

PCG patients less than 3 months of age, other type of congenital glaucoma, associated with eye syndromes or systemic disease and did not respect follow up times. All patients have been subjected to: a complete history taking, and examination under general anaesthesia including: Detailed anterior segment examination by portable Slitlamp, IOP(intra ocular pressure) measurement; which is the main diagnostic test, measured twice under general anaesthesia by using sevoflurane, IOP measurement done by two consultant ophthalmologist using Perkins tonometer, transverse corneal diameter (TCD) was measured by using sterile calipers (white to white), Cycloplegic refraction to look for myopia and astigmatism with auto refractor, axial length by A-scan ultrasonography and B-scan if the cornea was opaque to prevent fundus examination. IOP and TCD follow up at different follow up period was recorded.

2.3. *Statistical analysis*

Data were expressed as number and percentage for qualitative variables and mean $\pm$ standard deviation (SD) for quantitative one. Data ware collected throughout history, basic clinical examination, laboratory investigations and outcome measures were coded, entered and analyzed using Microsoft Excel software. The data collected was tabulated and analyzed by SPSS (statistical package for social science) version 25 (Armonk, NY: IBM Corp). Data were expressed as number and percentage for qualitative variables and mean + standard deviation (SD) for quantitative one.

3. Results

This study was conducted on 87 patients, tab. (1) (147 eyes), 48 (55.2%) were males, 39 (44.8%) were females, their age ranged from 3 months to 10 years with

mean 2.47 ± 2.39 years, the 147 eyes were 74 (50.3%) right, and 73 (49.7%) left, 127 (86.4%) eyes had trab. (combined trabeculectomy-trabeculotomy with mitomycin and ologen (CTTMO), while 20 (13.6%) eyes needed retrab. (Revision of the trabeculectomy_trabeculotomy with mitomycin and ologen when the 1st antiglaucoma surgery failed), 12 eyes of retrab. eyes the 1st antiglaucoma surgery was in Sohag ophthalmology dept., while 8 eyes the 1st antiglaucoma surgery wasn't at Sohag university Hospital.

Table (1): Patients' demographic data

	Group (n = 87)	
	No.	*%*
Gender		
• Male	48	55.2
• Female	39	44.8
Age (years)		
• (Min. – Max.)	(3 months –10 years)	
• Mean ± SD.	2.47 ± 2.39	
Eye		
• Right	74	50.3
• Left	73	49.7
Operation		
• Trab.	127	86.4
• Retrab.	20	13.6

3.1. *Preoperative and postoperative IOP measurements at different follow up periods*

Preoperative IOP was 31.28 ± 5.575 mmHg, then was measured on follow up after 1, 3, and 6 months post operatively and it was 11.35±5.562, 12.693±7.0528, and 12.626±6.1290 respectively, IOP was further followed up for 1, 2, 3, and 5 years post operatively and it was 12. 137±6.4846, 13.00±7.231, 15.08±7.933, and 14.65±6.863 respectively. There was a significant lower IOP in all follow up periods (p= 0.000), IOP values show improvement up to normal values and stability at normal level all over the 1st year postoperative. Then on follow up during the following 4 years IOP show a slight increase, as regard IOP values at 1st month postoperative and the 5th year postoperative (p<0.05) which is statistically significant as shown in fig. (1).

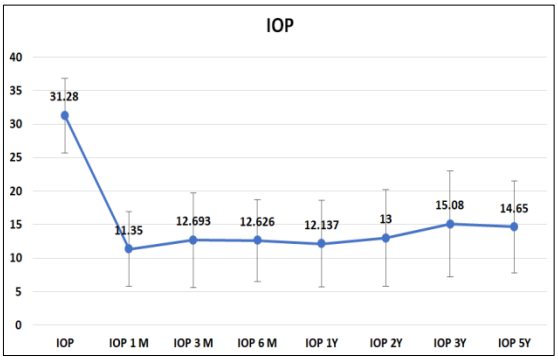

Figure (1): Preoperative and postoperative IOP measurements at different follow up periods of studied patients.

3.2. *Preoperative and postoperative TCD measurements at different follow up periods*

Preoperative TCD (transverse corneal diameter) was 12.81±1.68 mm, then was measured on follow up after 1, 3, and 6 months post operatively and it was 13.05±2.02, 12.95±0.80, and 12.90±1.72 respectively, TCD was further followed

up for 1, 2, 3, and 5 years post operatively and it was 13.30±1.56, 13.35±0.76, 13.38±1.83, and 13.84±0.73 respectively. TCD values showed increase in all stages of follow up, the change at 1st month postoperative TCD and 5th postoperative year (p value <0.05) which is statistically significant. As shown in fig. (2).

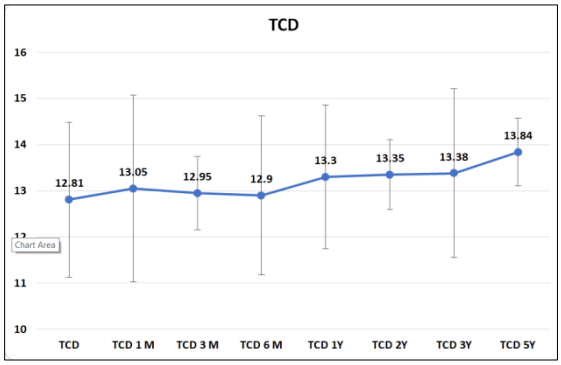

Figure (2): Preoperative and postoperative TCD measurements at different follow up periods of studied patients

3.3. *Preoperative and postoperative CDR measurements at different follow up periods*

Preoperative CDR (cup/disc ratio) was 0.63±0.20, then was measured on follow up after 1, 3, and 6 months post operatively and it was 0.71±1.26, 0.57±0.21, and 0.53± 0.21 respectively, CDR was further followed up for 1, 2, 3, and 5 years post operatively and it was 0.53± 0.21, 0.55±0.20, 0.59±0.18, and 0.60± 0.18 respectively. CDR was significantly lower at almost all periods of follow up in comparison with pre-operative values (p<0.05), decreasing in CDR at 1st postoperative month in relation to 5th postoperative year was statistically insignificant (p>0.05), as shown in fig. (3).

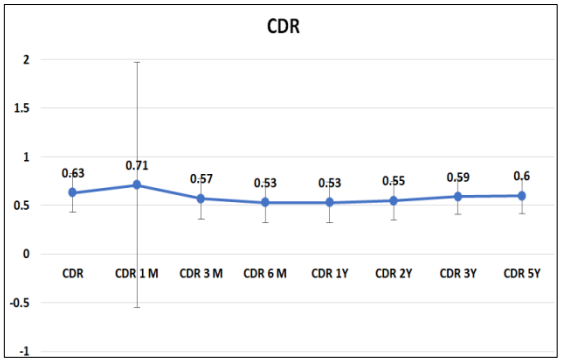

Figure (3): Preoperative and postoperative CDR measurements at different follow up periods of studied patients

3.4. *Postoperative anti-glaucoma medications distribution*

56 (38.1%) patients didn't have any postoperative anti-glaucoma, while 49 (33.3%) had monotherapy (16 eyes used single postoperative antiglaucoma edication as conservative in case of thin bleb, not for CTTMO failure; the antiglaucoma therapy aimed to decrease the aquoeus flow in case of thin blebs to all wound healing), and 42(28.6%) had combined anti-glaucoma postoperative. The anti-glaucoma given as an adjuvant if the IOP was more than 21 mmhg.

3.5. *Complications distribution*

From the total number of eyes, 94(64%) had no complications, while the other eyes had complications mainly thin cystic bleb in 16(11%) eyes, fig. (4) (three eyes

need bleb repair with tenon and conjunctival flap), high IOP in 15(10%) (tweleve eyes need retrab). hyphaema in 14 (10%), tab. (2). following complications happened, choroidal effusion, staphyloma, vitreous haemorrhage, hyperemic optic disc, cataract, blebitis, endophthalmitis, and floating ologen.

Figure 4: Shown thin cystic bleb in a child 2 years old after CTTMO surgery

Table (2): Complications distribution

Complications	N	%
No complications	94	64%
Hyphaema	14	10%
Choroidal effusion	1	1%
Staphyloma	1	1%
Vitreous haemorrhage	1	1%
Hyperemic optic disc	1	1%
High IOP	15	10%
Thin cystic bleb	16	11%
Cataract	1	1%
Blebitis	1	1%

3.6. *Success rate*

If IOP was 21 mmHg or less it considered success of the procedure, our study achieved a success rate of 94.6% after 6 months of follow up, after the 1st year of follow up the success rate was 93.6%, by proceeding the follow up success rate was 84.7% at the end of 2nd year, 83.5% after 3 years of follow up, finally after 5 years of follow up the success rate was 84.6% as shown in fig. (5).

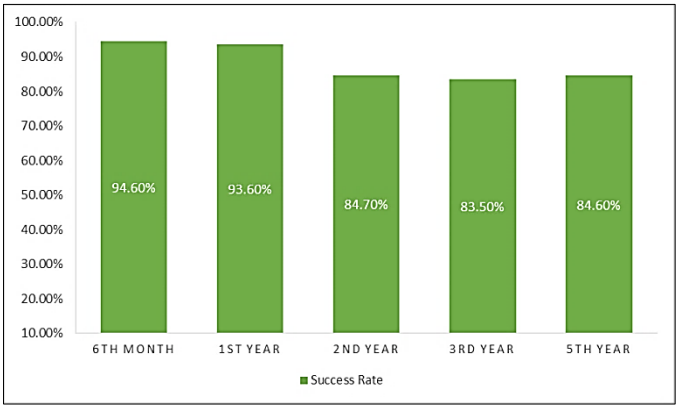

Figure (5): Success rate chart

Discussion

PCG patients will need mandatory surgery which is the backbone of treatment followed by follow up [11]. Hazy cornea, the most frequent PCG presentation, which eleminate the use of an ab-interno angle approach, and the combined pro-

cedure has the added benefit of allowing trabeculectomy to be done in the event that trabeculotomy fails [12]. Children's thick tenon's capsule, quick wound healing, lower sclera rigidity, and large buphthalmic eyes with thin sclera are obstacles to the effectiveness of filtering surgery [13]. Males have a higher prevalence of congenital glaucoma and a propensity toward bilaterality, which is consistent with our findings and what was previously found by Tamçelik [14] who examined the data from 600 eyes of 311 patients. In this study, we evaluated the clinical outcomes of glaucoma surgery (CTTMO) to avoid vision deterioration regarding intraocular pressure, corneal enlargement and optic disc cupping. Our results regarding improvement of IOP where comparable to what previously reported by sayed [11] that, The mean IOP at the 1st postoperative week was significantly lower than the IOP at the 1st postoperative month (P=0.00) then no significant difference was detected between each follow up visit and the preceding one. There was a statistically significant reduction in IOP at all postoperative periods of follow up (P=0.00). Moreover Hafez [15], mentioned that the consequences in his study indicated that the OLO implant had greater efficacy as the result validated that 40% of patients in the OLO group achieved the target IOP (<15 mmHg), while only 10% of patients in the MMC group carried out target IOP at the 6-month follow-up. Sen [16] in a prospective study, studied 50 eyes with primary open angle glaucoma, which specificall managed either via trabeculectomy with low dose MMC (1 gm /ml administrated for 1 minute) alone or trabeculectomy plus MMC and ologen implant, at 12 months follow up in the MMC group IOP was 25.96±4.82 mmHg and dropped to 11.33±3.81 mmHg postoperatively. In comparison, preoperative IOP in the MMC and ologen group was 26.32 ±4.27 mmHg then dropped to 14.35±3.34 mmHg postoperatively [16]. The surgery was considered to be successful if IOP was 21 mmHg or less with or without medical treatment (full success if IOP was less than 21 mmHg without medical treatment), our study achieved a success rate of 94.6% after 6 months of follow up, after the 1st year of follow up the success rate was 93.6%, by proceeding the follow up success rate was 84.7% at the end of 2nd year, 83.5% after 3 years of follow up, finally after 5 years of follow up the success rate was 84.6%. Schwenn [17] actually mentioned that trabeculotomy success rates of more than 90% after 1 year of follow-up, more than 80% after 2 years, and the percentage decreased to be 66.7% after 3 years, and 50% after 4 years. Other studies measured short term outcomes, whilst our study measured the long term results along the 5 years postoperative. In a study finished by Esfandiari [18], ab externo trabeculotomy resulted in 44% decrease in the IOP with a long-term success rate of 65%. In this study the ratio of hyphema as postoperative complication was 10% which is similar to a previous study [11] it was reported that the postoperative hyphema is 10.5% on a larger numbers of cases, others reported to range from 5% to 71.4% [19,20]. Same complications were reported by Zhang [21] and Sen [16] who stated that no obvious differences were noted in terms of complication rates between the ologen group and MMC group in his study. The learn about done by Hafez [15] mentioned that trabeculectomy with a collagen matrix implant was found to be more potent in reaching the target IOP with in the 6-month follow up, meaning that the OLO implant had increased efficacy than the MMC. Miao [22] said comparable outcomes in primary open angle glaucoma and concluded that the ologen implant is same to MMC for trabeculectomy in terms of success rates, tolerability, and effectiveness in lowering IOP. Dietlein [23] stated that implantation of subconjunctival collagen glycosaminoglycan matrices (CGM) added an additional surgical tool in the treatment of symptomatic ocular hypotony after filtrating surgical procedure. Marey [24] reported that the use of the

subscleral OLO implant in trabeculectomy is same with the use of MMC with the advantage of skipping the probably hazardous complications related to MMC use in the early observe up time (12-month). In contrast, Rosentreter [25] mentioned that the success rate in using trabeculectomy with the ologen implant has a lower than that occured trabeculectomy with the MMC. While the bleb configuration led to more issues in MMC group. In opposite to Sen [16], who concluded that in spite of the theoretical benefits of ologen it seem to offer no practical advantages. While in the preceding study [11] we concluded that ologen increase the short and long term surgical success with marked decrease in complications and time of MMC exposure. Success rate 93.6% at the 1st year of follow up , and 84.6% at the end of 5th year of follow up as the surgical technique used in our study CTTMO has the advantages of angle surgery ab externo (trabeculotomy) and the filterating surgery (trabeculectomy), using of antimetabolite as MMC decrease postoperative scarring, Ologen is a collagen matrix which used as a spacer to maintain subconjunctival and subscleral spaces early postoperative and has another benefit it decrease intraoperative MMC exposure time. All these factors give such high success rate.

4. Conclusion

The management of primary congenital glaucoma by combined trabeclectomy trabeculltomy with mitomycin and Ologen (CTTMO) at ophthalmology department at Sohag university Hospital achieved a high success rate with good control of the disease. However, Further studies should be done for that cases as regard long term follow up, assessment the visual outcomes (visual acuity recording in long term follow up) and management of refractive errors and amblyopia

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