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Epidemiological Pattern of Primary Congenital Glaucoma among Children Attending Menoufia University hospitals in Egypt up to four years

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Running title: Primary Congenital Glaucoma among Children

Abstract

Background: Congenital Glaucoma (CG) is a multiple disease features that can lead to loss of vision. Unfortunately, studies involved in the detection of Primary Congenital Glaucoma (PCG) in Egypt are not enough. Delayed diagnosis and management in those patients consequently lead to burdens on patients and their families.

Objectives: To Assess the frequency of CG among children aged 0 to 4 years during the period from 2017-2020، attending Menoufia hospital and primary congenital glaucoma regarding its demographic data, associated risk factors and the used surgical modalities.

Methods: A retrospective cohort study was conducted on children with congenital glaucoma aged 0- 4 years, presented to out-patient clinics at ophthalmic and pediatrics departments in Menoufia University hospitals during the period from 2017 to 2020.

Results: Incidence of glaucoma among the suspected cases was 65.8 per 100,000 cases during the 4 years. Conjunctivitis, Nasolacrimal Duct Obstruction (NLDO), and corneal abrasion were among the highest incidence that contributed to confusion with the diagnosis of PCG comprising 526.3, 394.7, and 78.95 per 100,000, respectively. Eighty-two percent of the cases had positive consanguineous marriage that contributed to the higher incidence of PCG among other gypsies. Positive family history of PCG was detected only in 20% of the cases. Axenfeld-Rieger syndrome was presented only in 1 case. Bilateral PCG comprised 84% of the total cases. Visual acuity was mostly managed either by fix and follow or poor fixation in 42 % and 56 % of the cases, respectively. Seven cases only experienced post-operative complications between hypotony, choroidal hypotony, or uncontrolled Intraocular Pressure (IOP). 32% of the cases gained visual acuity problems and the rest suffered non

Conclusion: PCG comprised high incidence in the cases presented to the outpatients' clinics as consanguineous marriage was remarkable in those cases. Most of the cases had classic trabeculectomy followed by equal percentage of both goniotomy and combined trabeculectomy-trabeculectomy (CTT). Secondary surgical management involved CTT and combined trabeculectomy with Ahmed valve. All the three measurement to assess post-surgical success rates were significantly differ whether IOP, cup diameter, or corneal diameter.

Key words: Primary Congenital glaucoma -Incidence of glaucoma.

Introduction

Primary congenital glaucoma is the most frequent childhood glaucoma and an important cause of blindness in this category. In developing countries, there is usually a delay in the discovery of affected children owing to illiteracy among the general population along with limited facilities for appropriate assessment. Consequently, the burden of childhood glaucoma in the Middle East and developing countries is so far high. The prevalence of blindness among children in the developing world is estimated to be 0.051% accounting for 3.9% of the total blindness worldwide. This percentage is predicted to continue its rise unless serious measures are taken[(1)].

The visual outcome of childhood glaucoma is determined by the stage at presentation, the establishment of the diagnosis of glaucoma and its etiology, the time of the intervention and the follow up[(2).]

The ultimate goal for pediatric glaucoma management is not to control increased intraocular pressure (IOP) yet to preserve vision. The visual prognosis in children with glaucoma is correlated with the severity of the associated ocular pathology. PCG has the best visual prognosis, with 52% to 79% having visual acuity of 20/50 or better. Glaucoma associated with congenital ocular anomalies and secondary glaucoma have the worst visual prognosis, with 30% to 50% of eyes noted to be 20/50 or better[(3)]. PCG is predominantly sporadic with bilateral manifestation in 85% of the cases[(4)]. It is characterized by high IOP, enlarged corneal diameter and marked optic disc cupping in the first year of life[(3)]**.** Elevated IOP causes enlargement of the globe (buphthalmos), resulting in breaks in the Descemet's membrane, the so-called Haab's striae[(4–6)]**.** As well, corneal opacification or haze is common[(7–9)]. To establish a concrete baseline; there should be a single, consistent classification system agreed upon by different practitioners. Numerous classification schemes have been introduced, although none are broadly followed[(1)].A critical step to build up plans for future intervention programs is to understand the distinctive pattern of childhood glaucoma in our region and thereby define our needs. Due to rareness of research in this field, this study was conducted.

The aim of this work was to assess the frequency of congenital glaucoma among children aged 0 to 4 years during the period from 2017-2020 and describing primary congenital glaucoma regarding its demographic data, associated risk factors and the used surgical modalities.

Methodology:

A retrospective cohort study was conducted on children with congenital glaucoma aged 0- 4 years, presented to out-patient clinics at ophthalmic and pediatrics departments in Menoufia University hospitals during the period from 2017 to 2020.

Statistical methods used : All children eligible for the study inclusion criteria aged from 0-4 and meet American Academy of Ophthalmology(AAO) criteria(10) for PCG with available complete medical records were included in the study. Records with incomplete data were excluded from the study. The statistical analysis was based on two tailed test using a level of significance for analysis at $p \leq 0.05$. All suitable graphs were done using R Software version 3.5.2 (2018-12-20) -- "Eggshell Igloo". Shapiro test was used to test the normality of the numeric variables. Descriptive analysis for quantitative data includes mean, Standard deviation and range for normal distributed variables were involved. When normal distribution was violated, the median and interquartile range was used instead of the mean and standard deviation. For qualitative categorical variables; frequency, chi square, and percentage were applied.

Data collection and inclusion criteria:

1- General characteristics: age, gender, family history, any other systemic disease and past history of previous medical illness or ocular illness.

2- Local Examination: All suspected patients had complete ocular examination including; refraction, IOP, corneal diameter and cup-disc ratio. IOP was measured in young and uncooperative children under inhalation anesthesia. Cup-disc ratio was examined by direct and indirect ophthalmoscope. Corneal diameter was measured horizontally (white to white) by calipers. In healthy children,

the normal horizontal corneal diameter was 9.5 to 10.5mm for newborns and 10.0 to 11.5mm by 1year of age. A diameter that was more than 1.0mm was considered above the normal range and was of concern. Glaucoma was suspected in any child with a corneal diameter greater than 13.0 mm.

3- Children aged from 0-4 with complete medical records

4- For management with surgical procedure; classic trabeculotomy, combined goniotomy, and Ahmed's valve with classic trabeculotomy while medications used during management and follow up were ; four groups of drugs: beta-blockers (timolol and betaxolol), carbonic anhydrase inhibitors (dorzolamide), alpha2-agonists (brimonidine), and prostaglandin analogs (latanoprost) in the management section under methodology.

Ethical considerations:

An informed written consent was obtained from all patients parents or caregivers before proceeding the study. All content of the informed consent was explained in details to the involved caregivers. Confidentially was ensured. The study was approved by the Ethical Committee, Faculty of Medicine, Menoufia University under the number (1219OPTh) in Dec 2017.

Results:

The study was carried out on 76000 children (population at risk) aged from 0 to 4 years. Only 1052 patients were suspected to have congenital glaucoma. After further examination, only 50 patients of them have been confirmed to have the symptoms of congenital glaucoma over the period from 2017 to 2020. Cumulative incidence and incidence rate of congenital glaucoma were calculated based on the given data according to the following equations:

CI for congenital glaucoma = 50 / 76000 = 66 / 100000 over 4 years. Incidence rate for each year = 66 / 4 = 16.5≈17 cases /100000 / year. Consequently, over 4 years there were 50 children who were diagnosed with PCG with an incidence risk (cumulative incidence) of 65.8 per 100,000 with (95 % CI: 48.8 - 86.7) over 4 years (Table 1, figure 1).

Table (1) Classification of the entire 1052 patients according to their diagnosis:

	(No=1052)	(%)	Incidence risk (/ 100000)	95% CI
Diagnosis				
- Glaucoma	50	4.8	65.8	48.8 - 86.7
- Conjunctivitis	400	38.0	526.3	476.1 -580.35
- NLDO	300	28.5	394.7	351.4 - 441.9
- Corneal abrasion	60	5.7	78.95	60.25 -101.6
- Corneal dystrophies	50	4.8	65.8	48.8 - 86.7
- Keratitis	50	4.8	65.8	48.8 - 86.7
- Megalocornea	30	2.9	39.5	26.6 - 56.4
- Myopia	50	4.8	65.8	48.8 - 86.7
- Forceps trauma	25	2.4	32.9	21.3 -48.6
- Uveitis	10	1.0	13.2	6.3 - 24.2
- Post keratoconus	10	1.0	13.2	6.3 - 24.2
- Squint	15	1.4	19.7	11.05 - 32.55
- Aniridia	2	0.2	2.6	0.32 - 9.5
Laterality				
- Both eyes	752	71.5		
- Left eye	125	11.9		
- Right eye	175	16.6		

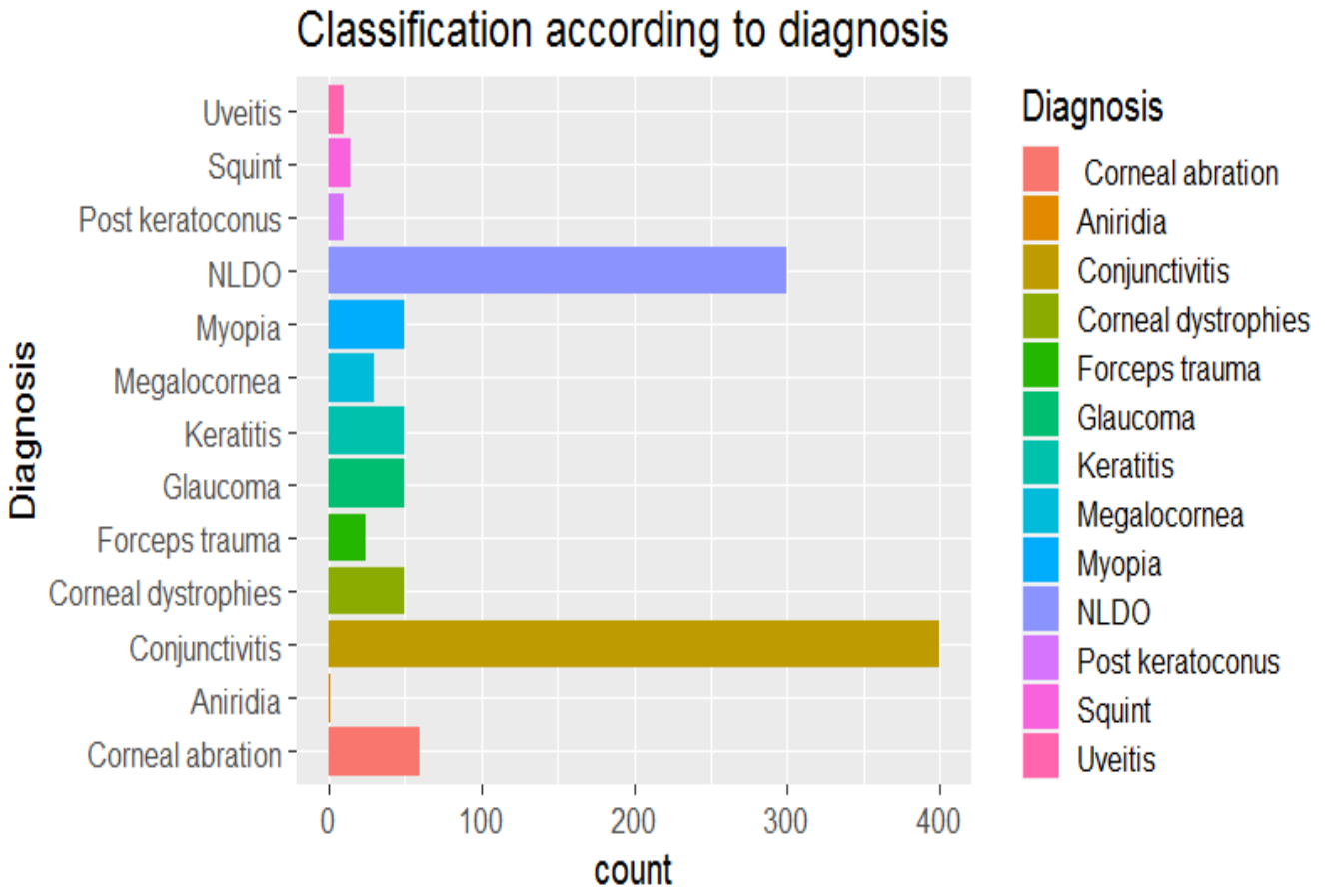

Figure 1: Classification of the involved patients according to diagnosis

Ninety two eyes for 50 patients with mean age = (6.7) months & SD (± 7.8). Male cases represented about (68%). About (80%) of cases didn't have a family history at all. Consanguinity comprises 82% of the cases. Blue cornea was the major symptom presented in all cases and represented about 58% followed by megalocornea which represented about 32%. About 56 %of patients with PCG had poor fixation before the surgery, 42%were fixed with follow-up & only one case had projection of light. Only (10%) of the cases had corneal opacity & there was only one linear abrasion case. One case aged 48 months detected to have acquired glaucoma. As well, only 1 rare case of Axenfeld-Rieger was detected as a systematic disease (Table 2, figure 2).

Table (2) Characteristics of congenital glaucoma children:

Diagnosis	**(No=50)**	**(%)**
Age (month)		
Mean ±SD	6.7 ±7.8	
Range	1- 48	
-Male	34	68.0
-Female	16	32.0
Symptoms		
-Blue cornea	29	58
-Megalocornea	16	32
-Epiphora	12	24
-Blepharospasm	6	12
-Buphthalmos	10	20
-Lacrimation	3	6
-Traumatic hyphema	1	2
Family History		
-Positive	10	20
-Negative	40	80
Ocular disease		
AXIEN field rigger	3	6.0
Cataract	1	2.0
No abnormality detected	46	92.0
Systemic disease		
AXIEN field rigger	3	6.0
Free	47	94.0
Consanguinity		
Positive	9	18.0
Negative	41	82.0
Laterality		
Right eye	4	8
Left eye	4	8
Both eyes	42	84
Visual acuity		
-Fix & Follow	21	42.0
-Poor Fixation	28	56.0
-Projection of light	1	2.0
Corneal opacity		
-Positive	5	10.0
-Negative	44	88.0
-Linear abrasion	1	2.0

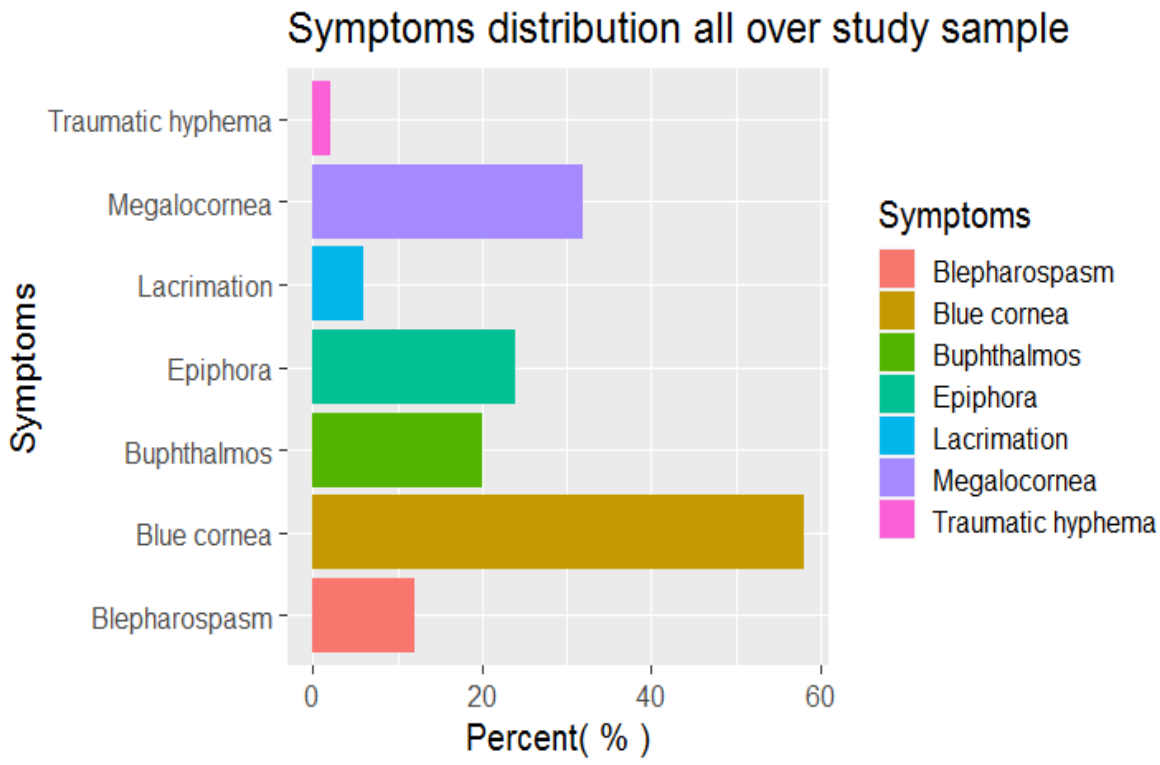

Figure 2: Symptoms distribution among the whole sample

For all study eyes (50 patients with 92 eyes): There were (40) patients with (74 eyes) representing about (80%) of the study sample had classic subscleral trabeculectomy (SST). Five patients with (8 eyes) representing about 10% of the study sample had goniotomy. Four patients with (8eyes) represented about 8% of the study sample had combined surgical procedures. Only one patient with (2 eyes) represented about 2% had classic SSTTrab. & Ahmed valve. Patients managed by more than one glaucoma surgical procedure were 3 patients with 6 eyes. Two patients with (4 eyes) represented about 66.7% of them had combined surgical procedures and one had classic SSTTrab. & A valve (Table 3).Post-operative corneal diameters had been decreased significantly in both eyes than pre–operative measurement. The post-operative cup diameter had been decreased significantly in both eyes than pre–operative measurement. The post-operative IOP of both eyes had been decreased significantly than pre-operative IOP (Table 4).

Table 3: Surgical procedure (Primary and secondary) among the studied

	No=92	%
Primary surgical procedure		
- Classic sst Trabeculectomy	74	80.4
- Goniotomy	8	8.7
- Combined	8	8.7
- ClassicSStTrab.& A valve	2	2.2
Secondary surgical procedure		
- Combined	4	4.4
- ClassicSSTtTrab.& A valve	2	2.2

Table 4: Pre-Post comparison of the studied group regarding corneal diameter, Cup diameter and IOP:

	Pre-operative No=92 eyes		**6 months–post operative No=92 eyes**		**1 year–post operative No=92 eyes**		**P value**
	Mean ±SD	**Median (IQR)**	**Mean ±SD**	**Median (IQR)**	**Mean ±SD**	**Median (IQR)**	
Corneal diameter							
Right eye	12.38± 0.86	12.5 (10.5-13.5)	12.1±0.7	12.5 (10.5-13.0)	12.03± 0.68	12.5 (10.5-13.0)	**< 0.001**
Left eye	11.9± 0.74	12.0 (10-14)	11.7±0.7	11.5 (9.5-13.5)	11.7± 0.67	11.5 (9.5-13.5)	**< 0.001**
Cup diameter							
Right eye	0.48± 0.08	0.5 (0.4- 0.7)	0.34±0.05	0.3(0.3-0.4)	0.34± 0.05	0.3(0.3- 0.4)	**< 0.001**
Left eye	0.44± 0.12	0.4 (0.3-0.7)	0.34±0.05	0.3(0.3- 0.4)	0.34± 0.05	0.3(0.3- 0.4)	**< 0.001**
IOP							
Right eye	20.7± 4.7	21.0 (8-32)	12.2±1.4	12.0 (9.8-16.0)	12.2± 1.4	12.0 (9.8-16.0)	**< 0.001**
Left eye	20.1± 4.1	20.0 (12- 28)	12.2±1.4	12.0 (9.8-16.0)	12.2± 1.4	12.0 (9.8-16.0)	**< 0.001**

Only 14 % of cases had developed post-operative complications and required the administration of anti-glaucoma drugs. There was about 24% of cases after 1 year of follow-up who developed post-operative visual acuity complications such as (amblyopia, myope, opacity, projection of light in left eye and only 4 % of them were "ON affection". The remaining cases represented about 68 % didn't show any visual acuity complications. There were 4 cases which represent about 8 % had been lost from the study after 6 months follow-up (Table 5, figure 3).

Table 5: Post-operative complications and Drug administration among the studied group

	No=50	%
Post-operative complications		
- Hypotony	3	6.0
- Hypotony choroidal detachment	1	2.0
- Elevated IOP need re-surgery	3	6.0
- No	43	86.0
Visual acuity		
- Amblyopia	3	6.0
- Myope	4	8.0
- Opacity	1	2.0
- Projection of light in left eye	2	4.0
- Optical nerve affection	2	4.0
- Lost	4	8.0
- No complication	34	68.0
Drugs administration		
- Yes	7	14.0
- No	43	86.0

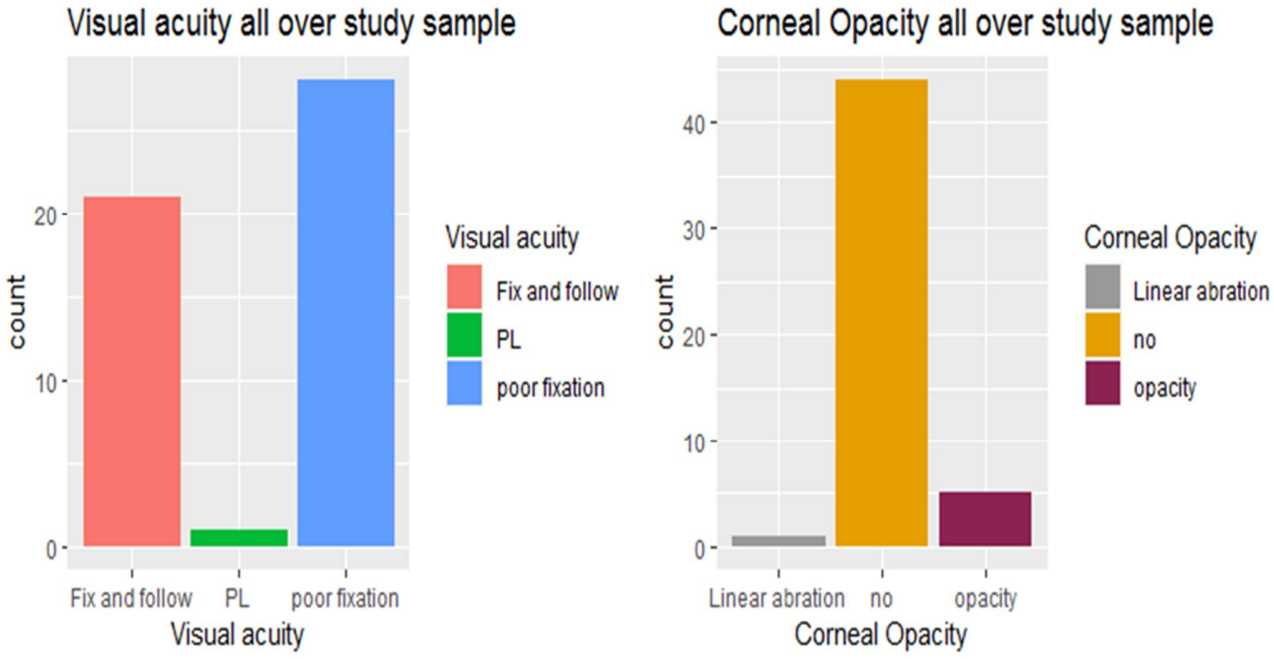

Figure 3: Visual acuity and corneal opacity among the studied sample

Discussion

Although congenital glaucoma is rare, its impact on the child and his/her family is quite serious. Congenital glaucoma is characterized by an increased IOP where 18% of children worldwide with congenital glaucoma became blind[11,12]. Primary congenital glaucoma is an inherent disease mainly

exists in children from consanguineous marriage and is an ethnic based disease[11].

In a study conducted in Korea, an incidence rate of 11.0 /100,000 births was detected with higher rates among males. The study conducted on a nationwide to find a significant decline in the person-year rate since 2011 onward[13]. In another study, in earlier era, PCG comprised 1.46/100,000 person-years in Olmsted County, Minnesota, USA from 1965 to 2004[2].

According to our study results, the calculated incidence rate was 65.8/100000 over 4 years (95 % CI: 48.8 - 86.7) indicating higher incidence compared to the two previously mentioned studies. The disparity between our results and the compared studies could be due to higher consanguinity among Egyptians compared to others; in some religions, consanguineous marriage is prohibited. Consanguinity was found in 82% of our positive cases. Our findings match those from Saudi Arabia (1:2500), Slovakia (1:1250) and India (38%) indicating higher PCG incidence associated with consanguineous marriage. As well, in some ethnic groups, PCG was found more protruding in black and Pakistani gypsies than others[14].

Inherited autosomal recessive patterns are found among families with PCG child(11). PCG was found predominant in our sample in around 23 cases and was detected at age younger than 3 months. This finding comes in the line with [3,8,15]. Chan & Cavuoto and Mokbel both have stated that PCG is the highest among other types of glaucoma followed by acquired glaucoma[16,17]. As well, our finding was found matched to that by Mokbel and colleagues who concluded that PCG was the most prevalent type of children glaucoma in Mansoura University hospital between 2014 and 2017[16].

In our study, the mean age detected was 6.7±7.8 months indicating that mostly they were infantile. Only one case of acquired glaucoma was detected in our sample prohibiting fair presentation. Regarding family history, only 20% of the congenital glaucoma had family history of congenital glaucoma. Most of the studies investigating family history of CG had similar results[2,11,18].Male sex was predominant by 68% of the cases and the result is consistent with previous literature regarding inherited PCG in males than female sex[16,19,20].

In our study, data was collected from 76000 children, 1052 were suspected cases and only 50 children had confirmed PCG between 2018 and 2020. Among 1052, 4.8% had congenital glaucoma, 38% had conjunctivitis and 28.5% had NLDO. The rest suffered similar diagnostic features of PCG but with lower incidence e.g. megalocornea, corneal dystrophies, corneal abrasion, and myopia. Blue cornea, megalocornea, and epiphora were among the highest symptoms noticed in children with PCG with 58%, 32%, and 24%, respectively. Epiphora was reported in 24% of cases yet it led to a misdiagnosis with conjunctivitis, NLDO, or uveitis (1%) in the suspected cases. It should be noted that most of the cases seek tertiary healthcare centers in suburbs or towns can lead to missing diagnosis which is common worldwide thus loss of sight can occur [13,14,19].

Around 5%, who had high axial myopia and 2.9% with megalocornea of the suspected cases were eventually turned to haveeither buphthalmia or Aniridia and not PCG. This discrepancy is common and should be taken into consideration when patients presented with similar symptoms [11,14].

As regarding to literality, children with bilateral glaucoma were 84% which is consistent with previous literatures reported that 70-80% of the PCG children had bilateral glaucoma (2,14,21). While an equal percentage of 8% had glaucoma in either their right or left eyes.

As the main age of the patients were around 6 months, visual acuity only maintenance procedure was to fix and follow in 42% of the cases as recommended by the American Academy of Ophthalmology [11]. Poor fixation was detected in 65% of the cases and 2% projected the light. As regards to corneal opacity, 10 % of the cases had corneal opacity while 2% had corneal abrasion. Corneal edema is a common sign associated with elevated IOP in children presented with PCG [2,11,14].

Concerning associated diseases, only 1 case represented with Axenfeld-Rieger syndrome, one was presented with cataract and the remaining cases were free. It is well known that

fifty percent of Axenfeld-Rieger syndrome develop glaucoma[22,23].

Among 92 cases, 80.4% of the cases had successful classic SST trabeculotomy furthermore, goniotomy and combined trabeculotomy and trabeculectomy shared the same number of patients of 8.7% and only 2% of the cases had classic SST trabeculotomy & Ahmed valve. Although goniotomy is known as the most popular glaucoma surgery to manage IOP in PCG, combined trabeculotomy- trabeculectomy has been once used with a significant success and safe profile in younger ages[5,24]. Trabeculotomy is used more frequently in older age[16,25]with more than 65% of success rates. During the full 4 years of our study period, only 3 cases were missed to follow up otherwise, all the studied cases were followed for one year after surgery with assessment of corneal diameter, cup diameter, and IOP. IOP mean value detected was 20.7±4.7before surgery then dropped to around 12±1.4 for both eyes 6 months post-surgery and maintained through the year. Pre-operative corneal diameter was 12.38±0.86 and after a year the readings dropped significantly to 12.03± 0.68 for right eyes and from 11.9± 0.74 mm to 11.7±0.67 mm for left eyes. Finally, cup diameter for the right eyes was 0.48 ±0.08 mm and dropped to 0.34 ±0.05 mm while left eyes had cup diameter of 0.44 ±0.12 mm and dropped to 0.34± 0.05 mm through the year. Many studies have pointed to the remarkable decrease in the three mentioned parameters indicating control of PCG and maintain preservation of sight in those children. Huang et al. (2011) concluded that filtering glaucoma surgery had nearly the ideal success rates followed by goniotomy then trabeculotomy. It also reported that successful probability was reduced with prolonged follow up period. Furthermore, IOP was dropped from 25 mm to less than 18 using trabeculotomy while goniotomy procedure was able to decrease IOP from 28.0±8.5 to 13.8±4.3[25]. In another study by Huang et al. (2016), assessing trabeculotomy in new born Chinese, IOP, cup diameter and corneal diameter were significantly lowered at their first visit post-operatively. Also, it was concluded that the success rates were inversely proportional to the number of follow up years[26].

Unlike other studies' reports, additional procedures were not required. Here, only 4.4% required combined surgery and 2.2 % involved trabeculotomy & Ahmed valve. In Fung and colleague study, 50% of the cases required secondary management[19] and at Mokbelstudy,15.0% of their patients required a secondary intervention before the end of the first year post-operatively[16].

Post-operative complications were seen in 14% of the cases (p value <0.001). Hypotony is frequently expected as an immediate post-operative complication[17,27]. In this study, 6% had post-operative hypotony while 2% developed choroidal hypotony. The result is consistent with another study conducted in Chiang Mai university hospital, where primary trabeculectomy with mitomycin C was associated with 27.2% hypotony after 3 months of operation [28].

Another study by Zhang et al. (2009) has reported 12.12% in the trabeculectomy post-surgical complications and similarly in the combined trabeculotomy- trabeculectomy surgery[29]. Some studies had reported post-operative long period hypotony with a mean follow up of 53.4 ± 31.4 months[30]. Ahmed valve can detain hypotony and choroidal hypotony to its least [31].Choroidal hypotony, retinal detachment, hemorrhage are common after cyclo-destructive procedure[17,27,28]. Choroidal detachment was the highest among older patients after trabeculectomy as reported in the Collaborative Initial Glaucoma Treatment Study (CIGTS) [17,27].

Six percent of the cases had failed operation therefore re-surgery was required. Myope, amblyopia, reflection of light, and on affection were among the highest visual acuity complications recorded in our study sample presenting 8%,6%,4%, and 4%, respectively. Myope in children with PCG may become more myopic after the surgery[27].

Cases that required medical treatment post-operatively comprised 14% of the total cases. In Zhang study, the author could not follow up the patients with failed surgery to establish the treatment[29]. Another review conducted by Ghateand Wang has concluded that among the different surgical procedures used to manage PCG, none of them was superior and that combined trabeculotomy- trabeculectomy was the most popular surgery

worldwide for managing PCG[32]. Unlike our study results, none of the six included studies required post -surgical treatment.

Conclusion: PCG was found in higher incidence among the children presented to outpatients' clinics at Menoufia university hospitals. Post -operative intervention has successfully managed children with PCG with lower incidence to get secondary managed by anti- glaucomatous drugs. Differential diagnosis with other diseases in children with CG is still challenging and could lead to delay in the diagnosis and detection of PCG to devoid blindness in those children. Consanguineous marriage that contributed to the higher incidence of PCG among other gypsies

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Standard of reporting:

Compliance with ethical standards.

Availability of Data:

All the data are available upon request. Please contact the corresponding author.

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Ethics declarations.

Conflict of interest

Heba Helmy, Zeinab Kasemy, Farid Wagdy, all authors have no conflicts of interest that are directly relevant to the content of this review.

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