Perioperative prognostic factors for outcome in primary congenital glaucoma

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Short title: Previously diagnosed unilateral primary congenital glaucoma

Abstract:

Purpose: To study prognostic factors that affects IOP control and surgical success rate of 3 different surgical techniques to treat patients with PCG.

Patients and Methods: This retrospective cohort study included 149 eyes of 85 children diagnosed with PCG who underwent single site trabeculotomy, combined trabeculotomy trabeculectomy or double site metal probe trabeculotomy. Logistic regression analysis was performed to detect correlations between the success rate (at 24 months postoperatively) and preoperative IOP, corneal diameter, axial length, age of onset of the disease, consanguinity, surgical technique and postoperative corneal and axial length growth.

Results: There were no correlations between success rate and sex, laterality, consanguinity, preoperative corneal diameter or axial length. Age of onset less than (2.00 ± 1.954) months was statistically associated with failure. Preoperative IOP higher than (30.37 ± 5.614) mmHg was associated with failure. Complete success was 100% in mild, 86.76 in moderate and 64.86% in severe cases, thus, severity had an association with failure. In severe cases, complete success was 90% in single site trabeculotomy, 47.83% in CTT and 88.23% in double site trabeculotomy group. Postoperative hypotony occured in 68.2% of the failed eyes and 34.9% of successful eyes and was statistically associated with failure. Postoperative accelerated corneal diameter and axial length growth was statistically associated with failure.

Conclusion: Early onset of glaucoma, high preoperative IOP, glaucoma severity and postoperative early hypotony can be correlated with failure in PCG. Angle surgery whether single or double site trabeculotomy had higher success than combined trabeculotomy trabeculectomy.

Key words: Primary Congenital Glaucoma, IOP, trabeculotomy, hypotony

INTRODUCTION:

Congenital glaucoma is a major potential cause of blindness that affects children before the age of three years due to an abnormal draining anterior chamber angle and trabeculdysgenesis, thus, increasing resistance to aqueous outflow. Children affected with congenital glaucoma usually present with enlarged eyes (buphthalmos), corneal edema, corneal opacity, and Descemet's membrane rupture (Haab's striae)[1]. Traditional angle surgery in the form of trabeculotomy and goniotomy shows comparable results, and the choice between both depends upon corneal clarity that is crucial for goniotomy procedures[2].

Many surgeons advocated combined trabeculotomy and trabeculectomy as a primary procedure for primary congenital glaucoma cases with corneal diameter > 14mm for fear that the anatomy in these cases can be markedly altered secondary to the

stretching at the limbal area. This altered anatomy can distort the landmarks needed to identify and accurately locate the Schlemm's canal and thus affecting the results of subsequent trabeculotomy[3].

The rationale for CTT is to obtain a dual outflow of aqueous through angle and the trabeculectomy fistula[4]. Other authors advocated that a larger corneal diameter, greater than 14 mm, appeared to be a predicting and prognostic factor for goniotomy and trabeculotomy, thus assumed that a modification of traditional incisional angle surgery is highly recommended to improve the results in such cases[5]. Various modifications of angle surgery have been proposed as 2 site goniotomy, temporal trabeculotomy and nasal goniotomy, Kahook dual blade goniotomy, 2 site trabeculotomy, 360 degrees microcatheter assisted (or proline suture) trabeculotomy, GATT and other MIGs procedures[6].

Some authors studied the correlation between surgical outcome and higher corneal diameter, preoperative IOP, axial length, severity, consanguinity and early onset especially neonatal PCG and many reported correlation with poor outcome[7-8], but few studies were carried in our locality.

In this study, perioperative factors that may affect the surgical outcome of PCG in the study's locality were evaluated to find out prognostic factors that can be correlated with failure. Also, the effect of different surgical interventions on IOP control and surgical outcome was studied that may help in deciding the appropriate surgical intervention in PCG.

PATIENTS AND METHODS:

This study was a retrospective cohort that included all primary congenital glaucoma cases that were operated in Mansoura Ophthalmic Center, Dakahlia, Egypt, during 2018–2023. The research protocol of the study was approved by the Research Local Ethical Committee R.23.06.2204.R1. The study included 149 eyes of 85 patients diagnosed as PCG. The records of patients were retrieved and data was recorded.

Inclusion Criteria: All children, both genders, diagnosed with primary congenital glaucoma in Mansoura Ophthalmic Center during the study duration were enrolled. All patients presented with glaucoma before age of three years .All patients fulfilled the diagnostic criteria defined in the last Childhood Glaucoma Research Network classification[9] in which at least two of the following criteria were required; intraocular pressure > 21 mmHg, Haab's stria, corneal edema, horizontal corneal diameter ≥11 mm in new-born, > 12 mm in children < 2 years old and > 13 mm in any age, increased (>0.3) or asymmetric (>0.2) cup–disc ratio or progressive myopia or myopic shift with increased AL.

Exclusion criteria: children with history of previous ocular surgery or trauma, patients with recurrent glaucoma, secondary childhood glaucoma as glaucoma following cataract surgery, glaucoma associated with local ocular abnormalities or syndromes as Peter's anomaly, aniridia or Sturge Weber syndrome.

The preoperative clinical data included the patient's age at time of first presentation and at time of surgery, gender, consanguinity, family history, systemic associations and medical treatment details. Preoperative examination was performed under sevoflourane inhalational anesthesia. Complete examination of the anterior segment included measurement of the horizontal corneal diameter (white to white) using surgical calliper; measurement of intraocular pressure using hand-held Perkins applanation tonometry (Haag–Streit, Harlow, UK), just after the induction of anaesthesia, corneal clarity was assessed with the aid of a hand held slit lamp; the fundus was examined by binocular indirect ophthalmoscope; axial length was measured by A scan ultrasonography and B scan ultrasonography (Nidek US-4000/500 Echo scan) was used to exclude any posterior segment pathology especially in cases with opaque cornea.

Surgery: Three types of surgeries were performed and included in the study; *Single site trabeculotomy, Combined trabeculotomy–trabeculectomy (CTT) and double site metal prove trabeculotomy.* Severity was calculated before surgery according to Al-Hazmi et al 2005[10]. This score classifies cases into mild, moderate or severe according to IOP, corneal diameter and corneal clarity[10].

1) Single site trabeculotomy:

Vicryl 7/0 corneal traction suture was taken. A superonasal conjunctival periotomy was performed followed by gentle diathermy. A 3 mm × 3 mm triangular scleral flap was made. A 2 mm radial incision was made starting from the grey zone up to the white zone in the flap bed. An incision made deeper with caution until the outer wall of Schlemm's canal was opened and aqueous humor was observed. A metal trabeculotome was used to cannulate and dissect through the inner wall of SC by 120° in both directions into the AC. Healon was injected in the anterior chamber to stop hyphema. The scleral flap and conjunctiva were then sutured with interrupted 10–0 nylon sutures with embedding of knots. Subconjunctival antibiotics and steroids were lastly injected.

2) Combined trabeculotomy–trabeculectomy (CTT):

A superionasal conjunctival periotpmy was dissected. A 4×3 mm rectangular scleral flap was fashioned and extended to the clear cornea. Then Trabeculotomy was performed as described above. Then, a 2 × 2 mm trabecular meshwork block was excised and a peripheral iridectomy was performed. The scleral flap was then sutured with 10/0 nylon. Lastly, the conjunctiva was tightly closed with interrupted 10/0 nylon suture.

3) ***Double site metal probe trabeculotomy:***

Two traction sutures is passed through the upper and lower corneal limbus to facilitate exposure of the sclera followed by fashioning of superonasal and infrotemporal scleral flaps, opening underlying SC in both sites, then performing trabeculotomy using the metal probe and closing the scleral flap and conjunctiva in the superior site first then the inferior site . closure of scleral flaps and conjunctiva was done with 10/0 nylon suture. Viscoelastic was used to form the anterior chamber and decrease the risk of hyphema.

Postoperative care:

The children were discharged on: Systemic antibiotics (the dose was calculated according to their body weight), topical antibiotic eye drops (Moxifloxacin) five times daily for one weak, topical corticosteroids (Dexamethasone 0.1%) were administered until there was a complete resolution of postoperative inflammation and tapered gradually over a 6-week period.

Follow up:

Post-operative visits were scheduled to be at the first day, one week, 2 weeks, one month, 3 months then every 3 months. During each visit; IOP was measured using Perkins applanation tonometry (Haag–Streit, Harlow, UK) Handheld Applanation Tonometer, HCD using Castroviejo caliper and CDR using direct or indirect ophthalmoscope, axial length and refraction were followed.

Success was calculated at 24 months postoperatively and defined as: *Complete success* when IOP >5mmHg and ≤16 mmHg without any further IOP-lowering medication with no progression of disc cup or corneal diameter at last follow up visit. *Qualified success* when IOP ≤16 mmHg but with the use of IOP lowering medications. Failed IOP control was defined as: IOP more than 16 mmHg despite the use of more than two IOP lowering medication, need for other glaucoma surgery to control IOP or hypotony: IOP ≤5mmHg persistent for more than two weeks (transient hypotony was not considered failure).

Logistic regression analysis was performed to detect correlations between the success rate (at 24 months postoperatively) and preoperative IOP, corneal diameter, axial length, age of onset of the disease, consanguinity, surgical technique and postoperative corneal and axial length growth.

Statistical Analysis

The collected data was analyzed using Statistical package for Social Science (IBM Corp. Released 2017. IBM SPSS Statistics for Windows, Version 25.0. Armonk, NY: IBM Corp.). Logistic regression analysis was used for the prediction of risk factors when the dependent variable is categorical.

RESULTS:

Data were collected from 149 eyes of 85 children presented with PCG of which 45 were males and 40 females. All cases had negative family history of PCG. Thirteen children (15.3%) showed positive consanguinity. Nineteen cases (22.4%) had unilateral PCG while 66 cases (77.6%) presented with bilateral PCG. Seventy-five eyes were right and the other 74 eyes were left. Severity was classified according to AlHazmi

score that used corneal diameter, clarity and preoperative IOP to classify cases into mild, moderate and severe. In this study, 4 eyes (2.68%) had mild PCG, 95 eyes (63.75%) had moderate PCG and 50 eyes (33.55%) had severe PCG. In the current study, single site trabeculotomy was performed in 57 eyes, non-augmented CTT in 51 eyes and double site metal probe trabeculotomy in 41 eyes.

There were no major complications in any case (as cyclodialysis cleft or choroidal detachment), transient hyphema was noticed in 83 cases and resolved completely before the first one-week follow up visit in all cases. Transient postoperative hypotony was noticed in 13 eyes (22.5%) of the single site trabeculotomy group, 43 eyes (84%) of the CTT group, and 6 eyes (14.6%) of the double site trabeculotomy group.

Success rate (qualified cases included) at the end of 24 months follow up was highest for double site trabeculotomy (96.7%) followed by single site trabeculotomy (95%) and lastly (76.4%) for combined non-augmented trabeculotomy and trabeculectomy. Eyes that had controlled IOP on antiglaucoma medications at 2 years follow up were 5% in single site trabeculotomy group, 6.7% in double site trabeculotomy group and 21.1% in CTT group. Eyes that required resurgery were 3.3% in double site trabeculotomy group, 5% in single site trabeculotomy group and 23.7% in CTT group.

There were no associations between surgical success and sex, laterality, consanguinity, preoperative corneal diameter, axial length and cup disc ratio. Age of onset less than (2.00 ± 1.954) months was statistically associated with failure. Preoperative IOP higher than (30.37 ± 5.614) mmHg was associated with failure. Complete success rate in mild cases was 100%, 86.76 in moderate eyes and 64.86% in severe cases, thus, severity had strong association with failure. ***(Table 1)***

Table 1 Logistic Regression analysis for prediction of failure and need of postoperative antiglaucoma medications: Preoperative factors

	Univariate				Multivariate			
	P	**OR**	**95% C.I.**		**P**	**OR**	**95% C.I.**	
Gender	0.344	1.594	0.607	4.190				
Side	1.000	1.000	0.392	2.551				
Bilaterality	1.000	1.000	.585	1.710				
Neonatal onset	<0.001*	2.858	1.615	5.059	<0.001*	3.729	1.939	7.174
Consanguinity	0.248	2.005	0.616	6.533				
Severe vs. (Mild+ Mod)	0.008*	3.731	1.412	9.861	0.033*	1.085	0.362	3.253
Time of surgery	0.001*	0.616	0.468	0.811	0.607	0.924	0.684	1.249
IOP preoperative	0.005*	1.158	1.046	1.282	0.503	1.036	0.933	1.151
CD preoperative	0.571	0.849	0.483	1.493				
AL preoperative	0.117	0.785	0.580	1.062				
Cup disc ratio preoperative	0.461	0.216	0.004	12.682				

Complete success was 100% in mild cases in the three interventions, while in moderate cases it was 86.67% in single site trabeculotomy group, 82.14% in CTT group and 95.45% in double metal group. In severe cases, success rate was 90% in single site trabeculotomy group, 47.83% in CTT group and 88.23% in double site trabeculotomy group. ***(Table 2) (figure 1)***

Table 2 Correlation between type of surgical intervention and prediction of failure and need for antiglaucoma medications:

	Univariate				Multivariate			
	P	**OR**	**95% C.I.**		**P**	**OR**	**95% C.I.**	
Traditional trabeculotomy	0.126	0.429	0.145	1.270				
Combined trabeculotomy and trabeculectomy	0.003*	4.521	1.683	12.145	0.012*	2.355	1.944	5.876
Double site metal trabeculotomy	0.109	0.345	0.094	1.266				

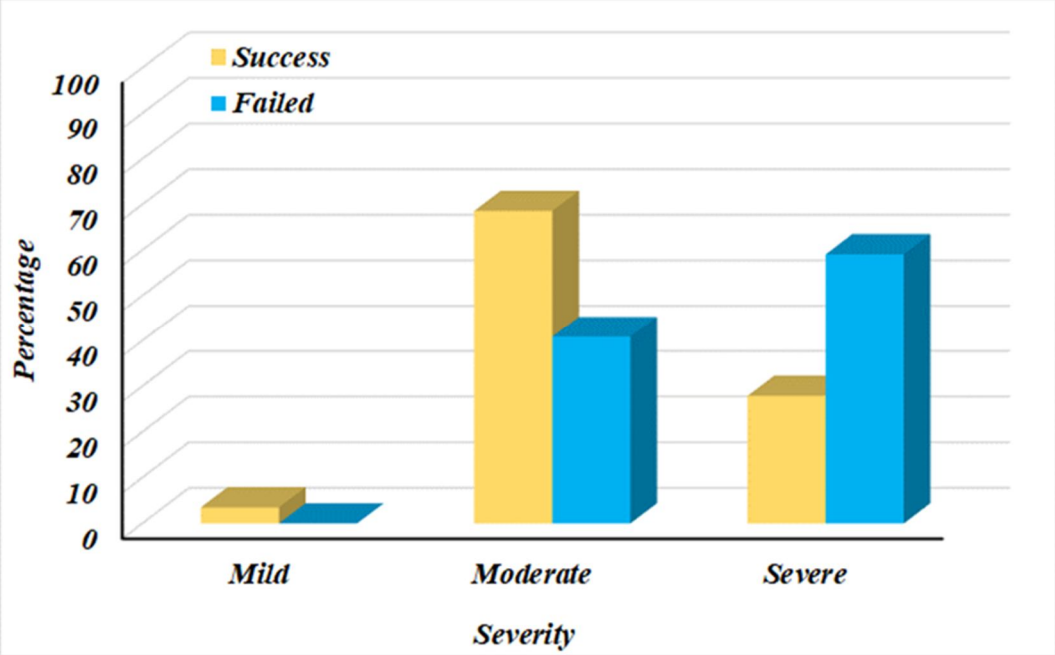

Figure 1 : Column chart for association between surgical outcome and severity of glaucoma

Postoperative hypotony was present in 68.2% of the failed eyes and only 34.9% of successful eyes, and was statistically associated with failure. *(Figure 2)* Accelerated corneal growth was associated with failure, difference in corneal diameter at the end of follow up from preoperative corneal diameter was (0.07 ± 0.02) mm in successful cases and (0.23 ± 0.10) in failed cases. Axial length growth in successful cases at the end of follow up was (0.12 ± 0.03) mm while in failed cases it was accelerated (0.84 ± 0.21) mm and this acceleration in both corneal diameter and axial growth was statistically associated with failure. Failed cases had more myopic refraction (-5.00 ± 0.77) at the end of follow up than successful cases (-3.58 ± 0.30) but it wasn't of statistical significance. ***(Table 3)***

Table 3 Correlation between postoperative factors and prediction of failure and need for antiglaucoma medications:

	Univariate				Multivariate			
	P	OR	95% C.I.		P	OR	95% C.I.	
Transient first weak hypotony	0.006*	2.203	1.261	3.849	0.035*	1.528	1.126	3.727
Change in CD after 2 years from preoperative values	0.006*	0.113	0.014	0.191	0.503	1.199	0.705	2.042
Change in AL after 2 years (mm) from preoperative values	0.002*	0.125	0.022	0.130	0.536	0.927	0.729	1.178

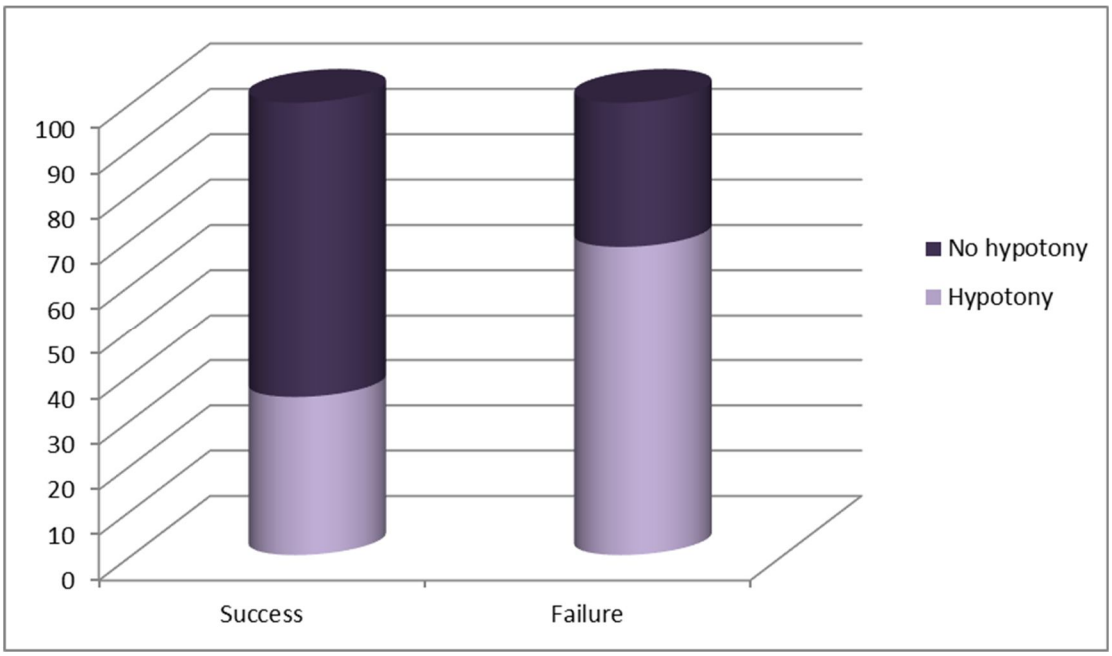

Figure 2: Association of hypotony in both successful and failed cases

DISCUSSION:

Primary congenital glaucoma still represents a challenge for ophthalmic surgeons. In a continuous search for higher success rates and better control, different modalities are being performed, enhanced and edited throughout the years. Many studies of trabeculotomy alone indicated success rate over 90% that is higher and more predictable than goniotomy[11].. Although debated, many studies from India, China and far east reported higher success rate of CTT than with trabeculotomy alone, and they chose it as a primary intervention because of higher severity of cases presented, though it is not until recently CTT was compared to trabeculotomy alone in many studies[12-13].

We studied factors that may affect the prognosis and success rate of the cases. Factors that were statistically significant when correlated with failure were early onset of glaucoma, preoperative higher IOP, severity of glaucoma, early postoperative hypotony and accelerated enlargement of corneal diameter and axial length with follow up.

Younger age of presentation as in neonatal onset cases offers an added challenge in managing the disease possibly due

to smaller eyes, more aggressive disease at presentation and excessive healing capability. Higher preoperative IOP may indicate a more extensive angle pathology and subsequently higher risk for failure. Severe cases have higher preoperative IOP and corneal edema that can also be correlated to more extent of abnormal angle.

Transient postoperative hypotony can be attributed to the continued effect of preoperative antiglaucoma medications (aqueous suppressants), reduced appetite for feeding few days after general anesthesia and thus reduced fluid intake or increased filtration in cases with trabeculectomy. In all cases, hypotony resolved spontaneously without intervention before the second follow up visit. Postoperative soft tension can lead to exaggerated healing process by creating a medium of more intense inflammatory mediators that can lead to accelerated healing of the bleb in CTT cases[14]. Healing usually occurs in the second and third weeks postoperative[15] and presents with elevated IOP. Another explanation for bleb failure is that altered aqueous dynamics and low scleral rigidity can lead to obstruction of the trabeculectomy site by the pathologically elongated ciliary processes in PCG eyes and its more anterior location, thus, obstructing aqueous outflow with subsequent flat bleb and failure[16-18].

Failure of trabeculotomy also can be correlated with postoperative hypotony and to liability of aqueous to escape through trabeculectomy site that poses less resistance to aqueous outflow. This possibly reduces the space between the cut edges of the trabeculotomy cleft, thus increasing the possibility of PAS formation, membrane growth or reattachment of the cleft edges. This assumption is encouraged by the results of other studies that compared use of viscoelastic at the end of trabeculotomy procedure to form the anterior chamber and deepen the angle, to cases where no viscoelastic was used. The results of these studies indicated better success with viscoelastic use (cohesive healon)[19-21] possibly due to barrier effect and separation of cut edges.

Factors that didn't affect the success rate were preoperative corneal diameter, preoperative axial length, preoperative use of antiglaucoma medications, association with systemic diseases, preoperative cup disc ratio, laterality and consanguinity. Extent of angle surgery didn't statistically affect the outcome though double metal trabeculotomy had highest success rate among studied groups. Mean myopic refraction was higher for failed cases but it was not statistically significant. Aktas et al[7] studied prognostic factors for success and reported that a preoperative corneal diameter more than 12.25mm, age at presentation of less than 4 months, higher baseline IOP than 24 mm Hg, bilateral involvement, and failure to perform circumferential trabeculotomy increases the risk of surgical failure of trabeculotomy in patients with primary congenital glaucoma. Unlike our findings, corneal diameter, laterality and the extent of angle surgery didn't statistically affect the outcome. Malek et al.[22] reported that onset before 3 months of age and preoperative corneal edema to be poor prognostic factors. Khairy et al.[23] reported that preoperative IOP>30mmHg was a poor prognostic factor. Helmy[5] reported that the success rate was significantly related to preoperative IOP, corneal diameter, axial length, consanguinity, and age of onset. Al-Hazmi et al[10] correlated severity with success and reported success rates for goniotomy, trabeculotomy and CTT augmented with MMC. Mild PCG showed high success rates of 81–100% in the three techniques. Moderate glaucoma had a 13%, 40%, and 80% success rate respectively for goniotomy, trabeculotomy, and CTT with mitomycin C. Severe PCG showed success rate of 10% and 70% for trabeculotomy and combined surgery respectively. Thus, they recommended primary augmented CTT with MMC for moderate and severe cases. That is opposite to our findings that actually severe cases had statistically significant higher failure rates but single site and double site trabeculotomy had highest success rates in severe cases 90% and 88.23% respectively, while non-augmented combined trabeculotomy and trabeculectomy had complete success rate of only 47.83%.

Khafagy et al[24] correlated consanguinity, young age of onset and higher preoperative IOP with less survival after initial procedure. This is relevant to our findings as regard high preoperative IOP and young age at presentation, and in that they

didn't find a correlation between failure and the preoperative axial length and corneal diameter.

Conclusion:

This study showed that some factors can be correlated with failure in PCG as early onset of glaucoma, high preoperative IOP, severity of the disease, early postoperative hypotony and accelerated corneal and axial enlargement. Unlike many other studies, preoperative corneal diameter itself was not correlated with outcome, but when combined with corneal clarity and IOP as a severity score it affects the outcome. Angle surgery had higher success than combined trabeculotomy trabeculectomy, and larger extent of angle incision (double site versus single site trabeculotomy) didn't show a statistically significant difference.

Abbreviations:

PCG: primary congenital glaucoma

IOP: intraocular pressure

CCT: central corneal thickness

AL: axial length

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Conflict of interest

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