

Original article

Combined trabeculotomy-trabeculectomy with antimetabolite and releasable suture: outcome with primary congenital glaucoma in a north Indian population

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Abstract

Objective: To determine the surgical outcomes of combined trabeculotomy-trabeculectomy with mitomycin-C and releasable suture in children with primary congenital glaucoma (PCG) in a North Indian population. **Design:** Retrospective, interventional, consecutive, non-comparative case series. **Materials and methods:** The medical records of 137 eyes of 77 patients who underwent combined trabeculotomy-trabeculectomy with 0.2 mg/ml mitomycin C (MMC) either bilaterally (49 patients) or unilaterally (28 patients) between January 2004 and March 2012 were reviewed retrospectively. The main outcome measures were postoperative intraocular pressures, corneal clarity and diameter, duration of follow-up, success rate and complications. **Results:** The mean preoperative intraocular pressure reduced from 34 ± 7 mm Hg (range 15- 54 mm Hg) to 17 ± 7 mm Hg (range 5 - 32 mm Hg) with a mean reduction of 44 % ($P < 0.001$). The mean follow-up period was 24.4 ± 10.3 months (range 6 – 48 months). Complete success defined as intraocular pressure < 21 mm Hg without any medication and clinically stable glaucoma at last follow-up was achieved in 113 eyes (83 %) while a 'qualified success' of intraocular pressure < 21 mm Hg with one medication was achieved in ten eyes (7 %). The Kaplan-Meier survival analysis revealed success rates (at 'n' months) of 90 % (6), 85 % (12), 82 % (24), 80 % (36) and 77 % (48). There were no significant intraoperative or postoperative complications. **Conclusion:** Primary combined trabeculotomy-trabeculectomy with mitomycin-C and releasable suture offers a viable surgical option in Northern Indian infants with primary congenital glaucoma. The use of 0.2 mg/ml mitomycin C for 2 minutes improves the overall success while the releasable suture decreases the risk of postoperative complications especially associated with the use of antimetabolites.

Keywords: Congenital Glaucoma, Trabeculotomy, Trabeculectomy, Mitomycin-C, Releasable Suture

Introduction

Appropriate and timely diagnosis and meticulous treatment of primary congenital glaucoma can alter the course of this disease and give hope for normal visual development (Mendicino ME et al, 2000; Papadopoulos M et al, 2007).

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Surgery is the accepted treatment method, with medical therapy playing only an adjunctive role before surgery (Barkan O, 1953). With the introduction of microsurgical techniques, prognosis of pediatric glaucoma has improved considerably. There are various surgical options described for developmental glaucoma and the success rate depends on various factors like the age of presentation and severity of glaucoma.

Goniotomy was considered to be the classic operation for developmental glaucoma. However, the trend seems to be changing and there are increasing advocates for primary trabeculotomy. (McPherson SD et al, 1980; Luntz MH, 1974 and Quigley HA, 1982). The reason for this change in trend is that approximately 50 % of the patients with developmental glaucoma present with variably opaque media and are therefore unsuitable for goniotomy. Large numbers of Indian children (> 80 %) present with a severe cloudy cornea and goniotomy is technically impossible.

Recent reports in the literature have found combined trabeculotomy-trabeculectomy (CTT) to yield superior results in comparison with conventional procedures (Elder MJ, 1994). Infants and children have vigorous healing responses including fibrosis (Wong TT et al, 2005). Due to the exuberant fibrotic response to surgery in children, several authors have investigated the use of antifibrotic agents and have reported a higher success rate (Mullaney PB et al, 1999; Al-Hazmi et al, 2005 and Low S et al, 2008). The use of mitomycin-C (MMC) with filtration surgery results in better control of IOP, but is associated with increased complications (Sidoti PA et al, 2000; Mandal AK et al, 1997, 2003). The use of mitomycin-C in concentration of 0.2 mg/ml in trabeculectomy in patients with PCG has been reported to have an equal success rate but a less complication rate than with 0.4 mg/mL MMC (Agarwal HC et al, 1997).

Releasable suture techniques allow tight closure of the wound intraoperatively and decrease the risk of early postoperative hypotony (Wanner JB & Katz LJ, 2004; Low S et al, 2008). Low S et al reported favorable results with releasable sutures in refractory congenital glaucoma. However, there are no reports describing their use in the initial surgery for PCG.

The advantages of trabeculotomy coupled with encouraging reports of primary trabeculectomy in developmental glaucoma prompted us to combine trabeculectomy with trabeculotomy as the initial surgery in our patient population. Considering the relatively-advanced nature of the disease in our series, we used 0.2 mg/ml Mitomycin-C (MMC) for two minutes in all cases as most of our patients presented with substantially enlarged and edematous corneas and IOP of > 33 mm Hg. With the idea of removing the releasable suture if indicated during examination under anaesthesia scheduled 2 - 3 weeks postoperatively, we applied releasable sutures if required intraoperatively.

Materials and methods

A retrospective file review of all cases of PCG who underwent primary CTT with MMC at a tertiary care eye hospital between January 2004 and March 2012 was performed. The Institutional Review Board approved this study. All surgeries were performed by a single surgeon (SD), after obtaining informed consent from the parents of all patients.

The medical records of 137 eyes of 77 patients who underwent combined CTT with MMC either bilaterally in a single session or unilaterally were reviewed retrospectively. Diagnosis of PCG was always established by examination under anaesthesia.

PCG was diagnosed and taken up for surgery on the basis of symptoms like epiphora, blepharospasm or photophobia coupled with signs of enlarged or hazy cornea with or



without raised intraocular pressure (IOP). So, children with intraocular pressure less than 18 mm Hg under treatment with anti-glaucoma medication with the presence of increased corneal diameter with or without hazy cornea or Haab's striae were also considered for surgery. The IOP was measured using the applanation method (Perkins tonometer by Clement Clarke International, Harlow, UK). The horizontal corneal diameter (white to white) was measured using calipers. Assessment of the anterior segment, refraction, gonioscopy and funduscopy was carried out when the corneal clarity was enough to allow it. The anterior segment was assessed under high magnification using a handheld slit-lamp (Zeiss HSO 10 Hand slit lamp) to rule out associated corneal and iris changes. Obvious cases of iridocorneal dysgenesis were excluded from the analysis. Also, the child was thoroughly examined to rule out the possibly associated systemic conditions such as neurofibromatosis, Sturge weber syndrome, Mucopolysacchroidosis.

Preoperatively, visual acuity could not be checked in most of the children because of photophobia and in those of less than 3 months old. Postoperative visual acuity was checked where possible in young children using fixation methods or Cardiff cards and with Snellen's chart in older children. Refraction was checked under cycloplegia.

Patients with a short follow-up (FUP) of < 6 months, history of previous surgical procedure for glaucoma or with associated ocular or systemic anomaly were excluded from the study. Also, patients in whom the Schlemm's canal could not be identified during surgery were excluded from analysis. In these eyes, only trabeculectomy with MMC was performed. The medical records of the patients were reviewed to obtain demographic data, age at presentation, age at which surgery was performed, preoperative visual acuity (if possible), postoperative visual acuity at the last

visit, horizontal corneal diameter (mm), corneal clarity at presentation, corneal clarity at the last FUP, preoperative IOP (mm Hg), IOP at the last FUP (mm Hg), preoperative optic disc vertical cup/disc ratio (VC/D), postoperative VC/D at the last FUP, preoperative medications used, postoperative medications used, refractive errors, and duration of follow-up. The details of the initial surgery including complications and re-surgeries performed were also noted.

The clinical outcome measures included postoperative IOP, stability of corneal diameter, corneal clarity, duration of follow-up, surgical success, and complications.

A single surgeon (SD) performed all the surgeries. Simultaneous bilateral surgery was performed in bilateral advanced cases. Under general anaesthesia and aseptic techniques, a corneal stay suture was placed using 8-0 vicryl. A fornix-based conjunctival flap was raised and haemostasis was achieved with wet field cautery. A half thickness rectangular sclera flap of 4×4 mm was then dissected up to the clear cornea. Three sponges soaked in 0.2 mg/ml MMC were applied in a diffuse area subconjunctivally and subsclerally for two minutes and the area was then washed thoroughly with saline solution (Figure 1). A paracentesis was created into the anterior chamber with a 30 Ga needle and Healon^R was injected to maintain the anterior chamber depth during surgery.

A radial incision was carried out across the scleral spur or the junction between the white and bluish transitional zone of the sclera (this marks the external site of the Schlemm's canal), until the canal was entered, evidenced by a gush of aqueous humour and/or blood. Trabeculotomy ab externo was then performed using the internal arm of Harm's trabeculotome probes, first to the left then to the right, to complete about 100 – 120 degrees of the circumference (Figure 2). Trabeculectomy was

then performed by removing the block anterior to the scleral spur. A peripheral iridectomy was performed and the scleral flap was sutured using 10-0 nylon sutures using two permanent and one or two releasable sutures as required after titration. The paracentesis was hydrated and, if required, Healon^R was again injected to form the anterior chamber.

A water-tight closure of the conjunctiva was performed by suturing it to the limbus with 8-0 vicryl sutures (Figure 2). One drop each of antibiotic-corticosteroid preparation and atropine was instilled into the conjunctival sac, and a patch and shield were applied on the eye. Postoperatively, all patients received intensive steroids, antibiotic and cycloplegic drops daily. The antibiotic preparation was stopped at two weeks postoperatively, and the steroid preparation was instilled every two hours initially and then tapered gradually over six weeks. Topical cycloplegics (atropine) was given two times a day and continued for three weeks postoperatively.

Postoperative follow-up was scheduled on day one, one week, one month, three months, six months and 12 months and thereafter every six months. Patients were called for evaluation earlier or more frequently whenever required. At each postoperative visit, the following parameters were noted: visual acuity, corneal clarity, corneal diameter and IOP (using Perkins tonometer or SL-mounted applanation tonometer). The optic nerve assessment by ophthalmoscopy and cycloplegic refraction was carried out periodically and especially at EUA. Release of releasable suture was carried out within one month in the postoperative period at EUA in most of the patients. Indications of suture release were an IOP greater than 18 mm Hg under anesthesia or a flat nonfunctioning bleb. Other ocular problems, reoperations and use of anti-glaucoma medications after surgery were also assessed.

The criteria for surgical success and failure were defined before the data analysis.

- a. Complete success was defined as achieving a final IOP of less than 21 mm Hg without anti-glaucoma medication, resolution of corneal oedema, no further increase in corneal diameter and with no documented progression of optic disc cupping.
- b. Qualified success was defined as achieving the same IOP criteria with a single anti-glaucoma medication.
- c. Failure was defined as IOP > 21 mm Hg with more than one medication, requirement of re-surgery, or the development of complications.

Statistical analysis

Statistical analysis was done using the statistical package for social studies (SPSS 17) software (Chicago, USA). Paired t-test was used to determine statistical significant changes in the various parameters preoperatively and postoperatively. Two-sided P value of less than 0.05 was considered as statistically significant. The cumulative success probability was determined using the Kaplan-Meier survival analysis.

Results

A total of 137 eyes of 77 patients were enrolled in the study. The patient characteristics are given in Table 1. All the patients were of Indian origin. The ratio of males to females was 1.75 : 1. The mean follow-up period was of 24.4 ± 10.3 months (range 06 – 48 months). The mean age of presentation was three years with a range of three days to 13 years. Fifty-five (71 %) patients presented after six months of age (Figure 3).

The mean preoperative IOP was $34 \text{ mm Hg} \pm 7 \text{ mm Hg}$ (Range = 15 - 54 mm Hg). Some of the patients had normal IOP levels before surgery, however, they were operated on because they were taking anti-glaucoma medications and the

diagnosis of glaucoma was confirmed based on the presence of other specific signs and symptoms as mentioned earlier. Postoperatively, the mean IOP was 17 ± 7 mm Hg (range 5-32 mm Hg). The percentage reduction in the IOP was 44 %. The postoperative reduction in the IOP was both clinically and statistically significant ($P < 0.0001$).

Out of 137 eyes, 28 (20 %) had a clear cornea or Haab's striae at presentation, and corneal edema with or without corneal scarring was present in 109 eyes (80 %), (Figure 4). Postoperatively, the cornea had cleared in 79 eyes (57 %) while central corneal scarring was present in 58 eyes (42 %). The mean \pm SD horizontal corneal diameter at presentation was 13 ± 1 mm (Range 10 - 15mm). There was no significant reduction in the corneal diameter postoperatively.

Preoperatively, the visual acuity could not be assessed in most of the patients either due to presentation in the preverbal age group or due to corneal edema and scarring at presentation. Hence, only fixation responses rather than Snellen's visual acuity could be determined in the majority of cases. Postoperative best-corrected visual acuity (BCVA) was possible in only 45 eyes (33 %). Twelve eyes (27 %) had a BCVA of 20/60 or better, followed by 10 eyes (22 %) with visual acuity ranging between 20/60 - 20/200. Nine eyes (20 %) had visual acuity in the range of 20/200 - 20/400, eight eyes (18 %) had visual acuity of counting finger \leq three meters and six eyes (13 %) could only perceive light.

Retinoscopy was done in 67 eyes. Myopia with or without astigmatism was seen in 51 eyes (76 %). Hyperopia with or without astigmatism was seen in 16 eyes (24 %).

No sight-threatening intraoperative or postoperative complication was noted in any case. Intra-operative complications were seen in five (4 %) eyes, which included premature entry into the anterior chamber in two (1.5 %)

eyes, vitreous prolapse in one eye and prolapse of ciliary processes in two (1.5 %) eyes. These eyes were not included in the statistical analysis. Postoperative complications were seen in nine eyes (7 %), which included transient shallowing of anterior chamber in six eyes (4 %). These formed spontaneously without intervention. Of the remaining three eyes, two eyes required anterior chamber reformation with Healon^R within one week after surgery, while in one eye, a flat anterior chamber with hyphema required AC washout with bleb re-exploration and chamber reformation. No eyes developed cystic avascular blebs or had any bleb-related infections or endophthalmitis.

Complete success as defined in the present study was achieved in 113 eyes (82 %). Qualified success was achieved in ten eyes (7 %). The analysis revealed a success rate of 90 %, 85 %, 82 %, 80 % and 77 % at 06, 12, 24, 36 and 48 months respectively (Figure 5). Fourteen eyes (10 %) failed, where an IOP of less than 21 mm Hg was not achieved after surgery. Out of these 14 eyes, in eight eyes, postoperative IOP of 21 mmHg could not be achieved with one drug treatment. In two eyes, repeat trabeculectomy was done while two eyes required tube shunt surgery. In the other two eyes, trans-scleral photoablation was done in order to control the IOP.



Figure 1: Showing application of MMC in diffuse area (subconjunctival and subsclear)

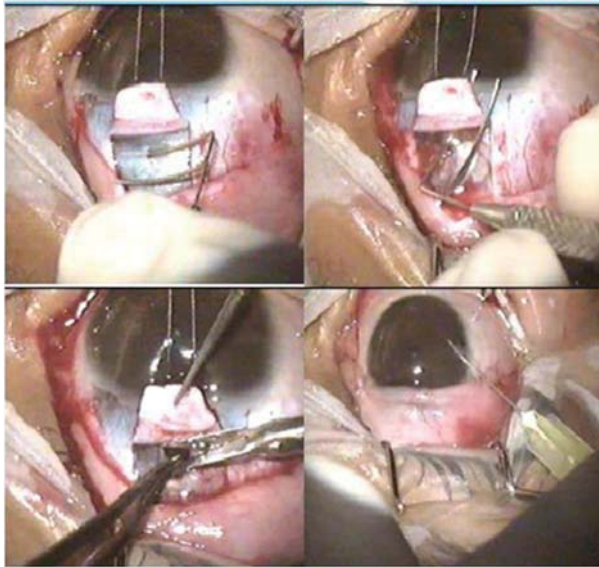


Figure 2: Intraoperative photographs
 a. Internal arm of trabeculotome in Schlemm's canal to the left of radial incision.
 b. Probe rotated in anterior chamber from right side of radial incision
 c. Sclerostomy and peripheral iridectomy
 d. Water tight closure of conjunctiva

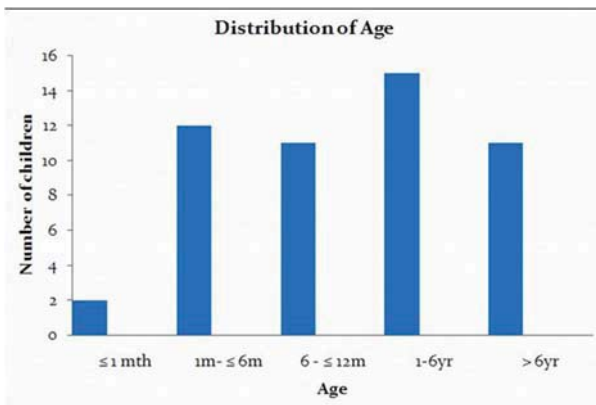


Figure 3: Showing age wise distribution



Figure 4
 a. Preoperative photograph of infant with edematous and enlarged cornea
 b. Postoperative photograph showing clearance of cornea

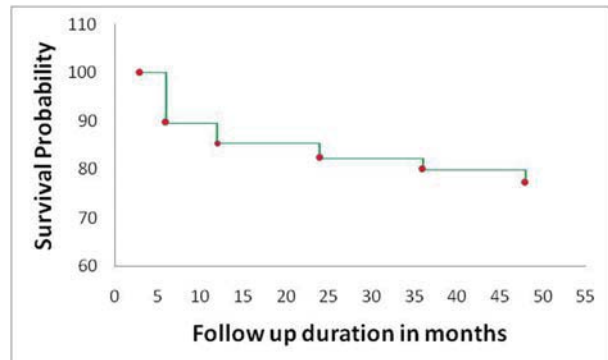


Figure 5: Kaplan Meier Survival Analysis Curve

Table 1: Patient demographics of 77 patients (137 eyes) with primary congenital glaucoma

Gender	Male	Female
	49 (63.64%)	28 (36.37%)
Affliction	Unilateral	Bilateral
	19 (24.47%)	58 (75.33%)
Horizontal Corneal Diameter at first Presentation	Mean±SD	Range
	12.95±0.9	10-15
Corneal Clarity at Presentation	Clear	Edema/Scar
	28 (20.43%)	109 (79.56%)
Corneal Clarity at last Presentation	Clear	Edema/Scar
	79 (57.6%)	58 (42.4%)
IOP	Preoperative	Postoperative
	34.3±7.3	17.4±7.1

Discussion

Conventionally, goniotomy and trabeculectomy have been regarded as procedures of choice for PCG (Papadopoulos M & Khaw PT, 2007). Our study showed that CTT achieved good success in patients with PCG in the intermediate term with an overall surgical success rate of 90 %. In absence of significant complications, complete success was achieved in 113 eyes (83 %) while a 'qualified success' was achieved in ten eyes (7 %). The Kaplan-Meier survival analysis revealed success rates (at 'n' months) of 90 % (6), 85 % (12), 82 % (24), 80 % (36) and 77 % (48). This corroborates findings from other studies in Southern India and The Middle East, where this procedure is commonly used, with reported surgical success rates ranging between 75 % and 94 % (Mandal



AK 2004,1998,2002,2003; Al-Hazmi A et al, 2005).

CTT was first reported by Maul et al (1980) in cases of severe bilateral primary congenital glaucoma that had not been controlled with initial goniotomy. The results of this procedure have been mostly reported in Middle Eastern and Indian populations, where it was used preferentially because it was felt that congenital glaucoma did not respond as well to angle surgery as previously described in western populations (Elder MJ, 1994; Mandal AK, 1998; Al-Hazmi A, 2005). The authors hypothesized that the poor results compared with those from the western literature were because these patients had a more severe degree of disease due to a higher rate of consanguinity and poor prognostic indicators such as corneal opacity, larger corneal diameters, onset since birth, later presentation and higher intraocular pressures.

Mandal et al (1998) advocated CTT as the surgical procedure of primary choice in the Indian population, as they found primary trabeculotomy in congenital glaucoma to have extremely poor results. They documented success rates of 81 to 94.4 % with this procedure. The results are similar to that reported by Elder et al (1994). They attributed this to the fact that the combined procedure provided two major outflow pathways: a direct continuity between the anterior chamber and the Schlemm's canal by trabeculotomy while trabeculectomy helps aqueous humor bypass the Schlemm's canal to be drained out of the anterior chamber. Thus, the authors felt that there was a two-fold greater probability of control of the IOP. Also in view of the advanced disease at presentation, the risk of failure of an individual procedure performed singly was minimized. A practical advantage was that in even those cases where the Schlemm's canal could not be identified, something that has been reported in up to 11 –15 % of trabeculotomies,

the procedure would not result in failure, since the trabeculectomy pathway could still function (Quigley HA, 1982; Elder MJ, 1994). Also, trabeculectomy is the standard surgical method of treatment for adults with glaucoma and most ophthalmologists are conversant with the surgical technique, which allows greater surgical flexibility in advanced Buphthalmos for conversion to trabeculectomy in difficult cases where identification of Schlemm's canal is not possible (Elder MJ, 1994; Mandal AK, 1998).

In our study, all the cases underwent CTT and the results obtained are comparable to those reported by Mandal (1998) and Elder (1994). In this series, 123 eyes (90 %) achieved overall success with 44 % reduction of the IOP ($p < 0.001$). The 14 eyes that showed surgical failure had advanced glaucoma with substantially enlarged and edematous corneas and an IOP of more than 37 mm Hg. In four of these eyes, the age at presentation was less than three months. The literature suggests that the surgical prognosis is poor in patients who are born with glaucoma (Quigley HA, 1982; Anderson DR, 1983; Hoskins et al, 1984). Several studies have shown that large corneal diameters > 14 mm, a high IOP and a young age at the time of surgery are independent risk factors for surgical failure. Al-Hazmi et al conducted a retrospective analysis on 532 pediatric glaucoma patients below the age of one year (820 eyes) to evaluate the outcome of the three surgical procedures in congenital glaucoma and their correlation with severity of disease (Al-Hazmi A et al, 2005). The eyes were grouped into mild (249), moderate (342), and severe (229) PCG, based on intraocular pressure, corneal diameter and clarity. All three surgical procedures resulted in high success rates of 81 –100 % for the mild form of PCG. Eyes classified with moderate glaucoma had a 13 %, 40 %, and 80 % success rate respectively for goniotomy, trabeculotomy, and CTT with

mitomycin C. The success rate for severe PCG was 10 % and 70 % for trabeculotomy and combined surgery respectively. Goniotomy was never done for eyes with this condition.

In our series, re surgery was advised for six eyes either in the form of repeat trabeculectomy, trans-scleral photocoagulation or tube shunts depending on clinical judgment and the status of other eye. The remaining eight eyes could be managed with two medications. Corneal edema cleared in 58 % of eyes. The reason for the comparatively less percentage of clear corneas could be because of the fact that many children had extensive edema and scarring at presentation.

Studies quote poor results of trabeculectomy in children because of the aggressive wound-healing response, presence of a thick Tenon's capsule and low scleral rigidity with a low success rate of 58 -59 % at two years (ShuklaGL & Parrish RK, 1987; Beck AD et al, 1998; Dietlein TS et al, 1999; Sidoti PA et al, 2000; Abraham LM et al, 2006). Several studies have shown that there are mild to serious ocular complications associated with adjunctive anti-fibrotic drug use, even though MMC use on average improves the trabeculectomy outcome (Ticho U & Ophir A, 1993; Greenfield DS et al 1998).

Besides the use of antimetabolites, other modifications that have been suggested to improve the outcome of this surgery in pediatric patients have been the use of a fornix-based flap because of lower rates of bleb-related infections, use of releasable sutures, and use of Healon GV to prevent early postoperative hypotony and shallow anterior chamber (Wells AP et al 2003; Low S et al, 2008). In the series by Low S et al, MMC and releasable sutures were used, but 89 percent cases were of refractive congenital glaucoma. We also applied releasable sutures along with the use of MMC in all our patients and, if required,

Healon^R was left in the anterior chamber at the end of the procedure. Our technique of the fornix-based conjunctival flap dissection and the broader application of antimetabolite achieved diffuse filtering blebs, with no thin avascular cystic blebs, bleb-related infections, or endophthalmitis.

In the study by Mandal et al (1998), myopia was the most common refractive error in 53.8 %, while hyperopia was found in approximately one quarter (25.6 %) of the eyes. In this study, refractive error assessment was done in 48 eyes. The results were in concordance with the above study, with myopia with or without astigmatism seen in 51 eyes (76 %) and hyperopia with or without astigmatism seen in 16 eyes (24 %).

Our post-operative complication rates were low (7 %) with none of the patients having sight-threatening complications. Mandal and colleagues have reported only minor postoperative complications in their previous studies. They did not use antimetabolite for the primary surgery. Al-Hazmi et al (2005) have reported more complications including exudative retinal detachment probably because of use of MMC. We attribute our low complication rate directly to the meticulous procedure with the use of releasable sutures and of Healon^R and the watertight closure of wound along with the use of antimetabolites.

The limitations of the present series were its non-randomized, retrospective design and the limited documentation of optic disc assessment, refraction results, and visual acuity findings. However, this study provides experiences of CTT procedure for primary congenital glaucoma in a North Indian pediatric population with the use of MMC and releasable suture. We feel that the use of MMC improves the success rate while the routine use of releasable suture with tight closure of wound minimizes the complication rate in congenital glaucoma surgery.



Conclusion

Primary CTT with MMC and releasable suture offers a viable surgical option in patients with primary congenital glaucoma. The use of MMC improves the overall success rate while the releasable sutures decrease the risk of postoperative complications especially associated with the use of antimetabolite. However, all the patients should be monitored for a long-term period for IOP control and bleb-related complications. Optical correction of the refractive error and aggressive amblyopia therapy is recommended at early ages.

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