**Tube Shunts in Advanced Angle Closure Glaucoma: A Pilot Study**

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**Abstract**

**Purpose:** To evaluate efficacy and safety of tube shunts in advanced angle closure glaucoma Vs. Standard Trabeculectomy.

**Method:** Fifteen cases of end stage angle closure glaucoma with visual acuity ranging from hand movements only to perception of light were implanted with pediatric model Ahmed glaucoma valve (AGV). The efficacy and complications (if any) of the implant group were evaluated in comparison to a control group of fifteen patients of similar profile with angle closure glaucoma subjected to trabeculectomy with releasable sutures. Both group cases were followed up over a 12 month period.

**Results:** Tube shunts were as effective as trabeculectomy in the early postoperative period of 4 months with increased complications like corneal edema and mild hyphema. Over a 1 year follow up tube related complications like tube erosion and retraction were noted with reduced efficacy of the shunt versus trabeculectomy at complete success of 66% and 80% respectively. The tube shunt surgery was performed with three modifications from conventional method due to the angle closure element.

**Conclusions:** Tube implants should not be attempted as primary surgical means in chronic angle closure glaucoma without considering certain surgical modifications and precautions. Standard Trabeculectomy remains gold standard primary procedure in this subtype of glaucoma.

**Keywords:** Ahmed glaucoma valve, pediatric sized implant, end stage chronic angle closure glaucoma, surgical modifications, trabeculectomy

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**Introduction**

Trabeculectomy is the standard surgical procedure for managing uncontrolled glaucoma patients but has not stood the test of time as a fool proof procedure. The associated complications such as shallow chamber, bleb leaks, bleb infections, and bleb dysesthesia have led to increase in use of tube shunts or glaucoma drainage devices as an alternative to trabeculectomy. Glaucoma drainage devices (GDD) have been conventionally used as secondary procedures in cases with prior failed glaucoma filtration surgeries. In refractory glaucomas like neovascular or post uveitic glaucoma, where the chances of failure of trabeculectomy are high, these devices have been implanted as a primary procedure. Recent studies have demonstrated comparable success of tube shunts versus trabeculectomy and laid the path for expanding indications of tubes. The Tube Vs Trabeculectomy (TVT) study\(^1\,\,^2\) was one such study which showed a comparable intraocular pressure reduction of 49.5% in Trabeculectomy and MMC group and 49.9% decrease in IOP in tube group at both 1 year and 3 year follow up. Conventionally tubes have been implanted in cases with open angle glaucoma or in cases with roomy chambers where the natural lens has been replaced with an IOL. In conditions with shallow anterior chamber configuration, like various subtypes of angle closure glaucoma, tube placement is perceived to be difficult. In an Asian country like India, with a large proportion of glaucoma population being constituted by angle closure glaucoma (ACG) cases with comparatively shallow anterior chamber depth tube placement in anterior chamber is difficult and increases risk of tube corneal touch postoperatively. The smaller ocular dimensions of angle closure eyes presumably can lead to increased risk of plate exposure and implant extrusion.

There is paucity of data to evaluate the role of GDDs in angle closure glaucoma in literature. Therefore, this pilot study was undertaken to evaluate efficacy and safety of Ahmed glaucoma valves in comparison to conventional trabeculectomy in patients of end stage angle closure glaucoma, a common subtype of recalcitrant glaucoma in south east Asia.

**Material and Methods**

Thirty eyes of thirty patients with end stage angle closure glaucoma, uncontrolled intraocular pressure and vision of either perception of light, and/or inaccurate projection of rays were scheduled for tube implant or trabeculectomy surgery. The inclusion criteria followed were cases with high IOP >25 mm Hg, uncontrolled on at least two anti-glaucoma drugs. All cases had documented synechial angle closure of >180 degrees, despite patent peripheral iridotomies. For ethical reasons, only patients with poor preoperative vision were included in AGV group (study group). In addition, only patients with visual acuity of > 6/60 (Log Mar 1.0) in the fellow eye were included in the study. Cases with severe dry eyes (Schirmer < 3 mm), corneal edema and/or central AC depth of less than 1.8 mm were excluded. The study was conducted after obtaining ethical approval as per Helsinki guidelines. Informed consent was taken from all patients. In the study group (tube group) 15 eyes were included in whom AGV pediatric model FP8 was used. This
modification was done as prior experience in using adult model FP7 resulted in difficulties during insertion of plate in the shallow fornices of these patients and led to subsequent tube migration. The surface area of FP 8 model being 96 mm$^2$ compared to much larger area of 184 mm$^2$ in FP 7 lend itself more suitable to placement in these shallow fornices eyes. In the control group (15 eyes) trabeculectomy with MMC with two releasable sutures was performed. Preoperative recording of visual acuity, intraocular pressure, corneal thickness (ultrasonic pachymetry), specular microscopy for corneal endothelial cell count, biometric parameters of anterior chamber depth and axial length was done, in addition to the routine ophthalmic and systemic examination.

Postoperative parameters evaluated were slit lamp biomicroscopy for anterior chamber reaction, tube status, bleb morphology, corneal thickness and endothelial cell count, ultrasonic biomicroscopy (UBM) to evaluate the bleb and peripheral anterior chamber morphology. Bleb morphology was scored objectively using Migdal and Hitchings classification. Complete surgical success was defined as attaining IOP less than 18 mmHg without medication.

**Surgical Technique**

The specifications of the technique of AGV implantation included 3 mm fornix based conjunctival flap with 5-6 mm relaxing incisions, made at the two ends of the limbal peritomy. A rectangular 5 x 5 mm partial thickness scleral flap was hinged at the limbus, in the supero-temporal quadrant. By blunt dissection of tenon’s capsule and episcleral tissue, space was created in the superior temporal quadrant between superior and lateral rectus. The valve was primed with sterile solution and the valve body was inserted between the rectus muscles and sutured to the sclera, with 8-0 silk/monofilament nylon sutures, placed through the eyelets in the body of the AGV. The leading edge of the device was placed at or beyond 8 mm from the limbus. The drainage tube was trimmed to permit 2-3 mm insertion of tube in to the anterior chamber for the initial 4 cases. The tube bevel was cut to face the corneal endothelium and tube was inserted beneath the scleral flap. After a slow paracentesis, the anterior chamber was partly filled with 2% methyl cellulose. The anterior chamber was then entered at the limbus under the flap, with a 23 gauge needle parallel to iris plane. Tube was then inserted through the entry track of the needle with a specialized Ahmed forceps designed for the same. The direction of tube was parallel to iris and away from corneal endothelium. It was anchored to the scleral bed with 2 or 3, 10-0 monofilament nylon sutures. Except for initial two cases a surgical peripheral iridectomy was performed adjacent to the tube to prevent iris bunching as shown in Figure 1.

The iridectomy was performed through a clear corneal incision adjacent and anterior to the 23 gauge needle entry site. The exposed drainage tube was covered with the superficial scleral flap which was sutured with two to three, loose 10-0 nylon sutures. The relaxing incisions of the conjunctival flap were sutured with 8-0 monofilament nylon. Anterior chamber was formed with sterile Ringer lactate solution, at end of procedure through the paracentesis site.

The ideal length of tube with adjacent peripheral iridectomy (PI) was left at 1.5 mm as shown in Figure 2. Post-operative medications included topical steroid antibiotic combination and cycloplegics for 6 to 8 weeks. Systemic Acetazolamide was prescribed for the first 2-3 days if required. Trabeculectomy with MMC was performed using fornix based flap, subconjunctival application of 0.02% MMC for 2 minutes and application of two releasable sutures using Wilson’s technique. Releasable sutures in trabeculectomy group were released between day 7 to day 14 when IOP of >14-16 mmHg was documented or when bleb height was poor. In case of good bleb height and adequate IOP control, the sutures were left in situ till end of first month. after which they were removed. The patients in both groups were followed up on post op day 1, 7, 14, 1 month, 4 months, 6 month and 12 months.

The data was entered in MS EXCEL spreadsheet and analysis was done using Statistical Package for Social Sciences (SPSS) version 21.0. Qualitative variables were compared using Fisher’s exact test. A p value of <0.05 was considered statistically significant.

**Results**

The patient profile is tabulated in Table 1.
Visual Acuity

In AGV group 8 eyes (53.3 %) had visual acuity (VA) of inaccurate projection of rays (PR) or worse, and six eyes (40 %) had VA of accurate projection of rays only. In the trabeculectomy (control) group 10 eyes (66.7%) had VA ranging between 6/60 to 6/36 (LogMar 1.0 to 0.8) preoperatively, the remainder had vision ranging from hand movements to inaccurate projection of rays. This vision was maintained in all cases except three in AGV group, at all follow ups after initial first month. Visual acuity in trabeculectomy patients returned to preoperative levels 1 month after removal of releasable and bleb forming sutures.

Intraocular Pressure (IOP)

Mean intraocular pressure (IOP) preoperatively was 39 mm Hg + 9.7 in tube group and 33 mmHg + 9.8 in trabeculectomy group. Post operatively IOP drop was noted in both groups, with mean IOP at day 1 being 13.40 mmHg + 3.602 in tube group and 6.87+ 6.545 in Trab group. Pressures on post op day 7, 14, 1 month, 4 months, 6 month and 12 months were significantly lower than preoperative values in both the groups which were statistically significant.

Table 1: Case profile in study and control group

|                      | Tube group                        | Trabeculectomy group               |
|----------------------|-----------------------------------|------------------------------------|
| Age                  | 54 + 10.42(Mean + SD)             | 53 + 9.41(Mean + SD)               |
| Sex                  | Males 11                          | Males 5                            |
|                      | Females 4                         | Females 10                         |
| Eye involved         | Right 7                           | Right 6                            |
|                      | Left 8                            | Left 9                             |
| Pre operative IOP    | 39+9.75 (Mean + SD)               | 33+9.8(Mean + SD)                  |
| ( Anterior chamber depth in mm ) | 2.50+.42(Mean + SD)           | 2.58+ .39 (Mean + SD)              |
| Pre op central corneal thickness mm | 509.87+46.22             | 525.80+43.20                       |

Table 2: Complications seen in postoperative period

|                          | Tube (15 eyes) | Trabeculectomy (15 eyes) |
|--------------------------|----------------|--------------------------|
| Inflammatory reaction    | 6 eyes         | 4 eyes                   |
| Lens swelling            | 3 eyes*        | 1 eye                    |
| Shallow AC               | 3              | 1 eye                    |
| Corneal edema (localized)| 3 eyes         | -                        |
| Hyphema on day 1         | 2 eyes /       | 1 eye                    |
| reabsorbed by day 7      | 2 eyes         | NA                       |
| reabsorbed by day 7      | 1 within 1 week, after 6th month | 1 eye |
| reabsorbed by day 7      | required re- surgery | NA |
| Tube retraction          | 1 eye at 4 month, required sclera patch graft and resuturing at 9 months | NA |
| Tube erosion             | NA             | NA                       |

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Figure 3: IOP drop from preoperative values in both groups on post op day 1, 7, 1 month, 4 months, 6 months and 1 year.
Complete success (IOP < 18 mmHg) without medication was achieved in 66.7% of cases in AGV group and in 86.7% in Trab group at 4 months (short term follow up). This success was maintained at 6 months in 60% and 86% cases of AGV and Trab respectively. At 6 months one patient of AGV group developed tube retraction requiring surgery with tube expander, and required anti-glaucoma medications for a period of 3 weeks. At 1 year, the complete success was stable at 66% and 80 % in AGV and Trab group. Requirement of one or more anti-glaucoma medication was there in 34% cases of AGV group and about 20% cases of Trabeculectomy group at end of 1 year. This inter group difference did not achieve statistical significance (p value 0.2). Qualified success defined as IOP of < 18 mmHg with 1 topical medication was achieved in 86.7% cases in AGV group and 100% in Trab group at the end of 4 months follow up and persisted till 1 year of follow up. This intergroup difference again did not achieve statistical significance (p value 0.24). The drop in IOP persisted till end of study at 1 year. In three eyes of the AGV group, a hypertensive phase lasting from third to sixth week was noted, with IOP in these patients rising to 20-25 mm Hg necessitating use of topical anti-glaucoma medications for a period of 6-8 weeks.

Complications

Post surgery pre clinical corneal edema manifested as an increase in central corneal thickness (CCT) was noted in both groups. At the end of 4 months mean CCT was 514.3 ± 40.7 µ in AGV group showing an increase of 1.2% and 516.7 ± 39.8 µ in Trab group with increase of 1.6%. The difference was not statistically significant by independent sample test. At final follow up of 12 months, no statistically significant difference was noted in CCT in both the groups. Corneal endothelium damage was further confirmed by specular microscopy. Mean specular count decreased from preoperative levels of 2505.8+196.5: 2455.5+166.0 to 2444.9+206.0: 2412.0+159.5 in AGV: Trab group to respectively, the inter group difference being statistically insignificant.

Other complications during postoperative period are tabulated in Table 2.

Discussion

Trabeculectomy with anti-metabolites is the gold standard for glaucoma drainage surgery. However, the nemesis of this surgery is shallow anterior chamber (CCT) was noted in both groups. At the end of 4 months mean CCT was 514.3 ± 40.7 µ in AGV group showing an increase of 1.2% and 516.7 ± 39.8 µ in Trab group with increase of 1.6%. The difference was not statistically significant by independent sample test. At final follow up of 12 months, no statistically significant difference was noted in CCT in both the groups. Corneal endothelium damage was further confirmed by specular microscopy. Mean specular count decreased from preoperative levels of 2505.8+196.5: 2455.5+166.0 to 2444.9+206.0: 2412.0+159.5 in AGV: Trab group to respectively, the inter group difference being statistically insignificant.

Complications noted in the tube group involved tube retraction and erosion in 2 and 1 eye respectively requiring surgical revision. The increase in anterior segment inflammation noted in tube implanted eyes could be a result of increased tissue insult subsequent to increased dissection of subconjunctival space. The creation of surgical PI with GDD (not the normal norm) could also contributed to inflammation. Trabeculectomy eyes fared better in these aspects as evident in table 2.

Conclusion

Tube implants in ACG eyes are feasible as a primary option only with certain modifications and due precautions. Tube shunts despite these modifications fared poorer than trabeculectomy at 1 year follow up. Tubes should not be attempted as primary surgical means in advanced ACG cases. Trabeculectomy remains gold standard primary procedure in this subtype of glaucoma.

Recommendations

According to this pilot study, surgical recommendations are:

- Creation of a surgical peripheral iridectomy immediately adjacent to the tube entry in addition to a patent pre operatively performed laser iridotomy at a different site.
- Use of a smaller sized tube implant to prevent plate migration and extrusion.
- Leaving a smaller tube segment residue of 1.5mm versus 2.5 mm in anterior chamber.
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