Study of The Efficacy and Safety of Ahmed Glaucoma Valve Implantation in the Management of Pediatric Glaucoma

Said A. Gomaa; Ahmed H. Abdallah; Hesham A. Ibrahim; Raed M. Ismail

Background: Pediatric glaucoma is a potentially blinding disease, which is often refractive to medical treatment. The Ahmed glaucoma valve implant has a unidirectional flow restriction system that was designed to prevent postoperative hypotony while maintaining IOP greater than 8mm Hg.

Objective: To study the efficacy and safety of Ahmed glaucoma valve implantation in the management of pediatric glaucoma.

Subjective: The present study was carried out on 20 patients with pediatric glaucoma that was not controlled with other previous glaucoma surgery.

Results: The IOP and corneal clarity was significantly improved in the two groups at 1 months till the end of follow up. While it was found that the corneal diameter and axial length show insignificant change all over the period of follow up in the two groups. The C/D ratio was significantly increase in group I after 1 months and significantly decrease from 3rd month till 12th months in group II.

Conclusions: AGV implantation is effective in lowering the IOP in children eyes with glaucoma with corneal opacity and eyes previously operated for childhood glaucoma.

INTRODUCTION

Pediatric glaucoma includes a variety of ocular conditions that lead to high intraocular pressure (IOP) and progressive optic neuropathy. The most common type of childhood glaucoma is primary congenital glaucoma (PCG).

Although the reported incidence of PCG varies between 1/10,000 and 1/20,000 live births in Western publications, the incidence is estimated to be much higher in the Middle East.[1]

Another important cause of childhood glaucoma is aphakic glaucoma. Glaucoma is a well-known complication of congenital cataract extraction and is the most frequent long-term complication of lensectomy with or without intraocular lens (IOL) implantation. [2]

The reported incidence in the literature is between 15% and 45%.3–5 Management of congenital glaucoma is mainly surgical, and medical therapy is used either as a temporizing measure or as an adjunctive treatment. [3]

Medications alone are not completely effective because of anomalous drainage angle, serious side effects, high nonresponder rate, and lack of adherence, which make surgery the main therapeutic option. [4]

Traditionally, “staged approach” has been favored by many ophthalmologists. This involves starting with angle surgeries and their repetition in the case of failure, proceeding with trabeculectomy or combined trabeculotomy– trabeculectomy for refractory patients, and drainage device or cyclodestruction for very advanced patients.[5]

The main cause of outflow failure in congenital glaucoma is maldevelopment or developmental arrest of the trabecular

meshwork. Hence, angle surgeries that remove the obstruction and restore physiologic outflow are the procedure of choice in these patients and markedly improved the prognosis of congenital glaucoma.[6]

Angle surgery enjoys high success rate of 80%–90% in Western countries, which is in stark contrast to low success rate in Middle East and South Asian countries. [7] These poor clinical outcomes prompted surgeons in these countries to adopt combined trabeculotomy–trabeculectomy as primary procedure especially in more severe cases.[8]

Next step in the case of failure is glaucoma drainage devices implantation. Molteno15 was the first one to use them in pediatric population. Since then, glaucoma drainage devices have been used in refractory congenital glaucoma patients and as a primary procedure for those who are poor candidates for trabeculectomy such as scarred conjunctiva or buphthalmos eyes. [9]

AIM OF THE WORK

The study of efficacy and safety of Ahmed glaucoma valve implantation in the management of pediatric glaucoma.

PATIENTS & METHODS

Patients:

The present study was carried out on 20 patients with pediatric glaucoma that was not controlled with other previous glaucoma surgery (goniotomy, trabeculotomy, and or trabeculectomy with or without antimetabolites) or cases with congenital glaucoma without previous surgery with corneal diameter more than 14 mm and opaque cornea.

The 20 cases was divided into two groups:

Group 1: Cases with congenital glaucoma subjected to other procedures but failed, followed by implantation of Ahmed valve.

Group 2: Cases with corneal diameter more than 14mm - and opaque cornea for which Ahmed valve was used as a primary procedure.

Methods:

Preoperative Examination

The cases was subjected to:

(I) History taking:

- History of the onset of Glaucoma
- History of the Anti glaucoma medications & previous surgeries.

(II) Examination under general anesthesia included:

1) Measuring corneal diameter and evaluation of its transparency
2) IOP measurement with Goldman applanation tonometer, an electronic tonometer (ton open) and / or a handheld applanation tonometer.
3) Gonioscopy (if possible)
4) Fundus examination (if possible)
5) Examination of the failed previous surgery in operated cases

Post Operative treatment:

- Topical corticosteroid and antibiotics.

Follow up period was extend for 6 months with examination under anaesthesia at 1 month, 3 months and 6 months where measurement of IOP, corneal diameter and clarity with comment on the valve position, tube position in the anterior chamber, with recording of any complications.

RESULTS

There was no statistical significant difference between the two studied groups regarding age and laterality (P> 0.05)

Table (1) showed that there was no statistical significant difference regarding diagnosis at valve surgery in the two studied groups (P > 0.05) Medical history in group I, number 1, 2 of prior glaucoma procedures was higher with the same ratio 6(40%), TM at 0 was higher (53.3%), TTM at

1 was higher (53.3%), N5FU was 4(26.7%), NM was 2(13.3%), TT5FU was 1(6.7%) and N was 1(6.7%). TT and TC were none.

Table (2) showed that there was no statistical significant difference between the two studied groups regarding different measurement at 1,3,6,12 and 6 months (P> 0.05). Regarding different measurement at 9 month, there was statistical significant difference between the two studied groups regarding success (P< 0.05%) while there was no statistical significant difference regarding other difference measurement at 9 months (P> 0.05). Regarding different measurement at last follow up, there was statistical significant difference between the two studied groups regarding C/D ratio (P< 0.05) while there was no statistical significant difference regarding other different measurement at last follow up (P > 0.05).

There was no statistical significant difference between the two studied groups regarding Duration of Last Follow Up (months) (P> 0.05).

Table (3) showed that non-glaucoma medication was higher 10(66.7%). Number of glaucoma medications 0 was higher 10(66.7%), N was higher at 0 with 12(80%), also CP was higher at 0 with 12(80%).

Table (1): Diagnosis at valve surgery (indication) in the two studied groups.

Diagnosis at Valve Surgery (Indication)	Group I "n=15"		Group II "n=5"	
	No.	%	No.	%
Uncontrolled primary congenital glaucoma	7	46.67	0	0.0
Aphakic glaucoma after congenital cataract surgery	5	33.33	2	40.0
Pseudophakic glaucoma after congenital cataract surgery	1	6.67	0	0.0
Traumatic Glaucoma after hyphema & Traumatic Aniridia	1	6.67	0	0.0
Traumatic Glaucoma after hyphema	1	6.67	0	0.0
Aniridia	0	0.0	2	40.0
Axenfeld Rieger Syndrome & Aphakic Glaucoma	0	0.0	1	20.0
P value	0.355 N.S.			

N.S. = Not significant

Table (2): Comparison between the two studied groups regarding different measurement at 1,3,6,9,12 month and at last follow up

Different measurement	Group I "n=15"		Group II "n=5"		P value
At 1 month					
IOP (mmHg)	8.50±5.73		7.75±7.04		0.414 N.S
IOP Change	14.79±7.79		10.25±10.40		0.176 N.S
C/D ratio	0.36±0.31		0.350±0.44		0.481 N.S
Axial Length	23.51±2.57		22.543±1.35		0.274 N.S
Number of Glaucoma Medications	**No**	**%**	**No**	**%**	0.234 N.S
No	13	86.7	4	80.0	
Yes	2	13.3	0	0.0	
Success (IOP<21 mmHg)	13	86.7	4	80.0	0.234 N.S
At 3 months					
IOP (mmHg)	12.36±8.23		11.000±1.00		0.393 N.S
IOP Change	11.18±9.21		8.333±6.81		0.315 N.S
C/D ratio	0.38±0.27		0.333±0.35		0.419 N.S
Axial Length	23.55±2.36		24.007±2.23		0.392 N.S
Number of Glaucoma Medications	**No**	**%**	**No**	**%**	0.126 N.S
0	11	73.3	5	100.0	
1	3	20.0	0	0.0	
2	1	6.7	0	0.0	
Success (IOP<21 mmHg)	9	60.0	3	60.0	0.500 N.S
At 6 months					
IOP (mmHg)	13.40±4.20		11.333±4.16		0.235 N.S

IOP Change	9.70±3.71		6.667±9.02		0.193 N.S
C/D ratio	0.44±0.29		0.60±0.0		0.102 N.S.
Axial Length	23.73±2.24		22.990±1.20		0.336 N.S
Number of Glaucoma Medications	**No**	**%**	**No**	**%**	
0	9	60.0	4	80.0	0.201 N.S
1	5	33.3	1	20.0	
2	1	6.7	0	0.0	
Success (IOP<21 mmHg)	10	66.7	3	60	0.400 N.S

N.S. = Not significant ** significant at level 0.05*

Table (3): Comparison between the two studied groups regarding different measurement at 1,3,6,9,12 month and at last follow up (cont.)

Different measurement	**Group I "n=15"**		**Group II "n=5"**		**P value**
At 9 months					
IOP (mmHg)	15.25±7.21		13.250±2.75		0.305
IOP Change	9.25±8.24		6.750±9.57		0.324
C/D ratio	0.45±0.36		0.525±0.41		0.384
Axial Length	24.15±2.26		23.27±1.31		0.312
Number of Glaucoma Medications	**No**	**%**	**No**	**%**	
0	9	60.0	3	60.0	0.419
1	5	33.3	2	40.0	
2	1	6.7	0	0.0	
Success (IOP<21 mmHg)	5	33.3	4	80.0	0.038*
At 12 months					
IOP (mmHg)	19.00±5.15		16.8±4.16		0.252
IOP Change	7.00±7.46		-1.33±6.43		0.062
C/D ratio	0.50±0.29		0.77±0.25		0.110
Axial Length	23.17±0.52		24.24±1.83		0.096
Number of Glaucoma Medications	**No**	**%**	**No**	**%**	
0	10	66.7	3	60.0	0.400
1	5	33.3	2	40.0	
2	0	0.0	0	0.0	
Success (IOP<21 mmHg)	6	40.0	3	60.0	0.231
At last follow up					
IOP (mmHg)	16.67±8.93		19.400±5.46		0.265
IOP Change	6.53±9.82		0.200±4.27		0.092
IOP Change-Percent	26.30±40.43		-1.844±27.60		0.084
C/D ratio	0.48±0.28		0.80±0.27		0.033
Axial Length	25.29±1.89		24.717±1.61		0.319
Number of Glaucoma Medications	**No**	**%**	**No**	**%**	
0	6	40.0	3	60.0	0.151
1	6	40.0	2	40.0	
2	3	20.0	0	0.0	
Success (IOP<21 mmHg)	10	66.7	3	60	0.400

N.S. = Not significant ** significant at level 0.05*

Table (4): Descriptive additional glaucoma procedures of group I

Group I	**No**	**%**
Glaucoma medication	10	66.7

No	5	33.3
Yes		
Number of Glaucoma Medications		
0	10	66.7
1	4	26.7
2	0	0.0
3	1	6.7
N		
0	12	80.0
1	2	13.3
2	1	6.7
3	0	0.0
CP		
0	12	80.0
1	3	20.0
2	0	0.0
3	0	0.0

N.S. = Not significant

DISCUSSION

The unequal distribution of the study eyes between the 2 groups was inevitable, given the relative rarity of the disease condition, as already reported. The age groups of the study children were not statistically significantly different, reflecting sample homogeneity regarding age. The relatively older age of the study participants (around 2 – 3 years of life) was secondary to the time lapse taken by the initial surgical intervention(s) in group 1 and by the relatively late presentation of the care-providers in group 2. [10]

This age of the study children is in accordance with the age reported in other studies. The almost equal laterality distribution of the study eyes reflects generally equal incidence of childhood glaucoma in right and left eyes.

The glaucoma diagnosis of the study eyes reflects important trends. The most common diagnosis was uncontrolled primary congenital glaucoma and glaucoma after congenital cataract surgery (in group 1). These were the most common types of childhood glaucoma reported in other studies as well.[11] In group 2, there was almost equal incidence of glaucoma after congenital cataract surgery and aniridia, which was expected given the keratopathy and corneal scarring commonly reported with aniridia. As per the study protocol, eyes in group 1 were subjected to previous glaucoma surgeries.[12]

Almost 40% of the patients were subjected to 1 procedure and 2 procedures respectively, with trabeculectomy and combined trabeculotomy-trabeculectomy, both with antimetabolites, being the major surgical procedures. The use of filtering surgery and combined angle and filtering surgery as a primary surgical procedure for childhood glaucoma is already reported. Attempts at saving a failing bleb were manifested by multiple needling procedures, paralleling other reports of the efficacy of needling of failing blebs in childhood glaucoma.[13]

Comparing the clinical data of the 2 studied groups reveals no statistically significant differences between the 2 groups in the IOP, corneal diameter, cup/disc ratio and axial length. The mean IOP in both study groups was clearly above the statistically normal for children, especially in group 1. It is worth note that these IOP values were measured under general anaesthesia, with all the artfactual reductions reported with general anaesthetics on the IOP.[14]

Additionally, the presence of corneal pathology, especially in group 2, added to

the difficulty and inaccuracy in measuring the IOP in group 2 eyes. The effect of corneal pathology on the measurement of the IOP is reported in other studies. The C/D ratio in group 2 eyes is not reported since the corneal opacity precluded examination of the fundus and assessment of the optic nerve. B Scan ultrasound was the only substitute. There was one important deviation from the study protocol that was necessary in group 2 which was the corneal diameter limit of 14 mm. The authors prioritized the presence of the corneal opacity over the diameter for study inclusion due to the relative rarity of eyes fulfilling both criteria.[15]

Studying the postoperative clinical characteristics of the 2 studied groups reveals important information. The IOP at 1 month was clearly decreased than the preoperative IOP, paralleling other published studies.[16] The corneal diameter was not different from the preoperative values, nor was the axial length. As reported in other studies, the biometric characteristics of successfully operated eyes do not decrease after surgery. The notable change is the reversibility of the optic nerve cupping, and the possibility to report on the C/D ratio in group 2 eyes, after resolution of the corneal oedema with successful reduction of IOP. An additional obvious benefit of the surgery was the reduction in the number of eyes on IOP-lowering medications after the surgery.[17]

This reduction of medication following valve implantation parallels other reports. Interestingly enough, the success percentage was marginally higher in group 1 than in group 2, although the small sample size does not permit robust conclusions.[18] The same trend of the efficacy of the surgery continues into the 3, 6, 9 and 12 months' follow up data although the IOP demonstrates a rising trend. This reduction of the efficacy of AGV in lowering the IOP as well as the decline in the success percentages, are already reported in other studies.[19]

The duration of follow up was not statistically significantly different between groups 1 and 2, both exceeding 2 years. Although the IOP at the final visit demonstrates an elevation over the earlier follow up visits, yet the IOP values remain below the preoperative values. This parallels other published studies.[20]

The fact that the axial length remains stable over the follow up period reflects the fact that the study eyes had passed the period of ocular enlargement with elevated IOP, the first 2 – 3 years of life than a reflection of controlled IOP. The need for adjunctive procedures after AGV implantation such as needling and cyclodestruction was to least in the current study, paralleling other reports.[21]

This study has obvious limitations. The small number of cases is top of the list. However, given the relative rarity of the cases, it was permissible to enroll such a few cases. The unequal distribution of the study eyes between the 2 groups was another issue and the fact that the authors omitted the condition of 1 14 mm diameter of the cornea for study inclusion is another limitation.[22]

CONCLUSION

AGV implantation is effective in lowering the IOP in children's eyes with glaucoma with corneal opacity and eyes previously operated for childhood glaucoma.

The IOP trend after AGV implantation demonstrates an initial decline followed by a gradual rise over time.

Children glaucoma eyes implanted with an AGV demonstrate a reduction of C/D ratio with reduction of the IOP.

The biometric characteristics of the eyes implanted with an AGV remain stable over time.

RECOMMENDATIONS

Larger studies with larger sample size and longer follow up periods are recommended.

AGV implantation is recommended in refractory childhood glaucoma cases, even after failure of primary procedures for glaucoma.

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