Outcome of low cost glaucoma implant in a tertiary center in Egypt

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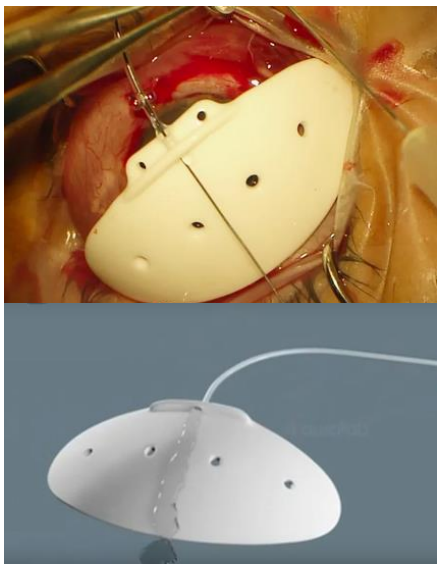
No Financial Interests

Introduction

- Glaucoma drainage devices (GDDs), such as the Ahmed Glaucoma valve (AGV) or Baerveldt glaucoma implant (BGI), have been reported to be useful in the management of childhood glaucoma when used in either a primary surgical procedure or following other angle-based glaucoma surgeries, such as trabeculectomy
- This represents a substantial burden to a large section of the population in developing countries).

Introduction

- The Aurolab Aqueous Drainage Implant (AADI, Aurolabs, Madurai, India) is a low-cost prototype of the Baerveldt 350 implant In collaboration with Bascom Palmer Institute.
- Its low cost, at approximately 20% of the price of the BGI (is a very strong advantage). However, little data is available regarding the safety and efficacy of the AADI outside India, the manufacturing country of the device



Aim of the Work

- To study the safety and efficacy of a low-cost glaucoma drainage device (GDD), the Aurolab aqueous drainage implant (AADI), in refractory childhood glaucoma.

Patients and Methods

This is a prospective case series of children below 16 years who had AADI implants

Study venue

Surgeries were performed at Assiut University Hospital, a tertiary-level care institute in Egypt, between April 2016 and May 2018 with a minimum 6 months of follow-up were included.

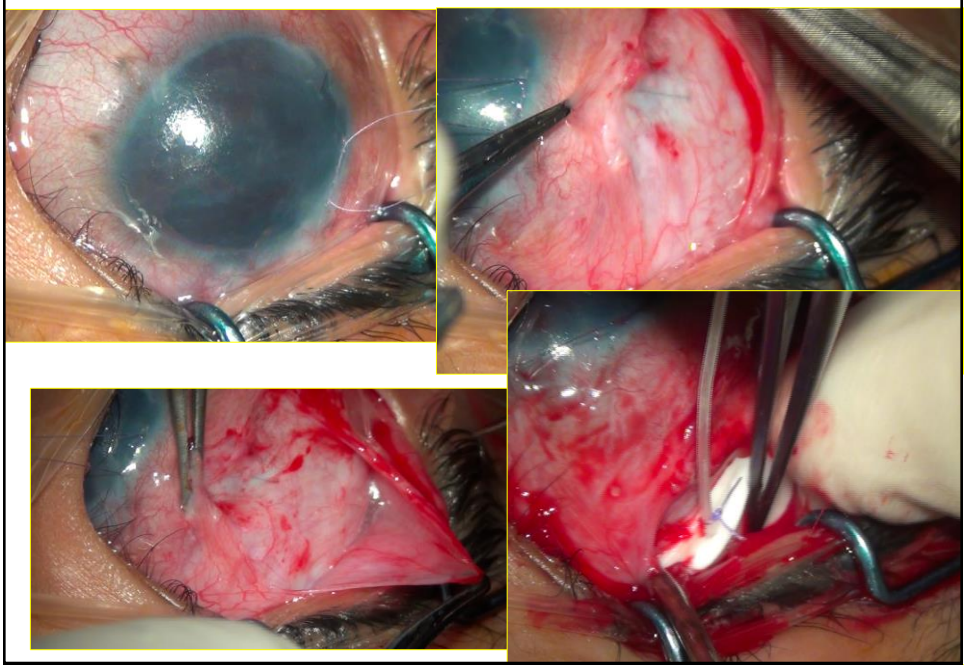
The primary outcome measure

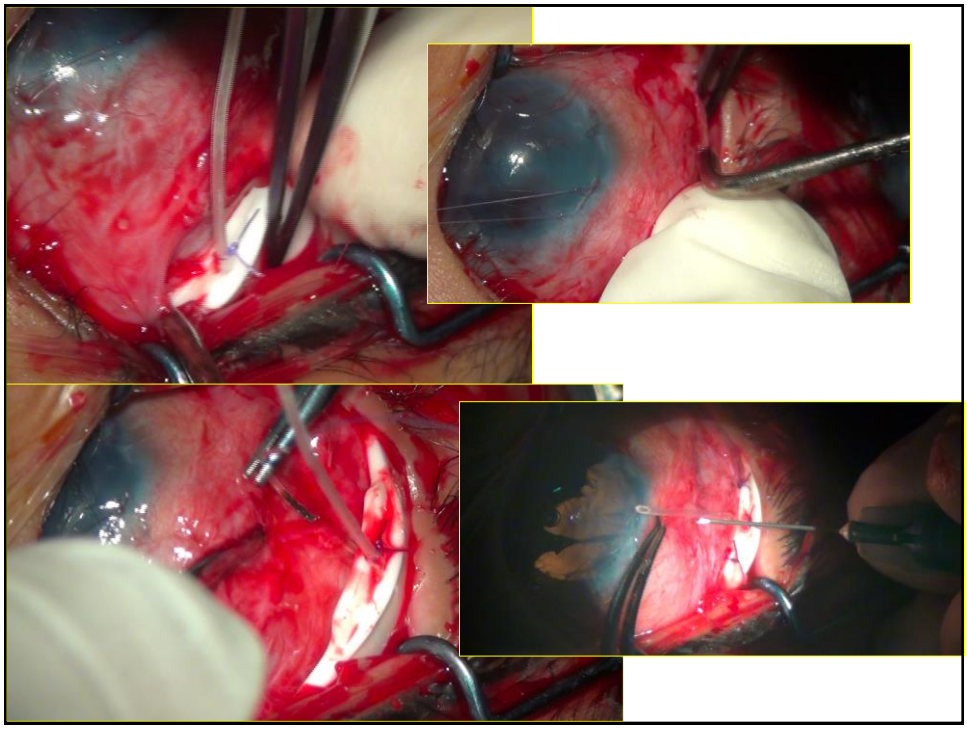
was IOP reduction relative to preoperative values, and the secondary outcome measure was the occurrence of postoperative complications.

Patients and Methods

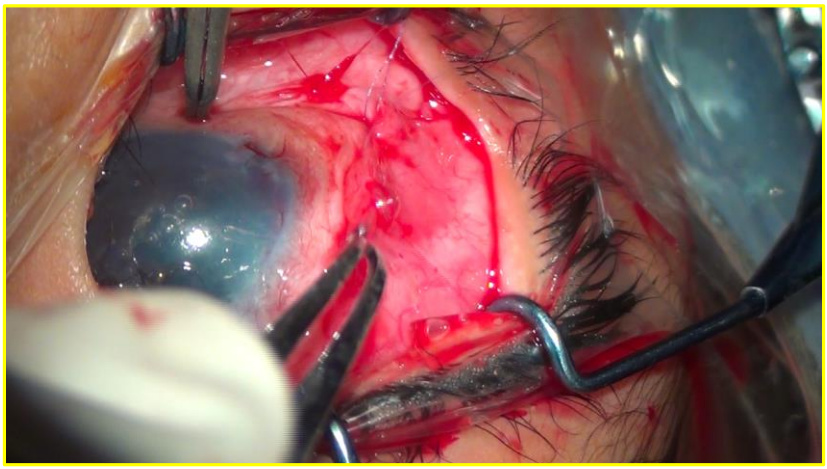
- Inclusion criteria
- Age <16 years old
- Eyes with uncontrolled IOP refractory to medical treatment
- Eyes considered at high risk of failure/complications following conventional filtering surgery, such as those with excessive conjunctival scarring after prior ocular
- A minimum 6 months of postoperative follow-up

- Exclusion criteria
- Corneal abnormalities that could lead to erroneous IOP readings, corneal haze due to buphthalmos or high IOP were accepted
- Uncontrolled systemic diseases
- Glaucoma secondary to uveitis even if the uveitis was controlled before surgery
- Any other active ocular disease (e.g., ocular infection).





Surgical Technique



Results

Demographics	N=27
Age* (months)	28.12
Sex	
Male	17
Female	10
Glaucoma diagnosis	
Primary congenital glaucoma	19 (70%)
Aphakic glaucoma	2
Pseudophakic glaucoma	2
Traumatic glaucoma	1
Glaucoma in a vitrectomized eye	1
Sturge-Weber syndrome	1
Axenfield-Rieger syndrome	1
Mean preoperative IOP * (mmHg)	34 ± 5
Mean preoperative anti-glaucoma medication *	3.2+0.6

Results

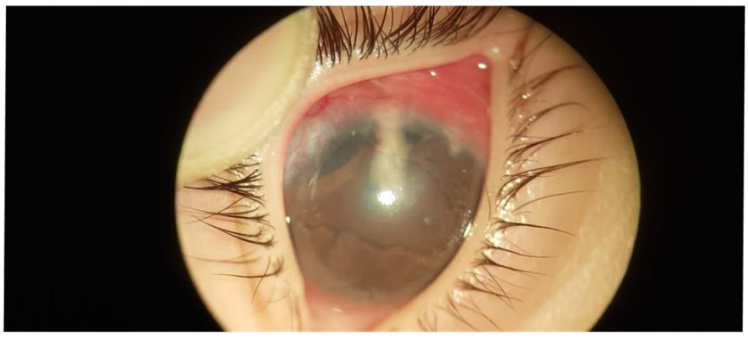
- Primary outcome (IOP):

	Baseline mean IOP	Mean IOP at week 1	Mean IOP at month 3	Mean IOP at month 6
Group A	34	13.28	12.8	12.6
P value	---------	**<0.001**	**<0.001**	**<0.001**

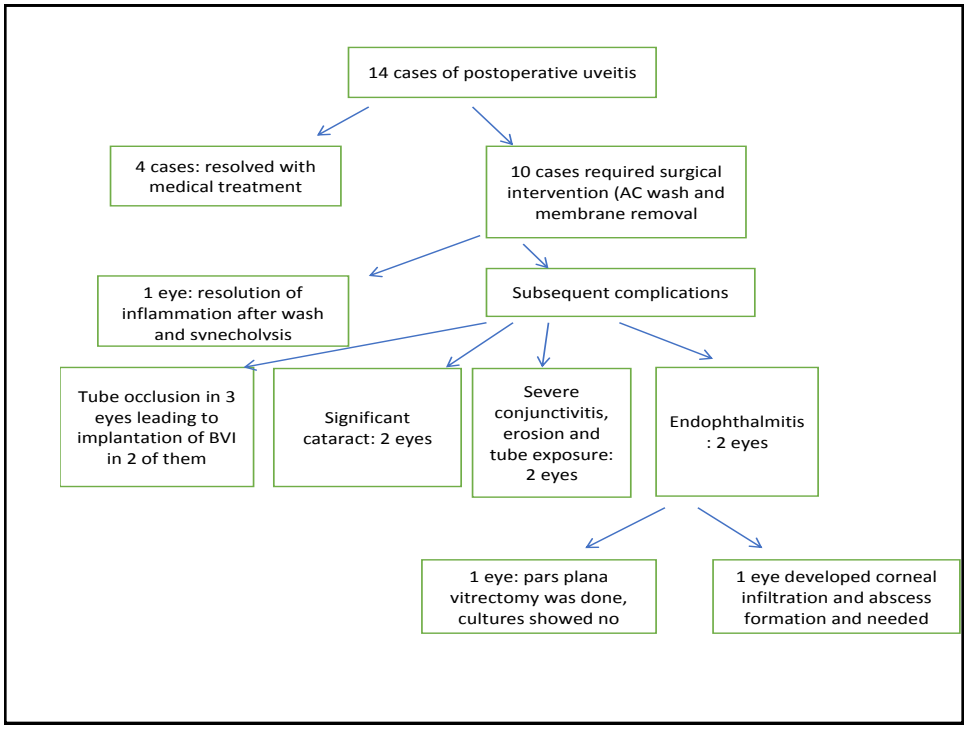
Results

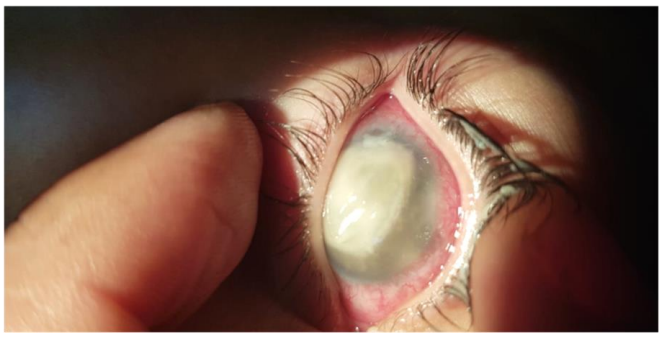
- Secondary outcome (Adverse reactions):

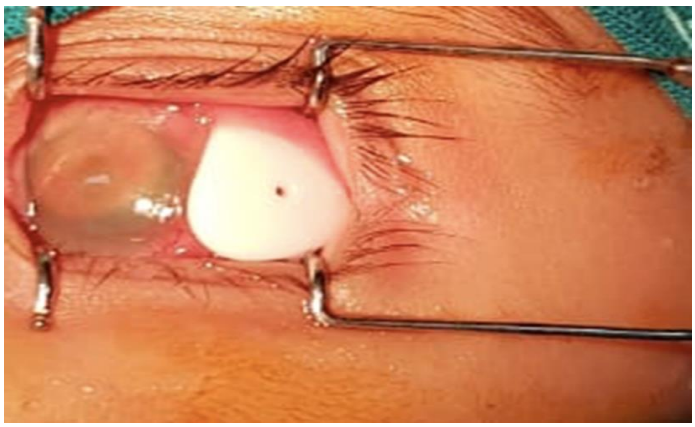
Complication	Number	Fate
Priamry tube failure	2	AC wash
Hypotony	7	resolved
Choroidal effusion	4	All resolved
Hemorrhagic Choroidal Effusion	1	Drainage, RD , Silicon
Corneal Edema	2	resolved
Severe Reaction	14	5 resolved



CytoPathology: intense fibrinoud reaction , with large inlflammatory cells


14 cases of postoperative uveitis
4 cases: resolved with medical treatment
10 cases required surgical intervention (AC wash and membrane removal
1 eye: resolution of inflammation after wash and svnecholvsis
Subsequent complications
Tube occlusion in 3 eyes leading to implantation of BVI in 2 of them
Significant cataract: 2 eyes
Severe conjunctivitis, erosion and tube exposure: 2 eyes
Endophthalmitis : 2 eyes
1 eye: pars plana vitrectomy was done, cultures showed no
1 eye developed corneal infiltration and abscess formation and needed





Discussion

- The two commonly used GDDs worldwide are AGV and BGI. The AGV has a built-in valve which prevents hypotony in the early postoperative period. On the contrary, BGI is non-valved and requires the tube to be temporarily ligated to prevent early postoperative filtration.
- Pooled data from randomized controlled studies that compared AGV and BGI at the end of 5 years showed that BGI group had a lower mean IOP on fewer medications than the AGV group possibly because larger surface area of BGI results and lower encapsulation. Although there is no previously published literature available comparing BGD 350 and AADI (also has a surface area of 350 mm^2), it is presumed that the two GDDs would be equivalent, as the former has been the design inspiration for the latter.

Discussion

- Our study showed that AADI yielded similar success rates and mean IOP reduction as other previous studies evaluating the use of AADI. However, approximately 48 % of eyes in our series experienced intense fibrinous postoperative reaction that required intensifying medical treatment and in some cases required a second surgical intervention to clear the AC from fibrin and exudates
- Some of the cases ended either with failure of the valve or loss of vision due to endophthalmitis or corneal ulcers. Those events, if went unrecognized and undertreated might jeopardize surgery outcomes and even put the eye at other risks up to phthisis bulbi especially in those children whose eyes are notorious for severe inflammatory reaction

Discussion

- In settings other than tertiary centers where repeated examinations of those patients under general anesthesia are feasible, this complication with all devastating consequences could be easily missed. This alarming rate of postoperative reaction reported here in our series has not been described in the previous series.
- Our team established a communication with the manufacturing company who explained the adverse events by the use of different lots of AADI. We believe that this statement is not adequate to explain the adverse events because these cases were done using multiple lots in a time period of two years.
- We strongly propose that the silicon material used for the valve may be the reason to cause such a reaction as we did not encounter any similar reaction with Ahmed Valve or Baerveldt glaucoma implant.

Conclusion

- **AADI implant, a low cost GDD, IS effective in lowering IOP. However, its use on our patients resulted in serious complications believed to be related to the material of the valve. We strongly do not recommend its use in children. In the future, randomized prospective comparative studies are warranted to validate the results of our study**

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