Original Article

Combined cataract extraction with a new nonvalved glaucoma drainage device in adult eyes with cataract and refractory glaucoma

Divya P Rao, Vanita Pathak-Ray[1]

Purpose: The purpose of the study is to report the outcomes of simultaneous cataract extraction (CE) and a new nonvalved glaucoma drainage device (GDD), Aurolab Aqueous Drainage Implant (AADI), in eyes with cataract and refractory glaucoma. **Methods:** This was a non-comparative, interventional, retrospective study. Consecutive patients who underwent AADI together with phacoemulsification from June-2015 to January-2017 by a single fellowship trained glaucoma surgeon with documented 3-months of follow-up were included. The main outcomes were intraocular pressure (IOP), antiglaucoma medication (AGM), visual acuity, and complications. **Results:** We included 19 eyes of 17 patients with average follow-up of 14.4 ± 8.4 months. IOP and AGM reduced from 36.9 ± 11.1 mmHg and 4 ± 0.8 preoperatively to 12 ± 4.5 mmHg and 0.8 ± 1.2, respectively ($P < 0.001$). Complications were seen in seven eyes (36.8%). Total success was seen in 17 eyes (89.5%). None of the patients lost vision. **Conclusion:** Combining cataract extraction with the new non-valved Aurolab Aqueous Drainage Implant, appears to be an effective and safe technique in eyes with refractory glaucoma and cataract. Larger studies and further follow-up is recommended for such patients.

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Cataract and glaucoma frequently coexist, as both tend to be diseases of advancing age. When the glaucoma is resistant to medical management or continues to show progression despite medication, then most surgeons combine cataract extraction (CE) with a glaucoma procedure. Under the circumstances, the options available are combined phacoemulsification and trabeculectomy with antimetabolites or sequential trabeculectomy and then CE.[1-3]

However, when the glaucoma is refractory to treatment or in the presence of severe conjunctival scarring, a phacotrabeculectomy, even with the use of adjuvant antifibrotics, is known to yield poor results.[4] A potential alternative is to combine phacoemulsification with a glaucoma drainage device (GDD). It is surmised that such a combination would not only reduce the intraocular pressure (IOP) but also offer an advantage of early visual rehabilitation, avoiding the high risks of failure of bleb-related infections associated with trabeculectomy in these complicated eyes. Sequential surgery, GDD first followed by CE, can also be considered. However, combining the surgeries not only reduces surgical cost but also potentially avoids the risk of infection and corneal decompensation associated with multiple surgeries.

There are a few retrospective studies reporting the outcomes of combining CE with the valved GDD, Ahmed glaucoma valve (AGV) and the nonvalved GDD, Baerveldt Glaucoma Device (BGD) in eyes with refractory glaucoma and have found good results regarding efficacy and safety.[5-8] However, there is a lack of consensus among surgeons concerning the optimal surgery, as there is a paucity of literature on the long-term outcomes of combining CE with GDD. Moreover, in developing countries, AGV comes at a substantial cost to the patient and BGD (and even Molteno implant) is unavailable. Aravind laboratories in Madurai, India, have indigenously manufactured the Aurolab aqueous drainage implant (AADI, Aurolabs, India) design of which is based on the Baerveldt 350. It is a low-cost device and has the potential to break the cost barrier in developing countries like ours. So far, there have been no studies reporting the results of combining CE with AADI in these cases of complicated and refractory glaucoma with cataract.

Therefore, the aim of this study was to report the efficacy and safety of combined phacoemulsification and the new nonvalved GDD, AADI, in Asian eyes with refractory glaucoma and cataract.

Methods

Study design

This was a retrospective, interventional study, where we reviewed the charts of consecutive adult patients who underwent AADI surgery together with phacoemulsification from June 2015 to January 2017 by a single fellowship trained

VST Centre for Glaucoma, L.V Prasad Eye Institute, [1]Centre for Sight, Banjara Hills, Hyderabad, India

Correspondence to: Dr. Vanita Pathak-Ray, Centre for Sight, Road No. 2, Banjara Hills, Hyderabad - 500 034, Telangana, India. E-mail: vpathakray@gmail.com

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glaucoma surgeon. Only those who had at least 3 months of documented postoperative follow-up were considered. The study was approved by the Institutional Review Board, and informed consent was taken for the surgery from all patients. The study adhered to the tenets laid down by the Declaration of Helsinki.

Surgical method

Phaco-Aurolab aqueous drainage implant surgical procedure

Following a regional anesthetic block and under sterile conditions, a fornix-based conjunctival opening is created most commonly in either the superotemporal (ST) or inferotemporal (IT) quadrant. The patency of the tube is checked with a balanced salt solution in a syringe with a 30G cannula. The tube is ligated with a 6-0 vicryl (Braided coated polyglactin 910 violet; Ethicon, Johnson and Johnson) suture at the plate-end and occlusion is tested. Venting incisions are made anterior to the ligated tube, approximately 3–4 pairs, depending on the level of preoperative IOP and vents are checked for patency. Adjacent recti are identified and hooked; under-belly of the recti is cleaned, before the placement of the wings of the AADI underneath them. The plate is anchored between two rectus muscles (superior and lateral recti for ST placement and inferior and lateral recti for IT placement) with the anterior edge approximately 10 mm posterior to the limbus. A permanent suture is preferred and 10-0 prolene suture (monofilament polypropylene blue; Ethicon, Johnson and Johnson, Himachal Pradesh, India) is used. The suture knots are rotated into the fixation eyelets to prevent erosion through the conjunctiva.

Once, the plate is secured, phacoemulsification is completed through a clear corneal incision and a foldable IOL is placed in the bag and the phaco wound is sutured with 10-0 nylon (monofilament polyamide black, Ethilon; Ethicon, Johnson & Johnson, Himachal Pradesh, India). Following this, the rest of the AADI procedure is completed. The tube length is shortened as appropriate, with bevel up. A 23G needle is used to create a track 1.5–2 mm behind the limbus through which the tube is inserted into the anterior chamber (AC), just anterior and parallel to the iris for AC placement and behind the iris for a sulcus placement. The tube is inserted through the needle track and secured to the sclera with a figure-of-eight 10-0 nylon suture. The majority of the length of the tube (except the ligating suture) is covered with a prepared corneal patch graft and secured to the sclera with fibrin glue. The conjunctiva and Tenon's are brought forward and secured with fibrin glue and 8-0 vicryl (Braided coated polyglactin 910 violet; Ethicon, Johnson and Johnson) wing sutures. Before patching, a subconjunctival injection of steroid is given. Postoperatively, topical antibiotics are administered for a week, and topical steroids are commenced every 2 h and tapered. A cycloplegic is also used as per indication.

Outcome criteria

The primary outcome measure was IOP and the secondary outcome measure was number of antiglaucoma medication (AGM), best-corrected visual acuity (BCVA), and complications. Complete success was defined as IOP ≥5 mmHg and ≤21 mmHg or reduction of IOP by ≥20% from baseline without the use of AGMs. Qualified success was defined as reaching the above IOP criteria with the use of AGM. Failure was defined as inability to meet IOP criteria, loss of perception of light, explantation of device, or any additional glaucoma surgery to reduce IOP.

Hypertensive phase was defined as a patent tube and tense cystic bleb around the plate with much-increased height accompanied with IOP >21 mmHg from the 3rd week onward in the postoperative period, requiring the need for AGM. The subsequent reduction in bleb height, with step-down of AGM, or discontinuation was defined as resolving or resolved hypertensive phase, respectively.

Statistical methods

Descriptive statistics were used for baseline demographic and ocular characteristics. Data of continuous variables are presented as the mean ± standard deviation (SD) with 95% confidence intervals (CI). Snellen visual acuity was converted to logMAR acuity for statistical analysis. Continuous and quantitative variables were analyzed using a Student's *t*-test or Wilcoxon signed-rank test, and discrete and qualitative variables were analyzed using a Pearson Chi-square test or Fisher's exact test. Data on IOP and number of glaucoma medications were censored once a patient underwent a reoperation for glaucoma and/or explantation of the implant for a complication, but not after failure due to high IOP, hypotony, or reoperation for complication. There was no censoring of visual acuity results. $P < 0.05$ was considered statistically significant.

Results

AADI surgery was performed in 42 eyes of 40 patients in the study period by a single fellowship-trained surgeon. Of these 19 eyes of 17 patients underwent combined phacoemulsification, IOL implantation and AADI surgery and were included in the study.

Preoperative baseline characteristics are shown in Table 1. A total of 17 patients (19 eyes) included in the study were followed up for an average of 14.4 ± 8.4 (range: 3–29 months), of which 13 (68.4%) had a follow-up of 1-year or more. The mean age of patients was 41.05 ± 12.2 years; male-to-female ratio was 6:11; and nine eyes were right eyes. Mean preoperative IOP was 36.9 ± 11.1 mmHg with a mean preoperative AGM use of 4 ± 0.8. 17 eyes also additionally needed preoperative oral acetazolamide for control of IOP.

Fig. 1 shows the etiology of glaucoma. The secondary glaucomas were found to be the most common type of

Table 1: Baseline demographic and ocular characteristics

	Mean	SD (95% CI)
Follow-up	14.4 months	8.4 (10.3-18.4)
Preoperative IOP	36.9 mmHg	11.1 (31.6-42.2)
Preoperative AGM	4	0.8 (3.6-4.4)
Preoperative LogMAR BCVA	1.17	0.7 (0.8-1.5)
PAS on gonio	2.5 quadrants	1.5 (1.9-3.1)
Disc cupping*	0.8	0.2 (0.6-0.8)
Previous surgery	0.8	0.99 (0.4-1.3)

*n=16 eyes. Three eyes had no view of fundus due to advanced cataract.
SD: Standard deviation, CI: Confidence interval, IOP: Intraocular pressure, AGM: Antiglaucoma medication, BCVA: Best-corrected visual acuity, PAS: Peripheral anterior synechiae, LogMAR: Logarithm minimum angle of resolution

glaucoma in 17 eyes (89.4%). In addition, three eyes had a history of failed trabeculectomy. Two patients had bilateral surgery; the etiology of glaucoma in one of these patients was bilateral uveitis (Vogt–Koyanagi–Harada syndrome), and the other had bilateral iridocorneal endothelial syndrome (ICE). The proportion of eyes with neovascular glaucoma (NVG) was 16%, and all such eyes with NVG had received panretinal photocoagulation and antivascular endothelial growth factor (anti-VeGF) injection in the weeks preceding Phaco-AADI surgery.

Per-operatively, out of the 19 eyes, 16 eyes had implant placement in the ST quadrant of which six were in the sulcus, and the rest (10 eyes) had tubes placed in the AC. Three eyes had IT placement, two of which were in the sulcus. Average number of venting slits were 3.7 ± 0.5 CI (3.5, 3.9), and these were placed in all eyes. Out of 19, five eyes had synechiolysis performed during phacoemulsification surgery, and two eyes also needed iris hooks for pupillary dilatation during cataract surgery. All the eyes had a foldable implant placed in the bag. In this cohort, none of the eyes had posterior capsular rupture or vitreous loss.

Table 2 shows mean IOP (±SD) and AGM (±SD) used preoperatively and postoperatively at day 1, week 1, week 6, months 3, 6, 12, and at last follow-up as well as the number of patients seen at every visit. A statistically significant difference was found in both the reduction in IOP and in the number of medications used at all-time points during follow-up.

Improvement in VA from the preoperative level occurred in 8 of 19 eyes (42.1%). Eight (42.1%) eyes had poor vision preoperatively (20/400 or worse), and it remained unchanged in six eyes postoperatively (31.6%). Visual acuity outcomes are summarized in Table 3.

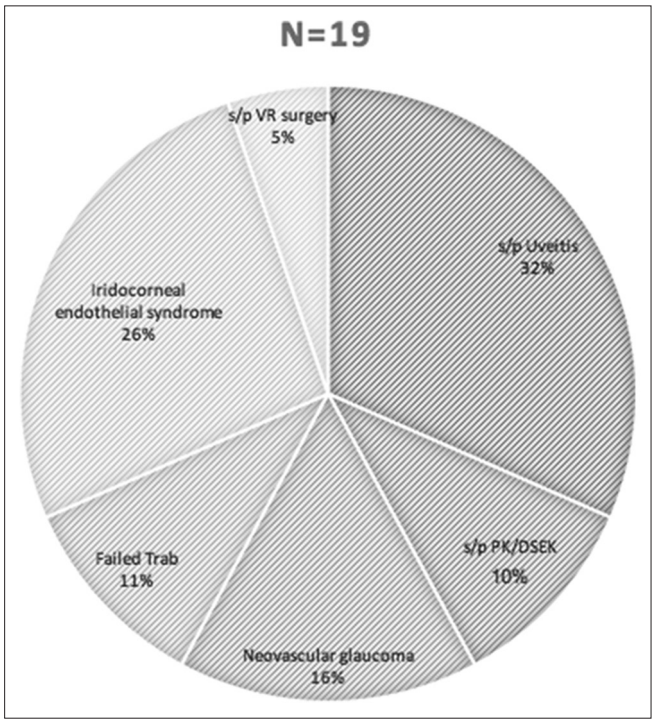

Figure 1: Etiology of glaucoma in the eyes undergoing combined cataract extraction and Aurolab Aqueous Drainage Implant surgery

Only six patients could perform a 24-2 test on Humphrey Field Analyzer (mean MD − 15.5 ± 5.9, mean Visual Field Index of 58.7 ± 22.8%) and another three on 10-2 test (stimulus III) (Mean MD − 22.27 ± 1.6), with involvement of fixation; further three patients managed with stimulus V only. The performance of visual field testing was not possible in six patients – three had poor vision due to advanced cataract, two had poor vision due to advanced glaucoma, and one eye had poor fixation due to macular scar; visual field was not done in one eye preoperatively. VA deteriorated in two patients at last follow-up, after initial improvement postoperatively; one was due to corneal decompensation in ICE syndrome and the other developed unrelated vein occlusion and vitreous hemorrhage. However, no patient developed loss of perception of light.

Postoperative characteristics

Mean postoperative IOP at 14.4 months was 12.0 ± 4.5 mmHg 95% CI (9.8, 14.7) and AGM required was 0.8 ± 1.2 95% CI (0.2, 1.4), both of which were significantly lower than preoperative IOP and AGM ($P < 0.001$). Postoperative LogMAR BCVA was 1.04 ± 0.7 95% CI (0.7, 1.3) and this was not statistically significant in comparison to preoperative BCVA 1.17 ± 0.7 95% CI (0.8, 1.5) ($P = 0.4$) [Table 4].

Hypertensive phase was noted in 9 (47.4%) out of the 19 eyes; two eyes showed resolution of hypertensive phase, with a further two showing signs of resolution, and AGM was stepped down as the bleb around the plate appeared more diffuse. Hypertensive phase was noted most commonly at the 3-month visit and started showing signs of resolution at the 6-month visit.

Postoperatively suture lysis was required in three eyes, two were done through laser, and one eye needed an operative forceps removal.

Table 5 enlists the complications that occurred postoperatively. Four eyes had blood clots in the early postoperative period (<3 months), and one eye developed a fibrin membrane; all resolved on conservative management. Late complication beyond 3 months was seen in one eye with ICE syndrome which developed corneal edema and has had a DSEK. None of the eyes developed loss of visual perception. One eye with ICE syndrome developed unrelated vitreous hemorrhage secondary to vein occlusion and had anti-VeGF injection along with pan-retinal photocoagulation.

Outcomes

Complete success was seen in 11 eyes (57.9%). Qualified success was seen in a further six eyes (31.6%); hence, the total success was 89.5%. Failure was seen in two eyes (10.5%); both due to uncontrolled IOP; one eye underwent transscleral diode cyclophotocoagulation following which IOP is controlled without AGM and BCVA is stable.

Discussion

The use of GDDs has increased in recent times and this also seems to have been validated by the outcomes reported in the Tube versus Trab study.[9] GDD used in the study was the nonvalved BGD. Even before that, increase in use of GDD was evident not only in anonymous surveys of the members of the American Glaucoma Society in 2002 and 2008[10,11] but also in published data obtained from Medicare. Between 1994 and

Table 2: Intraocular pressure trend and number of antiglaucoma medications required for control of intraocular pressure in the follow-up period

	Preoperative	Postoperative Day 1	Postoperative Week 1	Postoperative Week 6	Postoperative 3 months	Postoperative 6 months	Postoperative 1 year	Last follow-up
IOP (mmHg), mean±SD	36.9±11.1	25.7±10.3	17.8±8.3	11.5±8.7	14.8±5.6	12.8±3.9	12.7±3.7	12.0±4.5
P		0.004	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001
AGM, mean±SD	4±0.8	NA	1.7±1.3	1.1±1.3	1.2±1.3	1.3±1.2	0.8±1.2	0.8±1.2
P			0.001	<0.001	<0.001	<0.001	<0.001	<0.001
n	19	17	19	19	19	14	13	19
		n=2 GAT avoided due to epithelial defect*						

IOP: Intraocular pressure, AGM: Antiglaucoma medication, SD: Standard deviation, GAT: Goldmann applanation tonometry

Table 3: Visual acuity outcomes in phaco-Aurolab Aqueous Drainage Implant

VA	Preoperative (%)	Last follow-up (%)
20/20-20/40	0	4 (21.1)
20/50-20/200	10 (52.6)	9 (47.3)
20/200-20/400	1 (5.3)	0
<20/400	8 (42.1)	6 (31.6)

VA: Visual acuity

Table 4: Summary of preoperative and postoperative characteristics

	Mean IOP±SD (mmHg) 95% CI	Mean AGM±SD 95% CI	VA LogMAR±SD 95% CI
Presurgery	36.9±11.19 (31.6-42.2)	4±0.8 (3.6-4.4)	1.17±0.7 (0.8-1.5)
Mean follow-up at 14.4 months	12.0±4.5 (9.6-14.0)	0.8±1.2 (0.2-1.4)	1.04±0.7 (0.7-1.3)
P (*t*-test)	<0.001	<0.001	0.427

VA: Visual acuity, SD: Standard deviation, CI: Confidence interval, IOP: Intraocular pressure, AGM: Anti-glaucoma medication, LogMAR: Logarithm minimum angle of resolution

Table 5: Postoperative complications – early and late

Postoperative complications	*n* (%)	Management
Early (up to 3 months)		
Blood clots	4 (21.0)	Conservative
Fibrin membrane	1 (5.3)	Conservative
Late (>3 months)		
Corneal edema	1 (5.3)	Corneal transplant
Vitreous hemorrhage	1 (5.3)	Retinal laser, anti-VeGF injection
Total	7 (36.8)	

VeGF: Vascular endothelial growth factor

2012, Medicare claims in the US show a decline in the number of claims for trabeculectomy, with a concomitant increase in GDD implantation by 410%.[12] As their safety and efficacy have been established, they are also more frequently being combined with cataract surgery when refractory glaucoma coexists with lens opacity.[5,7]

Furthermore, in a large study of 978 eyes by Molteno *et al.*, which compared long-term results of primary trabeculectomy ($n = 718$) with the other non-valved device called the Molteno implant ($n = 260$) for primary open-angle glaucoma, the latter had superior IOP control. Though 24% ($n = 63$) of eyes receiving Molteno implant also had cataract surgery at the time of GDD implantation, a sub-group analysis of these eyes that received the drainage implant with cataract surgery, was not done by the authors.[13]

Our study used the nonvalved AADI, which has been made available only recently; so far there have been no studies reporting combined surgery with this new, indigenously manufactured GDD along with phacoemulsification in a

cohort of adults with refractory glaucoma and cataract. Indeed, there have been no published reports of the outcomes of this implant in adult refractory glaucoma, except one.[14] BGD 350 is the design inspiration for AADI and it offers an alternative in terms of cost-effectiveness in the developing world, where BGD (or Molteno) is either unavailable or more expensive.

There are a few retrospective studies which have found the technique of combining CE with either BGD or AGV to yield good IOP control, reduction in the use of AGM along with satisfactory visual outcome.[5-8]

The patients in our cohort were mostly complicated secondary glaucomas; even primary glaucomas included were refractory to treatment. Despite this, our study reveals a statistically significant decrease in IOP and AGM at every visit postoperatively. Total success at the end of 14.4 months of follow-up was 89.5% which is comparable to other studies where BGD was combined with cataract surgery.[6] We achieved 57.9% complete success, and this is comparable to the study conducted by Chung *et al*.[5] where the outcomes of combined phacoemulsification and either BGD or AGV (16 in each group) were reported in Asian eyes with refractory glaucoma. BGD group had a complete success rate of 63%. However, the failure rate was lower in our study (10.5% vs. 24%) probably due to a difference in etiology of glaucoma.

In our study, we found that 42.1% of eyes had improved VA, and one out of four, eye had improvement in VA of 20/40 or better. This is comparable to the study by Hoffman *et al*. where postoperative visual acuity at last follow-up was ≥20/40 in 12 of 33 patients (36%), whereas Chung *et al*. reported improvement in VA in 72%, with 69% of patients having final visual acuity of 20/40 or better. However, preoperative VA, number of previous surgeries and whether improvement in VA was in AGV or BGD group, has not been mentioned by the authors. Nonetheless, this difference in visual acuity may be explained by the fact that most of our patients had an underlying disease with limited visual potential preoperatively. This notwithstanding, none of the eyes in our study lost perception of light, and all eyes with poor VA preoperatively had maintenance of navigational vision postoperatively.

Hypertensive phase was noted in 9 (47.4%) out of the 19 eyes, and two eyes showed subsequent resolution; a further two eyes showed signs of resolution at last follow-up. This was seen in a much higher proportion than what was reported by Chung *et al*.[5] where hypertensive phase was seen in a total of seven eyes (22%) with the longest episode lasting 6 months in onepatient. We found that the proportion of eyes with hypertensive phase was higher when compared to nonvalved GDD surgery alone[14,15] and appeared to be more severe and prolonged. This phenomenon is likely due to persistence of inflammation for a longer duration in the postoperative period akin to when phaco is combined with trabeculectomy.[16] Thus, it is likely that inflammatory factors persist in the AC well beyond ligature autolysis at 5–6 weeks, with resultant hypertensive phase much later in the postoperative period. Predictably, we noticed that the onset of hypertensive phase was 3 months with resolution, or signs of resolution, at the 6 months postoperative visit.

We encountered early postoperative complications in five eyes. However, they were not alarming – (blood clots and fibrin membrane) and were managed conservatively. With the surgical technique followed meticulously, none of the eyes developed hypotony, shallow AC or choroidal effusion; Chung *et al*. reported hypotony in 4 of the 16 cases. At 6 weeks, if the IOP continued to be high on AGM, then it was presumed that autolysis of ligature was delayed and laser suturelysis was undertaken – this was required in 3 eyes. Laser suture lysis failed in one case; this was then removed in the operating room with forceps after exposure with a 2 mm conjunctival incision, approximately 8 mm posterior to the limbus. Conjunctiva was then sutured with 8-0 vicryl. Late complications were seen in two eyes – one had corneal edema due to decompensation in ICE syndrome and one eye encountered vitreous hemorrhage due to an unrelated vein occlusion.

As is inherent in all retrospective studies, ours too has limitations. Other limitations of this study are small sample size and relatively short follow-up. However, to the best of our knowledge with no available literature on this procedure, it describes a promising technique of combining an indigenously manufactured new nonvalved GDD with cataract surgery in refractory glaucomas with cataract, who would otherwise have a higher risk of failure if a conventional phacotrabeculectomy were to be performed.

Conclusion

We conclude that AADI when combined with CE in eyes with advanced refractory glaucoma and cataract appears to be an effective and safe technique. A slightly higher proportion of eyes encounter hypertensive phase, when compared to non-valved GDD surgery alone. However, larger studies with longer follow-up are recommended to ascertain long-term benefits for such patients with cataract and refractory glaucoma.

What was known

- In cases of coexisting cataract and refractory glaucoma, CE with posterior chamber IOL can be combined effectively and safely with AGV and BGD.

What this paper adds

- CE with posterior chamber IOL can also be combined effectively and safely with a new indigenously manufactured nonvalved GDD, AADI, in cases of refractory glaucoma with cataract, thus, providing an economical alternative especially for low-to-mid income developing and newly industrialized countries.

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Conflicts of interest

There are no conflicts of interest.

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