Complications of Baerveldt Glaucoma Drainage Implants

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Objectives: To report the incidence and identify risk factors of postoperative complications after Baerveldt glaucoma drainage implantation.

Methods: A retrospective review of the medical records of all patients at the Bascom Palmer Eye Institute, Miami, Fla, who underwent placement of a Baerveldt glaucoma drainage implant from October 1, 1992, through October 31, 1996, to determine demographic characteristics, preoperative and postoperative intraocular pressures, and complications. Variables were analyzed using the Student t test and Fisher exact test to determine the association between delayed postoperative suprachoroidal hemorrhage and various potential risk factors.

Results: A total of 107 eyes of 103 patients were identified. Suprachoroidal hemorrhage occurred in 4 eyes (4%), with onset ranging from 3 to 33 days after implantation. Two eyes (2%) had choroidal effusions requiring surgical drainage, and 20 eyes (19%) had low choroidal effusions requiring only close observation. Tube blockage was observed in 5 eyes (5%). Four eyes (4%) had aqueous misdirection, 2 eyes (2%) had corneal decompensation, and 1 eye (1%) each had endophthalmitis, tube migration, corneal ulcer, hyphema, and implant migration. Patients who were older (P = .04) or had postoperative choroidal effusions (P = .03), low intraocular pressure immediately after the tube opened (P = .03), hypertension (P = .08), or atherosclerosis (P = .09) were more likely to develop suprachoroidal hemorrhage.

Conclusions: A lower incidence of serious postoperative complications was observed in Baerveldt implantations in this study when compared with a recent report. Risk factors for serious complications were similar to trabeculectomy.


AQUEOUS humor drainage devices such as the Baerveldt implant are used in the surgical management of complicated glaucoma. Indications for using the Baerveldt drainage implant include a previously failed filtering procedure, conjunctival scarring from trauma or previous ocular surgery, neovascular glaucoma, uveitis, epithelial down-growth, and iridocorneal endothelial syndrome. Encouraging results of successful outcome with the use of Baerveldt implants have been reported, however, the incidence of complications related to this aqueous humor drainage device remains undetermined and is based on small sample sizes.

We retrospectively reviewed the postoperative course of all patients who had undergone a Baerveldt implant at the Bascom Palmer Eye Institute from October 1, 1992, to October 31, 1996. Four patients underwent bilateral implantations and the results of both eyes were included in the data. We included patients who had undergone concomitant pars plana vitrectomy or penetrating keratoplasty. Of the 107 eyes in our review, 13 eyes (12%) underwent combined Baerveldt implant placement and vitrectomy and 2 eyes (2%) had combined Baerveldt implant placement and penetrating keratoplasty. Patient characteristics are summarized in Table 1. The preoperative IOP (mean ± SD) and ocular medications were 31.1 ± 9.7 (range, 11-64 mm Hg; median, 31 mm Hg), and 2.0 ± 0.8 (range, 0-4 medications; median, 2), respectively. The length of follow-up in months was 12.5 ± 12.4 (range, 0.3-57; median, 7.3). The postoperative IOP and ocular medi-
SUBJECTS AND METHODS

A computerized search of surgical patients at the Bascom Palmer Eye Institute identified all patients who had received a Baerveldt glaucoma drainage implant from October 1, 1992 through October 31, 1996. The study protocol (protocol 95/209) was approved by the Institutional Review Board of the University of Miami School of Medicine prior to our review of the medical records. All operations were performed by one of the glaucoma faculty at our institution.

All medical records were reviewed to determine patient demographic, preoperative, intraoperative, and postoperative data. Ocular diagnoses, prior ocular procedures, and preoperative and postoperative intraocular pressures (IOP) were recorded to identify potential risk factors for complications. All patients who had concomitant trabeculectomy were excluded. Muscle imbalance was not examined in our series.

A similar surgical technique was used in all patients for placement of a 350-mm² Baerveldt implant. A supertemporal 5 clock hour conjunctival peritomy was performed and a relaxing incision was placed at the inferiormost extent of the incision. The adhesions between the conjunctiva and sclera were lysed with blunt dissection in the superotemporal quadrant in preparation for placement of the implant. The lateral and superior rectus muscles were isolated using muscle hooks. A 350-mm² Baerveldt glaucoma drainage implant was placed beneath the belly of the lateral and superior rectus muscle complex under direct visualization. Two interrupted No. 9-0 nylon sutures fixed the implant to the sclera. The tube was tied off at the junction between the tube and the plate with 910 polyglyactin suture to minimize immediate postoperative hypotony. A 30-gauge cannula was inserted at the end of the distal tube to confirm watertight closure. The tube was cut to the appropriate length with the bevel of the tube facing anteriorly. A 23-gauge needle was used to enter the anterior chamber at the posterior limbus and parallel to the iris plane. The tube was inserted through the needle tract and its position was checked. Donor sclera was measured to appropriate length and width and placed over the top of the Baerveldt tube. The sclera was sutured in place with 4 interrupted No. 7-0 910 polyglyactin sutures at the corners. The conjunctiva was reapproximated to its normal anatomical position using 910 polyglyactin suture with a running closure at the inferotemporal position and a single interrupted suture at the supertemporal position.

All patients were examined at postoperative day 1, postoperative week 1, and postoperative month 1. Dilated funduscopic examination was performed using indirect ophthalmoscopy at these intervals to check for choroidal effusions. Subsequent examinations were performed at the physician’s discretion.

Statistical analyses were performed to evaluate potential risk factors for suprachoroidal hemorrhage (SCH). Continuous variables (age, number of previous intraocular surgeries, preoperative IOP, IOP at the first visit after ligature release, difference between preligature-release and postligature-release IOP, and IOP after ligature release) were evaluated using an unpaired, 2-tailed Student t test. Categorical variables (aphakia or pseudophakia, history of previous pars plana vitrectomy, postoperative choroidal effusion, systemic hypertension, atherosclerosis, and diabetes mellitus) were evaluated using a Fisher exact test and odds ratios were calculated. A 95% confidence interval was determined for each potential risk factor.

| Table 2 | The time of onset ranged from 3 to 33 days with a mean of 18 days. There was a bimodal distribution in the time of onset of SCH, with 2 patients in the first week and the other 2 patients at about 4 weeks. Three of the patients required only close observation and 1 patient required surgical drainage. The risk factors for the occurrence of SCH are summarized in Table 3. Age (P = .04), opening IOP (P = .07), postoperative hypotony (P = .03), choroidal effusion (P = .03), hypertension (P = .08), and atherosclerosis (P = .09) were found to be associated with the occurrence of SCH.

COMMENT

Artificial aqueous humor drainage devices such as the Baerveldt implant provide an effective means of achieving long-term IOP reduction in refractory glaucoma. The success rate of such devices compared with traditional filtering procedures is excellent in groups that are at high risk for failure; however, related complications exist and can be devastating. In general, the complication rates are usually higher when compared with standard trabeculectomy, partly owing to patients having more severe ocular disease. Moreover, certain complications are unique to implantation.

The Baerveldt implant has a rate of posterior segment complications associated with it of 12% to 48%. Other devices, such as the Molteno implant (single or double plate) or the Krupin disc valve, have a rate of retinal complications of 14% to 50% and 38% to 40%, respectively. In a more recent series of 38 eyes that underwent aqueous humor shunt procedures, 83% had retinal complications. The high percentage of retinal complications in that report was evenly distributed among the 3 types of aqueous shunt devices (4 Baerveldt implants, 4 Molteno implants, and 4 Krupin disc valves).
In our series, only 29% of eyes had retinal complications (retinal detachment, SCH, or choroidal effusions).

One of the most devastating complications in ophthalmic surgery is the occurrence of SCH, either intraoperatively or postoperatively. The incidence of intraoperative SCH is 0.2% in cataract extraction and 2% in trabeculectomy. In the Fluorouracil Filtering Surgery Study, 6.2% of the eyes developed delayed postoperative SCH. In 2 previous reports of 36 eyes and 37 eyes, only 3% (1 eye) in each series had SCH in the postoperative period following placement of the 350-mm² Baerveldt implant. However, a much higher rate of SCH (8% of eyes) was reported in a recent publication. In our series, the incidence of SCH was 4% (4 eyes), which is slightly lower than for trabeculectomy in the 5-fluorouracil study, but slightly higher than reported by Lloyd et al. and Sidoti et al. In all of the eyes in our study with SCH, it occurred in the postoperative period ranging from 3 to 33 days and took on a bimodal distribution. We hypothesize that this bimodal distribution (immediately after and 1 month after surgery) is related to the 2 times at which the IOP might be at its lowest. Immediately after surgery, there may be leakage around the tube causing hypotony and choroidal effusions, which predisposes the eye to develop SCH. One month postoperatively, when the ligature dissolves, the IOP also falls suddenly to very low levels in some eyes, despite the formation of a fibrous capsule. In addition, variables such as preoperative IOP and the magnitude of change in IOP between preoperative and postoperative levels have been found to be related to the development of SCH.

The pathogenesis of SCH is thought to be mechanical stress on the posterior ciliary arteries by the choroidal effusions due to hypotony. Furthermore, high severe or hemorrhagic choroidal detachment may result in apposition and adherence of the retina leading to retinal detachment; this was observed in 1 patient in our series. A rapid and large change in preoperative and postoperative IOPs has been found to be a risk factor for developing SCH in Molteno implant placement and in trabeculectomy with 5-fluorouracil. In our patients who developed SCH, the mean change in IOP was 16.0 mm Hg following ligature release, compared with 20.7 mm Hg in patients who did not have SCH. This change in IOP was not found to be a contributing factor to the development of SCH.

The number of prior ocular surgeries, status of the lens, and history of vitrectomy may also play a role in developing SCH. Aphakia and intraoperative vitrectomy have been shown to be significantly associated with SCH. Of the 4 eyes with SCH in the current study, 3 were pseudophakic and 1 was aphakic. Two of these eyes had previous vitrectomy, yielding an odds ratio of 2.7. However, statistical significance was not reached, possibly because of the small number of patients in the SCH group. Prior ocular surgeries may also be a risk factor, as previously reported. In our study, the mean number of prior ocular surgeries was 1.8 in the patient with SCH compared with 1.7 in the patient without SCH. Again, no statistically significant difference was noted (Table 3). Previous reports have shown that hypertension and/or atherosclerosis are risk factors for developing SCH. The current study also suggests an association between SCH and hypertension or atherosclerosis.

The rate of SCH in our study was lower compared with that in the series by Law and associates. We speculate that the main reason for this difference lies in our technique of controlling postoperative IOP. We completely ligate the proximal part of the Baerveldt tube with a No. 7-0 polyglactin suture and test for watertightness prior to placing the tube in the anterior chamber. We then use a 23-gauge needle to make an opening for the tube into the anterior chamber, creating a near-

**Table 1. Characteristics of 103 Patients and 107 Eyes**

<table>
<thead>
<tr>
<th>Demographics of Patients</th>
<th>Values</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, mean ± SD, y (range)</td>
<td>64.6 ± 23.7 (2-95)</td>
</tr>
<tr>
<td>Race*</td>
<td></td>
</tr>
<tr>
<td>Hispanic</td>
<td>52</td>
</tr>
<tr>
<td>White</td>
<td>47</td>
</tr>
<tr>
<td>Black</td>
<td>3</td>
</tr>
<tr>
<td>Other</td>
<td>1</td>
</tr>
<tr>
<td>Types of glaucoma†</td>
<td></td>
</tr>
<tr>
<td>Open-angle</td>
<td>54 (51)</td>
</tr>
<tr>
<td>Angle-closure</td>
<td>14 (13)</td>
</tr>
<tr>
<td>Neovascular</td>
<td>13 (12)</td>
</tr>
<tr>
<td>Congenital</td>
<td>7 (7)</td>
</tr>
<tr>
<td>Traumatic</td>
<td>5 (5)</td>
</tr>
<tr>
<td>Uveitic</td>
<td>5 (5)</td>
</tr>
<tr>
<td>Pigmentary</td>
<td>3 (3)</td>
</tr>
<tr>
<td>Secondary</td>
<td>2 (2)</td>
</tr>
<tr>
<td>Pseudoexfoliation</td>
<td>1 (1)</td>
</tr>
<tr>
<td>Juvenile</td>
<td>1 (1)</td>
</tr>
<tr>
<td>Iridocorneal endothelial</td>
<td>1 (1)</td>
</tr>
<tr>
<td>Mixed-mechanism</td>
<td>1 (1)</td>
</tr>
</tbody>
</table>

* Values are expressed as number of patients.
† Values are expressed as number of eyes (percent).

**Table 2. Clinical Characteristics of Eyes With Suprachoroidal Hemorrhage**

<table>
<thead>
<tr>
<th>Patient No.</th>
<th>IOP, mm Hg</th>
<th>Visual Acuity</th>
<th>Day of Hemorrhage</th>
<th>Treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Preopening</td>
<td>Opening</td>
<td>Final</td>
<td>Preoperative</td>
</tr>
<tr>
<td>1</td>
<td>20</td>
<td>6</td>
<td>16</td>
<td>20/40</td>
</tr>
<tr>
<td>2</td>
<td>30</td>
<td>8</td>
<td>20</td>
<td>20/40</td>
</tr>
<tr>
<td>3</td>
<td>24</td>
<td>0</td>
<td>4</td>
<td>20/40</td>
</tr>
<tr>
<td>4</td>
<td>12</td>
<td>8</td>
<td>11</td>
<td>20/200</td>
</tr>
</tbody>
</table>

* IOP indicates intraocular pressure; pre-opening, IOP at office visit immediately prior to ligature release; opening, IOP at office visit immediately after ligature release; HM, hand motion; LP, light perception; and day of hemorrhage, number of days after implant surgery that hemorrhage occurred.
The incidence of post trabeculectomy endophthalmitis ranges from 0.2% to 9.6%,24,25 depending on the use of antimetabolites and the position of the bleb.

Our series had relatively fewer patients with diagnoses of neovascular (17%-100%) or inflammatory glaucomas (11%-14%) when compared with other series.2,11,18 The lower incidence of posterior segment complications in our study may reflect these differences. Eyes with neovascular or inflammatory glaucomas are generally considered to be sicker eyes; hence, a smaller number of these patients may have introduced a bias for lower complication rates in the current series of patients. However, these diagnoses have not been specifically identified as risk factors for SCH in prior series.

The current study demonstrates a lower rate of SCH and choroidal effusions than previously reported.11 We advocate complete ligation of the Baerveldt tube and the use of a 23-gauge needle tract for insertion of the tube to avoid high rates of retinal complications. The development of SCH may be multifactorial. Patients at particular risk for SCH include older patients with hypertension or atherosclerosis. Postoperative hypotony, which may lead to choroidal effusions and/or SCH, should be avoided if possible, as these also predispose the eye to SCH. There is probably nothing specific about the Baerveldt implant in comparison with similar devices in terms of avoiding complications, as long as it is possible to ensure that hypotony does not develop postoperatively. When the technique described in this study is used, the Baerveldt glaucoma drainage implant procedure has a complication rate comparable to trabeculectomy and other glaucoma drainage implant procedures.

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REFERENCES


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