Glaucoma Drainage Devices: Risk of Exposure and Infection

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• PURPOSE: To identify risk factors for device exposure and intraocular infection following implantation of a glaucoma drainage device.
• DESIGN: Retrospective case series.
• METHODS: The medical records of adult patients undergoing glaucoma drainage device implantation at an academic medical center between 2000 and 2010 were reviewed. Main outcome measures included device exposure and intraocular infection.
• RESULTS: Seven hundred and sixty-three cases were identified. These included 702 primary implants (ie, the first drainage device implanted into an eye) and 61 sequential implants. Among 702 primary implants, there were 41 cases of exposure (5.8%). None of the potential risk factors were statistically significant. Implant location was found to be a marginally significant risk factor. The exposure rates for inferior and superior implants were 12.8% (5 of 39) and 5.4% (36 of 663), respectively ($P = .056$). The highest rate of exposure for primary implants occurred in the inferior-nasal quadrant (17.2%, 5 of 29). The rate of exposure for sequential devices was 13.1% (8 of 61), with the highest rate also found in the inferior-nasal quadrant (20%, 5 of 25). Of 49 total exposures, 8 were associated with intraocular infection (16.3%). Exposures over inferior implants were more likely to be associated with infection than exposures over superior implants (41.7% vs 8.1%; $P = .0151$).
• CONCLUSION: Implant location approached, but did not reach, statistical significance as a risk factor for exposure. Exposures over inferior implants place patients at a higher risk of infection than superior exposures. More studies are needed to identify modifiable risk factors for device exposure. (Am J Ophthalmol 2015;160(3): 516–521. © 2015 by Elsevier Inc. All rights reserved.)

GLAUCOMA DRAINAGE DEVICES REPRESENT AN important surgical treatment option to bypass the dysfunctional anterior chamber angle in refractory glaucoma. The utilization of drainage devices has increased in recent years, since they have been found to be comparable to trabeculectomy for intraocular pressure (IOP) control and duration of benefit.[1]

These devices place patients at risk for unique complications related to the implantation of a foreign body on the surface of the eye. One particular risk is exposure of the glaucoma drainage device. The estimated incidence of exposure ranged from 0 to 12% in a meta-analysis of 38 studies that included 3255 eyes.[2] The Tube Versus Trabeculectomy study noted a 5% device exposure rate over 5 years.[3]

The most significant complication related to exposure is endophthalmitis. Most cases of endophthalmitis are late in nature and related to tube exposure. The reported rate of endophthalmitis following glaucoma drainage device implantation ranges from 0.8% to 6.3% with a mean of 2%.[4] A 9-year retrospective review reported an endophthalmitis rate of 1.7% following implantation of Ahmed drainage devices in 542 eyes.[5] In this study, exposure was a significant risk factor for endophthalmitis. Another study identified 4 cases of delayed-onset endophthalmitis following glaucoma drainage device implantation. All infections were related to exposure.[6]

Few risk factors for exposure have been identified. The purpose of this study is to identify risk factors for glaucoma drainage device exposure and to evaluate rates and risk factors for endophthalmitis.

METHODS

THIS STUDY IS A RETROSPECTIVE REVIEW OF THE MEDICAL records of all patients who underwent glaucoma drainage device implantation surgery at the Emory Eye Center between January 1, 2000, and December 31, 2010. Patients who were 18 years or older on the date of surgery were included for analysis. This retrospective review was approved by Emory University's Institutional Review Board and adhered to the tenets of the Declaration of Helsinki.

All glaucoma drainage device implantations were performed by either 1 of 5 attending physicians or a glaucoma fellow under direct supervision. For anterior chamber entry, the tubes were trimmed bevel-up. A 23 gauge needle was used to create an incision site for entry into the anterior

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chamber. The entry site was typically 1-2 mm from the limbus in the designated quadrant. The needle was passed in a manner to create a shelved opening in the sclera with entry into the anterior chamber at the limbus. The tube was inserted through this opening parallel to the iris and away from the corneal endothelium.

A search of the surgical database was used to identify patients that underwent glaucoma drainage device implantation during the study period. Distinction was made between primary devices (ie, the first device to be implanted into an eye) and sequential devices. In patients that received more than 2 implants in a single eye, data pertaining to the third or fourth implant were not included for analysis. It was proposed that having multiple glaucoma drainage devices in a single eye may itself be a risk factor for exposure. For this reason, primary and sequential devices were analyzed separately. All cases of exposure, regardless of whether they occurred in primary or sequential glaucoma drainage devices, were grouped together to study the risk of associated intraocular infection.

Studied risk factors included age, sex, race, implant location, patch graft material, device model, type of glaucoma, and number of prior incisional ocular surgeries. Implant locations included the superior-temporal, superior-nasal, inferior-temporal, and inferior-nasal quadrants. Patch graft materials included pericardium, sclera, and cornea. Device models included Ahmed FP7, Ahmed S2 (New World Medical, Rancho Cucamonga, California, USA), and Baerveldt (Advanced Medical Optics, Santa Ana, California, USA). Types of glaucoma included open-angle glaucoma (OAG), chronic angle closure glaucoma (CACG), inflammatory glaucoma, neovascular glaucoma (NVG), and traumatic glaucoma. Patients with multiple glaucoma diagnoses were placed in the "other" category. The number of previous ocular surgeries was stratified into "1," "2," "3," and "4 or more." For statistical purposes, age at the time of surgery was dichotomized at the median value of 61 years.

Clinical outcomes included device exposure and intraocular infection. Intraocular infection included cases of frank endophthalmitis as well as cases of suspected endophthalmitis in which there was sufficient clinical concern to warrant treatment with intravitreal antibiotics. Diagnoses of intraocular infection were made clinically and included cases for which no pathogen was isolated. Patient follow-up ended at the patient's last recorded clinic visit in the study period. In some cases, patients were seen at outside offices in addition to the Emory Eye Center. Outside records were used for data collection when available.

Kaplan-Meier survival curves were constructed to estimate device exposure rates vs time since surgery for each clinical variable. Comparisons between categories were made using the log-rank test. Each subject that did not experience exposure was censored at the last date of follow-up within the study period. The rate of intraocular infection at the time of exposure was compared for superior implants vs inferior implants using Fisher exact test. A 5% significance level was set to determine statistical significance. Fisher exact test was performed to assess whether a correlation existed for patients that underwent implantation in both eyes. This test was performed to verify that exposure in the second eye to undergo surgery was independent of the first eye. Statistical analysis was performed using SAS v 9.2 (Cary, North Carolina, USA).

RESULTS

A REVIEW OF THE MEDICAL RECORD IDENTIFIED 799 glaucoma drainage devices that met the inclusion criteria. Thirty-six cases (4.5%) were excluded owing to inaccessible medical records. A total of 763 devices were included for analysis. Of these, 702 were primary implants and 61 were sequential implants. Primary and sequential devices were considered separately. The Table contains the summary statistics for overall demographic and clinical characteristics and the results of a univariate risk factor assessment for primary and sequential glaucoma drainage device exposure.

The 702 primary devices were implanted in 702 eyes of 625 patients with a mean length of follow-up of 34.0 ± 26.1 months. The vast majority were implanted into the anterior chamber (682, 97.2%). Fourteen (2.0%) were placed posterior to the iris and 6 (0.9%) were inserted through the pars plana. The mean patient age at the time of surgery was 59.3 ± 16.1 years. The majority of devices were implanted in African American (333, 50.8%) and white (288, 44.0%) patients. The mean number of prior incisional ocular surgeries was 1.62 ± 1.33.

Open-angle glaucoma (182, 26.1%) was the most common diagnosis for patients in this study. The remaining glaucoma diagnoses included inflammatory glaucoma (20.6%), CACG (19.5%), NVG (14.6%), traumatic glaucoma (6.3%), and "other" (12.9%).

Ahmed devices constituted the majority of implants with 345 Ahmed FP7 models (51.0%) and 107 Ahmed S2 models (15.8%). Baerveldt models were used in 219 (32.4%) of the procedures performed in this study. Other models were used in less than 1% of cases. Patch graft materials included pericardium (381, 55.1%), sclera (209, 30.2%), cornea (98, 14.2%), and "other" (14, 0.6%).

Most primary devices were implanted superiorly (663, 94.4%) with a smaller number being placed inferiorly (39, 5.6%). By quadrant, devices were implanted superior-temporally (653, 93.0%), superior-nasally (10, 1.4%), inferior-temporally (10, 1.4%), and inferior-nasally (29, 4.1%).

Three hundred and sixty-one drainage devices were implanted into the right eye, and 341 devices were implanted into the left eye. Seventy-seven patients received implants in both eyes. Fisher exact test was conducted to assess whether exposure in the first eye to