HHS Public Access

Author manuscript

Am J Ophthalmol. Author manuscript; available in PMC 2016 September 01.

Published in final edited form as:

Am J Ophthalmol. 2015 September ; 160(3): 516–521.e2. doi:10.1016/j.ajo.2015.05.025.

Glaucoma Drainage Devices: Risk of Exposure and Infection

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Abstract

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 2000–2010 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 (5.8%) cases of exposure. 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=0.056). 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, eight 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=0.0151).

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.

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Financial Disclosures: no financial disclosures

Introduction

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 five 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 four 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 either by one of five 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 chamber. The entry site was typically 1 to 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 two 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, gender, 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, CA), and Baerveldt (Advanced Medical Optics, Santa Ana, CA). 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 utilized for data collection when available.

Kaplan-Meier survival curves were constructed to estimate device exposure rates versus 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 versus inferior implants using Fisher’s exact test. A 5% significance level was set to determine statistical significance. Fisher’s 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, NC).

Results

A review of the medical record identified 799 glaucoma drainage devices that met the inclusion criteria. Thirty-six cases (4.5%) were excluded due 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. Table 1 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 six (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 (51.0%) Ahmed FP7 models and 107 (15.8%) Ahmed S2 models. Baerveldt models were utilized in 219 (32.4%) of the procedures performed in this study. Other models were utilized 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’s exact test was conducted to assess whether exposure in the first eye to undergo operation impacted the risk of exposure in the second eye for patients that underwent drainage device implantation in both eyes. Four exposures occurred in each group, with one patient experiencing exposure in both eyes (p=0.1957).

Forty-one (5.8%) primary devices exposed during the study period. The mean time-to-exposure was 25.0 ± 21.3 months. Three exposures occurred in the first postoperative month which constituted 7.3% of the exposure group and 0.4% of all implants.

Exposure occurred most commonly over the tube (87%). Three exposures (7.3%) were noted over the plate. One (2.4%) exposure occurred over the Hofman elbow of a Baerveldt device. The site of one exposure could not be determined from the chart.

At a 5% significance level, none of the factors being evaluated put patients at a significantly higher risk of exposure. Implant location and patch graft material approached statistical significance.

The highest rate of exposure for primary devices was seen in those implanted in the inferior-nasal location where 5 of 29 (17.2%) devices exposed. The exposure rate for all inferiorly-placed devices was 12.8% compared to 5.4% for superior devices (p=0.056).

In the analysis of patch graft materials, exposure rates were highest for implants covered with cornea (9.2%) and pericardium (7.9%). The exposure rate for implants covered with

scleral patch grafts was the lowest with exposure occurring in only 1 of 209 cases (0.5%). Implants covered with pericardial patch grafts had the highest average length of follow up. Mean length of follow up for pericardial, corneal, and scleral patch grafts were 44.7 months, 34.7 months, and 13.6 months, respectively. It was noted that corneal patch grafts were used more often than other materials to cover inferior implants. An analysis was conducted to determine if the increased rate of exposure with corneal patch grafts was attributable to implant location. For corneal patch grafts, inferior devices exposed more frequently than superior devices although this difference did not reach statistical significance (18.5% vs. 5.6%, p=0.0621).

Glaucoma drainage devices implanted into eyes that had undergone 4 or more previous incisional surgeries exposed more often (4 of 46, 9.5%) than those implanted into eyes with less extensive surgical histories (35 of 620, 5.6%). This risk factor was statistically insignificant (p =0.8667).

Sixty-one sequential implants were included in a separate analysis. Exposure occurred in 13.1% of this sample (8 of 61). None of the studied clinical or demographic variables were found to put these patients at a significantly higher risk of exposure. As with primary devices, inferior implants exposed more often in this sample than superior implants (15.6% vs. 6.3%, p=0.2761) with the highest rate found in the inferior-nasal quadrant (20%, 5 of 25).

Forty-nine cases of exposure were identified including both primary and sequential devices. Thirty-seven exposures occurred over superior implants, and 12 occurred over inferior implants. Intraocular infection was present at the time of exposure diagnosis in 8 cases (16.3%). Exposed inferior implants were found to be at a higher risk of infection than exposed superior implants (41.7% vs. 8.1%, p=0.0151). Cases of intraocular infection included six cases of frank endophthalmitis and two cases in which purulent material in the anterior chamber was of sufficient clinical concern to warrant treatment with intravitreal antibiotics. Three culture-positive cases of endophthalmitis included two cases of streptococcus pneumonia and one case of coagulase-negative staphylococcus.

Discussion

The rate of exposure for primary glaucoma drainage devices implanted at the Emory Eye Center between 2000 and 2010 was 5.8%. This finding is consistent with previously cited values in the literature[2, 3]. None of the investigated risk factors put patients at a significantly higher risk of exposure at the pre-determined 5% significance level.

Comparison, however, of exposure rates for superior versus inferior devices found a marginally significant (p=0.056) difference with a higher rate of exposure inferiorly. Devices implanted in the inferior-nasal quadrant had the highest rate of exposure (17.2%) which was approximately 3-times greater than the exposure rate for devices implanted in the superior-temporal quadrant (5.5%). In a separate analysis of sequential drainage devices, the highest risk of exposure was also found in the inferior-nasal quadrant (20%).

It has been suggested that inferiorly placed devices may be at higher risk of exposure due to increased exposure of the anterior portion of the patch graft and mechanical disruption from the lower lid[7]. Most surgeons prefer to place implants in the superior-temporal quadrant to maximize coverage by the upper eyelid. Conjunctival scarring or the presence of an existing implant may limit placement in this quadrant. In this study, the implant location was chosen at the discretion of the surgeon.

Two published studies directly compared superior versus inferior drainage devices. In a retrospective review of 83 eyes by Rachmiel et al[8], wound dehiscence and/or conjunctival retraction with exposure of the underlying patch graft occurred more frequently with inferior implants (28.8% vs. 9.6%, p=0.04). Given the small sample size, statistical analysis was not performed for tube or plate exposures. A prospective parallel cohort study was conducted by Pakravan et al. in which consecutive patients underwent Ahmed glaucoma valve (AGV) implantation in the superior or inferior quadrants[9]. Superior and inferior AGV implants were found to have similar efficacy, although the overall rate of complications was higher for inferior AGV implants (25% vs 5.2%, p=0.004). AGV explantation due to implant exposure occurred in 8.3% of inferior AGV versus 1.7% of superior AGV (p=0.173).

Geffen at el. reported on conjunctival complications related to AGV insertion. This study examined conjunctival dehiscence over the patch graft and exposure of the device through the overlying conjunctiva[10]. They found significantly more cases of dehiscence in the inferior-temporal quadrant when compared to the superior-temporal location (p=0.006). However, no statistical difference between quadrants was shown for device exposure rates.

The choice of patch graft material to cover the tube portion of the device also approached, but did not reach, statistical significance (p=0.072). Exposure occurred more often in tubes covered with cornea (9.2%) and pericardium (7.9%) than for tubes covered with sclera (0.5%). The high rate of exposure seen with cornea patch grafts was likely influenced by the fact that they were more frequently used to cover inferior implants. The shorter inferior fornix and lower lid allow for increased visibility of the patch graft over inferior implants, and clear cornea grafts are often chosen for cosmetic purposes. The exposure rate for superior implants covered with corneal patch grafts was comparable to the overall risk of exposure for primary implants. In comparing patch graft materials in this study, it is important to note the differences in length of follow up between groups. Pericardial patch grafts had a longer average length of follow up which may contribute to the increased risk of exposure seen in this group. A switch from pericardial to scleral patch grafts during the study period was made by the glaucoma specialists due to a concern over the exposure rate noted with pericardial grafts. The scleral patch graft group, which had the lowest rate of exposure, also had the shortest duration of follow-up.

Other studies in the literature have analyzed the relationship between patch graft material and risk of exposure. A retrospective review of pericardium, dura, and sclera for covering superiorly placed drainage devices by Smith et al.[11] showed no preference for one material over the others. However, Wigton et al. reported a significantly lower rate of exposure for glaucoma drainage devices covered with glycerol-preserved cornea versus pericardium (1.9% vs. 8.9%, p=0.0125)[12]. Gil-Carrasco et al. reported positive results with the Ahmed

glaucoma implant without a patch graft when using long-needle tracks[13]. This technique was reported after the end of our study period. We believe the long-needle track technique is of value, although superior drainage device implantation using this technique would not have been possible in many of the included cases due to prior conjunctival scarring from previous filtering surgery.

Other risk factors for exposure have been identified in the literature. A matched case-control study by Koval et al.[14] found Hispanic ethnicity, neovascular glaucoma, prior trabeculectomy, and combined surgical procedures to be significantly associated with tube exposure. Byun et al.[15] reported a higher number of previous ocular surgeries to be a risk factor for exposure. Increased number of pre-operative glaucoma medications has been associated with an increased risk of wound dehiscence and device exposure[10]. In our study, type of glaucoma and number of prior surgeries were not found to be significant risk factors for exposure. No significant difference was found between racial groups, although our patient population included only a small number of Hispanic patients.

In the setting of exposure, inferior implants were found to be at a significantly higher risk of associated intraocular infection in this study. In recent years, surgeons have avoided choosing inferior sites for trabeculectomy surgery due to the increased risk of endophthalmitis and blebitis following these procedures. The increased risk of infection following inferior trabeculectomy is believed to be due in part to pooling of the bacteria-rich tear film[16]. The tear film is known to harbor organisms capable of causing endophthalmitis[17]. Inferior drainage device exposure creates a conduit for host flora to pass into the eye. It stands to reason that when inferior devices expose in the setting of this bacteria-rich tear film, patients are at a higher risk of infection than cases in which exposures occur superiorly.

This study is limited by its retrospective nature. The small number of exposure cases limits the statistical power of this analysis, especially in the sequential implant group. Given the relatively low rate of device exposure, cases would likely need to be pooled from multiple institutions in order to obtain a large sample. Eyes that were included in this study had varied ocular histories prior to drainage device implantation and suffered a variety of post-operative complications that were unrelated to device exposure. In many cases, these eyes underwent further surgery due to post-operative complications or an inability to maintain target intraocular pressure. Additional surgery following glaucoma drainage device implantation may itself be a risk factor for exposure. The selection of patch graft material may be influenced by the location of the implant which makes it difficult to discern which factor potentially contributes to the risk of exposure. This study included data pertaining to drainage devices implanted by five different attending physicians and multiple fellows without a standardized surgical technique.

We believe that further investigation is warranted for the marginally-significant risk factors of implant location and patch graft material. The decision to stop using pericardial patch grafts during the study period may have prevented a statistically significant result for the device exposure risk in this group.

This study demonstrated that inferior exposures place patients at a higher risk of intraocular infection than exposures over superior implants. Exposure of a glaucoma drainage device subjects patients to additional surgery and increases the risk of endophthalmitis and vision loss. For these reasons, it is imperative to identify modifiable risk factors for exposure and modify surgical techniques appropriately to minimize this risk.

Acknowledgements

Funding/Support Supported in part by NIH Departmental Core Grant EY006360 and Research to Prevent Blindness, Inc, New York, New York. The sponsor or funding organization had no role in the design or conduct of this research.

Other Acknowledgments: none

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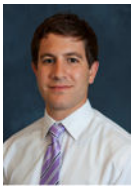
Biographies



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Am J Ophthalmol. Author manuscript; available in PMC 2016 September 01.

Table 1

Univariate Risk Factor Assessment for Primary and Sequential Glaucoma Drainage Device Exposure

Risk Factor	Number of Primary Drainage Devices (% of total)	Number of Primary Device Exposures (% of group)	p-value*	Number of Sequential Devices (% of Total)	Number of Sequential Device Exposures (% of Group)	p-value*
Age at Surgery			0.4397			0.9222
≤ 61	362 (51.6%)	20 (5.5%)		33 (54.1%)	5 (15.2%)	
> 61	340 (48.4%)	21 (6.2%)		28 (45.9%)	3 (10.7%)	
Gender			0.7828			0.5694
Female	384 (54.7%)	22 (5.7%)		34 (55.7%)	5 (14.7%)	
Male	318 (45.3%)	19 (6.0%)		27 (44.3%)	3 (11.1%)	
Race[a]			0.3269			0.8197
African American	333 (50.8%)	21 (6.3%)		31 (55.4%)	3 (9.7%)	
White	288 (44.0%)	15 (5.2%)		24 (42.9%)	4 (16.7%)	
Hispanic	13 (2.0%)	2 (15.4%)		1 (1.8%)	0 (0.0%)	
Asian	13 (2.0%)	0 (0.0%)		0 (0.0%)	0 (0.0%)	
Other	8 (1.2%)	0 (0.0%)		0 (0.0%)	0 (0.0%)	
Model[a]			0.7576			0.8575
Ahmed FP7	345 (51.0%)	13 (3.8%)		35 (58.3%)	5 (14.3%)	
Baerveldt	219 (32.4%)	14 (6.4%)		18 (30.0%)	2 (11.1%)	
Ahmed S2	107 (15.8%)	10 (9.4%)		7 (11.7%)	1(14.3%)	
Other	6 (0.9%)	0 (0.0%)		0 (0.0%)	0 (0.0%)	
Implant Location			0.0698			0.4730
Superior-temporal	653 (93.0%)	36 (5.5%)		6 (9.8%)	1 (16.7%)	
Inferior-nasal	29 (4.1%)	5 (17.2%)		25 (41.0%)	5 (20.0%)	
Inferior-temporal	10 (1.4%)	0 (0.0%)		20 (32.8%)	2 (10.0%)	
Superior-nasal	10 (1.4%)	0 (0.0%)		10 (16.4%)	0 (0.0%)	
Implant Location			0.0560			0.2761
Superior	663 (94.4%)	36 (5.4%)		16 (26.2%)	1 (6.3%)	
Inferior	39 (5.6%)	5 (12.8%)		45 (73.8%)	7 (15.6%)	
Patch Graft[a]			0.0720			0.9718
Pericardium	381 (55.1%)	30 (7.9%)		23 (37.7%)	4 (17.4%)	

Risk Factor	Number of Primary Drainage Devices (% of total)	Number of Primary Device Exposures (% of group)	p-value*	Number of Sequential Devices (% of Total)	Number of Sequential Device Exposures (% of Group)	p-value*
Sclera	209 (30.2%)	1 (0.5%)		10 (16.4%)	1 (10.0%)	
Cornea	98 (14.2%)	9 (9.2%)		26 (42.6%)	3 (11.5%)	
Other	4 (0.6%)	0 (0.0%)		2 (3.3%)	0 (0.0%)	
Glaucoma Type[a]			0.9539			0.7268
Open angle	182 (26.1%)	11 (6.0%)		18 (29.5%)	1 (5.6%)	
Inflammatory	144 (20.6%)	8 (5.6%)		8 (13.1%)	1 (12.5%)	
Chronic angle closure	136 (19.5%)	8 (5.9%)		18 (29.5%)	2 (11.1%)	
Neovascular	102 (14.6%)	5 (4.9%)		8 (13.1%)	2 (25.0%)	
Traumatic	44 (6.3%)	4 (9.1%)		4 (6.6%)	1 (25.0%)	
Other	90 (12.9%)	5 (5.6%)		5 (8.2%)	1 (20.0%)	
Prior surgeries[a]			0.8667			0.9338
0	121 (18.2%)	7 (5.8%)				
1	221 (33.2%)	11 (5.0%)		5 (9.4%)	0 (0.0%)	
2	201 (30.2%)	12 (6.0%)		13 (24.5%)	3 (23.1%)	
3	77 (11.6%)	5 (6.5%)		21 (39.6%)	3 (14.3%)	
4+	46 (6.9%)	4 (9.5%)		14 (26.4%)	2 (14.2%)	

*The p-value is for the log-rank test comparing the time-to-exposure curves among the categories of the corresponding risk factor.

[a]There were a small number of cases in which the required information could not be determined from the medical records. For these characteristics, the analyzed sample is less than the total sample.