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ORIGINAL PAPER

Bleb-related infections and long-term follow-up after trabeculectomy

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Abstract
Purpose Bleb-related infections are serious complications after trabeculectomy. They can be limited to the bleb or disseminate and lead to endophthalmitis. We herein report on all bleb-related infections that have been diagnosed at the Eye Center of the University of Freiburg, Germany, since 1999.
Methods We reviewed a total of 1816 consecutive trabeculectomies that were performed at our hospital between the years 1999 and 2014 (353 without and 1463 with intraoperative application of mitomycin C). All bleb-related infections that were diagnosed at our clinic during the same period were included in the analysis. We fitted a Cox proportional hazards model to characterize risk factors for bleb-related infections.
Results We diagnosed a total of 19 bleb-related infections in this period. Three patients with bleb-related infections that came to our clinic had their trabeculectomy performed elsewhere. The overall percentage of bleb-related infections was 0.1% after 2 years (Kaplan–Meier estimate at median follow-up). Nine eyes suffered from only localized infection of the bleb. Seven eyes developed endophthalmitis. Four infections occurred during the first postoperative month. The median age on the day of diagnosis was 71 years; the median age at surgery was 69 years. In the Cox model, intraoperative application of mitomycin C and a fornix-based conjunctival flap were identified as significant risk factors (hazard ratio: 79.02, 4.69; $p < 0.01$, $p < 0.01$). The whole group showed a reduction of visual acuity in the median from logMAR 0.12 to 0.2. Eyes that suffered from endophthalmitis showed a loss from 0.3 to 0.96, while the localized infections had a reduction from 0.04 to 0.07.
Conclusion Bleb-related infections are a rare complication following trabeculectomy and can be localized on the bleb or can lead to endophthalmitis, thereby threatening visual acuity. The risks and benefits of mitomycin C-augmented trabeculectomies should be taken into consideration.

Keywords Trabeculectomy · Blebitis · Bleb-related infection · Endophthalmitis · Mitomycin C

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Introduction

Bleb-related infections are a severe, visual acuity-threatening complication after trabeculectomy. They

can be divided into two subgroups: localized forms that focus on the bleb itself, and an infection that involves the whole eye with endophthalmitis. The widespread use of antimetabolites such as mitomycin C (MMC) and 5-fluorouracil (5-FU) since the 1990s has lowered the tendency of blebs to scar, improving the functional outcome of blebs with regard to intraocular pressure regulation [1–3]. It was shown in multiple studies that this effect is bought with higher rates of bleb-related infections. Without any augmentation, infection rates between 1978 and 1999 were reported to be within the range of 0.2–1.5% [4–7]. Following the use of 5-FU, the rate of infections rose to 0.8–13%, depending on follow-up time [4, 8, 9]. MMC augmentation lead to infection rates of 1.3–5.9% [4, 10–13]. Other risk factors that have been identified are a young age at surgery, postoperative bleb fistulation, an inferiorly located bleb, diabetes mellitus and dark-colored skin [10, 11, 14–16].

A poor functional outcome concerning visual acuity has been described previously. For example, 23–35% of patients that suffered from bleb-related endophthalmitis had no light perception after treatment of the infection [17, 18].

The broadly varying data in the literature show the need for further investigation on this topic. In this study, we present an analysis of bleb-related infections that were treated at the Eye Center in Freiburg.

Methods

The local ethics committee of the University of Freiburg approved this retrospective observational study (vote no. 226/15).

With the help of an internal database searching system, all trabeculectomies performed between 1999 and 2014 were identified. Sex, age at surgery, usage of MMC and conjunctival flap basis were documented for all eyes. The date of each patient's last visit was identified to calculate an individual follow-up time. This trabeculectomy group was compared to all bleb-related infections diagnosed at our clinic during the same period. Only eyes that underwent initial trabeculectomy at our clinic were included in the statistical analysis. For these eyes, visual acuity at the last visit before the infection, and again after rehabilitation, was evaluated. The type of infection (localized vs. endophthalmitis) and the causative organism (if identified from aqueous and/or vitreous humor) was documented. Localized infections were defined as blebs showing signs of infection without involvement of intraocular structures in the anterior chamber or the vitreous body. The usage of MMC and the conjunctival flap localization were recorded for all trabeculectomies. All infections were screened for previously reported risk factors, such as inferior bleb localization, dark skin color or bleb fistulation. Using a Kaplan–Meier estimate, the risk of developing a bleb-related infection was calculated. The influence of age at surgery, usage of MMC and the conjunctival flap basis was determined using a Cox regression model. Mean values of visual acuity were logarithmically calculated. Visual acuity is given in logMAR values.

All statistical evaluations were performed using R (R foundation for Statistical Computing) and Microsoft Excel 2011.

Results

In the examined period, a total of 1816 trabeculectomies were performed. Nineteen eyes of 19 patients presented with bleb-related infections, of whom 16 underwent trabeculectomy at our clinic. Only these 16 infections are shown in further detail in the following descriptive and statistical evaluations. The mean follow-up time for all trabeculectomies was 23 months. Table 1 shows all infection patients who had trabeculectomy performed at our clinic, subdivided into subgroups of localized infections and bleb-related endophthalmitis, as well as the whole group of trabeculectomies, including the percentage that underwent MMC application during trabeculectomy. For localized infections, we saw a reduction of visual acuity from 0.05 to 0.07, while a reduction from 0.3 to 0.96 was found in the endophthalmitis group. This indicates a reduction of 0.12–0.2 for the whole group of infections. Forty-two percent of the patients that suffered from endophthalmitis ($n = 3$) had a visual acuity of hand movement or light perception following the infection.

The bleb-related infection patients who had their trabeculectomy performed at our clinic were subdivided into localized infections and endophthalmitis, shown in Tables 2 and 3 in more detail.

Causative organisms could be identified in 37.5% ($n = 6$) of the infected eyes. In five out of seven

Table 1 Mean age (with standard error), percentage of eyes that underwent MMC application during surgery, percentage of fornix-based conjunctival flaps and mean visual acuity values before and after infection for the groups of localized infections, endophthalmitis, all infections and, if applicable, for the whole group of trabeculectomies

	Local infection ($n = 9$)	Endophthalmitis ($n = 7$)	All bleb-related infections ($n = 16$)	All trabeculectomies ($n = 1816$)
Age at surgery (years)	68.8 (3.07)	70.4 (3.37)	69.5 (2.20)	67.1 (0.288)
MMC intraoperatively	77.8% ($n = 7$)	100% ($n = 7$)	87.5% ($n = 14$)	80.6% ($n = 1463$)
Fornix-based conjunctival flap	77.8% ($n = 7$)	100% ($n = 7$)	87.5% ($n = 14$)	79.5% ($n = 1443$)
Mean visual acuity before infection (logMAR)	0.05	0.3	0.12	–
Mean visual acuity after infection (logMAR)	0.07	0.96	0.2	–
Mean period between trabeculectomy and infection (days)	531	744	637.5	–

Descriptive data on infections and all trabeculectomies

Table 2 Localized infections (Loc1–Loc9) shown with age at surgery, period until infection, intraoperative application of MMC, conjunctival flap basis, postoperative bleb fistulation and, if available, the causative organism that was identified

	Loc1	Loc2	Loc3	Loc4	Loc5	Loc6	Loc7	Loc8	Loc9
Age at surgery (years)	69	66	69	79	76	60	49	71	79
Period until infection	10.2 years	2.7 years	5.2 years	0.8 years	14 days	2.8 years	1.5 years	10 days	31 days
MMC	0.02% for 1.5 min	0.02% for 1.5 min	–	0.02% for 3 min	0.02% for 3 min	0.02% for 3 min	0.02% for 3 min	0.02% for 3 min	0.02% for 3 min
Conjunctival flap basis	Limbus-based	Limbus-based	Fornix-based	Fornix-based	Fornix-based	Fornix-based	Fornix-based	Fornix-based	Fornix-based
Causative organism	–	–	–	–	Staphylococcus aureus	–	–	–	Staphylococcus aureus
Postoperative fistulation	–	–	–	–	–	–	–	–	–

Data on localized infections

endophthalmitis cases (71.4%), a pathogen could be found. Three of these infections were caused by *Staphylococcus aureus*, and one each was caused by *Staphylococcus epidermidis*, *Staphylococcus homini* and *Streptococcus pneumoniae*. In the other eyes, no causative organism could be found on microbiological analysis, or (especially in localized infections) no microbiological analysis was performed.

In a Kaplan–Meier estimate, a 0.1% risk was calculated for developing a bleb-related infection after the mean follow-up time of 23 months (Fig. 1).

In a Cox regression model, the intraoperative application of MMC and a fornix-based conjunctival flap were found to be a statistically significant risk factor for developing a bleb-related infection ($p < 0.01$ and $p < 0.01$, respectively) (Table 4). Age at surgery had no significant influence on the risk of developing an infection.

Discussion

Our results show a 0.1% risk of developing a bleb-related infection within 2 years after trabeculectomy. The significant risk factors for developing infection were intraoperative application of MMC and a fornix-based conjunctival flap. Compared to localized infections, the reduction of visual acuity was more severe in eyes that suffered from endophthalmitis. The risk of developing an infection is, according to our data,

Table 3 Endophthalmitis eyes (End1–End7) shown with age at surgery, period until infection, intraoperative application of MMC, conjunctival flap basis, postoperative bleb fistulation and, if available, the causative organism that was identified

	End1	End2	End3	End4	End5	End6	End7
Age at surgery (years)	76	61	72	86	69	68	60
Period until infection	14 days	8.9 years	4.9 years	2 years	7 days	2.3 years	57 days
MMC	0.02% for 3 min	0.02% for 3 min	0.02% for 3 min	0.02% for 3 min	0.02% for 3 min	0.02% for 3 min	0.02% for 3 min
Conjunctival flap basis	Fornix-based	Fornix-based	Fornix-based	Fornix-based	Fornix-based	Fornix-based	Fornix-based
Causative organism	Staphylococcus aureus		Staphylococcus epidermidis		Streptococcus pneumoniae	Staphylococcus homini	
Postoperative fistulation	–	–	–	–	–	–	–

Data on generalized infections

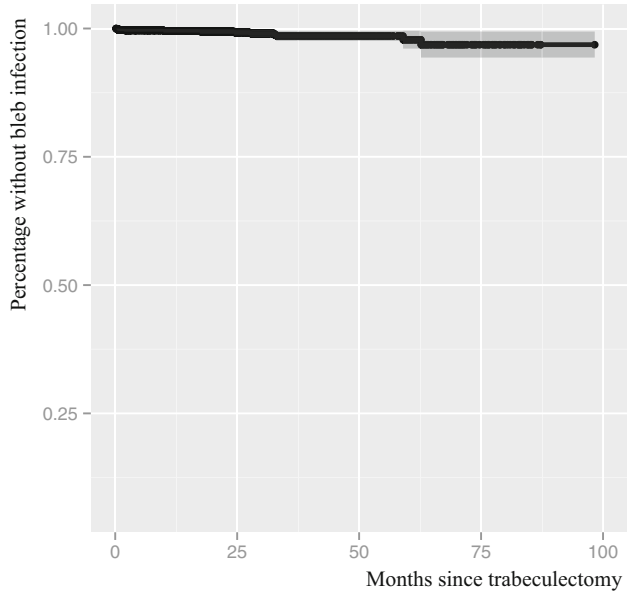

Fig. 1 Kaplan–Meier estimate for all trabeculectomies until the diagnosis of a bleb-related infection. The *x*-axis describes the months after trabeculectomy, and the *y*-axis is the percentage of eyes without infection, given in decimal scale. The dark gray area represents the 95% confidence interval. Kaplan–Meier estimate for bleb-related infections

lower than previously reported. To match these results with other studies, the risk must be viewed in relation to the follow-up time. Yamamoto et al. reported a 1.5% risk of developing an infection after 2.5 years [11]. Solomon et al. found a risk of 0.3–1.3% during the first 2 years after trabeculectomy, depending on the usage of MMC, 5-FU or no antimetabolite at all [4]. These follow-up periods almost match our follow-up time of 23 months. In a study of a group from Saudi Arabia, an endophthalmitis rate of 0.00197–0.007% after trabeculectomy was reported, but the follow-up time and the period between trabeculectomy and infection were not stated [19]. Another influence on the infection risk might arise from different concentrations of the antimetabolites used, and their application time during surgery. Almost all of our cases of infected blebs had 0.02% MMC applied for 3 min. Yamamoto et al. reported varying concentrations of

Table 4 Cox regression model for age at surgery, fornix-based conjunctival flap and intraoperative application of MMC, and their influence on developing a bleb-related infection

	Hazard ratio	*p* value
Age at surgery	1.03	0.27
Fornix-based conjunctival flap	4.69	< 0.01
Intraoperative application of MMC	79.02	< 0.01

Statistical analysis on causing factors

MMC, from 0.02 up to 0.05%, and application times ranging between two and five minutes in their prospective study of more than 1000 trabeculectomies [11]. It seems likely that higher concentrations and longer application times increase the risk of bleb-related infections. Concerning MMC concentration and its stability Kinast et al. showed that storage conditions and duration affect the actual concentration of the agent applied during surgery, what should also be taken into account for varying infection rates [20].

Especially with chronic diseases such as glaucoma, there is a risk of losing patients to follow-up. This might occur more often over long postoperative periods, such as that after trabeculectomy, or patients might switch to a different eye clinic for further therapy. On the other hand, patients who underwent trabeculectomies at other clinics could present to us for the treatment of their bleb-related infections; however, there were only three such cases out of 19 eyes in our study, so this could not account for the low rate of infection. Our Eye Center is the main facility in Suedbaden for the treatment of patients with severe and complicated eye diseases. This could be an explanation for the small number of our own trabeculectomies lost to follow-up.

Another possible explanation for lower infection rates could be the large number of only minor infections that were treated by private practice ophthalmologists in our region, without being referred to our clinic. We found an almost balanced correlation between localized infections and endophthalmitis cases (9 vs. 7). DeBry et al. and Alwitry et al. reported similar findings, so we do not see an indication of a potential imbalance in infection types explained by missing referrals [12, 21].

Concerning risk factors, the intraoperative application of MMC and a fornix-based conjunctival flap were identified. Besides other risk factors, the usage of MMC was already reported in former studies [4, 13]. The previously described risk factors of young age at surgery, inferior bleb localization, dark skin color and postoperative bleb fistulation could not be reproduced in our data. The latter three of these risk factors were not found in any of the bleb-related infections we treated. Another potential risk factor is bleb manipulation by the patient itself [15]. This is a factor that is hard to control after surgery in general. We could not identify any bleb manipulation as a risk factor in our data, but in the same way it is hard to control, only few patients would admit manipulation may it be willingly or unwillingly.

The higher risk for patients with fornix-based conjunctival flaps has been reported before, but could not be found in all studies that examined its influence. Rai et al. found a lower incidence of infections after switching to fornix-based conjunctival flaps, while Kuroda et al. reported a statistically insignificant smaller number of infections with fornix-based surgery [22, 23]. In the prospective Collaborative Bleb-Related Infection Incidence and Treatment Study, no influence of conjunctival flap localization could be found in the 5-year data, and Lehmann et al. also did not find any influence in their trabeculectomy study [11, 14]. We cannot give a reliable explanation for this finding, as we would have expected the contrary, with a limbus-based flap giving pathogens the chance to spread under the upper eyelid. The more exposed conjunctival opening toward the limbus could possibly account for a higher grade of irritation and could therefore be a better target for pathogens. These thoughts are mere speculation, but this finding should be addressed in further studies concerning bleb-related infections.

Lehmann et al. [14] also reported that they found a relationship between the postoperative use of local antibiotics and the incidence of bleb-related infections. Other studies reported that local antibiotics were regularly used as therapy after trabeculectomy [24, 25]. At our clinic, antibiotics are not prescribed routinely after trabeculectomy, and the only topical medication is a steroid. The use of local antibiotics must not be seen as a potential risk for developing bleb-related infection because of this, but it should be taken into account in future studies.

On the other hand, our data show a slightly higher percentage (31.25%) of infections within the first 30 days after surgery compared to other studies but still shows a greater part of late-onset infections as

commonly describe [14, 15]. This finding might suggest that immediate postoperative therapy could influence the rate of early onset infections.

Compared to other postoperative infections, bleb-related infections have been described as more common. Following cataract surgery, less than one out of 1000 eyes develops endophthalmitis [26]. This rate is comparable to our findings for the risk of infection after 2 years. However, the moment of risk in cataract surgery is during the procedure itself, while an infection after trabeculectomy can occur even several years after the initial surgery (the longest period between surgery and infection in our data was almost 9 years).

The loss of visual acuity in our patients that developed bleb-related endophthalmitis is comparable to other studies [17, 18]. In endophthalmitis following cataract surgery, a similar reduction of visual acuity can be seen. In a study including 615 cases of endophthalmitis following cataract surgery in the USA, 34% of the eyes only reached a visual acuity of logMAR 1 or less [27]. Especially relevant for the functional outcome concerning visual acuity could be diagnosis at an early stage of the disease. If an infection spreads from the localized form to an endophthalmitis, this could worsen the functional visual outcome. The discrepancy between the groups of localized infections (mean visual acuity after infection: 0.07) and endophthalmitis cases (0.96) shows this very impressively.

With regard to microbiological findings, no clear statements can be made. A causative organism could only be found in 37.5% of all infected eyes and in 71.4% of endophthalmitis cases. Busbee et al. reported a series of 68 endophthalmitis cases following trabeculectomy, which showed a rate of 59% with identified causative organisms. In our data, only gram-positive bacteria could be found. That group of bacteria accounted for 50% of Busbee's cases [17]. Evidently, most of the causative organisms are part of the skin's natural flora, so the infection might not be caused by contact with any unusual pathogens. However, given the small number of cases we found, we do not think that there is a clear conclusion to be drawn from these findings.

Conclusion

Bleb-related infections are a rare complication following trabeculectomy. The intraoperative application of MMC seems to increase the risk of developing such an infection. Considering other potential risk factors, a fornix-based conjunctival flap might increase the chance of infection. A bleb-related infection can occur even years after the initial surgery, and this must be taken into consideration for every eye with a history of trabeculectomy and showing any signs of infection. The extent of the eye infection is crucial for the functional outcome, since endophthalmitis can severely threaten visual acuity.

Limitations of this study

There are a few limitations to this study. First, its design is of a retrospective nature. Especially in long-term analyses, there is a risk of losing patients for follow-up examinations. The retrospective nature of the study also accounts for the unbalanced groups of MMC augmentation versus no augmentation and of fornix-based versus limbus-based trabeculectomies. Second, all of the trabeculectomies and bleb-related infections were identified with the help of a keyword search within our clinic's database. There is no guarantee that all of the trabeculectomies that were performed and all of the infections that occurred were identified. However, given the large number of trabeculectomies performed, there would probably not be a significant difference if single procedures were missed.

Compliance with ethical standards

Conflict of interest None of the authors has any financial or proprietary interest in any of the materials or methods mentioned.

Ethical approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional research committee and with the 1964 Declaration of Helsinki and its later amendments or comparable ethical standards. Informed consent was not needed due to the retrospective nature of the study (confirmed by the local ethics committee, Vote No. 226/15).

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