Jpn J Ophthalmol (2014) 58:490–495
DOI 10.1007/s10384-014-0346-0

THE OFFICIAL INTERNATIONAL JOURNAL OF THE JAPANESE OPHTHALMOLOGICAL SOCIETY

CLINICAL INVESTIGATION

Blindness following bleb-related infection in open angle glaucoma

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Received: 5 February 2014 / Accepted: 14 August 2014 / Published online: 25 September 2014

Abstract
Purpose To estimate the risk of blindness following bleb-related infection after trabeculectomy with mitomycin C in open angle glaucoma, utilizing data obtained from two prospective multicenter studies.
Methods The incidence of bleb-related infection in open angle glaucoma after the first or second glaucoma surgery was calculated using a Kaplan–Meier analysis and data from the Collaborative Bleb-related Infection Incidence and Treatment Study (CBIITS). The rate of blindness following bleb-related infection was calculated using data from the Japan Glaucoma Society Survey of Bleb-related Infection (JGSSBI). Finally, the rate of blindness following bleb-related infection after filtering surgery was estimated based on the above two data sets. Blindness was defined as an eye with a visual acuity of 0.04 or less.
Results The incidences of development of bleb-related infection at 5 years were 2.6 ± 0.7 % (calculated cumulative incidence ± standard error) for all infections and 0.9 ± 0.4 % for endophthalmitis in all cases in the CBIITS data. The rates of blindness in the JGSSBI data were 14 % for the total cases with bleb-related infection and 30 % for the endophthalmitis subgroup. The rate of blindness developing within 5 years following trabeculectomy was estimated to be approximately 0.24–0.36 %.
Conclusions The rate of blindness following bleb-related infection within 5 years after trabeculectomy is considerable and thus careful consideration must be given to the indication for trabeculectomy and the selection of surgical techniques.

Keywords Bleb-related infection · Blindness · Glaucoma · Surgery · Trabeculectomy

Introduction

Trabeculectomy is an effective procedure for maintaining intraocular pressure (IOP) at lower levels [1, 2]. However, there are several significant postoperative complications [3, 4] which can result in severe visual loss. For example, bleb-related infection can result in permanent vision loss. The visual outcome of bleb-related infection has been reported in previous studies. Song et al. [5] combined previously published data [6–9] with their own findings and reported that the proportion of patients with a final visual acuity following bleb-associated endophthalmitis of less than 20/400 was 41 % (63/153 eyes). Similarly, Leng et al. [10] reported a rate of 45 % (31/69 eyes). It is unfortunate that, even in the early 21st century, bleb-related endophthalmitis has a generally poor prognosis.

In recognition of the clinical significance of this complication, the Japan Glaucoma Society initiated two prospective multicenter studies of bleb-related infection in 2004. One was the Collaborative Bleb-related Infection Incidence and Treatment Study (CBIITS) [11, 12] and the other was the Japan Glaucoma Society Survey of Bleb-related Infection (JGSSBI) [13, 14]. The CBIITS was a 5-year prospective study focused on the incidence, severity and prognosis of bleb-related infection. The CBIITS estimated that the cumulative incidence of bleb-related infection is 2.2 % at the 5-year follow-up in eyes that underwent

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filtering surgery with adjunctive mitomycin C(MMC) [12]. The JGSSBI was a 5-year multicenter survey on bleb-related infection. The JGSSBI found that the percentage of cases with a post-infection visual acuity of less than 20/400 was 44 % in bleb-related infections with vitreous involvement [14].

Since trabeculectomy is the most common glaucoma surgery, there is growing recognition of the need for careful risk evaluation when it is indicated. To our knowledge, this is the first report that evaluates the risk of blindness following bleb-related infection after trabeculectomy. In the present study, we attempted to quantify the risk of blindness following bleb-related infection after trabeculectomy in open angle glaucoma, utilizing data from the CBIITS and JGSSBI.

Materials and methods

The data analyzed in the present study were obtained in two independent prospective multicenter studies on bleb-related infection conducted by the Japan Glaucoma Society comprising the CBIITS and the JGSSBI. The Japan Glaucoma Society approved our usage of the data and provided them in an anonymous fashion.

The CBIITS was a prospective multicenter cohort study that primarily investigated the incidence of and risk factors for bleb-related infection. The details of the CBIITS are described elsewhere [11, 12]. In short, the enrollment period was 2 years and the follow-up period was up to 5 years, with intervals of 6 months. Ophthalmological examinations were conducted at each follow-up according to a pre-determined protocol. Thirty-four institutions participated in the CBIITS and institutional review board approval was obtained at each institution. The JGSSBI was also a prospective multicenter study, the details of which are presented elsewhere [13, 14]. The JGSSBI aimed to investigate the status quo of bleb-related infection, with special attention to its severity, prognosis, and bacteriological findings. Briefly, the study included a surveillance period of 5 years in which all patients with bleb-related infection were consecutively registered from 82 medical centers in Japan and clinical and microbial data were collected. The management of bleb-related infection in the JGSSBI was at the discretion of local investigators. Institutional review board approval was obtained at each institution. In the JGSSBI, patients who developed bleb-related infection during the study period were enrolled irrespective of the time of glaucoma surgeries. On the other hand, all the patients in the CBIITS had received their filtering surgery during the study period of 2 years. The patients who developed bleb-related infection in the CBIITS were not included in the JGSSBI. In both the CBIITS and JGSSBI, all patients gave written informed consent after thorough explanation of the study and gave permission to use their individual data for scientific research on the condition of anonymity.

Bleb-related infection was defined as an infection fulfilling all of the following three conditions in both the CBIITS and the JGSSBI: (1) history of a filtering surgery, (2) an episode developed no sooner than 4 weeks postoperatively, and (3) slit-lamp microscopically confirmed clinical signs of infection related to a filtering bleb. Infection was subclassified into the following three stages [15, 16]: stage I or blebitis denotes infections confined to the bleb site with a mild cell reaction in the anterior chamber; stage II denotes infections wherein the anterior chamber is the main locus and the vitreous is not involved; stage III denotes infections involving the vitreous. Stage III is further subdivided into stages: IIIa and IIIb; stage IIIa denotes mild involvement of the vitreous and stage IIIb denotes more advanced involvement.

In the present study, we calculated the incidence of bleb-related infection in open angle glaucoma after either the first or second glaucoma surgery using the CBIITS data. Open angle glaucoma includes primary open angle glaucoma and normal tension glaucoma. The Kaplan–Meier survival analysis was applied. The analysis was conducted using IBM® SPSS® 20.0 software (IBM Japan Ltd., Tokyo, Japan). We studied a total of 525 eyes of 525 subjects. The subjects' backgrounds are shown in Table 1. Unpaired *t*-tests, chi-square tests or Fisher exact probability tests were used to compare the factors between subgroups that underwent trabeculectomy alone and trabeculectomy combined with phacoemulsification and intraocular lens implantation. Each subject underwent either trabeculectomy alone or trabeculectomy combined with phacoemulsification and intraocular lens implantation. We estimated the incidence of bleb-related infection in all 525 eyes as well as in the subgroup that underwent trabeculectomy alone and trabeculectomy combined with phacoemulsification and intraocular lens implantation. We also investigated the rate of blinded eyes following bleb-related infection in open angle glaucoma eyes in the JGSSBI data. Based on World Health Organization (WHO) criteria for blindness [17], blindness was defined in the present study as eyes with a visual acuity of 0.04 or less. The eyes studied were selected from a total of 170 infections that developed in 157 eyes of 156 patients. The selection criteria were: (1) primary open angle glaucoma and normal tension glaucoma, (2) a history of one or two glaucoma surgeries, (3) a pre-infection visual acuity of at least 0.5, and (4) availability of 6-month and/or 12-month follow-up results.

Finally, we estimated the rate of blindness in open angle glaucoma following trabeculectomy with MMC by the

Table 1 Subject backgrounds 1 (selected from the CBIITS data)

Factor	Trab alone	Combined	*P*	Total
Number of eyes	432	93	>0.999	525
Number of eyes developing bleb-related infection	10	2		12
Age (years)	62.5 ± 11.7 (20 to 86)	70.2 ± 10.5 (18 to 92)	<0.001	63.8 ± 11.9 (18 to 92)
Sex (male/female)	252/180	50/43	0.419	302/223
Preop IOP (mmHg)	21.4 ± 7.4 (8.0 to 56.7)	21.2 ± 6.8 (9.3 to 46.0)	0.745	21.4 ± 7.3 (8.0 to 56.7)
Mean deviation (dB)	−18.85 ± 7.77 (−2.68 to −33.34)	−18.42 ± 6.84 (−3.20 to −33.31)	0.640	−18.77 ± 7.59 (−2.68 to −33.34)
Follow-up (months)	53.3 ± 14.2 (12 to 60)	49.8 ± 16.4 (12 to 60)	0.059	52.7 ± 14.7 (12 to 60)
Number of previous glaucoma surgeries	0.14 ± 0.34 (0 to 1)	0.09 ± 0.28 (0 to 1)	0.134	0.13 ± 0.33 (0 to 1)
Conj. flap (limbal-based/fornix-based)	274/158	34/59	<0.001	308/217
Bleb leakage (positive/negative)	34/398	5/88	0.516	39/486

Values are mean ± standard deviation (range)

CBIITS Collaborative Bleb-related Infection Incidence and Treatment Study, *Preop* preoperative, *IOP* intraocular pressure, *Trab* trabeculectomy, *Combined* trabeculectomy combined with phacoemulsification and intraocular lens implantation, *Conj.* conjunctival

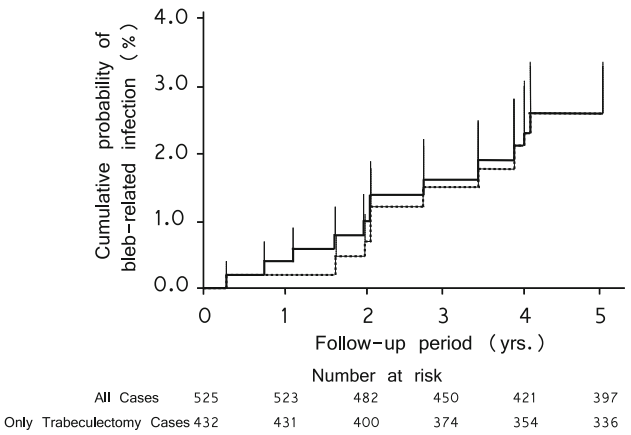

Fig. 1 A Kaplan–Meier estimate of the incidence of developing a bleb-related infection after filtering surgeries with mitomycin C in open angle glaucoma. Cases studied: 432 eyes that underwent trabeculectomy alone and 93 eyes after combined surgery. *Solid lines* indicate the estimated incidence after trabeculectomy and combined surgery and *dotted lines* show that after trabeculectomy alone. The incidences were 2.6 ± 0.7 and 2.6 ± 0.8 % at the 5-year follow-up (cumulative incidence ± standard error) for all cases and only trabeculectomy cases, respectively. *Fine lines* denote standard errors

estimated incidence of development of bleb-related infection in the CBIITS multiplied by the rate of blindness following bleb-related infection in the JGSSBI.

Results

During the entire follow-up period in the CBIITS, bleb-related infection developed in 12 eyes in open angle glaucoma cases that had a history of less than two glaucoma surgeries. As shown in Table 1, there was no significant difference in patients' backgrounds between the subgroup that underwent trabeculectomy alone and trabeculectomy combined with phacoemulsification and intraocular lens implantation except age and conjunctival incision. Bleb-related infection at diagnosis developed in stage I in 8 eyes (67 %), stage II in 3 eyes (25 %), stage IIIa in 0 eyes and stage IIIb in 1 eye (8 %). Kaplan–Meier survival analysis revealed that the incidence of development of bleb-related infection was 2.6 ± 0.7 % [calculated cumulative incidence ± standard error (SE)] at the 5-year follow-up (Fig. 1). When only trabeculectomy cases (432 eyes) were subjected to the Kaplan–Meier survival analysis, the incidence of development of bleb-related infection was 2.6 ± 0.8 % (calculated cumulative incidence ± SE) at the 5-year follow-up (Fig. 1).

When only cases developing endophthalmitis, i.e. stage II and stage III, were taken into account, the incidence at the 5-year follow-up was 0.9 ± 0.4 % (cumulative incidence ± SE) (Fig. 2). Similarly, when only trabeculectomy cases (432 eyes) were subjected to the Kaplan–Meier survival analysis, the incidence at the 5-year follow-up of development of bleb-related endophthalmitis was 0.8 ± 0.5 % (calculated cumulative incidence ± SE) (Fig. 2).

A total of 43 eyes fulfilled the selection criteria and were selected from the JGSSBI dataset for further analysis. The subjects'backgrounds are shown in Table 2. Table 3 shows the visual acuity at the last available visit after infection for cases in which the pre-infection visual acuity was at least 0.5. No eyes (0 %) showed a post-infection visual acuity of 0.04 or worse in stage I, 1 (13 %) in stage II, 3 (43 %) in

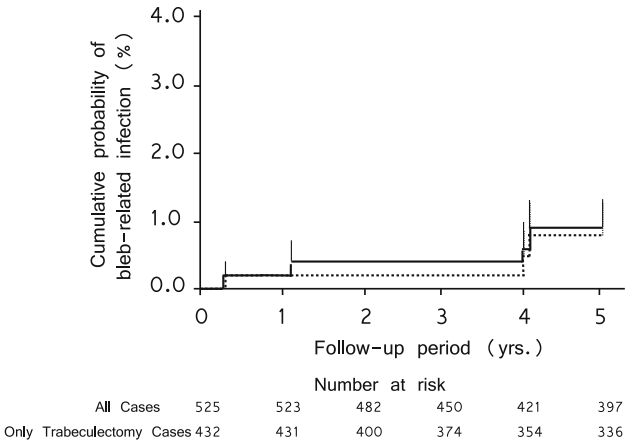

Fig. 2 A Kaplan–Meier estimate of the incidence of developing a bleb-related endophthalmitis after filtering surgeries with mitomycin C in 432 open angle glaucoma eyes that underwent trabeculectomy alone. *Solid lines* indicate the estimated incidence after trabeculectomy and combined surgery and *dotted lines* show that after trabeculectomy alone. The incidences were 0.9 ± 0.4 and 0.8 ± 0.5 % at the 5-year follow-up (cumulative incidence ± standard error) for all cases and only trabeculectomy cases, respectively. *Fine lines* denote standard errors

Table 2 Subject backgrounds 2 (selected from the JGSSBI data)

Age at the last glaucoma surgery	
Mean ± SD (range)	55.8 ± 14.4 (18 to 79) years
Sex	
Male	34 eyes
Female	9 eyes
IOP before infection (not available in 1 eye)	
Mean ± SD (range)	10.3 ± 3.6 (4 to 19) mmHg
Total number of glaucoma surgeries	
1	35 eyes
2	8 eyes
Bleb leakage noticed before developing infection	
Yes	22 eyes (51 %)
No	20 eyes (47 %)
Unknown	1 eye (2 %)
Bacterial culture done	34/43 (79 %)
Bacterial culture positive	17/34 (50 %)

JGSSBI Japan Glaucoma Society Survey of Bleb-related Infection, *SD* standard deviation, *IOP* intraocular pressure

stage IIIa and 2 (40 %) in stage IIIb. The rates of there being a visual acuity of 0.04 or worse were 14 % (6/43) and 30 % (6/20) for the total cases with infection and the endophthalmitis (i.e., stage II and stage III) subgroup, respectively.

Table 3 Visual acuity at the final follow-up for cases in which pre-infection visual acuity was at least 0.5

Stage	0.5 or better	0.05 to 0.4	0.04 or worse
I	22/23 (96 %)	1/23 (4 %)	0/23 (0 %)
II	7/8 (88 %)	0/8 (0 %)	1/8 (13 %)
III	6/12 (50 %)	1/12 (8 %)	5/12 (42 %)
IIIa	4/7 (57 %)	0/7 (0 %)	3/7 (43 %)
IIIb	2/5 (40 %)	1/5 (20 %)	2/5 (40 %)
Total cases	35/43 (81 %)	2/43 (5 %)	6/43 (14 %)

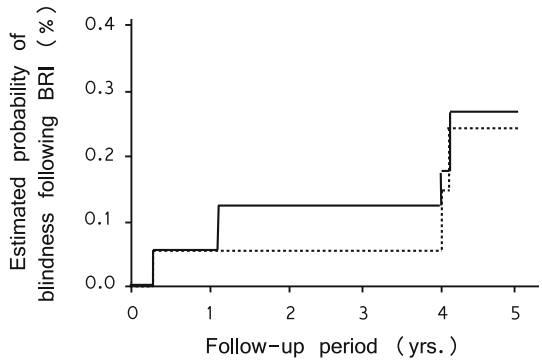

Fig. 3 An estimate of the probability of blindness following bleb-related infection after trabeculectomy alone or combined surgery. Calculated based on the CBIITS data on the incidence of bleb-related infections and the JGSSBI data on the visual outcome following bleb-related infection. *Solid lines* indicate an estimate based on cases after trabeculectomy alone and combined surgery. *Dotted lines* show one based on trabeculectomy cases alone. Definition of blindness: visual acuity following infection of 0.04 or less. *BRI* bleb-related infection, *CBIITS* Collaborative Bleb-related Infection Incidence and Treatment Study, *JGSSBI* Japan Glaucoma Society Survey of Bleb-related Infection

In all the bleb-related infection cases, the rates of blindness developed in open angle glaucoma eyes within 5 years following trabeculectomy with MMC were estimated to be 0.36 % (2.6 × 0.14 %) for cases that underwent trabeculectomy alone or trabeculectomy combined with phacoemulsification and intraocular lens implantation and 0.36 % (2.6 × 0.14 %) for the trabeculectomy alone cases (Fig. 3). When only cases developing endophthalmitis were taken into account, the rates were also estimated to be 0.27 % (0.9 × 0.30 %) for cases that underwent trabeculectomy alone or trabeculectomy combined with phacoemulsification and intraocular lens implantation and 0.24 % (0.8 × 0.30 %) for the trabeculectomy alone cases (Fig. 4).

Discussion

To our knowledge, this is the first study to estimate the rate of blindness following bleb-related infections after filtering

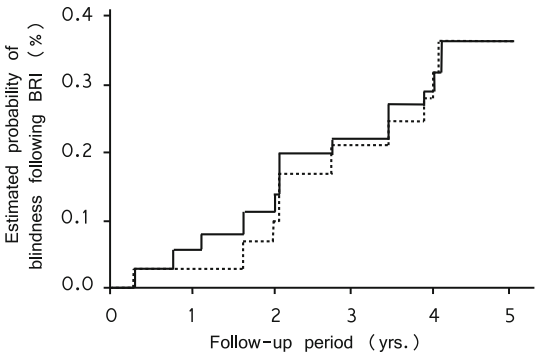

Fig. 4 An estimate of the probability of blindness following bleb-related endophthalmitis. Calculated based on the CBIITS data on the incidence of bleb-related infections and the JGSSBI data on the visual outcome following bleb-related infection. *Solid lines* indicate an estimate based on cases after trabeculectomy alone and combined surgery. *Dotted lines* show one based on trabeculectomy cases alone. Definition of blindness: visual acuity following infection of 0.04 or less. *BRI* bleb-related infection, *CBIITS* Collaborative Bleb-related Infection Incidence and Treatment Study, *JGSSBI* Japan Glaucoma Society Survey of Bleb-related Infection

surgeries. We estimated that blindness following bleb-related infection occurs in approximately 0.24–0.36 % of cases during the 5 years after trabeculectomy with adjunctive MMC. Thus, one out of every 280–420 eyes will lose useful vision during that period due to this late complication. Of course, such a high rate of complications should not be considered negligible, and the present findings should be carefully considered whenever a filtering surgery is indicated.

In the authors'opinion, it is problematic to estimate the rate of blindness following bleb-related infections after filtering surgery based on a single observatory cohort because thousands of patients and long follow-up periods are required to determine the true incidence. Thus, we utilized the data obtained in two prospective multicenter studies. The cumulative probability of the development of a bleb-related infection could be calculated using the CBIITS data because the original dataset included 1,098 MMC-augmented trabeculectomy cases with a variety of glaucoma subtypes, including 21 eyes which developed a bleb-related infection [12]. Likewise, the rate of blindness after bleb-related infection could be obtained using the JGSSBI data which includes data on 170 infections [13, 14]. Combining these two datasets allowed us to estimate the blindness rate with good precision.

The present study only included cases of primary open angle glaucoma and normal tension glaucoma that had undergone a first or second glaucoma surgery. It may be argued that we should not have limited the analysis to cases of open angle glaucoma only and with no more than one previous surgery. However, we chose our enrollment criteria because excluding secondary glaucomas and cases with a history of multiple bleb failures is more clinically relevant, since they can produce a specific pattern of results in the course of trabeculectomy [2, 18].

Glaucoma itself is a blinding disease. Thus, every treatment modality should be evaluated in light of its long-term effect on glaucomatous optic neuropathy and possible adverse effects. The possible timeline of the glaucomatous optic neuropathy should be evaluated on an individual basis. The visual prognosis of open angle glaucoma remains poor, even with the advent of sophisticated technology for early diagnosis and effective treatment [19]. Malihi et al. [20] estimated the cumulative probability of open angle glaucoma-related blindness in at least one eye at 20 years after diagnosis to be 13.5 % (95 % CI 8.8–17.9 %), defining blindness as visual acuity of less than or equal to 20/200 or visual field constriction to less than or equal to 20°. They also found significant reduction of blindness over a 45-year period, but noted that there is still a significant proportion of patients who progress to blindness despite recent advancements in management. Peters et al. [21] determined the life-time risk in open angle glaucoma and calculated the percentage of unilateral and bilateral blindness to be 38.1 and 13.5 %, respectively, adopting the WHO criteria for blindness, i.e., visual acuity of less than 0.05 and/or visual field of less than 10°.

Bleb-related infection is an emergent ophthalmic condition. Even with modern ophthalmic practices, the prognosis remains poor [14]. Yamamoto et al. [14] identified stage III infection and positive bacterial culture as risk factors for poor visual acuity after developing bleb-related infection. Our et al. [22] reported that recurrence of infection, negative Seidel tests, aphakia, avitreous, positive *Streptococcus* species and prolonged inflammation were identified as risk factors for a decrease in visual acuity of more than 2 lines following bleb-related infections. However, prognostic factors related to poor visual acuity in stage III bleb-related infection still remain to be elucidated. Ophthalmologists should notify all the patients with a functioning bleb about the potential risks and proper responses in case of complications in order to minimize the visual damage. Indications for filtering surgery should now also be considered in light of the present findings.

The present study has several limitations. First, all surgery and case management was performed in Japan. This might limit the generalizability of the results to other populations. Nonetheless, we believe that they are relevant to ophthalmologists practicing both within and out of Japan. Second, in the JGSSBI the management of bleb-related infection was at the discretion of local investigators which may have affected outcomes due to heterogeneous methods. Third, the data in the CBIITS included only 21 bleb-related infections [12], which is a relatively small sample size for robust subgroup analysis.

In conclusion, we estimated the rate of blindness developed in open angle glaucoma eyes following bleb-related infection within 5 years after trabeculectomy with MMC to be approximately 0.24–0.36 %. This high probability warrants more thoughtful decision-making on the indication for a filtering surgery, careful selection of surgical techniques, and intensive postoperative care of the patients with a filtering bleb.

Acknowledgments The authors wish to express their deep appreciation to the Japan Glaucoma Society for the opportunity to perform this research.

Conflicts of interest H. Yamada, None; A. Sawada, None; Y. Kuwayama, None; T. Yamamoto, None.

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