

# The Effect of Early Posttrabeculectomy Bleb Leakage on Surgical Outcome: A Prospective Cohort Study

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## Abstract

**Purpose:** To evaluate the effect of early posttrabeculectomy bleb leakage on trabeculectomy surgery outcomes and success rate.

**Methods:** The present prospective cohort study was conducted on 203 eyes of 203 patients who underwent trabeculectomy at Torfeh and Imam Hossein Medical Centers, Tehran, Iran, between 2016 and 2021. Patients were divided into two groups: those with early bleb leakage (within the 1<sup>st</sup> month of surgery) and those without bleb leakage. The success rate of surgery was compared 12, 18, and 24 months after surgery in the two groups. The average intraocular pressure (IOP) and the need for medications in patients 1, 3, 6, 9, 12, 18, and 24 months after the trabeculectomy were also compared.

**Results:** Bleb leakage was detected in 33 eyes during the 1<sup>st</sup> month after a trabeculectomy (16.3%). The mean decrease in IOP in the group with leakage was significantly lower than in patients without leakage at 1, 6, 9, 12, 18, and 24 months after surgery ( $P < 0.05$ ). The need for antiglaucoma medication was significantly higher among patients with bleb leakage at 3 months ( $P = 0.04$ ) and 9 months ( $P = 0.047$ ) after surgery ( $P < 0.05$ ). The success rate at 12, 18, and 24 months after surgery was significantly lower in the group with leakage than the group without.

**Conclusions:** The results of our study suggest that early posttrabeculectomy bleb leakage negatively impacts surgery success. Furthermore, IOP reduction was lower in patients with early leakage.

**Keywords:** Bleb leakage, Glaucoma, Trabeculectomy

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## INTRODUCTION

Glaucoma is a progressive optic neuropathy that can lead to complete blindness.<sup>1-3</sup> It is the second cause of blindness in the world after cataracts. Detecting asymptomatic patients and providing effective and timely treatment is particularly critical.<sup>4,5</sup> Although nonsurgical treatments including topical antiglaucoma drugs and laser therapy are recommended as the first line of treatment, many patients do not respond to these treatments and need surgery. Trabeculectomy is considered the gold standard for glaucoma surgery.<sup>6-8</sup> Trabeculectomy has a

high success rate compared to other procedures. It also reduces eye pressure, dependence on treatment continuation, and the need for ocular pressure-lowering drugs.<sup>9</sup> Trabeculectomy has some complications during and after the operation (early and late complications). These complications include uveitis, inflammation, conjunctival infection of the suture site, anterior chamber reaction, malignant glaucoma, and bleb leakage.<sup>10-16</sup> They also include hypotony, choroidal effusion, suprachoroidal hemorrhages, and maculopathy.<sup>10-16</sup> Studies have also reported between 0% and 56% bleb leakage after a trabeculectomy.

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This complication might be observed at different times after the operation. Still, in most cases, this complication is reported in the 1<sup>st</sup> days after surgery due to injuries caused by surgical techniques.<sup>17,18</sup> This complication is associated with the risk of endophthalmitis, hypotonia, and a shallow anterior chamber.<sup>18</sup> There is controversy regarding the effect of bleb leakage on trabeculectomy outcomes. Therefore, the present study was designed to investigate the effect of early leakage on trabeculectomy results.

## METHODS

The present study was approved by the Ethics Committee of Shahid Beheshti University of Medical Sciences, Tehran, Iran, with the code number IR.SBMU.ORB.REC.1401.014. In this prospective cohort study, 203 eyes of 203 patients with glaucoma surgery who underwent trabeculectomy surgery between April 2020 and October 2021 at Torfeh and Imam Hossein Medical Centers, Tehran, Iran were enrolled. Informed consent was obtained from all patients at study entry. All patients underwent a trabeculectomy by the same experienced glaucoma surgeon. The inclusion criteria included patients over 18 years of age with primary open-angle glaucoma, chronic angle-closure glaucoma, or pseudoexfoliation glaucoma who had undergone a trabeculectomy. The exclusion criteria included patients with other complications except bleb leakage, patients with eye surgery during the follow-up period, patients with simultaneous trabeculectomy and cataract surgery, noncooperative patients for follow-up, and patients with a history of previous ocular surgery as well as patients with factors complicating the wound healing process such as drugs and systemic diseases. During the 1<sup>st</sup> month after surgery, patients were divided into two groups based on the presence or absence of bleb leakage. Patients were visited at 1, 3, 6, 9, 12, 18, and 24 months after surgery.

Trabeculectomy was performed using fornix-based conjunctival and trapezoidal 3 mm × 2 mm scleral flaps in the superior area under general or local anesthesia. Then, mitomycin C (0.2 mg/mL) was applied by thin sponges under the scleral flap and conjunctiva for 2 min. After enough irrigation, sclerectomy, and peripheral iridectomy, the scleral flap was closed with two 10-0 nylon releasable sutures. The conjunctiva was then closed using 10-0 nylon sutures. Chloramphenicol eye drops 4 times a day for 1 week and betamethasone eye drops every 2 h for 1 week (tapered off in 6–8 weeks) were prescribed for all patients postoperatively. Antiglaucoma medication was started if necessary. The early postoperative leak was diagnosed by a glaucoma specialist using a slit-lamp.

The main outcome measure was success rate at 12, 18, and 24 months after surgery based on two different criteria. Criteria A were defined as postoperative intraocular pressure (IOP) of ≤21 mmHg and at least 20% reduction of IOP (with or without medication indicating complete or partial success, respectively). Criteria B were defined as postoperative IOP of ≤15 mmHg and at least 20% reduction of IOP (with or

without medication indicating complete or partial success, respectively). Patient information including demographics (age and sex), clinical findings (visual acuity logMAR, type of lens (phakic or pseudophakia or aphakia), type of glaucoma, as well as postoperative findings including operational success rate, average IOP changes in the intervals during the follow-up period and antiglaucoma medication were recorded and collected for all patients. The average IOP and the need for antiglaucoma treatment were recorded before surgery as well as at 1, 3, 6, 9, 12, 18, and 24 months after surgery. Postoperative complications were also recorded for all patients. Among patients with bleb leakage, we used acetazolamide every 6 h, and in cases of nonresponse after 1 week, we intervened surgically.

## Statistical analyses

The data were analyzed using SPSS version 22 statistical software (IBM, Armonk, New York, USA). Descriptive statistics and central parameters (mean and standard deviation) were utilized. The normality of quantitative variables' distribution in the two groups was evaluated by the Kolmogorov–Smirnov test. Assuming that the variable distribution was normal, the *t*-test was applied to compare the quantitative variables between the two groups. If the variable distribution was not normal, the Mann–Whitney nonparametric test was applied. Chi-square statistical test was used to compare qualitative variables between the two groups. The repeated measures analysis of variance test was utilized to evaluate average IOP changes during postoperative intervals. To control confounding variables, multivariate logistic regression analysis was used. *P* < 0.05 was considered statistically significant.

## RESULTS

Overall, 203 eyes of 203 patients were evaluated in the present study. The mean age of all patients entering the study was 59.72 ± 13.62 years. There were 33 eyes with bleb leakage and 170 eyes without leakage. The rate of leakage after surgery was 16.3%. No statistically significant difference was observed regarding the demographic and clinical variables at the beginning of the study between the two groups of patients with and without leakage [Table 1].

The IOP changes in the two groups were significantly different (*P* < 0.001). There was a significant decrease in the IOP at all postoperative follow-ups in both groups, with significantly more decrease in the group without leakage compared to the group with bleb leakage at all follow-up intervals (months 1, 3, 6, 9, 12, and 24). Table 2 compares changes in mean IOP between the two groups at different follow-up times.

The need for antiglaucoma medication at 3 and 9 months after surgery was significantly higher in patients with leakage than in those without leakage (*P* < 0.05). However, there was no significant difference in the need for antiglaucoma medication at 1, 6, 12, 18, and 24 months after surgery [Table 3].

**Table 1: Comparison of demographic and clinical findings between patients with and without posttrabeculectomy bleb leakage**

Parameter	Total (n=203), n (%)	Group		P
		Without leakage (n=170), n (%)	With leakage (n=33), n (%)	
Age, mean±SD	59.72±13.62	60.47±12.83	56.28±16.62	0.12*
Sex				
Male	127 (62.6)	107 (62.9)	20 (60.6)	0.7**
Female	76 (37.4)	63 (37.1)	13 (39.4)	
Eye				
OD	119 (59)	101 (59)	18 (55)	0.536**
OS	41 (41)	69 (41)	15 (45)	
Lens				
Phakic	163 (80.3)	139 (81.8)	25 (75.8)	0.58**
PCIOL	39 (19.2)	30 (17.6)	8 (24.2)	
Aphakia	1 (0.5)	1 (0.6)	0	
Type of glaucoma				
POAG	113 (55.7)	90 (52.9)	22 (66.7)	0.251**
CACG	57 (28)	51 (30)	7 (21.2)	
PXG	33 (16.3)	29 (17.1)	4 (12.1)	

\*Based on Independent *T* test. \*\*Based on Chi-square Tests. SD: Standard deviation, OD: Right eye, OS: Left eye, PCIOL: Posterior chamber intraocular lens, POAG: Primary open-angle glaucoma, CACG: Chronic Angle-closure Glaucoma, PXG: Pseudoexfoliative glaucoma

**Table 2: Comparison of intraocular pressure between patients with and without posttrabeculectomy bleb leakage**

Time	Total (mmHg)	Group		P**
		Without leakage (mmHg) (n=170)	With leakage (mmHg) (n=33)	
Before surgery	23.28±6.76	22.99±6.92	24.73±5.73	0.178
Month 1 postsurgery	11.02±4.08	10.67±3.47	12.85±6.12	0.005
Change	12.25±7.31	12.32±7.23	11.88±7.82	
P	<0.001*	<0.001*	<0.001*	
Month 3 postsurgery	11.11±3.59	10.83±3.28	12.58±4.67	0.01
Change	12.16±7.39	12.16±7.33	12.15±7.81	
P	<0.001*	<0.001*	<0.001*	
Month 6 postsurgery	11.89±3.59	11.5±3.29	13.88±4.41	0.000
Change	11.39±7.19	11.49±7.39	10.85±6.16	
P	<0.001*	<0.001*	<0.001*	
Month 9 postsurgery	11.75±3.99	11.23±3.58	14.45±4.87	0.000
Change	11.52±6.94	11.76±7.23	10.27±5.14	
P	<0.001*	<0.001*	<0.001*	
Month 12 postsurgery	12.69±4.9	12.06±4.39	15.94±6.07	0.000
Change	10.59±7.5	10.94±7.7	8.79±6.11	
P	<0.001*	<0.001*	<0.001*	
Month 18 postsurgery	13.15±4.69	12.84±4.42	15.5±5.97	0.017
Change	9.46±7.32	9.6±7.48	8.4±6.04	
P	<0.001*	<0.001*	<0.001*	
Month 24 postsurgery	13.74±4.6	13.45±4.35	15.9±5.88	0.025
Change	8.86±7.28	8.97±7.44	8±5.99	
P	<0.001*	<0.001*	<0.001*	

\*Based on paired *T* test. \*\*Based on Independent *T* test

The overall success rate was significantly higher among patients without leakage according to the two criteria, A and B. Based on the criterion A, the rate of complete success 12 months after surgery in the group of patients with leakage was (42.4%) significantly lower than that of patients without leakage (58.8%) ( $P = 0.001$ ). Furthermore,

18 and 24 months after the operation, the complete and partial success rates were significantly higher for patients without leakage than for patients with leakage ( $P < 0.05$ ). Based on the criterion B, the rate of complete success 12 months after surgery in the group of patients with leakage was (39.4%) significantly lower than that of

**Table 3: Comparison of medicine usage between patients with and without posttrabeculectomy bleb leakage**

Time	Total	Group		P*
		Without leakage (n=170)	With leakage (n=33)	
Before surgery	2.95±0.71	2.98±0.7	2.79±0.78	0.132
Month 1 postsurgery	0.13±0.48	0.13±0.49	0.15±0.44	0.584
Change	2.81±0.92	2.85±0.92	2.64±0.9	
P	<0.001	<0.001	<0.001	
Month 3 postsurgery	0.23±0.64	0.18±0.56	0.45±0.94	0.04
Change	2.72±1	2.79±0.95	2.33±1.16	
P	<0.001	<0.001	<0.001	
Month 6 postsurgery	0.35±0.77	0.3±0.69	0.64±1.08	0.094
Change	2.59±1.08	2.68±1	2.15±1.35	
P	<0.001	<0.001	<0.001	
Month 9 postsurgery	0.55±0.93	0.49±0.89	0.85±1.09	0.047
Change	2.39±1.18	2.48±1.13	1.94±1.32	
P	<0.001	<0.001	<0.001	
Month 12 postsurgery	0.79±1.07	0.74±1.04	1.06±1.2	0.165
Change	2.16±1.24	2.24±1.21	1.73±1.35	
P	<0.001	<0.001	<0.001	
Month 18 postsurgery	0.99±1.12	0.99±1.15	0.95±0.89	0.278
Change	2.02±1.26	2.05±1.28	1.85±1.04	
P	<0.001	<0.001	<0.001	
Month 24 postsurgery	1.14±1.17	1.16±1.19	1±0.97	0.473
Change	1.86±1.29	1.87±1.32	1.8±1.06	
P	<0.001	<0.001	<0.001	

\* Based on Chi-Square Tests

**Table 4: Comparison of success rate between patients with and without posttrabeculectomy bleb leakage**

Time	Total		Group				P*
			Without leakage (n=170)		With leakage (n=33)		
	Complete success, n (%)	Partial success, n (%)	Complete success, n (%)	Partial success, n (%)	Complete success, n (%)	Partial success, n (%)	
Success rate (IOP <21)							
Month 12 postsurgery	114 (56.2)	56 (27.6)	100 (58.8)	51 (30)	14 (42.4)	5 (15.2)	0.001
Month 18 postsurgery	77 (45)	73 (42.7)	70 (46.4)	67 (44.4)	7 (35)	6 (30)	0.004
Month 24 postsurgery	66 (38.8)	78 (45.9)	59 (39.3)	72 (48)	7 (35)	6 (30)	0.029
Success rate (IOP <15)							
Month 12 postsurgery	113 (55.7)	50 (24.6)	100 (58.8)	46 (27.1)	13 (39.4)	4 (12.1)	0.001
Month 18 postsurgery	77 (45)	61 (35.7)	70 (46.4)	57 (37.7)	7 (35)	4 (20)	0.007
Month 24 postsurgery	65 (38.2)	64 (37.6)	58 (38.7)	61 (40.7)	7 (35)	3 (15)	0.009

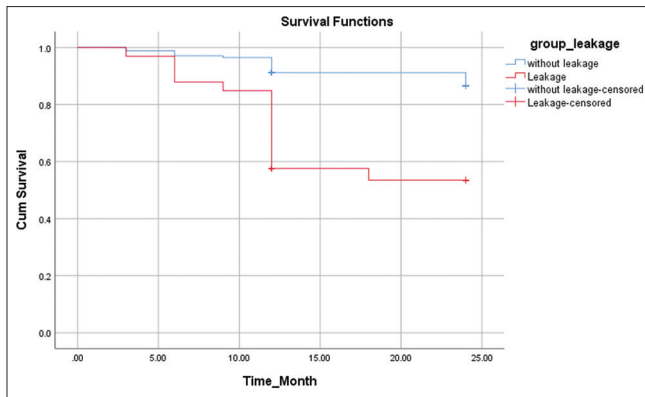
\*Based on Chi-Square Tests. Significance between two groups in follow-up times, Significance between two groups (with leakage and without leakage). IOP: Intraocular pressure

patients without leakage (58.8%) ( $P = 0.001$ ). Furthermore, the total and partial success rate, 18 and 24 months after the operation, was significantly higher in the group of patients without leakage compared with patients with leakage ( $P < 0.05$ ) [Table 4 and Figures 1 and 2].

Among patients with bleb leakage, 9 patients underwent bleb reconstruction, 10 patients needed resuturing, and 4 patients received needling. Needling was also used in 9 control cases. There was no statistically significant difference between the case and control groups regarding the needling procedure.

## DISCUSSION

Some studies have shown that complications after surgery can affect trabeculectomy results.<sup>19-21</sup> Leakage is a relatively common complication after trabeculectomy surgery. In general, very limited studies have evaluated the effect of bleb leakage on trabeculectomy surgery results. In this prospective study, we evaluated the effect of leakage on trabeculectomy surgery outcomes and success rate. Based on our results, 16.3% of the patients developed postoperative bleb leakage, which was consistent with other studies' results.<sup>19,20</sup>



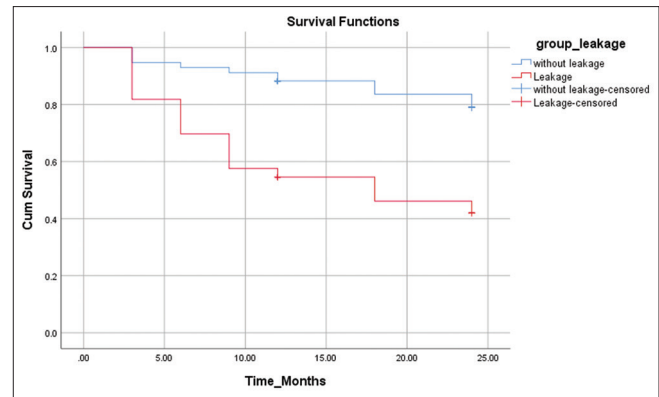
**Figure 1:** The survival rate of trabeculectomy based on the criterion B (intraocular pressure of  $\leq 21$  mmHg)

We observed that the improvement in the mean IOP in the group without leakage was significantly better than in the group with leakage. In a 2-year follow-up period, our study also showed that the need for antiglaucoma medication after surgery was significantly higher in the leakage group than in patients without leakage. The need for antiglaucoma medication 3 and 9 months after the operation was significantly higher in patients with leakage than in patients without leakage.

Based on both criteria used to assess surgery's success, the success rate at 12, 18, and 24 months after surgery was significantly lower in patients with leakage compared with patients without leakage. Parrish *et al.*<sup>21</sup> evaluated the prognosis, success rate, and surgical outcomes of patients with postoperative leakage after trabeculectomy among 213 patients. Similar to our findings, the early postoperative leakage was a risk factor for trabeculectomy failure.<sup>21</sup> After 12 months, the success rate of trabeculectomy in groups with and without leakage was 28% and 54%, respectively, which is consistent with our results. Alwitry *et al.*<sup>16</sup> evaluated the leakage effect after trabeculectomy on surgical outcomes and IOP changes in 119 patients. The follow-up time in this study was longer than in our study. This study indicated a 22.7% leakage rate, which is slightly higher than our study.<sup>16</sup> Contrary to our results, there was no statistically significant difference between the two groups in IOP measurements at follow-up times.<sup>16</sup> This difference could be due to the difference in follow-up times, sample size, and surgical techniques between the two studies. They used both fornix-based and limbal-based conjunctival flaps, while we used a fornix-based conjunctival flap.

Furthermore, contrary to our study results, Henderson *et al.*<sup>22</sup> did not find a significant relationship between bleb leakage and surgical outcomes after trabeculectomy. This difference in the results can be due to the difference in patient selection criteria in the two studies; in our study, only patients who underwent trabeculectomy were examined, while in their study, patients with other surgical methods were also evaluated.

In our study, unlike other studies, only the effect of leakage on surgery results and success rate was evaluated. Patients



**Figure 2:** The survival rate of trabeculectomy based on the criterion B (intraocular pressure of  $\leq 15$  mmHg)

who underwent other surgical methods were excluded from the study. Our study had some strengths and weaknesses that should be noted. The most significant weakness of the present study was the small sample size of patients (especially in the subgroup of patients with leakage) in the 2<sup>nd</sup> year of follow-up, which can affect the outcomes estimation. The most significant strength of our study was the prospective study design and prolonged follow-up of patients after surgery, homogeneity of samples (kind of surgery and surgical technique), and exclusion of other probable affective complications.

Our study results suggest that early posttrabeculectomy bleb leakage has a negative effect on the success rate of the surgery. Furthermore, the average IOP changes are lower in patients with early leakage.

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Nil.

### Conflicts of interest

There are no conflicts of interest.

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