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RESEARCH ARTICLE

Determinants of Glaucoma Therapy Escalation After Descemet-Stripping Automated Endothelial Keratoplasty To Treat Pseudophakic Bullous Keratopathy: A Nested Case-Control Study

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Abstract:

Purpose:

To study the determinants of glaucoma therapy escalation (GTE) after Descemet-stripping automated endothelial keratoplasty (DSAEK) for pseudophakic bullous keratopathy in an eye-care hospital in Saudi Arabia.

Methods:

This nested case-control study evaluated patients who required medical or surgical treatment for controlling glaucoma after DSAEK (defined as GTE; GTE group). A group of patients who did not require any intervention post-DSAEK served as controls (control group). Data were collected on preoperative, intraoperative, and postoperative parameters for DSAEK. Variables were compared between groups to evaluate risk factors for GTE and graft failure.

Results:

The study sample comprised 117 eyes (40 in the GTE group and 77 in the control group). Glaucoma was present in 20 (17.1%) of the eyes before DSAEK. The median duration of follow-up was 27 months [Interquartile range (IQR): 24; 42]. Intraoperative complications occurred in 4 eyes, and 2 eyes had a decentered donor button. Graft failure causing vision impairment and GTE at the final follow-up were noted in 19 (16.2%) and 40 (34.2%) eyes, respectively. Glaucoma prior to DSAEK was significantly associated with GTE [odds ratio (OR) = 6.4; 95% confidence interval (CI) 2.4; 18.3; $P = 0.0004$]. A history of penetrating keratoplasty (PK) was significantly associated with GTE after DSAEK [OR = 6.2 (95% CI 1.5; 24.7) $P = 0.008$]. At the last visit, GTE and graft failure were positively associated (OR = 27.2, $P < 0.005$).

Conclusion:

Escalation of glaucoma therapy was warranted in one in 3 eyes that had undergone DSAEK. GTE and graft failure are interrelated complications. Patients with glaucoma and PK have a higher risk of GTE post-DSAEK.

Keywords: Glaucoma therapy escalation, Descemet stripping automated endothelial keratoplasty, Pseudopkakic bullous keratopathy, Cornea, Pseudophakia, Treatment.

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1. INTRODUCTION

Glaucoma after keratoplasty is clinically challenging because it negatively affects the viability of the corneal endothelium and often results in graft failure and loss of vision [1]. The incidence of glaucoma after keratoplasty ranges from 5.5% to 31%. Glaucoma before surgery, peripheral anterior synechia in the early postoperative period, and uncontrolled intraocular pressure postoperatively are known risk factors of glaucoma following keratoplasties [2]. The glaucoma therapy escalation (GTE) after penetrating keratoplasty was reported to occur in one in 8 patients in Saudi Arabia [3]. Of the patients, 82% had medical escalation, and 18% had surgical GTE. A study with a large cohort in the United States revealed that glaucoma surgery was needed after keratoplasty if there was preexisting glaucoma in the eye. But the rate was 5% if preexisting glaucoma was not present in the eye operated on by

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keratoplasty [4]. The incidence of GTE was 32.4% in 102 eyes that underwent Descemet's membrane-stripping automated endothelial keratoplasty (DSAEK) [5].

Pseudophakic bullous keratopathy is a rare complication of cataract extraction with intraocular lens implantation, especially if intraoperative maneuvers cause corneal endothelial damage [6]. Eyes with pseudophakic bullous keratopathy have a higher probability of developing glaucoma after keratoplasty compared with eyes that have undergone surgery for keratoconus and corneal dystrophy [7]. The use of endothelial keratoplasty and penetrating keratoplasty (PK) to treat bullous keratopathy remains debatable [8, 9]. There are two types of endothelial keratoplasties: DSAEK and non-Descemet's membrane-stripping automated endothelial keratoplasty (nDSAEK) [10]. In DSAEK surgery, Descemet's membrane and endothelium are taken from the posterior surface of the donor cornea button. In the nDSAEK surgery, only endothelium, excluding Descemet's membrane, is harvested from donor material and inserted in the anterior chamber for the transplant. Although some report better outcomes with nDSAEK, the indication for corneal surgery, availability of resources, and the surgeon's experience dictate the selection of the procedure [11].

The development of glaucoma during the early post-keratoplasty period is difficult to detect because conventional intraocular pressure measurements may not be appropriate or reliable [12].

This study evaluates the factors influencing GTE and graft failure among pseudophakic bullous keratopathy patients managed by DSAEK.

2. MATERIALS AND METHODS

This nested case-control study was conducted to determine the factors influencing GTE and graft failure among pseudophakic bullous keratopathy patients managed by DSAEK. Patients who required medical or surgical treatment for controlling glaucoma after DSAEK (defined as GTE; GTE group) were compared with a control group. The ethical and research committee approved the research of King Khaled Eye Specialist Hospital (R- 15138). This study adhered to the tenets of the Declaration of Helsinki. Written consent of the participants was waived because of the retrospective nature of data collection. However, patient data were anonymized for the study.

The patients in this study were from a tertiary eye hospital, an ophthalmology training center that includes subspecialty training and provides free eye-care services to all Saudi nationals. This hospital also serves as a referral center for complex ophthalmic care from regional ophthalmologists and other gulf countries.

This hospital's cornea and glaucoma subspecialty performs approximately 1,200 keratoplasties annually and has its eye bank. However, the donor material is imported from other countries after strict quality checks [13].

To estimate the sample size, we assumed that among the eyes that required GTE post-DSAEK, glaucoma was managed before DSAEK in 32%.5 In the control group, only 10% of eyes were managed pre-DSAEK. Achieving a 95% confidence interval (CI) and 80% power to case-control-design, the study required 42 eyes for the GTE group and 84 for the control group. The sample size for this case-control study was calculated using OpenEpi software [14].

A retrospective chart review was conducted on the electronic health records of patients diagnosed with pseudophakic bullous keratopathy (H59.012) who underwent DSAEK (CPT code 65756) between January 2009 and December 2014 [15]. Data were collected on patient demographics, including age at DSAEK, gender, and the eye operated on. The preintervention information included past ocular history, glaucoma surgeries and medications, corneal status, lens, and intraocular pressure (IOP). The Tonopen XL (Medtronic Plc, Dublin, Ireland) was used to measure IOP before and after the intervention. Presenting vision and best-corrected distance visual acuity (BCVA) are reported here.

The DSAEK procedure had been previously described [16]. Postoperative follow-up visits were performed after days 1 month 3, 6, 12 and 24 and the last follow-up after 2 years (final visit). At each visit, data were collected on BCVA, cause of dim vision, IOP, glaucoma medications and surgeries, corneal status, lens, optic nerve head, and macula status.

GTE was classified as either surgical escalation or medical escalation. Surgical escalation was defined as the need to perform any surgical procedure to control IOP. Medical escalation was defined as the need to (a) institute glaucoma medications to control IOP in an eye without preexisting glaucoma or (b) increase the number of glaucoma medications required to control IOP in an eye with preexisting glaucoma [17]. In all cases of GTE, medical treatment was initiated at diagnosis. If three medication regimens failed to control IOP, we opted for surgery. If the vision was good in that eye, we selected drainage glaucoma surgery and/or laser iridotomy. If the vision was markedly compromised, we opted for pars plana laser cyclophotocoagulation.

We collected data on a pretested data collection form and then transferred the form to an Access® spreadsheet (Microsoft Corp., Redmond, WA, USA). After consistency checks, data were transferred to Statistical Package for Social Studies (SPSS 25; IBM Corp., Armonk, NY, USA). We reported qualitative data as numbers and percentages. We reported normally distributed data as mean and standard deviation. Median and interquartile ranges (IQR) were reported for data that were not normally distributed. The odds ratio (OR), its 95% CI, and the two-sided P-values were calculated to compare the determinants between groups. A *P*-value of less than 0.05 was considered statistically significant.

3. RESULTS

This study evaluated 117 eyes with bullous keratopathy managed with DSAEK (Table **1**). Twenty eyes were being managed for glaucoma before DSAEK. Before DSAEK, 11 (9.4%) eyes were managed with PK, 6 (5.1%) eyes had undergone intraocular lens (IOL) exchange, and four eyes had undergone anterior vitrectomy. The median diameter of the recipient bed for DSAEK was 8.00 mm (IQR 7.5; 8.0) (min 6.0, max 8.5mm). The median diameter of the donor button for DSAEK was 8.00 mm (IQR 7.5; 8.0) (min 6.0, max 8.5mm). Intraoperative complications occurred in four eyes. In two eyes, there were decentered donor buttons; and in another two

eyes, fold-in donor material at the lowered edge was managed with viscoelastic material. We noted graft failure causing impaired vision and GTE at the last visit in 19 (16.2%) and 40 (34.2%) eyes, respectively.

Based on postoperative IOP and glaucoma management, there were 40 eyes in the GTE group and 77 in the control group. (Table **2**) presents the different ocular and visual parameters at follow-up. A detached graft one day postoperatively was noted in five eyes. At the final visit, 19 (16.2%) eyes had a failed graft, causing impaired vision. After an increase in the follow-up duration, the visual impairment grades improved. More than half of the operated eyes had functional normal vision 2 years after DSAEK. However, nearly 20% of eyes operated on had severe visual impairment. Graft failure seemed to be a delayed outcome and was noted in one in 8 eyes 2 years after DSAEK.

Table 1. Profile of Pseudophakic Bullous Keratopathy Patients Who Had Undergone Descemet Stripping Automated Endothelial Keratoplasty.

Age (Years)	**Mean Standard Deviation**	**70.6 ± 10.0**	
Intra ocular pressure (mmHg)	Mean Standard deviation	15.8 3.74	
		Number	Percentage
Gender	Male Female	56 61	47.9 52.1
Eye involved	center center	66 51	56.4 43.6
Preoperative vision	20/20 to 20/60 <20/60 to 20/200 <20/200 to 20/400 <20/400	1 23 12 81	0.9 19.7 10.3 69.2
Past ocular surgeries	Cataract +IOL Anterior vitrectomy IOL removal PPV	113 1 1 4	96.6 0.9 0.9 3.4
Glaucoma	Present Open angle glaucoma Pigmentary glaucoma Chronic angle closure glaucoma Other Not known	20 4 4 9 1 2	17.1 3.4 3.4 7.7 0.9 1.8
Cupping status	<0.7 0.7 and more	109 8	93.2 6.8
Glaucoma medications	None One Two	100 10 7	85.5 8.5 6.0
Glaucoma medications	Beta blockers Alpha agonists Prostaglandin analogues B blockers and carbonic anhydrase	3 5 4 12	2.6 4.3 3.4 10.3
Glaucoma surgeries	Trabeculectomy Trabeculectomy + MMC Laser iridotomy Glaucoma drainage device implant Laser cyclophotocoagulation	1 3 7 2 5	0.9 2.6 6.0 1.7 4.3

abbreviation IOL = intraocular lens; MMC = mitomycin C.

Table 2. Status Of Ocular Parameters Over The Duration Of Follow Up After Descemet Stripping Automated Endothelial Keratoplasty For Pseudophakic Bullous Keratopathy.

-		**Day 1**		**3 Months**		**6 Months**		**12 Months**		**24 Months**		**Last follow up**	
		#	**%**	**#**	**%**	**#**	**%**	**#**	**%**	**#**	**%**	**#**	**%**
Best corrected distance vision	20/20 to 20/60	13	11.1	36	30.8	50	42.7	56	47.9	58	49.6	44	37.6
	<20/60 to 20/200	54	46.2	42	35.9	36	30.8	37	31.6	26	22.2	36	30.8
	<20/200 to 20/400	15	12.8	11	9.4	9	7.7	10	8.5	10	8.5	11	9.4
	<20/400	35	29.9	28	23.9	22	18.8	24	20.5	23	19.7	26	22.2

(Table 2) contd.....

-		Day 1		3 Months		6 Months		12 Months		24 Months		Last follow up	
		#	%	#	%	#	%	#	%	#	%	#	%
Cause of impaired vision	Detached graft	5	4.3	0	0.0	1	0.9	0	0.0	0	0.0	0	0.0
	Graft failure	5	4.3	12	10.3	16	13.7	14	12.0	16	13.7	19	16.2
	Cystoid Macular Edema	1	0.9		0.0		0.0		0.0		0.0		0.0
	Microbial Keratitis		0.0	2	1.7		0.0		0.0	1	0.9		0.0
	Other	1	0.9		0.0	1	0.9		0.0	1	0.9		0.0
Glaucoma surgery	No	113	96.6	116	99.1	116	99.1	117	100	112	95.7	112	95.7
	Yes	4	3.4	1	0.9	1	0.9			5	4.3	5	4.3

Table 3. Determinants of glaucoma therapy escalation after descemet stripping automated endothelial keratoplasty to treat pseudophakic bullous keratopathy.

-	-	GTE (n = 40)		No GTE (n=77)		Validation
Age	Mean	70.2		70.8		Diff of mean0.6, (95% CI -3.4; 5.6) *P* = 0.77
	SDV	10.5		9.8		
	Range	47.5; 97.4		40.8; 89.0		
IOP	Mean	16.1		15.7		Diff of mean0.4, (95% CI -1.0; 1.8) *P* = 0.6
	SDV	3.7		3.8		
	Range	6.0; 36.0		9.0; 22.0		
Duration of follow up (months)	Mean	35.6		32.1		Diff of mean -3.6, (95% CI –10.2; 3.0) *P* = 0.28
	SDV	16.5		18.0		
	Range	12; 79		12; 82		
Gender	Male	16	40	40	51.9	OR = 0.6 (95% CI 0.3; 1.3) *P* = 0.23
	Female	24	60	37	48.1	
Eye affected	center	21	52.5	45	58.4	OR = 0.78 (95% CI 0.4; 1.7) *P* = 0.5
	center	19	47.5	32	41.6	
Glaucoma before DSAEK	Present	14	35	6	7.8	OR = 6.4 (95% CI 2.4; 18.3) *P* = 0.0004
	Absent	26	65	71	92.2	
Vision before DSAEK	20/20 to 20/60	0	0.0	1	1.3	Chi square = 2 df =3 *P* = 0.08
	<20/60 to 20/200	6	15.0	17	22.1	
	<20/200 to 20/400	1	2.5	11	14.3	
	<20/400	33	82.5	48	62.3	
Glaucoma surgery in past	Yes	9	22.5	3	3.9	OR = 7.2 (95% CI 1.8; 28.2) P = 0.003
	No	31	77.5	74	96.1	
Intraoperative complications	Present	2	5	2	2.6	OR = 2.0 (95% CI 0.3; 14.5) *P* = 0.5
	Absent	38	95	75	97.4	
PK in past	Yes	8	20	3	3.9	OR = 6.2 (95% CI 1.5; 24.7) *P* = 0.008
	No	32	80	74	96.1	
IOL exchange	Yes	4		2		OR = 4.2 (95% CI 0.7; 23.8) *P* = 0.12
	No	36		75		

abbreviations GTE = glaucoma escalation therapy, IOP = intraocular pressure, IOL = intraocular lens, PK = penetrating keratoplasty, OR = odds ratio, CI = confidence interval, Diff = difference, $P < 0.05$ is statistically significant.

We associated both qualitative variables, demographic and ocular, noted before DSAEK with the presence and absence of GTE after surgery. We calculated the odds ratio, 95% confidence interval, and two-sided *P*-values. We compared the mean and standard deviation of eyes with and without GTE for quantitative variables. We estimated the difference in mean, 95% confidence interval, and two-sided *P*-value (Table **3**). The presence of glaucoma before DSAEK was statistically significantly associated with GTE [OR = 6.4 (95% CI 2.4; 18.3) $P = 0.0004$]. Among the GTE group, seven eyes had chronic angle closure glaucoma, two eyes had open-angle glaucoma, three had pigmentary glaucoma, and two had other or undetermined causes. Among the non-GTE group, three had open-angle glaucoma, one had pigmentary glaucoma, and two had chronic angle closure glaucoma. Due to the small number of eyes by type of glaucoma before DSAEK, we could not associate them with GTE. There was a statistically significant association between a history of PK and GTE after DSAEK [OR = 6.2 (95% CI 1.5; 24.7) $P = 0.008$]. The GTE and graft failure were positively associated at the final follow-up (OR = 27.2, $P < 0.005$). In this univariate parametric analysis, variables significantly associated/correlated with the presence of GTE were used for regression analysis.

We performed bivariate regression analysis with outcome variables as GTE-present or -absent and independent variables such as glaucoma before DSAEK and glaucoma surgery in the past because they were significantly associated with GTE in univariate analysis. The presence of glaucoma in the eye before DSAEK was a significant predictor of GTE after DSAEK ($P = 0.05$). However, a history of glaucoma surgery was not a significant predictor of GET ($P = 0.55$).

4. DISCUSSION

The outcomes of the current study indicate that one in 3

eyes with pseudophakic bullous keratopathy more than 2 years after DSAEK required escalation of glaucoma therapy; and despite proactive management of glaucoma (including GTE), graft failure occurred in half of the eyes. We found that surgical and medical management of glaucoma and PK before DSAEK were statistically associated with GTE. Hence, these outcomes indicated that careful preoperative selection of patients for DSAEK is warranted, and patients with existing risk factors should be made aware of the prognosis. To the best of our knowledge, this is perhaps the first longitudinal study associating risk factors with GTE post-DSAEK in eyes with pseudophakic bullous keratopathy.

We found that post-DSAEK eyes developed GTE over a follow-up period of at least 24 months. Trufanov *et al*. [18] evaluated 41 eyes with bullous keratopathy and glaucoma after endothelial keratoplasties or reported adjusting glaucoma medication regimen in 7 (17%) eyes within 2 years of follow-up. We recommend a judicious comparison of the outcomes of the current study to previous literature because we enrolled some patients with glaucoma before DSAEK. In their large series of DSAEK eyes, Kaleem *et al*. reported an incidence of increased postoperative IOP in 54% of eyes with bullous keratopathy [19]. In another study comparing the outcomes of DSAEK to PK after a 3-year follow-up, Chan *et al*. [20] noted that de novo ocular hypertension was noted in 47.2% of eyes, and 29.7% of these eyes required glaucoma surgery. Our study shows nearly similar rates of GTE.

Glaucomatous eyes before DSAEK were associated with GTE in our study. This increased the need for glaucoma treatment and a higher rate of graft failure in eyes with glaucoma before DSAEK, which is consistent with the findings mentioned in the literature [21 - 23]. Bonnet *et al*. [24] opined that the presence of a drainage device for glaucoma before DSAEK is a risk for GTE and graft failure. Because of the small number in the subgroup of type of glaucoma before DSAEK in the present study, we cannot conclusively say which type of glaucoma has a higher risk of GTE. However, it seems that chronic angle closure glaucoma had a higher rate of GTE than other types of glaucoma. The risk of angle closure due to air bubbles in the anterior chamber is noted to cause glaucoma post-DSAEK [25].

We found that PKP before DSAEK was a risk for GTE. Nahum *et al*. [22] noted that failed PK was a risk for endothelial graft detachment, which could compromise the cornea and warrant intervention. Hence, patients with previous PK scheduled for DSAEK surgery should be counseled regarding the risk of GTE and graft failure.

Although graft failure and GTE in our study were outcome variables, we investigated whether they were associated with understanding a possible causal link. We found a strong association between these two outcomes. Ward *et al*. [26] also noted higher rates of graft failure in eyes surgically managed for glaucoma. They recommended offering a guarded visual prognosis after keratoplasty in eyes managed surgically for glaucoma. In addition to counseling such patients, we propose a more frequent follow-up schedule and remaining clinically vigilant if GTE occurs.

In our study, the eyes with GTE were managed by topical antiglaucoma medication and surgery. Surgery mainly included glaucoma drainage, a valve implant, and one eye pars plana cyclophotocoagulation. Greenlee *et al*. [27] also found a positive response to a drainage device and CCP to manage GTE post-keratoplasty. In another review from the United States, researchers recommended laser trabeculoplasty, cyclodestructive procedures, and glaucoma drainage devices (GDDs). The latter surgery had a 75% success rate in addressing GTE [2].

Our study has some limitations, including those inherent to retrospective data collection. Because this study evaluated 6 years of data, different surgeons, changes in individual surgical preferences, or case selection could have influenced the outcomes over time. One of the risk factors pointing to possible GTE and graft rejection is a mismatch of donor and graft size, resulting in a graft-host junction bump [28]. Although the size of donor and recipient corneas matched in all patients, we did not document if there was a graft-host junction bump.

The definition of GTE in the present study omits steroid-induced glaucoma. However, some genetically predisposed patients may show a prolonged effect from steroid therapy. This is notable because steroids are usually prescribed post-keratoplasty. A longitudinal study is recommended to differentiate between steroid-induced IOP elevation and its influence on GTE and graft failure [29].

CONCLUSION

In summary, we found that there seems to be a high rate of GTE and graft failure in post-DSAEK eyes. Previous studies reported weak evidence because, in these studies, patients were operated on for either a combination of many indications for DSAEK or evaluated as different endothelial keratoplasties for the same indication. We recommend stringent selection criteria for DSAEK candidates to minimize the known risk factors and improve the outcomes of DSAEK for bullous keratopathy. If risk factors exist, the patients should be educated about the postoperative prognosis before DSAEK.

LIST OF ABBREVIATIONS

GTE	=	Glaucoma Therapy Escalation
DSAEK	=	Descemet Stripping Automated Endothelial Keratoplasty
PK	=	Penetrating Keratoplasty
nDSAEK	=	Non- Descemet Stripping Automated Endothelial Keratoplasty
CI	=	Confidence Interval
BCVA	=	Best-Corrected Visual Acuity
IOP	=	Intraocular Pressure
IOL	=	Intraocular Lens

ETHICS APPROVAL AND CONSENT TO PARTICIPATE

The Instituional Review Board committee approved this study at King Khaled Eye Specialist Hospital, Saudi Arabia. Approval number (R- 15138).

HUMAN AND ANIMAL RIGHTS

No animals were used in this research. All human research procedures were followed in accordance with the ethical standards of the committee responsible for human experimentation (institutional and national) and with the Helsinki Declaration of 1975, as revised in 2013.

CONSENT FOR PUBLICATION

All research participants signed a written informed consent form.

STANDARDS OF REPORTING

STROBE guidelines were followed.

AVAILABILITY OF DATA AND MATERIALS

The data is the property of the research department, King Khaled Eye Specialist Hospital. The data is available upon request to the Principal Investigator.

FUNDING

None.

CONFLICT OF INTEREST

The author declares no conflict of interest, financial or otherwise.

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