Non-enhanced trabeculectomy by non-glaucoma specialists: are results related to risk factors for failure?

Abstract

Purpose To determine the 1 year success rate of non-enhanced trabeculectomy under the care of non-glaucoma specialists and the effects of risk factors on the surgical outcome as measured by intraocular pressure (IOP) control.

Methods A retrospective study of 167 patients undergoing trabeculectomy was performed. One hundred and four cases were performed in a teaching hospital and 63 in a district general hospital (DGH). Non-glaucoma specialists performed all the operations, enhanced trabeculectomy with antimetabolites being excluded. Information was recorded from a retrospective review of case notes, and post-operative IOPs at 12 months follow-up were analysed. Risk factors for failure were defined as: (1) age less than 40 years old, (2) black race, (3) diabetes mellitus, (4) miotic therapy \ge 18 months, (5) sympathomimetic therapy \ge 6 months, (6) pseudophakia or aphakia, (7) previous failed filtration procedure, (8) argon laser trabeculoplasty, (9) previous ocular surgery and (10) high-risk glaucoma (angle recession glaucoma, uveitic glaucoma and neovascular glaucoma). A success was defined to be a post-operative IOP at 1 year of less than 21 mmHg and at least 20% less than the presenting IOP on no medication. Results The overall success rate was 139 of 167 (83.2%). Eighty-seven of 104 eyes (83.7%) were classified as a success in the teaching hospital group and 52 of 63 (82.5%) were classified as a success in the DGH group. There was no significant difference in the number of risk factors between the success and failure groups. Eyes with two or more risk factors had significantly higher IOPs at 1 year when compared with eyes with 0 or 1 risk factor (mean \pm SD: 17.4 \pm 6.34 mmHg vs 14.2 \pm 5.0 mmHg, p = 0.022). When only 'successful eyes' were analysed, those with two or more risk factors still had significantly higher IOPs at 1 year (mean \pm SD: 15.0 \pm 3.0 mmHg vs 12.8 \pm 3.9 mmHg, p = 0.046). There were significantly fewer eyes in the two or more risk factor group V.C.T. SUNG, T.K.H. BUTLER, S.A. VERNON

with IOPs < 16 mmHg at 1 year (26.1% vs 60.4%, p = 0.021).

Conclusions Eyes at relatively low risk for failure operated upon by non-glaucoma specialists appeared to have success rates similar to previously published series. Eyes with two or more risk factors for failure have higher IOPs at 1 year in non-enchanced trabeculectomy. Adjunctive anti-scarring agents may be considered for these patients when filtration surgery is scheduled.

Key words District general hospital, Glaucoma, Intraocular pressure, Risk factor, Specialists, Trabeculectomy, Teaching hospital

Trabeculectomy has become the standard surgical treatment for primary and most types of secondary glaucoma.¹ This procedure is currently widely performed by ophthalmologists with or without glaucoma as a special interest. As far as we know, there are no previous reports looking at trabeculectomy results from non-glaucoma specialists. Established risk factors for failure include: black race,² young age,³ diabetes, ⁴ previous ocular surgery with conjunctival incision,⁵ pseudophakia,⁶ aphakia,⁷ previous failed filtration surgery,⁶ previous argon laser trabeculoplasty,^{8,9} prolonged usage of antiglaucoma medications,^{10,11} chronic uveitis,¹² angle recession glaucoma¹³ and neovascular glaucoma.¹⁴ The recent era of antimetabolite therapy as an adjunct to filtration surgery has significantly increased the success rate in patients with risk factors for failure.^{2,6,15–17} However, their use is considered by some to be within the remit of glaucoma specialists.¹⁸

The primary aim of our study was to evaluate the 1-year success rate following nonenhanced trabeculectomy by non-glaucoma specialists in terms of intraocular pressure (IOP) control. We also assessed the effects of known risk factors for filtration surgery failure on the 1 year success rate in the same group of eyes. V.C.T. Sung T.K.H. Butler S.A. Vernon Department of Ophthalmology Queen's Medical Centre University Hospital Nottingham, UK

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Method

A retrospective study was undertaken on 167 patients undergoing trabeculectomy over an 11 month period (from 1 February 1996 to 31 December 1996) in a teaching hospital and a nearby district general hospital (DGH). Entry subjects were detected using theatre registers. Only trabeculectomies performed under the care of nonglaucoma specialists were included in the study. In the present study, we defined non-glaucoma specialists as consultants who do not receive tertiary referral of glaucoma patients from other ophthalmologists. One eye per patient was included in the study and, in the case of bilateral operations within the study period, the first eye was selected for study. Enhanced trabeculectomies with adjunctive antimetabolites, trabeculectomies performed by the glaucoma specialist firm at the teaching hospital, and combined cataract extraction and trabeculectomy operations were excluded. Success was defined as a postoperative IOP of less than 21 mmHg and at least a 20% reduction in IOP below the presenting IOP on no medication at the 12 month review. IOP was recorded by standard Goldmann applanation tonometry in the outpatient department.

Risk factors for failure were defined according to previous study series.^{2–14} They are: (1) age less than 40 years old, (2) black race (African descent), (3) diabetes mellitus, (4) miotic therapy ≥ 18 months, (5) sympathomimetic therapy ≥ 6 months, (6) pseudophakia/aphakia, (7) previous failed filtration procedure, (8) argon laser trabeculoplasty, (9) previous ocular surgery involving conjunctival incision (other than cataract and filtration surgery), (10) high-risk glaucoma (neovascular glaucoma, uveitic glaucoma and angle recession glaucoma). These risk factors were identified from the case notes. Patient characteristics, presenting and pre-operative IOPs were also recorded. Pre-operative, early (the first 3 months) and late postoperative complications were also noted. Post-operative IOPs at the 12 month follow-up visit (or at the visit closest to this time point and not less than 6 months) were used in the study. The number of glaucoma medications, and subsequent cataract surgery and repeat filtration procedures performed within the first 12 month period, were noted. Patients whose racial group was not recorded in the records were telephoned and asked to state their race.

An IBM-compatible microcomputer was used for data analysis. Statistical calculations were carried out with StatView software version 5.0 (SAS Institute, Cary, NC). The chi-squared test and Fisher's exact test (when a number in the 2 \times 2 table was < 5) were used for categorical data comparison, and the Mann–Whitney *U*test was used to compare non-parametric unpaired numerical data. A *p* value of less than 0.05 was defined as statistically significant. Logistic regression analysis was used to examine the relationship between the defined risk factors for failure and the success rates. Table 1. Teaching hospital versus DGH (district general hospital)

	Teaching hospital	District general hospital	p value
No. of patients	104	63	
Age (years)	68.2 ± 12.3	69.5 ± 10.8	NS
Sex			
Male	63	22	NS
Female	41	41	
Mean no. of risk factors	0.6 ± 0.8	0.4 ± 0.7	$p = 0.038^{a}$
Presenting IOP (mmHg)	29.2 ± 8.7	30.8 ± 9.8	NS
Pre-operative IOP			
(mmHg)	26.5 ± 6.3	27.1 ± 6.8	NS
Surgeon grade			
Consultant	42	53	$p < 0.0001^{b}$
Non-consultant	62	10	
Post-operative IOP			
(mmHg)	14.9 ± 5.5	$14.1~\pm~5.0$	NS
Success	87 (83.7%)	52 (82.5%)	NS

^aMann–Whitney U-test.

^bChi-squared test.

Results

A total of 206 trabeculectomies were performed by nonglaucoma specialist firms during the 11 month period. One hundred and twenty-seven trabeculectomies were performed in the teaching hospital (ten consultant unit) and 79 were performed in the DGH hospital (two consultant unit). The 13 eyes which had trabeculectomy performed with adjunctive 5-fluorouracil were excluded, as were the 19 second eyes operated on within the 10 month period. Three patients died within 12 months of the operation, and 4 patients were lost to follow-up due to moving away from the area. Hence data from a total of 167 eyes were analysed, 104 cases having been performed in the teaching hospital and 63 in the DGH. The mean follow-up period was 12.3 months (SD \pm 2.4, range 7–20 months).

All the operations were performed by consultant, specialist registrar or associate specialist grades. The technique of the trabeculectomy procedure was based on that described by Watson.¹⁹ Factors including the base of the conjunctival flap, the size and the site of the scleral flap, and the number and type of sutures on the scleral flap were varied according to the surgeon's discretion. No suture-lysis procedure was performed in these cases. Some patients were instructed to perform ocular massage during the early post-operative period.

Table 1 shows the patient characteristics, pre-operative and post-operative data from the teaching hospital group and the DGH group. There were no significant differences in the post-operative IOPs and the success rates between these two groups. Table 2 shows the patient characteristics, pre-operative anti-glaucoma therapy, distribution of glaucoma subtypes, number of risk factors by our definitions, presenting IOPs, pre-operative IOPs (IOPs at the last clinic visit before the operation) and grade of the surgeon who performed the operation in the success and failure groups. There were no recorded intraoperative complications in the two groups. The early post-operative (the first 3 months after the operation) and

 Table 2. Success versus failure

	Success	Failure	p value
No. of patients	139	28	
Age (years)	68.9 ± 11.4	67.5 ± 13.7	NS
Sex			
Male	70	15	NS
Female	69	13	
Pre-operative intraocular procedure	0.1 ± 0.3	0.1 ± 0.4	NS
No. of pre-operative medications	1.6 ± 0.8	1.9 ± 0.9	NS
Miotic therapy			
No. of patients	56	12	NS
Duration of miotic treatment (months)	12.8 ± 29.5	14.9 ± 35.0	NS
Sympathomimetic therapy			
No. of patients	24	6	NS
Duration of sympathomimetic treatment (months)	3.7 ± 11.1	5.3 ± 13.8	NS
Combined miotic and sympathomimetic treatment			
No. of patients	11	1	NS
Type of glaucoma			
POAG	108	16	NS
NTG	7	4	NS
AACG/CACG	13	2	NS
Pseudoexfoliation glaucoma	6	2	NS
Pseudophakic glaucoma	1	1	NS
Pigmentary glaucoma	1	0	NS
Uveitic glaucoma	1	3	NS
Angle recession glaucoma	1	1	NS
Steroid-induced glaucoma	1	0	NS
Mean no. of risk factors	0.5 ± 0.8	0.7 ± 0.9	NS
Presenting IOP (mmHg)	30.3 ± 9.4	27.4 ± 7.4	NS
Pre-operative IOP (mmHg)	26.6 ± 6.0	27.4 ± 8.5	NS
Surgeon grade			
Consultant	76	19	NS
Non-consultant	63	9	
Early complications			
Conjunctival wound leak	12	4	NS
Shallow anterior chamber	26	5	NS
Choroidal detachment	12	7	$p = 0.013^{a}$
Hyphaema	25	10	$p = 0.035^{a}$
Prolonged hypotony	7	0	NS
Late complications			
Cataract required operation	3	2	NS
Endophthalmitis	0	1	NS
Post-operative IOP (mmHg)	13.1 ± 3.8	22.2 ± 5.3	$p < 0.0001^{b}$
Follow-up period (months)	12.2 ± 2.4	12.7 ± 2.2	NS

^aChi-squared test.

^bMann–Whitney U-test.

POAG, primary open angle glaucoma; NTG, normal tension glaucoma; AACG, acute angle closure glaucoma; CACG, chronic angle closure glaucoma.

the late post-operative complications (after the first 3 months to the end of the observation period) are listed in Table 2. The overall success rate was 139 of 167 (83.2%; 95% confidence interval CI 80.0%–86.4%). The success rate of patients with POAG (primary open angle glaucoma) was significantly higher than that in patients with other glaucoma subtypes (108/124 (87.1%) vs 31/43 (72.1%); p = 0.023, chi-squared test).

The overall complication rates in all the study patients were: conjunctival wound leak 9.6%, shallow anterior chamber 18.6%, choroidal detachment 11.4%, hyphaema 21.0%, prolonged hypotony (IOP less than 5 mmHg for more than 2 weeks) 4.2%, cataract formation requiring surgery 5.3% and endophthalmitis 0.6%. Two patients in the success group had shallow anterior chambers requiring reformation during the first post-operative month. Two patients in the failure group had filtering bleb revision within the first 3 months. One patient had undergone repeat trabeculectomy with antimetabolites during the first 12 month period. The failure group had a significantly higher number of patients with choroidal detachment and hyphaema in the early post-operative period (p = 0.031 and p = 0.035 respectively) (Table 2).

There were 82 right eyes and 85 left eyes in the study. The number of risk factors was not significantly different between the two sides. The left eyes showed a significantly higher success rate (77/85 (90.6%) vs 62/82 (75.6%); p = 0.0096, chi-squared test) and a significantly lower IOP at 1 year (mean \pm SD; 13.5 \pm 5.0 mmHg vs 15.7 \pm 5.4 mmHg; p = 0.0043, Mann–Whitney *U*-test).

Table 3 shows the defined risk factors and the number of patients with these risk factors in the success and failure groups. There was no significant difference in the success rate in individual risk factors. When logistic

Table 3. The number of patients in each definition of risk factor for failure

	No. of patients with the defined risk factors			
Risk factors for failure	Success	Failure	p value	
Age less than 40 years	3	1	NS	
Black race (African descent)	2	1	NS	
Diabetes mellitus	8	0	NS	
Miotic therapy ≥ 18 months	27	6	NS	
Sympathomimetic therapy				
\geq 6 months	19	5	NS	
Pseudophakia/aphakia	4	2	NS	
Previous failed filtering procedure	e 0	0	NS	
Argon laser trabeculoplasty	2	0	NS	
Previous ocular surgery involving conjunctival incision (other than cataract and filtering surgery)		1	NS	
High-risk glaucoma				
Uveitic glaucoma	1	2	NS	
Angle recession glaucoma	1	1	NS	
Neovascular glaucoma	0	0	NA	

regression analyses were performed on patients with these risk factors, only uveitic glaucoma had a possible direct relationship with failure at 1 year, the odds ratio being 10.6 (p = 0.057; 95% CI: 0.9 to 121.4). There was no other new risk factor identified as affecting the success rate or the level of post-operative IOPs in our study.

Table 4 shows the means and standard deviations (SD) of presenting IOPs, pre-operative IOPs, postoperative IOPs and number of post-operative glaucoma medications in eyes grouped into a 'no risk factor group' (one or more risk factors), and also a 'one or less risk factor group' and a 'two or more risk factors group'. The post-operative IOPs were significantly higher in the two or more risk factors group (p = 0.022, Mann–Whitney Utest), and the two or more risk factor group had significantly fewer patients with IOPs of less than 16 mmHg (6/23 (26.1%) vs 87/144 (60.4%); p = 0.021, chisquared test). The mean time until failure was significantly longer in the two or more risk factors group than the one or less risk factor group (mean \pm SD: 2.5 \pm 2.2 months vs 1.0 \pm 2.5 months; p = 0.0006, Mann–Whitney U-test).

To eliminate the confounding effects of some eyes with high IOPs in the failure group, the results for only the 'successful eyes' were analysed. Of these, 17 eyes had two or more risk factors and 122 eyes had one or less risk factors. The index IOPs at follow-up were still significantly higher in the two or more risk factor group (mean \pm SD: 15.0 \pm 3.0 mmHg vs 12.8 \pm 3.9 mmHg, p = 0.046, Mann–Whitney *U*-test). The two or more risk factors group also had significantly fewer patients with IOPs of less than 16 mmHg at 1 year (6/17 (35.3%) vs $\frac{86}{122}$ (70.5%), p = 0.004, chi-squared test). When only eyes with POAG were analysed, the IOPs at 1 year and the success rate were not significantly different between the two or more risk factors group and one or less risk factor group, but the two or more risk factors group had significantly fewer patients with IOPs of less than 16 mmHg at 1 year (5/14 (35.7%) vs 70/110 (63.6%), p = 0.044, chi-squared test).

Discussion

To our knowledge, there have been no previous reports on the success rate of non-enhanced trabeculectomy by non-glaucoma specialists. The overall success rate in our study was 83.2%, which compared favourably with previously published series on trabeculectomy surgery.^{9,19–26} This is also comparable with results reported from the glaucoma specialist firm of the same teaching hospital^{27,28} (88% after a mean follow-up period of 13.4 months). The success rate, the post-operative IOPs at 1 year and the complication rate were not significantly different between the teaching hospital and the DGH, or between the consultant and the non-consultant grade. These results substantiate a study by Morrell et al.²⁵ in which no significant difference was found in the success rate and complication rate between the consultants and surgeons in training.

Previous studies have shown that glaucoma secondary to rubeosis, uveitis and angle recession have significantly higher failure rates.^{3,22} This has beeen emphasised in a recent study by Mietz *et al.*²⁹ who studied 534 eyes undergoing non-enhanced trabeculectomy with a mean follow-up period of 27.9

Table 4. No risk factor group versus risk factor	group, and one or less risk factor	group versus two or more risk factors group
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	No risk factor group	Risk factor group (one or more)	p value	One or less risk factor group	Two or more risk factors group	p value
No. of patients	103	64		144	23	
Laterality						
Right	53	29	NS	72	10	NS
Left	50	35		72	13	
Presenting IOP (mmHg)	30.1 ± 8.6	29.3 ± 10.0	NS	29.7 ± 8.5	30.5 ± 12.7	NS
Pre-operative IOP (mmHg)	26.3 ± 6.0	27.4 ± 7.1	NS	26.3 ± 6.0	29.5 ± 8.9	NS
Post-operative IOP (mmHg)	14.3 ± 5.2	15.2 ± 5.6	NS	14.2 ± 5.0	17.4 ± 6.3	$p = 0.022^{a}$
No. of post-operative glaucoma						
medications	0.1 ± 0.4	0.2 ± 0.5	NS	0.1 ± 0.4	0.30 ± 0.64	NS
Success	88 (85.4%)	51 (79.7%)	NS	122 (84.7%)	17 (73.9%)	NS
Post-operative IOP < 16 mmHg	61 (59.2%)	32 (50.0%)	NS	87 (60.4%)	6 (26.1%)	$p = 0.021^{b}$

^aMann–Whitney U-test.

^bChi-squared test.

months. They found significantly higher failure rates in the neovascular glaucoma (80%), uveitic glaucoma (50%), buphthalmos (40%) and traumatic glaucoma groups (30%). In the present study, patients with POAG had significantly better success rate than other glaucoma subtypes, but other glaucoma subtypes did not show a significantly higher failure rate. This was likely to be due to the small number of patients in our study with secondary glaucoma. However, the logistic regression analysis showed a possible direct relationship between uveitic glaucoma and failure (95% CI: 0.9 to 121.4).

The overall complication rates were not excessive compared with previously published series.^{17,21-27} Interestingly, the failure group had a significantly higher choroidal detachment rate and hyphaema rate. As far as we know, these complications have not previously been shown to be associated with poorer success rate. D'Ermo et al.²⁶ studying the long-term results of trabeculectomy in 90 eyes, found that the presence of surgical complications did not affect the long-term result of the trabeculectomy operation. Stewart and Crinkley³⁰ prospectively examined the incidence of serious choroidal detachment after trabeculectomy and did not find this factor to have any effect on the long-term intraocular pressure control. Konstas and Jay³¹ studied the effect of varying the position of the trabeculectomy fistula on the rate of post-operative hyphaema, and found the occurrence of hyphaema did not influence the post-operative IOPs at 4 months. However, in our study, the incidence of post-operative choroidal detachment and hyphaema relied on the entries in the case notes, and this may be underestimated in both the success and failure groups.

Patients in our study who had trabeculectomy on left eyes had a significantly higher sucess rate and lower IOPs at 1 year when compared with patients whose right eyes were operated on. Sanders et al.²³ have previously shown that nasally sited trabeculectomies have a better success rate than superior or temporal trabeculectomies, a finding later confirmed by our group.²⁷ In our current study the IOP differences may be explained by the fact that the majority of surgeons are right-handed, and therefore the filtration sites might be more commonly on the nasal side when left eyes were operated upon. Another possibility is that most patients tend to have their right eye IOP measured first, and, as breath-holding during applanation tonometry is a common phenomenon, the involuntary Valsalva manoeuvre might increase the IOP readings preferentially on right eyes.32

Risk factors for failure have been identified in previous studies.^{2–14} Longstaff *et al.*³³ identified cumulative years of pre-operative topical therapy as a significant risk factor for failure in patients undergoing glaucoma triple procedures. Lavin *et al.*¹⁰ found that patients who received at least 1 year of treatment with glaucoma medication had a significantly higher risk of failure. They found the hazard ratio for trabeculectomy failure was 16.6 for sympathomimetics (adrenaline) and 0.82 for miotics (pilocarpine hydrochloride). These findings were confirmed later in a study by Broadway et al.¹¹ They found that patients treated with a combination of beta-blockers, miotics and sympathomimetics or the combination of beta-blockers and miotics had a significantly lower success rate than patients treated with beta-blockers alone or primary surgery (the success rates were 45%, 72%, 93% and 90% respectively). In the absence of data on which to base a decision, in the present study we took an arbitrary period of 6 months for sympathomimetic therapy and 18 months for miotic therapy in our definition of significant risk factors for failure. However, we did not find significant differences in the success rates of patients treated with a combination of miotics and sympathomimetics or treated with either treatment alone. This may be due to the short follow-up period in our study.

Failure of filtration in trabeculectomy is commonly due to scarring of the fistula and the filtering bleb.³⁴ In the present study, eyes with two or more risk factors failed at a significantly later stage than eyes with one or no risk factors (mean: 2.5 vs 1.0 months, p = 0.0006). Histopathological study of failed blebs has shown a marked inflammatory response with abundant fibroblasts and deposition of new collagen.³⁵ However, there are no data in the literature on the different histopathological changes in relation to the time of filtration failure in trabeculectomy. Additionally, as the patients in this study did not have a standardised follow-up protocol, the time to failure may not be accurate to within 1 or 2 months. Therefore we consider this finding does not have any clinical significance.

Pre-operative use of topical glaucoma medications and previous surgery involving conjunctival incision have been shown to increase the number of fibroblasts, macrophages and lymphoctyes in the substantia propria of the conjunctiva.^{5,36} The aqueous humour has also been shown to have higher chemotactic activity towards fibroblasts in eyes that have had previous surgery.37 These changes enhance the healing process and hence scarring of the filtering bleb in filtration surgery. In the present study, eyes with two or more risk factors had significantly higher IOPs at 1 year - a result found to be still significant when only the 'successful eyes' were analysed. Furthermore, significantly fewer eyes with two or more risk factors had an IOP of less than 16 mmHg at 12 months. This was still significant when only patients with POAG were analysed. It is possible that the combination of two or more risk factors for failure may have a more profound effect on the conjunctival inflammatory cell profile.

Other authors have provided a scoring system for different risk factors¹⁶ or divided the known risk factors into high-risk and low/moderate-risk groups.^{17–38} In the present study, no individual risk factor had a significant effect on the success rate or the IOPs at 1 year. This was likely to be due to the limited number of patients with multiple risk factors for failure, as most of these patients would have been treated with adjunctive antimetabolite or have been referred to the glaucoma specialist

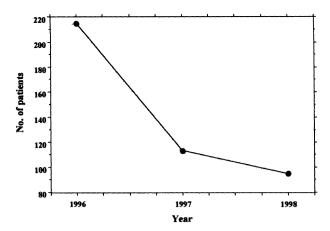


Fig. 1. Total number of trabeculectomies performed per year (1996–1998) in our teaching hospital unit.

consultant. Furthermore, the relatively short follow-up period in this study would limit the observation of the late effects of these risk factors, and further study of the same group of patients over a longer follow-up period may provide a better indication of the effects of these risk factors on the success rates and the IOPs.

With the advent of new medical treatments for glaucoma in recent years, the number of patients who need filtering surgery for IOP control appears to be decreasing. Ophthalmologists in our department are now performing fewer trabeculectomies than during the time of our study period (Fig. 1). As experience with the operation and its post-operative care decreases, it is possible that success rates may reduce and therefore it will be interesting to repeat the study at a future date. We recognise that our study has not attempted to determine outcome in terms of visual field or visual acuity, but as follow-up is limited to 1 year post-operatively, we consider these aspects of function are best reserved for a study with longer follow-up.

Agents that modulate the healing process, including the pre-operative use of topical corticosteroid,³⁹ and intraoperative and post-operative application of antimetabolite agents, have all been shown to improve the success rate or achieve a lower IOP in eyes with risk factors for failure undergoing trabeculectomy surgery.^{2,6,12,15,16,40-42} Further studies are necessary to assess the use of adjunctive anti-scarring agents in eyes with two or more risk factors for failure or in eyes requiring low target IOPs when trabeculectomy surgery is scheduled.

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