Sutureless versus Conventional Trabeculectomy for Management of Primary Open Angle Glaucoma

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Abstract

Purpose: To assess the efficacy and safety of sutureless punch trabeculectomy as substitute for conventional scleral flap trabeculectomy.

Methods: In a prospective, randomized study, 44 eyes of 42 patients with primary open angle glaucoma (POAG) who were candidate of trabeculectomy were included and randomly assigned into two groups; sutureless punch trabeculectomy or conventional scleral flap trabeculectomy. Intraoperative complications and postoperative visual acuity, IOP, bleb status, and complications were evaluated for a follow-up period of 6 months.

Results: Mean IOP was 21.9±7.9 mmHg before surgery and 16.0±4.7 mmHg 6 months after surgery in sutureless group, and 22.7±10.2 preoperatively and 15.8±5.2 postoperatively in the control group. No significant difference in complication rate was noted between the two groups. The absolute success rate was 50% and 59% in study and control group, respectively (P=0.545), and qualified success rate was 86.3% and 90.9% in the study and control group, respectively (P=0.365).

Conclusion: It appears that sutureless scleral tunnel trabeculectomy is a safe and effective drainage procedure for treating uncomplicated POAG, and can effectively substitute for conventional scleral flap trabeculectomy.

Keywords: conventional scleral flap trabeculectomy, sutureless scleral tunnel trabeculectomy

Introduction

Glaucoma accounts for blindness in 5.1 million people, responsible for 13.5% of global blindness. Trabeculectomy (TX) and its modifications, as the classic surgical procedures in treatment of glaucoma, have many complications such as laceration of the scleral flap, foreign body reaction, excessive tissue trauma, and local irritation due to use of sutures.[1] Keeping in mind these complications, a study was conducted in 1996 by Lai and Lam, in which they did trabeculectomy through a sutureless scleral tunnel.[2] This has overcome many of the complications associated with the classic trabeculectomy with sutures and had good success rate for treating uncomplicated primary open angle glaucoma (POAG).

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Keeping in mind the complication of conventional trabeculectomy and advantages of sutureless trabeculectomy as reported in literature, we performed a study to compare the results of conventional trabeculectomy with sutureless trabeculectomy in patients with POAG.

Methods

Patients

Following ethics committee approval, 42 patients (44 eyes) with indication of operation for POAG were randomized, between March 2003 and September 2005, to either conventional scleral tunnel trabeculectomy (22 eyes) or a sutureless scleral flap trabeculectomy (22 eyes). Randomization was performed using a sealed envelope system, where 44 shuffled envelopes designating the surgery to either conventional trabeculectomy or sutureless trabeculectomy, were opened immediately before surgery by the theatre nurse. Patient demographic data are shown in Table 1.

Table 1: Demographics and clinical characteristics of 22 cases of sutureless punch trabeculectomy (G_1) versus 22 cases of conventional scleral flap trabeculectomy (G_2)

	G_1 (N=22)	G_2 (N=22)	P value
Gender			
Male	18 (81.8%)	19 (86.4%)	
Female	4 (18.2%)	3 (13.6%)	
Age (mean)	64.2±6.81	63.04±7.98	
IOP			
Preoperative	21.9±7.97	22.77±10.20	0.756
Postoperative			
1 week	9.00±2.84	9.59±2.98	0.50
1 month	12.22±2.46	12.40±2.73	0.81
3 months	14.04±4.51	14.68±4.17	0.32
6 months	16.00±4.75	15.86±5.24	0.925
Mean IOP decrease postoperatively (6 months)	5.9	6.9	0.7
Drug number			
Preoperative	2.36±0.78	2.22±0.84	
Postoperative (6 months)	0.63±0.84	0.63±0.84	
Mean drug number reduction	1.72	1.59	0.7
Keratometry change (diopter)	0.61±0.26	0.50±0.08	0.081
Success			
Complete	11 (50%)	13 (59%)	0.545
Qualified	19 (86.3%)	20 (90.9)	0.365
Complication			
Intraoperative			
Hyphaema	4 (18.2%)	2 (9.1%)	0.664
Postoperative			
Hyphaema	6 (27.3%)	4 (18.2%)	0.721
Shallow AC	2 (9.1%)	3 (13.6%)	1
Wound leak	3 (13.6%)	2 (9.1%)	1
Blebitis	0	1 (4.5%)	0.312
Endophthalmitis	0	0	
Choroidal detachment	3 (13.6%)	5 (22.7%)	0.698
Hypotonia	5 (22.7%)	4 (18.2%)	0.973
Visual loss	1 (4.5%)	0	0.233
Encapsulated bleb	1 (4.5%)	0	0.312

Before entry into the study, informed consent was obtained from all patients. Inclusion criteria for the study were medically uncontrolled intraocular pressure (IOP) on maximal medical treatment or if they suffered from unacceptable side effects of their antiglaucoma medication and poor compliance of patient to treatment. Exclusion criteria were previous ocular surgery, previous anterior segment laser therapy, presence of ocular inflammation, presence of advanced cataract, congenital glaucoma, and any type of angle closure glaucoma. Study was performed in a double masked manner.

Preoperatively, full baseline data were obtained for each patient and included a full ocular and medical history, logMAR visual acuity (Early Treatment of Diabetic Retinopathy Chart), visual field assessment (Humphrey 24-2 computerized perimetry), slit lamp biomicroscopy, Goldmann applanation tonometry, gonioscopy, and mydriatic funduscopy. In addition, corneal topography was evaluated using a computerized photokeratoscope.

Surgical techniques
Immediately preoperatively single applications of pilocarpine 2% and chloramphenicol 0.5% drops were instilled into the operative eye. A single surgeon (YE), using retrobulbar anaesthesia with 2% lidocaine, performed all surgeries. Following insertion of a lid speculum, a 4/0 silk traction suture was inserted at the superior rectus if required.

Sutureless scleral tunnel trabeculectomy
Sutureless scleral tunnel trabeculectomy was performed via a fornix based conjunctival flap. If readily apparent, Tenon's capsule was excised. Haemostasis was achieved using cautery. A 3.00 mm in horrizontal length one third thickness scleral tunnel 3.00 mm from limbus was created and advanced to within 0.5 mm of the limbus. A crescent blade was used to tunnel into clear cornea. A paracentesis was performed 90 degrees from the trabeculectomy site. The anterior chamber was entered just beyond the limbus using a 3.2 mm slit blade. A punch trabeculectomy was performed using a crozeform punch (Altomed, UK). A peripheral iridectomy was fashioned and after reforming anterior chamber, the conjunctiva was closed with a continuous 8/0 vicryl suture.

Conventional scleral flap trabeculectomy
In patients that underwent conventional scleral flap trabeculectomy, the same procedure was used as for other group in sutureless TX in creating conjunctival flap and haemostasis. Then a 3.00 mm, triangular-shaped, one third thickness scleral flap was fashioned to within 0.5 mm of the limbus. After using a crescent blade for creating scleral tunnel and then paracentesis as fashioned with sutureless TX, 1.5x0.5 mm limbal block was removed with 15° stab and vannas scissor. A peripheral iridectomy was fashioned and the scleral flap closed with three 10/0 nylon sutures, two at the base near the limbus and one at the apex. The conjunctiva was closed with a continuous 8/0 vicryl suture.

Postoperative management
Immediately postoperatively, a subconjunctival injection of betamethasone and gentamycin was given, and the eye padded overnight. Postoperatively, topical chloramphenicol 0.5% was administered three times a day for 2 weeks and betamethasone 6 times a day for 2 weeks; this was then reduced over the next 2 months.

Postoperatively patients were examined at day 1 and then at 1, 4, and 6 weeks, and 3 and 6 months. At each visit a full ocular examination was performed, including logMAR visual acuity, slit lamp biomicroscopy, Goldmann applanation tonometry, gonioscopy, and mydriatic funduscopy. In addition, keratometry was performed preoperatively and then at 6 months after surgery.

Complete success was defined as an IOP of 21 mm Hg or less without antiglaucomatous medications and qualified success was defined as an IOP≤21 mmHg with or without medication.

Statistical methods
Student's t tests for variables with normal distribution and Mann-Whitney U test for other variables were used to compare continuous variables between the groups such as IOP differences. Chi-Square test or Fisher's exact test was used to compare qualitative data. Results with $P<0.05$ were considered statistically significant.

Results

Patient demographics
There were no significant differences in terms of age, sex, preoperative IOP, and number of preoperative glaucoma medications between eyes undergoing sutureless or conventional trabeculectomy (Table 1).

Operative data
Rupture of Descemet's membrane was not reported in eyes undergoing TX during surgery with exposure or prolapse of iris tissue and in every case the Descemet's window appeared to be grossly intact. The

only intraoperative complication was hyphaema that occurred in 4 cases in sutureless group and 2 cases in conventional group.

Intraocular pressure control

The follow-up period was 6 months. In all groups immediately postoperatively IOP was significantly reduced. Mean IOP at the follow-up period 1, 4 and 6 weeks and also 3 months after surgery did not differ between two groups (P>0.05). The mean IOP decrease in the sutureless TX group was 5.9 mm Hg at 6th month compared to 6.9 mm Hg in the conventional TX group. Mean IOP pre- and post- opearatively and the number of drug reduction after surgery are shown in Table 1.

After 6 months the percentage of eyes with successful drainage, or complete success was 50% with sutureless TX and 59% with conventional trabeculectomy (P=0.545). At the same time, the qualified success rate was in sutureless and conventional groups were 86.3% and 90.9%, respectively (p=0.36). There were no significant differences in terms of complete and qualified success rates between eyes underwent sutureless or conventional trabeculectomy (Table 1).

During 6 months follow-up, only 1 case in sutureless group underwent further bleb revision, 6 months postoperatively that after procedure IOP was controlled without medication. At the last follow-up visit the average number of antiglaucomatous medications per treated eye was 0.63 for both groups. Hypotony occurred in 5 cases in sutureless group compared to 4 cases in conventional group (P=0.973) with all eyes maintaining IOPs of 6 mmHg or greater.

Visual acuity

With exception of unaided logMAR visual acuity at 1st week, visual recovery was similar, with no differences either in unaided or pinhole acuity between the two groups. At the last postoperative visit logMAR unaided and pinhole visual acuity was either improved or unchanged in 95.5% of eyes undergoing sutureless TX and 100% after conventional trabeculectomy. One eye in the sutureless TX group lost more than two lines of logMAR acuity. This patient lost follow-up after one week postoperatively and returned 6 months later which at that time had developed

encapsulated bleb, raised IOP to 54 mmHg without any medication, and advanced (total) cup.

Keratometry and corneal topography

With exception of 3 patients in conventional TX group that developed 1 diopter with the rule astigmatism at 6 months postoperatively, changes in keratometric values during this period were less than 1 diopter in other patients. There were no significant changes in keratometry measurements between preoperative values and those at 6 months in either treatment groups (Table 1).

Complications

Postoperative complications are detailed in Table 1. Early complications such as transient bleb leaks and transient hyphaema were not significantly different between groups. Choroidal detachment in cases that were related to wound leakage was managed with treatment of leakage. Blebitis was seen in one patient in conventional group that developed at 4th week after surgery. It was managed with fortified broad spectrum antibiotics (cefazolin and gentamycin) for 7 days and then topical and systemic ciprofloxacin for 10 days, so that after 2 weeks blebitis was controlled and IOP and visual acuity did not change.

Discussion

In a randomized, prospective study on patients with POAG that underwent TX, we compared the outcome of sutureless TX with conventional TX. Without suturing, the amount of surgical manipulation and trauma will be less. The absence of suture material in the scleral flap minimizes local tissue irritation and foreign body reaction. The risk of suture tract abscess is also omitted. Furthermore, the sutureless technique may induce less postoperative astigmatism. On the other hand, overdrainage is a potential risk despite guarded aqueous outflow by the sclerocorneal tunnel. In our series, 9.1% of the eyes in the sutureless group and 13.6% in the conventional group had a transient shallow anterior chamber in the early postoperative period. Some perform suturing of scleral flap and then lysis sutures with laser. However, Suture lysis is not without risk. It can cause conjunctival perforation, sudden hypotony, shallow anterior chamber, and malignant

glaucoma.[3–6] With this consideration and the advantages of not using sutures as mentioned above, the sutureless technique may be recommended in scleral tunnel trabeculectomy.

In addition to above notes, a sutureless wound has other several advantages. In the absence of suture materials, local irritation and foreign-body reaction reduces, leading to less fibrosis and scarring of the conjunctival and scleral flaps. Also, don't passing a needle through the scleral flap minimizes tissue trauma and could decrease the incidence of intraoperative hyphema. The risk of suture-associated complications such as buttonholing through the conjunctival filtration bleb or suture-tract abscess formation, which might lead to an increased chance of endophthalmitis, is removed.[7] The incidence of "wipeout" syndrome correlated positively to the number of sutures used in the scleral flap closure, as demonstrated by Costa et al.[8] Using sutureless trabeculectomy incisions might theoretically protect against this complication. The correct tension of trabeculectomy scleral flaps, and thereby the speed of aqueous filtration, is regulated by sutures in conventional filtration surgery, leading to potential inter-individual and interprocedural variations, which sometimes require postoperative manipulations such as suture adjustment or release[9,10] or laser suture lysis.[3,11] All additional manipulations carry an added risk of complications, such as sudden hypotony (although in our study difference between the two groups was not significant) and conjunctival perforation[3,4] or malignant glaucoma.[5] Further, using an intact scleral tunnel roof, as in our sutureless trabeculectomy technique, seems to be a unique way of anatomically "standardizing" the one-way valve tension of the filtration fistula. Other advantages of our sutureless trabeculectomy procedure include minimal modification to existing self-sealing tunnel incision techniques, with no special or expensive instruments needed other than those already available on the standard surgical tray for glaucoma surgery. It is also a fast and relatively easy procedure.[7]

These are significant advantages since health care worldwide places an ever higher premium on cost containment and efficiency.[12] The astigmatism induced by sutureless

trabeculectomy is minimal, and visual rehabilitation occurs sooner because of early refractive stabilizing and minimal postoperative shift[13] although in our study keratometric values were not different between the two groups.

In our sutureless scleral tunnel trabeculectomy incision, most of the aqueous outflow was directed toward a single outflow channel instead of toward a two- or three-sided flap as in existing methods. The greater the amount of outflow through a fistula, the more likely the fistula will remain patent. The traditional methods result in random filtration to either side of the flap, essentially creating more than one fistula for filtration. A critical amount of "bulk flow" is necessary to maintain patency of a fistula. With a single outflow channel, as in the modified scleral tunnel trabeculectomy, this minimum bulk flow is more likely. Given a limited amount of total outflow available (to prevent profound hypotony), one fistula with a relatively high flow win more likely remains patent than two or more fistulas with less flow each, as in the conventional triangular or square scleral flaps.[14]

We did not use antimetabolites in our cases. A surgical procedure with results similar to antimetabolite filtering procedures but without the accompanying complications, would be ideal. Cillino et al[15] used punch trabeculectomy with intraoperative application of MMC and reported complete success (< or = 21 mmHg target IOP) in 71.4% of their patients, while qualified success was achieved in all the eyes. When a target IOP of ≤ 17 mmHg was considered, complete and qualified success were found in 13 (61.9%) and 15 eyes (71.4%), respectively. In Fontana et al[16] study on patients with phakic POAG by application of trabeculectomy and intraoperative MMC, the success rate (IOP≤18 mmHg and IOP reduction of 20%) after one and 3 years follow-up were 85% and 62%, respectively.

Keeping the scleral flap intact has an added advantage. An unwinged scleral tunnel roof would be more resistant to lateral instability because of the stabilizing effects of the two intact scleral tissue pillars on either side of the incision. Such a wound should withstand progressive long-term astigmatic shift better than conventional winged and

sutured scleral flaps or larger incision procedures, especially when used in conjunction with antimetabolites.[7]

Infectious endophthalmitis after sutureless cataract surgery has been reported.[17-19] The endophthalmitis occurred in the early postoperative course in most cases, which suggests the introduction of pathogens at the time of surgery.[20,21] Since the risk of infection is known to increase incrementally with extended surgical times, the short duration of a sutureless filtration procedure might decrease the inoculum of bacteria at the time of the surgery. In the absence of data from randomized prospective studies, there is no conclusive, objective evidence to suggest an increased incidence of endophthalmitis after scleral tunnel incision surgery. Low rates of infection after sutureless surgery have been reported.[22] It seems that it was not due to the sutureless wounds, but rather the surgical manipulation and complications combined with host factors that predisposed to the development of infections. We anticipate no higher incidence of endophthalmitis in sutureless trabeculectomies than is seen in conventional TX alone.

In none of our patients there was any clinical evidence of posterior wound gape postoperatively. If the surgeon meticulously adheres to the principles of aseptic technique, avoids excessive surgical manipulations, and maintains an exact wound configuration (e.g., an overlap of not less than 1 mm between the tunnel roof and the internal sclerostomy) and watertight conjunctival flap closure, the unidirectional valve effect of the modified scleral tunnel trabeculectomy incision should prevent retrograde reflux of pathogens into the anterior chamber during the postoperative period.[7]

Conclusion

In our study, although no statistical significant difference was seen in terms of effectiveness and complication between both groups, however, with respect to short duration of surgery in sutureless TX and short-term learning curve compared to conventional TX, this procedure can be advised for treatment of POAG. Authors of this article recommend a large prospective study with lager sample size and long-term follow-up for confirming findings of this study.

Finally, the sutureless trabeculectomy technique seems to be an effective, quick, repeatable, and safe procedure, and we believe it should not be restricted to glaucoma patients with uncontrolled IOP alone.

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