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Original Article

Effectiveness of combination of permanent and releasable scleral flap sutures in trabeculectomy: A randomized clinical trial

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Abstract
Introduction: Trabeculectomy is a commonly used surgical treatment for glaucoma.
Purpose: To evaluate the effectiveness of combination of permanent and releasable scleral flap sutures to minimize the immediate postoperative complications of trabeculectomy.
Materials and methods: This study was carried out in Department of Ophthalmology, B P Koirala Institute of Health Sciences, Dharan, Nepal. Forty one eyes of 34 patients undergoing trabeculectomy were randomized to undergo either conventional trabeculectomy (Group A= 20 eyes) or trabeculectomy with combination of permanent and releasable scleral flap sutures (Group B =21 eyes). The parameters studied were intraocular pressure (IOP), anterior chamber depth (ACD) and surgical complications over a period of 6 weeks.
Results: Significantly higher number of eyes belonging to group A (14 eyes) had shallower anterior chamber than group B (7 eyes) on first post operative day (p=0.042). Six eyes (30%) in group A had peripheral or central irido-corneal touch in early postoperative period as compared to only one in Group B. Hypotony was noted in 3 eyes in each group. Two patients in group A required reformation of anterior chamber. Other surgical complications in the two groups were similar.
Both the groups had a significant drop in IOP following surgery. However, there was no significant difference in the IOP between the two groups after 6 weeks (Group A: 10.95 ± 3.03 mmHg vs. Group B: 12.29 ± 4.67 mmHg; p=0.87). There was a significant drop in IOP following removal of sutures (15.19 ± 6.15 mmHg to 13.19 ± 6.13 mmHg; p=006) in group B.
Conclusion: Use of combination of permanent and releasable scleral flap sutures is a safe technique that significantly reduces the incidence of immediate postoperative shallow anterior chamber after trabeculectomy.

Key words: Trabeculectomy, Intra ocular pressure, anterior chamber depth, combination of releasable and permanent scleral flap sutures

Trabeculectomy is one of the most commonly performed incisional surgical procedures for glaucoma. Success following trabeculectomy has been variously described. Central to these definitions is ideal control of intraocular pressure (IOP). Either abnormal increase or decrease in IOP can have detrimental effect on the optic nerve function and thus determine the eventual outcome of this procedure.

Proper tension in the scleral flap suture will determine the IOP in the immediate post operative period. Of the various causes of raised IOP in the immediate post operative period in an uncomplicated trabeculectomy, tighter scleral flap sutures probably are responsible for majority of the cases[1,2]. Management option for this condition includes digital massage, laser suturolysis and releasable sutures[3,4]. Since laser suturolysis requires costly equipment and can be associated with other complications related to the bleb (post operative inflammation, button holing, subconjunctival haemorrhage and hypotony), is not preferred by many ophthalmologists. On the other hand, releasable sutures, which are easy to apply, are free of these limitations[5].

Early removal of releasable sutures on the other hand , is reported to have higher incidence of hypotony and bleb failure[6]. To prevent such a complication we proposed a combination of releasable and permanent sutures, where the placement of permanent sutures will prevent those complications. With these factors in mind we planned to study the anterior chamber depth, incidence of shallow anterior chamber and IOP in patients undergoing trabeculectomy with permanent scleral flap sutures and a combination of permanent and releasable sutures.

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Materials and Methods

The study was conducted in the Department of Ophthalmology, B P Koirala Institute of Health Sciences, Dharan, Nepal. All patients undergoing trabeculectomy for primary open angle and angle closure glaucomas were included for the study. Patients diagnosed with secondary glaucoma and congenital glaucoma were excluded from the study population. Also excluded were the patients not consenting for this study.

Study population

Forty one eyes of 34 patients fulfilling the inclusion criteria were randomised into 2 groups. Group A consisted of 20 eyes that underwent conventional trabeculectomy where as Group B having 21 eyes underwent trabeculectomy with combination of permanent and releasable scleral flap sutures. In all cases an informed consent was obtained.

Preoperative Assessment

Detailed history was obtained pertaining to duration and treatment for the glaucoma. Ocular examination included best corrected visual acuity, anterior segment evaluation with slit lamp biomicroscope and posterior segment examination using direct and stereoscopic means (90 D evaluation of optic nerve head). Anterior chamber depth was graded using van Herick's method [7]. Angles were examined and graded using Goldmann single mirror indirect goniscope.

Intraocular pressure (IOP) was measured with Goldmann applanation tonometer and an average of three IOP readings were obtained during each evaluation. Effort was made to record the IOP during similar times in all cases. Also a note was made regarding the number of topical or systemic medications the patient was on.

Operative Procedure

All patients in this study were admitted to the hospital 1 day before the planned surgery. Local anaesthesia was achieved using peribulbar block. Surgical interventions in all patients were performed as per allocation to one of the two groups. In both the groups a limbal based conjunctival flap was made from 11 to 1 o'clock positions 8 to 10 mm from the limbus. Haemostasis was achieved using bipolar wet field cautery at the site of the intended scleral flap. A corneal side port was made at 9 o'clock position. A 4 x 4 mm rectangular scleral flap of one-half scleral thickness was dissected to the limbal zone. Internal opening of 3 x1.5 mm was made into the anterior chamber. A peripheral iridectomy was done. The scleral flap was closed with two interrupted 10.0 nylon sutures on each superior corner of the flap. The tightness of the sutures was adjusted to maintain anterior chamber depth with minimal aqueous flow around the flap edges. The conjunctival flap was closed with continuous suture using 8-0 vicryl. In addition to above in group B two additional releasable sutures were applied in the proximal end of the scleral flap as described by Cohen and Osher [8].

At the end of the surgery, in both the groups subconjunctival injection of 2mg of dexamethasone and 20mg of gentamycin sulfate were given 180^0 away from the bleb site. The operated eye was bandaged overnight immediately after surgery. Topical antibiotic (Gtt ciprofloxacin qid) and corticosteroid drops (1% Prednisolone acetate 2 hourly) were prescribed for 6 to 8 weeks postoperatively with 1% tropicamide drops thrice a day for 2 weeks. All patients were followed up on day 1, 7, 14 and 6 weeks as out patients. The parameters recorded during follow-up were bleb characteristics (bleb score [9], table 4), intraocular pressure (IOP) and anterior chamber depth (ACD).

Releasable sutures were released with the patient under topical anaesthesia and seated at the slit lamp, by pulling the exteriorized corneal loop with a suture holding forceps.

Time for release of sutures

(i) The releasable sutures were removed whenever the IOP was more than 10 mm Hg even after digital massage. One suture was removed at a time. The second suture was removed if there was persistent IOP greater than 10 mmHg or after 2 weeks which ever was earlier.
(ii) In rest of the cases the releasable sutures were removed on 14^{th} postoperative day irrespective of the IOP.

Outcome measurement

The success of the procedure was defined as the eyes having level of IOP below 20 mmHg without any anti-glaucoma medications after 6 weeks of operation.

Statistics

Chi square test, Student's t-test and Fisher exact test were used to find out the probability values between the groups. P value of <0.05 was considered significant. All calculations were executed using SPSS 11.0 software program.

Results

The patients' characteristics of both the groups are provided in Table 1.

Intraocular Pressure

There was a significant drop in intraocular pressure from the preoperative values during the entire follow up period in both the groups (p=<0.001). However, there were no significant changes in IOP during the post operative period (from day 1 to 6 weeks) within both the groups (Group A ; p = 0.982 and Group B p=0.869; ANOVA).

Patients undergoing conventional trabeculectomy had lower IOP in the post operative period than those having releasable sutures, though this difference was not statistically significant (table 2).

Mean reduction in IOP from the preoperative IOP in the groups A and B at 6 weeks was 30.45 ± 8.89 mm Hg and 31.38 ± 10.16 mmHg respectively.

Release of sutures

Eleven eyes required scleral suture removal before the scheduled 14th post operative day, of these 10 had IOP below 20mm Hg (mean IOP = 13.89 ± 5.79 mm Hg) and one eye had IOP of 28 mm Hg. Mean duration of removal of sutures was 9.95± 4.32 days. In the conventional group only 5 eyes had IOP > 20 mm Hg during the early post operative period, which was managed by digital massage. None of the eyes required additional antiglaucoma medications in either group in the postoperative period. There was a significant drop in IOP after removal of suture (15.19 ± 6.15 mmHg to 13.19 ± 6.13 mmHg p = 0.006, paired t test). Most of this change occurred when the sutures were released in the first week or first 4 days of surgery. And almost none occurred when sutures were released on 14th day. It is also interesting to note that 2 eyes where suture removal was done after 7 days actually had increase in the IOP when measured at 6 weeks. There was no significant change in the anterior chamber depth following removal of sutures (p=1.000, Wilcoxon rank test)

Anterior chamber depth

More patients in group A had shallow anterior chamber (Grade II or less) in the post operative period. The anterior chamber depth in the two groups was similar during follow ups; except for the first post operative day when patients undergoing conventional trabeculectomy had significantly more eyes with shallower anterior chamber (Table 3).

Bleb Score

Patients undergoing trabeculectomy with releasable sutures had better bleb score at 6 weeks. None of the eyes had bleb score of less than 4, though the difference was not found to be statistically significant (Table 4).

Complications

The incidence of transient hypotony (defined as IOP < 6mm Hg lasting for <1 month) in the group A and group B was 15% and 14.3% respectively (3 cases in each group). Flat anterior chamber on 1st postoperative day was observed in 3 eyes in group A and one eye in group B, whereas grade I shallow anterior chamber (peripheral iridocorneal touch) was observed in 3 and 0 eyes in group A and B respectively (Table 5).

Two patients in group A required surgical reformation of anterior chamber. In group A, one eye had encysted bleb which improved with bleb needling, one eye developed a single posterior synechia and two eyes had progression of cataract. Choroidal detachment was noticed in one eye with flat anterior chamber. This patient improved on conservative management.

In group B, one eye each had blebitis, posterior synaechiae, cataract and hyphaema in immediate postoperative period. Hyphaema and blebitis resolved with conservative management.

Visual acuity

The pre operative visual acuity in the two groups was similar. At 6 weeks, 2 eyes each in group A and B had decrease in visual acuity from the preoperative level. Out of these only 2 eyes, belonging to group A had visual loss ≥ 2 lines. Three of these eyes had cataract and one eye had blebitis as complication. (Table 6)

Table 1: Patients' characteristics

	Permanent sutures (Group A) n =20	**Combination of permanent and releasable sutures (Group B) n=21**	**P value (* - chi square test, # - t test)**
Age (mean ± SD) years	51.50 ±10.65	47.25 ±12.47	0.251#
M : F	9:11	10:11	0.885*
Type of glaucoma			
Open angle	3	6	0.511*
Angle closure	15	14	
Mixed type	2	1	
Pre operative			
IOP ± SD mm Hg	41.60 ± 9.37	43.67 ± 7.38	0.436#
ACD (grade)			
≤II	9	8	0.895*
>II	11	13	
Visual acuity			
>6/60	12	14	0.906*
≤ 6/60	8	7	

Table 2: Postoperative Intraocular Pressure (Mean ± SD)

Postop follow ups	**Permanent sutures (Group A) mm Hg**	**Combination of permanent and releasable sutures (Group B)(mmHg)**	**P Value**
Day 1	11.70 ± 6.22	12.38 ±7.30	0.750
1 week	11.65 ± 5.37	13.67 ± 7.08	0.312
2 weeks	11.70 ± 5.03	13.14 ± 5.07	0.366
6 weeks	10.95 ±3.03	12.29 ± 4.67	0.287

Table 3: Postoperative Anterior Chamber Depth (van Herrick grading)

	Day 1	**One week**	**2 weeks**	**6 weeks**
Permanent sutures (Group A)				
≤ Grade II	14	12	10	8
> grade II	6	8	10	12
Combination of permanent and releasable sutures (Group B)				
≤ Grade II	7	8	6	5
> grade II	14	13	15	16
P value	**0.042**	0.276	0.278	0.437

Table 4: Bleb score[#] (after 6 weeks) in the two groups

Bleb score	**Permanent sutures (Group A)**	**Combination of permanent and releasable sutures (Group B)**
1	0	0
2	3	0
3	1	0
4	2	3
5	11	12
6	3	6
Median	5	5
Mean	4.5±1.28	5.1±0.64

[#]Bleb score (Migdal & Hutchings[9])

Score	**Characteristics**
1	Flat bleb
2	Elevated engorged conjunctiva
3	Pale elevated area with engorged conjunctiva
4	Residual conjunctival engorgement around the suture line
5	Pale and diffusely elevated conjunctiva
6	Pale cystic conjunctival elevation

Table 5: Postoperative complications

Complications	**Permanent sutures (Group A)** Number of eyes (%)	**Combination of permanent and releasable sutures (Group B)** Number of eyes (%)
Encysted bleb	1 (5)	0 (0)
Blebitis	0 (0)	1 (4.76)
Hyphema	0 (0)	1 (4.76)
Post synechae	1 (5)	1 (4.76)
Cataract	2 (10)	1 (4.76)
Choroidal detachment	1 (5)	0 (0)
Shallow Anterior Chamber		
Grade 1 (peripheral iridocorneal touch)	3	0
Grade 2 (central irido-corneal touch)	3	1
Grade 3 (lenticular touch)	0	0

Table 6: Visual acuity in the two groups

Visual acuity	**Permanent sutures (Group A)**	**Combination of permanent and releasable sutures (Group B)**
Pre operative visual acuity		
>6/60	12	14
≤ 6/60	8	7
Post operative visual acuity		
>6/60	11	13
≤ 6/60	9	8
Eye with visual loss	2	2
P value (Chi Square test)	0.906	

Discussion

Clinical observation in the present study supports the fact that combination of permanent and releasable sutures provides satisfactory drainage with less reduction in anterior chamber depth (ACD) in the early postoperative period. Following trabeculectomy increased filtration in the post operative period is expected to produce a shallower anterior chamber[10]. Inadequate tension in the scleral sutures is responsible for the majority of cases of flat anterior chamber in otherwise uneventful trabeculectomy[11]. Eyes with flat anterior chamber are complicated by hypotony maculopathy, choroidal effusion, suprachoroidal haemorrhage, cataract, corneal endothelial cell loss, peripheral anterior synechiae and aqueous misdirection[12].

Many studies have documented beneficial role of postoperative release of sutures in trabeculectomy. Sutures applied in the form of releasable sutures can be released in the post operative period or else can be removed with laser.[2]

Laser suturolysis despite being costly requires tenectomy. It is also associated with local complications and bleb leak. Pressure by the contact lens during suturolysis is suggested to be one of the reasons for flat chamber following this procedure.[5] On the other hand, application of releasable sutures, though requires surgical expertise, is free from these complications. Removal of the releasable sutures in the early post operative period can also lead to hypotony and shallow anterior chamber requiring reformation[12] , whereas the same may not happen when it is applied in combination with permanent sutures, which was the basis for our study.

However, the correct timing of release to have maximum beneficial effect is not known. To complicate matters further, this timing is affected with adjuvant antimetabolite use or when combined with cataract surgery.

Some of the studies demonstrate lowering of IOP till 2 weeks of surgery with maximum lowering occurring when sutures are released within 3-4 days[12,13]. It is also known that early suture removal is associated with hypotony and is an independent risk factor for bleb failure[6].

In the present study, eyes undergoing conventional trabeculectomy (Group A), had higher incidence of shallow, flat anterior chamber and anterior chamber reformation in the early post operative period, although the incidence of hypotony was similar in the two groups (3 eyes in each group). Our figures of these complications are lower than those described by other investigators[13] , which can be due to the use of combination of releasable and permanent sutures.

In accordance with other studies, we found maximum lowering of IOP where sutures were released within first 4 post operative days. None of these eyes developed prolonged hypotony supporting our hypothesis. Since there were only 3 eyes, which required early suture removal, further studies can be carried out to consolidate this hypothesis. As expected, most of the change in anterior chamber depth occurred in the early postoperative period corresponding to maximum lowering of IOP. Patients undergoing conventional trabeculectomy were found to have shallower anterior chamber in the first postoperative day as compared to eyes where a combination of permanent and releasable sutures was used. However, there was no difference in the anterior chamber depth at the final follow up. Though

the follow up period was short, there was no case of bleb failure or prolonged hypotony.

In terms of bleb score and control of IOP both the groups were similar at the end of follow up period. Both the groups had on an average of 31mm drop from the preoperative values. Other studies have documented similar findings with higher drop in IOP from the preoperative values on follow up[12, 13]. Complications associated with the use of combination of permanent and releasable scleral flap sutures were minimal in present study. No case of hypotony maculapathy, choroidal detachment, was noted in our study. No eyes developed corneal abrasion from the free end of suture, which may be due to the fact that suture end was buried in the corneal stroma[12].

Kolker et al [12] reported suture breakage on attempted removal in six eyes (4.1%). This complication was noted in one eye in the present study. No cases of endophthalmitis or corneal infection were encountered in this study, though there was one case of blebitis which was successfully managed conservatively. The most important limitation of this study is the duration of follow up. Though the IOP remained controlled and there were no cases of bleb failure, long term follow up is required to find out this difference in the two groups. The other limitation of this study could be consideration of the peripheral anterior chamber depth only for grading the ACD using the van Herrick method, which ignores the central anterior chamber depth.

Conclusion

The combination of releasable and permanent scleral flap sutures in trabeculectomy is a simple and safe technique that significantly reduces the incidence of immediate postoperative shallow AC. It also arms the surgeons with a better control over the IOP in the postoperative period.

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