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Trabeculectomy with Mitomycin-C Versus Modified Adjustable Sutures Trabeculectomy with Mitomycin-C in Primary Open-angle Glaucoma: Comparative Study

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Abstract

Background: Trabeculectomy is the most common glaucoma surgery worldwide. Overflow may lead to serious complications, fine control of IOP by adjustable sutures technique decreased complications and increased success rates.

Methods: A comparative, prospective, interventional clinical study in which 50 eyes of 50 patients with primary open-angle glaucoma were included, and randomly assigned to Trabeculectomy with Mitomycin-C and modified adjustable sutures trabeculectomy with Mitomycin-C. It was conducted at Al-Hussein University Hospital, Cairo, between January 2017 and December 2021. Patients were followed-up for 1 year IOP was compared, and complications were recorded.

Results: Our results demonstrated that mean postoperative IOP was statistically less in group (A) compared with group (B) on the first postoperative follow-up day ($P < 0.0001$), 1 week ($P = 0.005$), 1 month ($P = 0.0014$) and at 3 months ($P = 0.0177$), postoperatively. Preoperative and at 6 and 12 months, there was no significant difference between both groups. Hypotony was observed in four patients in group (A) only. 9 (36%) cases in group (B) required suture adjustments, done on the first and second follow-up visits. Postoperative antiglaucoma medication boxes were more in group (B).

Conclusion: Trabeculectomy with adjustable sutures is a procedure promising as regards safety and prevention of excessive drainage.

Keywords: Adjustable sutures, Glaucoma, Mitomycin, Trabeculectomy

1. Introduction

Glaucoma is not a single disease process, but a group of disorders characterized by a progressive optic neuropathy resulting in a characteristic appearance of the optic disc and a specific pattern of irreversible visual field defects that are associated frequently but not always with raised IOP. Thus, IOP is the most common risk factor for the development of glaucoma.¹

IOP is the major risk factor that can be changed. The goal of glaucoma treatment is to slow the rate of

progression throughout a patient's lifetime in order to maintain visual functions and related quality of life.²

Trabeculectomy is the most performed surgery worldwide. Over-filtration is one of the major Complications that may occur and leads to flat anterior chamber, hypotony, choroidal detachment, cataract, hypotony maculopathy, aqueous misdirection, and suprachoroidal hemorrhage.³

A technique of adjusting sutures can be used in which a special forceps can be used trans-conjunctivally to adjust the sutures and hence the IOP downward gradually until the target pressure is reached.⁴

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2. Patients and methods

In this prospective, comparative, interventional clinical study, 50 patients with primary open angle glaucoma were included. One eye was selected from each patient and randomly assigned into two groups. It was conducted at Al-Hussein University Hospital, Cairo, between January 2017 and December 2021.

2.1. Patient selection

Surgery was done for patients having glaucomatous visual field defect progression with IOP of more than 21 mmHg despite maximum medical therapy. We exclude angle closure glaucoma, pediatric glaucoma, secondary glaucoma, and patients with previous ocular surgery.

Written informed Consent was taken from all patients, after explanation of the nature of the surgery. The current study follows the medical research Ethical Committee principles at Al-Azhar University as well as the Helsinki Declaration. The participants who fulfilled the inclusion criteria were assigned randomly into two groups. Group (A) in which 25 patients who were submitted for subscleral trabeculectomy (SST) with Mitomycin-C. Group (B) in which 25 patients who were submitted for subscleral trabeculectomy with Mitomycin-C and adjustable sutures.

2.2. Preoperative evaluation involves

Visual acuity assessment, refraction, slit lamp biomicroscopic examination, IOP was measured using applanation tonometer, optic nerve head was assessed using either 90 lens, anterior chamber angle was assessed using Goldmann three mirror contact lens and automated perimetry. All data was recorded in the preoperative sheet.

2.3. Operational procedure

Surgeries were performed under complete septic conditions. Vicryl 8/0 bridle suture is used to fix the eye in the downward gaze. A conjunctival flap fornix-based was fashioned. The Tenon's capsule is cleared away. Hemostasis was achieved with light cautery. Tissue remnants on sclera were scraped. A lamellar 4 × 4 mm scleral flap was performed with a #15 blade. Scleral flap was advanced towards the limbus into 1 mm clear cornea. Sponges soaked in 0.02 (2 mg in 10 ml) Mitomycin-C was placed at the site of filtration for 2 min Then thorough irrigation with balanced salt solution. Paracentesis was made

with MVR. With a super blade, an incision was made in the clear cornea 3 mm in length and as far anteriorly as possible, 2 vertical cuts were made, then the rectangular tissue block was excised. Peripheral iridectomy was then done using Vannus scissors. The sclera flap is sutured at its posterior corners by Two 10/0 nylon fixed sutures.

In group (A) the scleral flap was closed in the conventional way. In group (B) the scleral flap was closed by two fixed loose sutures at the corners of the scleral flap using 10/0 nylon, Three adjustable sutures one superiorly and two at each side of the flap. Adjustable sutures were designed by making four throws and then closed in a bow-tie pattern.

In the peripheral clear cornea about 1 mm from the limb we make four grooves, each one about 1 mm long, and formed independently from each other. Conjunctiva was closed tightly by 10/0 nylon in a mattress fashion to prevent leakage.

Conjunctival sutures knots then embedded in the corneal grooves. Paracentesis edges were finally hydrated.

2.4. Postoperative care

Eye drops prednisolone sodium phosphate 1% every 4 h for two weeks and then decreased according to the intraocular inflammation. Eye drops Moxifloxacin 0.3% every 4 h on the first day. The next day, it was reduced to quater in die (qid) for 2 weeks. Follow up intervals were scheduled for the 1st day, 1st week, then 1st month. Then follow-up was every month for one year, any complications were recorded and managed. We adjust the sutures transconjunctivally using a slit-lamp by a Khaw forceps in patients with IOP more than 18 mmHg. We explained the procedure to the patients, reassuring them that the adjustment was not painful. In all patients we used anesthetic eye drops and decongestant eye drops to enhance good visualization of the sutures and to decrease conjunctival hemorrhage. We measure the IOP after an hour of adjusting the suture. And if the IOP is still high we do another suture adjustment.

3. Results

50 eyes of 50 patients with primary open-angle glaucoma were assigned randomly into two groups: group (A) 25 patients were submitted for SST with Mitomycin-C and group (B) 25 patients were submitted for SST with Mitomycin-C and adjustable sutures. The age variant from (47–75) years in group A with mean ± SD (63 ± 7.9) and in group B the age variant from (48–72) year with mean ± SD (63 ± 6.6)

there were no differences between the two groups as regard the sex or preoperative VA (Table 1).

3.1. Intraocular pressure

In Table 2 we summarize preoperative and postoperative IOP results during postoperative follow-up period, range and the mean \pm SD.

Mean postoperative IOP was statistically significantly lower in group A compared with group B at the first postoperative day ($P < 0.0001$), 1 week ($P = 0.005$) 1 month ($P = 0.0014$) and at 3 months ($P = 0.0177$), postoperatively. Preoperative and at 6 and 12 months, the difference between both groups was not significant.

3.2. Visual acuity

The mean \pm SD preoperative VA was 0.20 ± 0.16 in group (A) and 0.22 ± 0.14 in group (B) ($P = 0.5$). At 3 months postoperatively VA was slightly reduced from preoperative values. Mean \pm SD Postoperative VA was 0.15 ± 0.14 in group (A) and 0.20 ± 0.14 in group (B) ($P = 0.2$). No correlation or significant difference was found between the two groups V/A (Tables 3 and 4).

3.3. Complications

Intraoperative complications included conjunctival tear 4 (16%) and 2 (8%) in group (A) and (B), respectively. Intraoperative hyphema 1 (4%) and 1

Table 1. Demographic characteristics and preoperative assessment.

	Group A n = 25	Group B n = 25	P value	R
Age (years)			0.73	0.050
Range	45–75	48–72		
Mean \pm SD	63 \pm 7.9	63 \pm 6.6		
Sex			>0.99	= =
Males	14 (65%)	14 (65%)		
Females	11 (35%)	11 (35%)		
Eye			0.98	= =
Right	14 (65%)	12 (48%)		
Left	11 (35%)	13 (52%)		
V/A pre			0.50	–0.35
Range	0.05–0.50	0.05–0.50		
Mean \pm SD	0.20 \pm 0.16	0.22 \pm 0.14		
IOP pre			0.18	–0.15
Range	25–43	24–42		
Mean \pm SD	33 \pm 5	31 \pm 5		
Vertical C/D			0.97	–0.06
Range	0.50–0.90	0.60–0.90		
Mean \pm SD	0.80 \pm 0.09	0.80 \pm 0.08		
MD (dB)			0.05	0.09
Range	–21: –7.2	–22: –7.4		
Mean \pm SD	–14 \pm 4.8	–16 \pm 4.4		

Table 2. IOP preoperative, 1 day, 1 week, and 1, 3, 6, and 12 months postoperative.

	Group A n = 25	Group B n = 25	P value	R
IOP mmHg pre			0.18	–0.15
Range	(25–43)	(24–42)		
Mean \pm SD	33 \pm 5	31 \pm 5		
Post 1 day			<0.0001****	0.12
Range	(2–20)	(7–37)		
Mean \pm SD	7.5 \pm 4.7	15 \pm 8.4		
Post 1 week			0.005**	0.32
Range	(2–22)	(7–25)		
Mean \pm SD	8.8 \pm 5.1	12 \pm 4.7		
Post 1 month			0.0014**	0.22
Range	(8–17)	(7–20)		
Mean \pm SD	9 \pm 2.9	12 \pm 3.3		
Post 3 months			0.0177*	0.06
Range	(8–17)	(7–17)		
Mean \pm SD	10 \pm 2.9	12 \pm 2.5		
Post 6 months			0.32	–0.076
Range	(8–22)	(8–20)		
Mean \pm SD	11 \pm 3.7	12 \pm 3		
Post 12 months			0.24	0.11
Range	(8–15)	(8–18)		
Mean \pm SD	11 \pm 2.7	12 \pm 2.5		

* $P \leq 0.05$, ** $P \leq 0.01$, **** $P \leq 0.0001$.

(4%) in group (A) and (B), respectively. Postoperative complications such as Cataract 5 (20%) and 2 (8%) in group (A) and (B), respectively. Also, hypotony was observed in 4 (16%) in group (A) only. Wound leak repair 1 (4%) Choroidal effusion 1 (4%) was observed in group (A). Wound leak alone 1 (4%) and Suture exposure 5 (20%) was found in group (B).

3.4. Number of antiglaucoma medication required postoperatively

To get the target IOP, 2 cases required one antiglaucoma medication and 2 cases required two antiglaucoma medications in group (A), while 5 cases required two antiglaucoma medications in group (B). Both procedures significantly decreased the need for antiglaucoma medications. The mean number of preoperative antiglaucoma was 2.16 and 2.32 in group (A) and group (B), respectively, while the mean number of postoperative antiglaucoma was 0.28 and 0.4 in group (A) and group (B),

Table 3. V/A preoperative, and 3 months postoperatively.

	Group 1 n = 25	Group 2 n = 25	P value	R
V/A pre			0.50	–0.35
Range	(0.05–0.50)	(0.05–0.50)		
Mean \pm SD	0.20 \pm 0.16	0.22 \pm 0.14		
V/A 3 months			0.25	–0.15
Range	(0.00–0.50)	(0.05–0.50)		
Mean \pm SD	0.15 \pm 0.14	0.20 \pm 0.14		

Table 4. Adjusted cases in group (B) (intraocular pressure measurements before and after adjustable sutures).

patient no.	Pre-OP (IOP)	1st day (IOP)	1st day -adjustment (no)	Result	1st week - adjustment (no)	Result	Iop 1 month	IOP 3 months	IOP 6 months	IOP 12 months
26	29	23	2	19	1	12	12	12	12	14
27	31	24	2	10		11	11	11	11	11
28	42	37	3	20	2	20	11	12	12	13
31	40	28	2	21	2	18	18	10	10	11
33	36	19	1	9		9	9	12	12	13
35	40	28	2	12	1	7	7	8	8	8
38	24	17	1	10		10	10	10	12	12
47	37	27	2	25	2	25	17	17	18	18
50	30	21	1	13		13	13	14	14	14

respectively. The difference between both groups was insignificant.

3.5. Number of suture adjustments

9 cases (36%) in group (B) required suture adjustments, done on the first and second follow-up visits. Three patients required one suture adjustment, one patient required two suture adjustments, two patients required three suture adjustments, two patients required four suture adjustments, and one patient required five suture adjustments (Table 5). The mean adjustments were 2.67 ± 1.5 adjustments/case.

3.6. Success rate

Twenty (80%) patients in group (A) and 21 (84%) patients in group (B) had an IOP less than 18 mmHg 1 year postoperatively without any medication (complete success), while five (20%) patients in group A and four (16%) patients in group (B) had an IOP less than or equal to 18 mmHg 1 year postoperatively with medication (Qualified success). None of our patients had IOP more than 18 mmHg with medication or need another glaucoma surgery (Failure). Differences between both groups in success rate were insignificant (P value: 0.65).

Table 5. Number of suture adjustments done and results of the procedure.

Case no	Total no suture adjustments	Success
26	3	C.S
27	2	C.S
28	5	QS
31	4	QS
33	1	C.S
35	3	C.S
38	1	C.S
47	4	C.S
50	1	C.S

CS, complete success; QS, qualified success.

4. Discussion

Adjustable suture technique is a safe procedure for intraocular pressure control and for the maintenance of anterior chamber depth Kaplan and colleagues.⁵

Authors described different procedures for adjustable sutures. Some have adopted the use of two adjustable sutures with 4-throw at the apices of the flap to make a form of slipknot Ashraff and Wells, Khaw and Chang.^{6,7} Kobayashi and Kobayashi, used three 4-throw adjustable sutures one superiorly, Two at the centers of the flap sides and two fixed sutures at the corners of the flap.⁸ While Kaplan and colleagues used four 3-throw adjustable sutures, two superiorly, one suture on each side of the flap, and two fixed sutures at the corners of the flap.⁵ Adjustable sutures were designed in a bow-tie pattern and made with three throws Kaplan and colleagues, Ashraff and colleagues, Khaw and colleagues, Kobayashi and Kobayashi.^{5–8}

In the current study, we preferred to use three 4-throw adjustable sutures, we thought that sutures with fewer throws are less secure and may loosen with eye rubbing or minor trauma. We also preferred to put three adjustable sutures, one superiorly and two at each side of the flap, to allow easy management of each suture at a time without affecting other sutures. And we add 2 fixed lose sutures at the corners of the flap.

We also chose to do suture adjustments as early as possible, in the 1st and 2nd follow up visits (in the first postoperative week) before complete wound healing that may prevent further drainage. Sutures were adjusted using Khaw forceps trans-conjunctivally under slit lamp in patients with postoperative IOP more than 18 mmHg. We measured IOP another time after an hour of suture adjustment. And if IOP is still high, suture adjustment is repeated.

In their study, Ashraf and Wells documented that the IOPs more than 15 mmHg in day 1 have been successfully lowered to 10–15 mmHg (mean IOP was 10.4 ± 3.1 mmHg).⁷ In the current study day 1

postoperative was 7–37 mmHg (mean IOP was 15 ± 8.4 mmHg) because Ashraff and Wells performed only 2 adjustable sutures for 38 patients without fixed sutures and only 2 patients with fixed sutures. In the current study, we performed 3 adjustable sutures and 2 fixed losing sutures for 25 patients.

Studies of the success rate of trabeculectomy with adjustable sutures have reported different success rates. This may be because the studies had defined the success rates based on different criteria and different follow-up durations Kaplan and colleagues, Kobayashi and Kobayashi.^{5,8}

In the current study, we compared preoperative and 3-month postoperative visual acuity. We didn't consider early postoperative visual outcomes due to the impact of operative and early postoperative complications, as hyphema, hypotony, and cataract. Both groups showed a significant decrease in the mean BCVA at 3 month follow-up, yet differences between both groups were insignificant.

In the current study on considering the adjusted cases only within the adjustable suture group (B), 9 of 25 cases (36%) had adjustments with resultant CS in 7 (77.8%) cases and QS in 2 (22.2%) cases. The number of adjustments ranged from 1 to 5 adjustments (meaning 2.67 ± 1.5 adjustments/case), all adjustments were done on the first and second follow-up visits within the first postoperative week.

Also, there was no agreement between authors regarding the number of required adjustments, which confirms the 'on demand' nature of the procedure. Most patients in the published paper required more than one adjustment per case. In Kobayashi and Kobayashi study, 13 of 25 patients (52%) had sutures adjustments, which were done 1–3 times (meaning 1.6 ± 0.6 times) Kobayashi and Kobayashi.⁸ While Kaplan and colleagues reported adjustments in 26 of 35 patients (74.3%), 10 (38.5%) of them had 2 adjustments, and number of suture adjustments ranged from 1 to 7 times (meaning 2.88 ± 1.6 times). Also, they reported no correlation between suture adjustment and postoperative complications or between suture adjustment and postoperative visual acuity changes Kaplan and colleagues.⁵

In the current study we performed suture adjustments in 9 of 25 patients (36%). Three patients required one suture adjustment, one patient required two suture adjustments, two patients required three suture adjustments, two patients required four suture adjustments, and one patient required five suture adjustments. The mean adjustments were 2.67 ± 1.5 adjustments/case.

Reducing the number of medications is one of the success criteria of glaucoma surgeries. In the current

study, both groups had significantly decreased postoperative number of antiglaucoma medications. The mean number of preoperative medications decreased from 2.16 to 0.28 postoperatively in group (A) and from 2.32 to 0.4 in group (B).

In the current study, all cases in both groups got the target IOP either with or without medications. 20 (80%) patients in group (A) and 21 (84%) patients in group B had an IOP of less than or equal to 18 mmHg 1 year postoperatively without any medication (complete success), while five (20%) patients in group A and four (16%) patients in group (B) had an IOP of less than or equal to 18 mmHg one year postoperatively with medication (*Qualified success*). None of our patients had IOP more than 18 mmHg with medication or need another surgery (Failure).

We reported wound leaks in 1 case in group (A), that required suturing, both cases improved with conservative treatment. Intraoperative conjunctival tear was observed in the current study with four patients in group (A) and two patients in group (B). Intraoperative conjunctival tears may be attributed to poor instrument quality. Another one case in group (B) had conjunctival tear during suture adjustment, as mentioned above. Tears were small and limbal and responded well to therapeutic contact lenses. No patient had a shallow anterior chamber inserted from a conjunctival tear, meaning that the tension of the scleral flap was able to maintain intraocular pressure. Differences between both groups were significant.

Cataract development and progression was another noticeable complication in the current study. We reported 5 cases in group (A) and 2 cases in group (B). Cataract was visually significant and required phacoemulsification surgeries that were performed within a few months postoperatively. Some authors reported no progression of cataract was found in their series Kobayashi and Kobayashi.⁸

In the current study we reported 5 cases with suture exposure, all were in the suture adjustment group (B) and were treated with a soft contact lens and we removed the suture after three weeks.

4.1. Conclusion

Trabeculectomy with adjustable sutures is a promising procedure as regards safety and prevention of excessive drainage. Complications in adjustable group sutures were simple complications with no need to enter the operative room. Both groups had significantly decreased postoperative number of postoperative antiglaucoma medications,

but the number of medications was more in adjustable sutures group.

Conflicts of interest

None declared.

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