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Indian	ARIPET GLAN	ROTRABECULECTOMY VERSUS CONVENTIONAL BECULECTOMY IN PRIMARY OPEN ANGLE JCOMA- A COMPARATIVE STUDY	KEY WORDS: Filtering Bleb, Intraocular Pressure, Kelly's Descemets Membrane Punch, Perimetery.		
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ABSTRACT	 BACKGROUND: Glaucoma is a group of potentially blinding ocular condition which broadly involves a defect in the drainage angle, raised intraocular pressure, optic nerve head damage and visual field loss. Goal of glaucoma surgery is to preserve and enhance the patient's quality of life. AIM: The purpose of this randomized clinical study was to evaluate and compare microtrabeculectomy with conventional trabeculectomy in the management of primary open angle glaucoma. MATERIALS AND METHODS: Fifty eyes of forty-seven patients were randomized to have a microtrabeculectomy (25 eyes) or a conventional trabeculectomy (25 eyes) by one surgeon and followed up prospectively for 6 months. RESULTS: The mean intraocular pressure at presentation was 41.38 mmHg in microtrabeculectomy group and 36.8 mmHg in microtrabeculectomy group and 14.97 mmHg in conventional trabeculectomy group (p < .0001). Mean fall in intraocular pressure in Group-I was 66.65% and in Group-II was 59.51%. In Group-I, 84% patients had absolute success, 12% qualified success and 4% failure, whereas in Group-II, 80% patients had absolute success, 16% qualified success and 4% failure. CONCLUSION:.Microtrabeculectomy allows the surgeon to perform a controlled procedure with less tissue disruption and a chance of success that is at least equivalent to conventional trabeculectomy. 				

INTRODUCTION:

Glaucoma is a group of potentially blinding ocular conditions which broadly involve a defect in the drainage angle, raised intraocular pressure, optic nerve head damage and visual field loss. Goal of glaucoma surgery is to preserve and enhance the patient's quality of life. An association between glaucoma and raised intraocular pressure was first suggested by Richard Banister in 1662. D'Ermo et al analyzed the long-term results of trabeculectomy and proposed that the presence of filtering bleb was important for the success of trabeculectomy [1].

It is well accepted fact that conventional trabeculectomy is a better procedure than full thickness procedure but has a higher failure rate [2,3]. Trabeculectomy is the long-term solution to control of intraocular pressure in glaucoma patients not responding to medical and laser therapy [3,4]. In case trabeculectomy fails, repeat trabeculectomy is considered hazardous because of fibrosis of the conjunctiva due to previous surgery. So, attempts were being made to decrease the size of superficial scleral flap, and internal osteum, so that more of the virgin space is left in case repeat trabeculectomy is required. But the possible suspected drawback is higher failure rate [5,6,7].

Duzanec and Kreigelstein reported that the size of the internal osteum did not affect the long-term control of intraocular pressure in glaucoma surgery [8]. Ang GS et al further reported that scleral flap size had no significant effect on the medium-term control of intraocular pressure and complication profile [9]. They found that the fall in intraocular pressure was almost equal in both the groups and complications were also comparable.

Taking a lead from these surgeries, Vernon and Spencer reported a new procedure, "microtrabeculectomy" using Kelly's descemets membrane punch. They decreased the size of superficial scleral flap to 2x2mm and that of internal osteum to 0.75x0.75mm in microtrabeculectomy. The internal osteum was made with specially designed instrument, Kelly's descemets membrane punch [10]. Zhody et al and Avinoam Ophir also reported the results of punch trabeculectomy through a scleral tunnel with similar success [11,12]. Another study concluded that microtrabeculectomy was effective at reducing intraocular pressure in low risk eyes with intraocular pressure control similar to previous reports of filtering surgery utilizing larger scleral trapdoors[13,14].

As compared to full thickness procedures trabeculectomy has very

less complications but many surgeons have not advocated it as the procedure of choice for glaucoma control [3]. Thus, the glaucoma surgery remained in evolution for want of a procedure that could control the glaucoma effectively but with very less or no complications at all. Thus, this study was undertaken to evaluate and compare microtrabeculectomy with conventional trabeculectomy.

MATERIALS AND METHODS:

The present prospective, randomized, hospital based and comparative study comprised of fifty eyes of forty-seven patients of primary open angle glaucoma. Due approval from the Ethics Committee of the Institution was taken prior to initiating the study.

Patients of primary open angle glaucoma with uncontrolled intraocular pressure above 21 mmHg on maximum tolerated medical therapy or progression of visual field changes characteristic of glaucoma despite controlled intraocular pressure were enrolled in the present study. The patients were admitted 1day prior to the surgery and an informed written consent for the study was taken. Preoperative assessment consisted of a careful and detailed history taken to rule out any systemic disease. Complete general physical examination and systemic examination with relevant investigations was done. Local examination consisted of a thorough ophthalmic examination carried out with diffuse torch light and slit-lamp, visual acuity with and without glasses and fundus examination. Special attention was given to size, shape, margins, color, cupping of the optic disc, disc hemorrhages, cup-disc ratio, and nerve fiber bundle defect. Intraocular pressure recorded with Non-contact tonometer. Gonioscopy performed with Goldman three-mirror lens. The angle was graded as per Schaffer's classification. Perimetery was done with Humphrey visual field analyzer. Patients were randomly assigned to two groups of 25 eyes each. Group-I: 25 eyes of this group underwent microtrabeculectomy with a superficial scleral flap of 2x2 mm and an internal sclerostomy of 0.75x0.75 mm using Kelly's descemets membrane punch at 120'clock position. Group-II: 25 eyes of this group underwent conventional trabeculectomy with a superficial scleral flap of 4x4 mm and internal sclerostomy of 4x1 mm. Surgery was performed by single surgeon in all the patients.

Postoperative care consisted of oral antibiotics and non-steroid anti-inflammatory drugs for 5 days. No systemic or topical antiglaucoma drugs were given. Pad and bandage was removed after

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24 hours and eye examined with slit-lamp to observe for the condition of the conjunctiva, cornea, anterior chamber, iris, pupil, lens, and filtering bleb [Fig:1]. Dark glasses with antibiotic-steroid eye drops along with mydriatics were prescribed. At discharge and every follow up on 1st, 12th and 24th week intraocular pressure was measured with non-contact tonometer. Visual acuity and fundus were also examined along with detailed slit lamp examination [Fig: 2&3]. Conjunctival sutures were removed after two weeks. At the end of the follow-up i.e. after six months, automated perimetry was carried out to find out the status of visual fields.

CRITERIA FOR SUCCESS

ABSOLUTE SUCCESS: - Intraocular pressure less than 21 mmHg without antiglaucoma medication after 24 weeks of the follow-up.

QUALIFIED SUCCESS:- Intraocular pressure less than 21 mmHg with medication.

FAILURE:- Intraocular pressure greater than 21 mmHg with medication.

Statistical analysis was done by using the Statistical Package for Social Sciences version 20.0 (SPSS 20.0). Comparison between the two groups for the continuous variables was made using analysis of variance (ANOVA). Chi-square test was used to analyse nominal categorical variables (like sex, operated eye). Difference between the two groups was labeled as significant when p-value was \leq 0.05%.



Fig-1. Microtrabeculectomy-1st Postoperative Day.



Fig-2. Filtering Bleb After 1 Month Following Microtrabe culectomy.



Fig-3. Filtering Bleb After 3 Months Following Microtrabec Ulectomy

RESULTS:

The results are shown in Table I-III. Age and sex distribution between the groups in our study was statistically not significant. The mean age in Group-I was 60.72+9.62 years (range 40-74 years) and in Group-II was 57.92+8.66 years (range 40-73 years). Females were slightly more in number than the males in the ratio of 1:1.27. No deterioration was detected in the visual fields after follow up. Visual acuity was also maintained at the preoperative level except in one case in Group-II, where visual acuity deteriorated due to progression of cataract, after 24 weeks of follow up [Table-I].

Table-i: Visual Acuity Group I

dioup-i			Group-II					
VA	Preop.	1wee	12we	24we	Preop.	1we	12we	24we
	VA	k	eks	eks	VA	ek	eks	eks
<6/60	7[28]	7[28]	7[28]	7[28]	9[36]	9[36]	10[40]	10[40]
6/60-	11[44]	11[44]	11[44]	11[44]	7[28]	7[28]	5[20]	5[20]
6/36								
6/24-	3[12]	5[20]	3[12]	3[12]	4[16]	4[16]	5[20]	5[20]
6/18								
6/12- 6/6	4[16]	2[8]	4[16]	4[16]	5[20]	5[20]	5[20]	5[20]

*Figures in parenthesis indicate percentage.

The preoperative mean intraocular pressure in Group-I was 41.38 mmHg. After 24 weeks of follow up, it was 13.8 mmHg. 21 patients (84%) had intraocular pressure less than 21 mmHg without any medications (absolute success). Three patients (12%) had intraocular pressure less than 21 mmHg with topical antiglaucoma drugs (two patients on timolol-0.5% only, while one patient on timolol-0.5% and brimonidine) (qualified success). There was only one (4%) patient in Group-I who had intraocular pressure above 21 mmHg even with medication (failure). Mean fall in intraocular pressure in Group-I was 66.65%.

In Group-II, mean preoperative intraocular pressure was 36.98 mmHg. After 24 weeks of follow up, it was 14.97 mmHg. 20 patients (80%) had intraocular pressure less than 21 mmHg without any medications (absolute success). Four patients (16%) had intraocular pressure less than 21 mmHg with topical antiglaucoma drugs (three on timolol-0.5% only, while one on the combination of timolol-0.5% and brimonidine) (qualified success). Only one (4%) patient had intraocular pressure above 21 mmHg even with medications (failure). Mean fall in intraocular pressure in Group-II was 59.51%. A significant fall in intraocular pressure (P<.0001) was present in both the groups at all time intervals in comparison to their preoperative values [Table-II]. But the difference of post-operative fall in intraocular pressure among the two groups was statistically not significant (p=0.9).

Table-II: Mean Preoperative & Postoperative IOP [mmHg].

	Group-I	Group-II	p- value
Preop. IOP	41.38	36.8	
Postop. IOP			
1 week	12.85	14.26	P=0.9
12 weeks	12.99	14.95	
24 weeks	13.8	14.97	

p<.0001

Filtering bleb was present in twenty one (84%) eyes and absent in four (16%) cases in Group-I. One (4%) case out of these three was an absolute failure while the other three (12%) cases required medications to keep the intraocular pressure below 21 mmHg, whereas, in Group-II filtering bleb was present in twenty (80%) eyes and absent in five (20%) cases. one (4%) case out of these five was an absolute failure while the other four (16%) cases required medications to keep the intraocular pressure below 21 mmHg.

Complications are shown in Table-III. No major intraoperative complication was observed in both the groups. Postoperative complications rate was also not significant between the two groups (p=0.7).

Table-iii: Complications

Complication	Group-I	Group-ll
Hyphemia	3(12)	4(16)
Shallow anterior chamber	4[16]	4[16]
Hypotony	0	2(8)
Anterior chamber reaction	4(16)	3(12)
Cataract progression	0	1(4)
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*Figures in parenthesis indicate percentage.

DISCUSSION:

From the time glaucoma as a symptom complex was established in

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the medical literature and different modalities of its management came into vogue, it was recognized that there were many patients who did not respond to medical therapy and for whom surgery was the only recourse if they were to retain whatever vision they were left with [4]. The goal of glaucoma treatment is to stabilize visual field loss and preserve vision. Intraocular pressure is believed to be the primary cause of glaucomatous damage and it is the factor most amenable to modification. So, treatment is aimed at lowering intraocular pressure because substantial evidence exists that the prognosis in glaucoma depends largely on the level of intraocular pressure as shown in the studies by Odberg and Mao et al [15,16]. Surgical intervention in glaucoma attempts to lower the intraocular pressure sufficiently to prevent further pressure dependent progressive ganglion cell loss. Trabeculectomy can be performed in many ways as described originally by Cairns, Phillips and Linner [17, 18, 19].

In the present study, maximum number of patients had the age of 60 years or above i.e. 68% in Group-I and 52% in Group-II. The mean age in group-I was 60.72+9.62 years (range 40-74 years) and in group-II was 57.92+8.66 years (range 40-73 years). In the study conducted by Vernon et al mean age of the patients was 70.1+9.3 years (range 44-85 years) [10]. In another study conducted by Vernon et al mean age of the patients was 69.8 years (range 44-85 years) [13]. Most of the studies that have examined the relationship of primary open angle glaucoma and age has confirmed that the older the individual, the greater the prevalence of glaucoma [20].

In the present study male female ratio was 1:1.27, females being slightly more in number than the males. Framingham Eye Study has reported higher prevalence of primary open angle glaucoma among males, the Sweden Eye Study among females, while the Baltimore Eye Study has found no sex preponderance in the prevalence of primary open angle glaucoma [20,21,22]. In the present study also, no significant sex preponderance was observed.

In our study, 72% patients in Group-I and 64% patients in Group-II had visual acuity 6/36 or less at the time of presentation. Causes of decreased vision besides glaucoma were lenticular changes, corneal edema and degenerative changes in the fundus. Both the groups had comparable visual acuity. After 24 weeks of follow-up, visual acuity deteriorated in one case in Group-II due to progression of cataract. Rest of the patients had visual acuity similar to the preoperative levels. Starita et al reported no significant difference in the postoperative visual acuity in the two groups after 13 months of follow-up [23].

The preoperative mean intraocular pressure in Group-I was 41.38 mmHg. After 24 weeks of follow up, it was 13.8 mmHg. Mean fall in intraocular pressure was 66.65%. In Group-II, mean preoperative intraocular pressure was 36.98 mmHg. After 24 weeks of follow up, it was 14.97 mmHg. Mean fall in intraocular pressure was 59.51%. A significant fall in intraocular pressure (P<.0001) was present in both the groups at all time intervals in comparison to their preoperative values. The finding in the present study conforms to the finding of Watson and Grierson that higher the presenting intraocular pressure, the greater the fall after surgery [24].

Filtering bleb was present in twenty one (84%) eyes and absent in four (16%) cases in Group-I. One (4%) case out of these three was an absolute failure while the other three (12%) cases required medications to keep the intraocular pressure below 21 mmHg, whereas, in Group-II filtering bleb was present in twenty (80%) eyes and absent in five (20%) cases. one (4%) case out of these five was an absolute failure while the other four (16%) cases required medications to keep the intraocular pressure below 21 mmHg. Thus, importance of the presence of a filtering bleb was established for the successful surgery. D'Ermo et al reported filtering bleb in 96.87% of the successful trabeculectomy cases [1]. Comparative success rates of microtrabeculectomy in different studies including present study are shown in Table-IV.

Table-iv:	Comparative	Success	Rates	Of	Microtrabec
ulectomy	In Different Stu				

Author	Year of study	Success rate in %age
Vernon et al	1995	87.5%-absolute success
		96%-qualified success
Vernon et al	1998	80%-absolute success
Present study	2017	84%-absolute success
		96%-qualified success

No major intraoperative complication was observed in both the groups. Among postoperative complications, in Group-I, 4(16%) cases had shallow anterior chamber, 3(12%) cases had hyphaema, and postoperative anterior chamber reaction was observed in 4(16%) cases, whereas, in Group-II 4(16%) cases had shallow anterior chamber, 4(16%) cases had hyphaema, 2(8%) cases had hypotony and postoperative anterior chamber reaction was observed in 3(12%) cases. All the cases improved with conservative management. Cataract progression was observed in 1(4%) case in Group-II. These findings between groups were statistically not significant (p=0.7) and were comparable with other studies [9].

Microtrabeculectomy occupies a small area on the surface of the eye. If microtrabeculectomy fails, still there is sufficient space for at least three microtrabeculectomies around the superior limbus. This feature is of particular advantage, when performing surgery on eyes that have had previous drainage and/or cataract surgery. In such cases, microtrabeculectomy can also be combined with various antimetabolites like mitomycin-C, 5-fluorouracil, daunorubicin etc [10,25,26]. In addition, with the use of a smaller scleral trapdoor, the scleral sutures are situated more anteriorly, allowing for easier laser suture lysis, should this be necessary [10]. By reducing the size of the surgical field, corneal astigmatism thus induced will be less as compared to conventional trabeculectomy [26,27]. This in turn may lead to more rapid visual rehabilitation. Dellen formation is not seen in microtrabeculectomy as the bleb formed is thick, diffuse/flat and situated more posterior to the limbus [10]. The time required to perform the procedure is decreased when Kelly's punch is used. Microtrabeculectomy greatly shortens the recovery period from glaucoma surgery and stay in the hospital.

CONCLUSION:

In the present study, microtrabeculectomy achieve comparable reduction in mean post-operative intraocular pressure and had similar complication rates, but occupies small area on the surface of the eye and consume less intraoperative time as compared to conventional trabeculectomy. Thus, microtrabeculectomy allows the surgeon to perform a controlled procedure with less tissue disruption and a chance of success that is at least equivalent to conventional trabeculectomy.

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