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Study of Efficacy and Safety of 5-Fluorouracil in Trabeculectomy

Manjunath D Patil[1], Jayaramula H Sankaram[2]

Abstract

Background: In majority of cases of glaucoma the disease progresses in such a slow symptomfree course, that by the time patient, seeks help from the ophthalmologist, a great deal of permanent damage has occurred already. Thus, delay on the part of patient in many cases is due to his ignorance about glaucoma. The present study was undertaken to assess the efficacy & safety of intraoperative 5 – Fluorouracil in Trabeculectomy.

Methods: The present study was undertaken in the Department of Ophthalmology, ARMCH & RC, Kumbhari and cases which were diagnosed clinically as having primary glaucoma with raised intraocular tension were randomly selected to receive or not to receive intraoperative 5 – Fluorouracil application between conjunctival flap and sclera for 1 minute duration.

Results: There was 67% reduction in baseline intraocular tension with intraoperative use of 5 – Fluorouracil while 58% reduction in baseline intraocular tension was observed without use of 5 – Fluorouracil. Intraocular tension was controlled below 15 mmHg in 92% cases with intraoperative use of 5 – Fluorouracil and 64% cases without use of 5 – Fluorouracil. In high risk glaucoma, adequate control of intraocular tension was observed with intraoperative use of 5 – Fluorouracil.

Conclusion: It is a safe and effective alternative to subconjunctival injections of 5 – Fluorouracil. It is also useful in controlling the intraocular tension in high risk eyes.

Keywords: Glaucoma; Trabeculectomy; 5-Fluorouracil; Visual Acuity; Bleb.

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Introduction

In majority of cases of glaucoma the disease progresses in such a slow symptomfree course, that by the time patient, seeks help from the ophthalmologist, a great deal of permanent damage has occurred already. Thus, delay on the part of patient in many cases is due to his ignorance about glaucoma.

Author Affiliation: [1]Associate Professor [2]Professor, Department of Ophthalmology, Ashwini Rural Medical College, Hospital & Research Centre, Kumbhari, Solapur, Maharashtra 413006, India.

Corresponding Author: Jayaramulu H. Sankaram, Professor, Department of Ophthalmology, Ashwini Rural Medical College, Hospital & Research Centre, Kumbhari, Solapur, Maharashtra 413006, India.

E-mail: jayaram_dr@rediffmail.com

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Nearly 1 in 10 blind persons in the world is blind due to glaucoma. Extensive literature on its incidence has been built up over the past century. Various survey's reveal that 1-2% of the population over the age of 40 years have glaucoma and its incidence increases with age.

In a country like India, where patient finds it difficult to stick to a strict regime of putting medicines in the eye at frequent intervals for the rest of their lives or are financially handicapped causing inability to buy medicines for a long period of time or do not enjoy the facility of a nearby eye centre for periodic check up. Surgery is preferred to medical treatment in many cases.

Lowering the IOP effectively decreases the development of glaucoma due to evidence-based medicine to glaucoma, several prospective, randomized trials are carried out and treatment of glaucoma seems simple [1,2].

Any operation devised for the relief of glaucoma should ideally be such as to preserve the function of the eye, maintain the intraocular tension within normal limits and retain the integrity of the globe [3]. The various types of operations advocated from time to time proved that this idea has never been attained.

Trabeculectomy or removal of trabecular meshwork was first described by Cairns [4] in 1968. He reflected the corneoscleral flap posteriorly. It allows the aqueous to flow through the now exposed cut ends of Schelmm's canal, and then leave the eye via normal exit channels.

Later in 1970, it was modified by P.G. Watson. He reflected the comeoscleral flap anteriorly and advised iridectomy in all cases [5].

It is observed that in trabeculectomy there is failure to maintain the intraocular tension below target level over a prolonged period of time in eyes which are high risk for surgical failure, such as pseudoexfoliation glaucoma, topical use of antiglaucoma drugs for more than three years and secondary glaucoma. Such failure occurs due to excessive scarring at the trabeculectomy site due to fibroblast proliferation resulting in non–filtering bled.

To prevent such scarring, intraoperative use of 5 – Fluorouracil was first suggested by Heur et al. 1984 as subconjunctival injections of 5 – Fluorouracl, these subconjunctival injections were associated with serious comeal complications like comeal epithelial defect, ulceration and endophthalimitis [6]. To avoid these complications Doyle J et al. first suggested the use of 5- Fluorouracil as sponge application between conjunctival flap and sclera [7]. Considering the facts, the present study was planned to determine the efficacy & safety of intraoperative 5 – Fluorouracil in Trabeculectomy

Objectives

To study the efficacy & safety of intraoperative 5 – Fluorouracil in Trabeculectomy.

Material And Methods

This study was undertaken in the Department of Ophthalmology, ARMCH & RC, Kumbhari. Informed written consent under guarded visual prognosis was obtained from all patients. Intraocular tension was recorded by using Schiotz tonometer. 50 cases were operated for Trabeculectomy by using following two methods.

1. 25 cases with intra – operative use of 5 – Fluorouracil.
2. 25 cases without use of 5 – Fluorouracil

Selection Criteria

Cases which were diagnosed clinically as having primary glaucoma with raised intraocular tension were randomly selected to receive or not to receive intraoperative 5 – Fluorouracil application between conjunctival flap and sclera for 1 minute duration.

Criteria for Success

Achieving the mean intraocular tension, which is not harmful to the eye. i.e. less than 20 mmHg post operatively.

Detail history and clinical examination was done on following lines.

Every patient was subjected for retinal examination by opthalmoscopy of both eyes for optic disc changes. In every patient sac syringing was carried out to see the patency of the sac. Visual acuity was recorded of both eyes. Routine investigations were done. Initially, high levels of intra – ocular tension was treated by Tab – Acetazolamide 250 mg 2 stat & then by bid.

5 – Fluorouracil

The most common cause for failure of filteration surgery is excessive scarring at the filteration site resulting in a non – filtering bleb.

5 – Fluorouracil is a fluorinated pyramidine analogue, a potent antimitotic, antimetabolic agent. It competitively ibhibits thymidylate synthetase and cell division thereby decreasing the fibroblast proliferation.

Procedure

Procedure was performed under local Anaesthesia. Painting & drapping was done. Superior rectus suture was taken. A limbal/ Fornix based conjunctival flap was raised. A cellular sponge soaked in 50 mg /ml solution of 5 – Fluorouracil was placed between conjunctival flap and sclera for 1 minute. After 5 – Fluorouracil application conjunctival flap and sclera was copiously washed with 20 ml Ringer lactate solution. Triangular 2/3 thickness 4 mm x 3mm x 3 mm outer sclera flap was raised. Anterior chamber entry was done with 11 number blade & peripheral

buttonhole iridectomy performed. An inner block of trabecular tissue 1 mm x 5 mm in size excised. Scleral flap re-apposed with interrupted 10-0 nylon sutures. The conjunctival flap was sutured with 8 – o black silk. Subconjunctival injection of gentamicin + dexamethasone + atropine was given in inferior fornix. Chloramphenicol eye ointment was put. Eyepad & shield was given.

Trabeculectomy Bled

After Trabeculectomy the control of intraocular tension depends upon the type of bleb formed. When the bleb is diffusely formed, elevated, and with increased microcystic conjunctival changes with decreased vascularity is associated with good control of intraocular tension.

All the patients were examined at the time of discharge by routine eye examination, visual acuity fundoscopy & slit lamp examination. Every patient was followed up weekly for one month and then monthly for 6 months.

Statistical Analysis

Descriptive statistics such as mean, SD and percentage was used to present the data. Comparison between groups was performed by using t-test for quantitative data and chi-square test for qualitative data. A p-value less than 0.05 were considered as significant.

Results

Table 1: Age and Sexwise distribution of patients

Sex	Age in Years					Total
	31-40	41–50	51–60	61–70	71 & above	
Male	01	07	05	05	02	20
Female	03	07	12	08	00	30
Total	04	14	17	13	02	50

Most of the patients were evenly distributed in the Fifth, Sixth and Seventh decade. Highest number of patients were in the Fifth and Sixth decade indicating glaucoma is more common in Fifth and Sixth decade (Table 1).

Out of 50 glaucoma patients 62% were of open angle glaucoma, 36% were of closed angle glaucoma and 2% patients of secondary glaucoma, thus confirming that prevalence of open angle glaucoma is more in the community (Fig. 1).

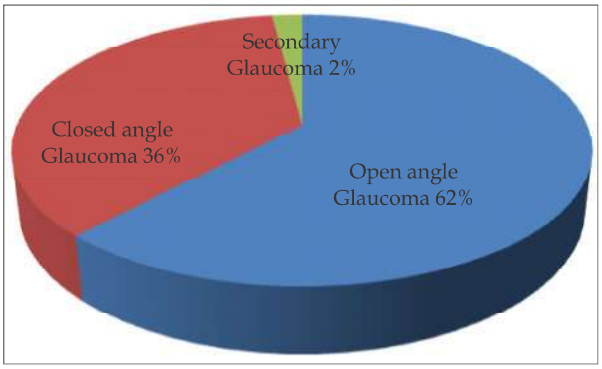

Fig. 1: Type of glaucoma

Table 2: Type of glaucoma according to sex

Sex	Type O Glaucoma			Total
	Open Angle Glaucoma	Closed Angle Glaucoma	Secondary Glaucoma	
Male	16	04	---	20
Female	15	14	01	30
Total	31	18	01	50

Above table 2 indicates that open angle glaucoma is evenly distributed in both sexes while closed angle glaucoma is three times more common in females.

In Trab with 5 – Fluorouracil group, 8% patient were in 6/6 – 6/12 group, 12% patient were in 6/18 – 6/24 group, 4% patient were in 6/36 – 6/60 group, and 56% patient were in PL + PR + to No PL group. In 1 patient of ACG visual acuity was improved from Fc 3 mt to 6/60 (Table 3).

Table 3: Pre- operative and post – opoerative visual acuity status in trabeculectomy with 5 – fluorouracil.

Visual Acuity	With 5 – Fluorouracil		Without 5 - Fluorouracil	
	Pre-Operative	Post-Operative	Pre-Operative	Post-Operative
6/6 – 6/12	02	02	03	03
6/18 – 6/24	03	02	10	10
6/36 – 6/60	01	03	05	06
Fc 5 mt – Fc 3 mt	04	03	01	-
Fc 2 mt – Fc 1 ft	01	01	02	02
PL + PR + to No PL	14	14	04	04

In Trab without 5 – Fluorouracil group, most of the patients had visual acuity above 6/60 and approximately 40% cases were in the 6/18 – 6/24 group. 1 patient of ACG improved from Fc 4 mt. – 6/60 while in other 6 cases improvement of visual acuity occurred by 1 Snellen's line (Table 3).

elevated avascular with conjunctival microscopic changes.

Bleb formation was seen in 100 % cases, Blebs seen without intraoperative use of 5 – Fluorouracil were shallow diffuse blebs with relative vascularity at bleb site (Table 5).

Table 4: Post–operative intraocular tension control in trabeculectomy with 5–fluorouracil & without 5–fluorouracil

Pre–Op Intraocular Tension In Mmhg	No. of Cases	Controlled Post Op Intraocular Tension 10-20 Mmhg	Percentage
With 5 – Fluorouracil			
20 – 40 mmHg	16	16	100%
41 – 60 mmHg	08	06	75%
61 – 80 mmHg	01	01	100%
Intraocular tension			
(Mean + SD)	40.19 + 12.89 mmHg	13.78 + 2.62 mmHg.	
Without 5 – Fluorouracil			
20 – 40 mmHg	16	16	100%
41 – 60 mmHg	09	06	75%
61 – 80 mmHg	--	01	100%
Intraocular tension			
(Mean + SD)	37.56 + 9.78 mmHg	15.75 + 2.86 mmHg	
p-value	0.42	0.01	

In with 5–Fluorouracil group one case of absolute glaucoma failed completely with minimal hyphema throughout post – operative period and secondary glaucoma formation. While a case of secondary glaucoma had post – operative intraocular tension of 21.8 mmHg, 21.8 mmHg at second and third Month respectively.

In without 5–Fluorouracil group, one patient of POAG there was rise in intraocular tension as 21.8 mmHg at first and second month and 25.8 mmHg at third month.

There is no statistically significant difference of mean intraocular tension between with and without 5-Fluorouracil groups (p=0.42) in pre-operative whereas there is statistically significant difference of mean intraocular tension between with and without 5-Fluorouracil groups (p=0.01) in post-operative (Table 4).

Table 5: Type of bleb formed in trabeculectomy with 5 – fluorouracil & without 5 – fluorouracil

Type of Bleb	With 5 – Fluorouracil (%)	Without 5 – Fluorouracil (%)
Diffuse elevated bleb	23 (92)	24 (96)
Shallow diffuse bleb	02 (08)	01 (04)
Flat bleb	--	--
Encapsulated bleb	--	--

Bleb formation was seen in 100% cases with 5 – Fluorouracil Conjunctival blebs seen with intraoperative use of 5 – Fluorouracil were diffusely

Discussion

We have used the 50 mg/ml concentration of 5 – Fluorouracil intraoperatively by applying a surgical sponge soaked in 5–Fluorouracil solution between the conjunctiva and sclera for 1 minute duration to prevent the fibrosis which causes failure of filtration surgery over a prolonged period of time.

Age and Sex Distribution

Most of the patients were from the fifth, sixth and seventh decade. Highest number of patients 17 i.e. (34%) were in the age group of 51-60 years. Mean age of the patients in the Trabeculectomy with 5–Fluorouracil group was 55.28+10.20 years and 57.32 + 8.5 in the Trabeculectomy without 5–Fluorouracil group.

According to Becker Shaffer's, incidence of POAG increases after 40 years of age and most common in 5th & 6th decade [8].

Type of Glaucoma

Out of 50 cases of glaucoma 31 cases (62%) were of open angle glaucoma and 18 cases (36%) were of closed angle glaucoma and 1 case (2%) of secondary glaucoma, thus indicating that open angle glaucoma is more common in the community.

P.A. Lamba have noted 36% patients with open angle glaucoma and 64% patients with chronic

angle closure glaucoma [9].

Peter R Egbert in his study of 55 patients noted that, 51 patients had open angle glaucoma, 2 patient had chronic angle closure glaucoma while 2 patients had angle recession glaucoma after trauma [10].

Secondly, out of 31 cases of open angle glaucoma, 14 were males and 17 were females thus indicating that open angle glaucoma having approximately equal prevalence in both sexes.

Our findings correlate to Ruderman's study in which 40% POAG patient were male and 60% patients POAG patients were female [11].

Out of 18 cases of closed angle glaucoma 4 were males (23%) and 14 were females (77%) thus indicating that closed angle glaucoma is three times more common in females than males, due to typical anatomical predisposition of hypermetropic eye with small anterior chamber. Duke Elder reported that angle closure glaucoma is twice more common in females than males [3]. According to Becker Shaffer's angle closure glaucoma is two or three times more common in females than males [8].

Visual Acuity

Preoperative visual acuity records shows that in trab with 5 – Fluorouracil group, 2 patients (8%) were in 6/6 to 6/12 group, 1 patient (4%) in the 6/36 to 6/60 group, 4 patients (16%) in the FC 5 mt to FC 3 mt group, 1 patient (4%) in the FC 2 mt to FC 1 ft group and 14 patients (56%) in PL (+) PR + to NO PL group.

In trab without 5 – Fluorouracil group, 3 patients (12%) were in 6/6 to 6/12 group. 10 patients (40%) were in the 6/18 to 6/24 group, 5 patients (20%) in the 6/36 to 6/60 group, 1 patient (4%) in the FC 5 mt to FC 3 mt group, 2 patients (8%) in the FC 2 mt to FC 1 ft group and 4 patients (16%) in the PL (+) PR X to No PL group.

In this study with intraoperative use of 5 – Fluorouracil, out of 25 patients 4 patient (16%) had improvement in visual acuity of 1 or 2 Snellen's lines. Two patients of angle closure glaucoma had improvement in the visual acuity of 2 and 3 Snellen's lines respectively, while two patients of chronic simple glaucoma had improvement in visual acuity of one Snellen's line. 21 patients (84%) had stable visual acuity postoperatively.

In Trabeculectomy without intra-operative use of 5–Fluorouracil (40%) had visual acuity in the range of 6/18 to 6/24, out of 25 patients, 7 patients (28%) had improvement in visual acuity of 1 or 2 Snellen's lines and were stable in 18 patients (72%) post operatively. Out of these 7 patients, 6 were of angle closure glaucoma while one patient of chronic simple glaucoma showed improvement in visual acuity by 1 Snellen's line.

Our results are comparable to Lumina Lanigan Jorg Sturmer et al. in their study, visual improvement occurred in 12 % patients, deterioration of visual acuity was seen in 21% cases and visual acuity was stable in 68% cases with intraoperative use of 5–Fluorouracil [12].

Our results do not correlate to Mielke C, who observed loss of visual acuity of more than two Snellen's line in 6 eyes (7.9%) in the 5–Fluorouracil group and in 4 eyes (5.17%) in the control group while in our study none of the patient had loss of visual acuity [13].

Kuldev Singh noted improvement in visual acuity of more than 2 Snellen's lines in 3 patients (8.1%) and worsening of visual acuity by 2 snellen's lines in 7 patients (18.9%) while visual acuity was stable in 27 patients (73%) with intraoperative use of 5 – Fluorouracil [14].

V.L. Membrey reported loss of 2 Snellen's lines of visual acuity in 15–20% cases with itnraoperative use of 5–Fluorouracil due to progression of lens opacities and hypotonous maculopathy [15].

Intraocular Tension

In Trab with 5–Fluorouracil group, 16 patients (64%) had intraocular tension in the range of 20-40 mm Hg and 8 patients (32%) had intraocular tension between 41-60 mm Hg while 1 patient (4%) had intraocular tension between 61-80 mm Hg.

In Trab. Without 5–Fluorouracil group 16 patients (64%) had intraocular tension in the range of 20-40 mmHg and 9 patient (36%) had intraocular tension between 41-60 mmHg.

Mean preoperative intraocular tension in the trab with 5–Fluorouracil group was 40.19 + 12.89 mmHg while in trab without 5–Fluorouracil group mean preoperative intraocular tension was 37.56+ 9.78 mmHg.

Our mean preoperative intraocular tension values correlate to P.A. Lamba's study with mean preoperative intraocular tenson in 5–Fluorouracil group was 42.72+3.7 mmHg and 40.4+6.1 mmHg in the control group [9].

Our Pre-operatively intraocular tension values do not correlate with Peter R Egbert's study with mean preoperative intraocular tension of 29.2

(18-46) mmHg in the 5–Fluorouracil group and 33.4 (16.76) mmHg in the control group [10]. 5–Fluorouracil was used intraoperatively in this study for achieving the low levels of intraocular tension and maintaining the patency of functional bleb over prolonged duration of time.

In this study intraocular tension recorded at each follow up post–operatively–mean preoperative intraocular tension in the 5–Fluorouracil group was 40.19+12.89 mm Hg while it was 37.56+9.78 mm Hg in the trab without 5–Fluorouracil group.

Mean post–operative intraocular tension in the 5 –Fluorouracil group at last visit (about 6th month) was 13.78+2.62 mmHg and 15.75+2.6 mmHg without use of 5 – Fluorouracil.

There was 67% reduction in intraocular tension with intraoperative use of 5–Fluorouracil and 58% reduction in intraocular tension in trab without use of 5–Fluorouracil.

Our results correlate to findings of Anand N who observed intraocular tension less than 21 mm Hg for all eyes was 93% and 81% with intraopertive use of 5–Fluorouracil in low risk and high risk groups [16].

Our findings were not correlated with Peter R Egberts observation of intraocular tension less than 20 mmHg or less in 71% eyes with intraoperative use of 5–Fluorouracil and 32% eyes without use of 5–Fluorouracil because our success rate is greater in both groups as 96% in Trab with 5–Fluorouracil and 96% in trab without 5–fluorouracil group respectively [10].

If the criteria for success was intraocular tension 15 mmHg, or less 12 out of 25 cases (88%) in the 5 – Fluorouracil group had intraocular tension less than 15 mmHg while 16 out of 25 patients (64%) had intraocular tension less than 15 mmHg at 6 months.

Our results confirms findings of Lamba et al who observed 90.9% (intraocular tension 15.8 mm Hg) success rate with intraoperative 1 minute use of 5 –Fluorouracil while 66.7% (intraocular tension 18.3 mm Hg) without use of 5–Fluorouracil [9].

Anand N with intraocular tension of less than 15 mmHg documented that low risk group had significantly longer survival rate than high risk group [16].

Our results are not correlated with Peter R. Egbert's study with intraocular tension of 15 mm Hg or less 46% patients in the 5–Fluorouracil group and 16% in the trab without 5–Fluorouracl group had intraocular tension less than 15 mm Hg while in our study 88% patients in the 5–Fluorouracil group and 64% patients in the trab without 5–Fluorouracil had intraocular tension less than 15 mm Hg [10].

Our results are comparable to study conducted by Detry Morel M, who reported overall success rate of 94% with intraoperative use of 5–Fluorouracil [17] and by Lanigan who reported 94% success rate with intraoperative use of 5–Fluorouracil [12].

Bleb Formation in Trabeculectomy without 5–Fluorouracil:

In Trabeculectomy successful outcome usually demonstrate a reasonable bleb during the first week. In trab without 5 – Fluorouracil there was flat bleb on 1st post operative day which gradually became little diffuse with persistant hyperemia towards the end of the first week, with obscure borders.

The bleb tends to be more localized in the 2nd and 3rd week with persistant hyperemia, little elevated with obscure margins. At the end of one month the bleb was well established, hyperaemic, moderately diffuse with distinct margins. In the 2nd month bleb become more diffuse with some decrease in the hyperemia and distinct borders. Towards the end of 3rd month bleb was shallow diffuse elevated and some hyperaemia remaining in the wall of the bleb, with small microcystic changes visible on the conjunctival epithelium in few cases by slit lamp examination. At the last follow – up about six months, most of the patient had shallow diffuse bleb extending over 2-3 clock hours with presence of blood vessels in the wall of the bleb in most of the cases and evidence of microcystic changes in the conjunctival epithelium with slit lamp examination.

In most cases of Trabeculectomy without intraoperative use of 5 – Fluorouracil type II i.e. shallow diffuse bleb was formed with relative avascularity.

It was flat on first post – operative day. In this type bleb became diffuse towards the end of first week with no increase in the hyperemia of the conjunctiva. Towards the end of 2nd week bleb became more diffuse, much elevated and extending over longer area than the Trabeculectomy without 5–Fluorouracil. At the end of 3rd week the bleb was diffuse more localized with distinct borders and much avascular than trab without 5–Fluorouracil. At the end of 1 month use the bleb was more diffuse elevated extending over 3-4 clock hours and relatively avascular than trab without 5–Fluorouracil with distinct margins. At the end of

2nd month bleb was more diffuse elevated and with presence of minimal vessels on wall of the bleb with few microcystic changes seen in the wall of the conjunctiva. At the end of 3rd month most of the cases has diffuse elevated avascular bleb extending over 3-4 clock hours with more microcystic changes seen in conjunctival epithelium.

With the passage of time, bleb became more diffuse extending over larger area, elevated and again decreases in the vascularity. At the end of 6th month there was diffuse elevated bleb with microcystic changes in the conjunctival epithelium indicating good drainage of aqueous through the conjunctiva.

In both the groups bleb was formed in all cases. In two cases cystic bleb was formed with intraoperative use of 5–Fluorouracil at 6 months. It was diffuse elevated avascular bleb with large cystic spaces in the conjunctival epithelium. There was no evidence of leak through bleb by negative Schidel's test. In these two patients there was minimal migration of bleb over cornea. Total migration of bleb all around the cornea giving bogginess to cornea was not observed in any case. In one case of absolute glaucoma and other case of secondary glaucoma the bleb was shallow, diffuse with vascularity at bleb site. In one patient of chronic angle closure glaucoma operated for trab without 5–Fluorouracil had bleb migration over cornea in both eyes while left eye had developed cystic bleb causing discomfort to the patient.

Bleb Formation in Trabeculectomy with 5–Fluorouracil

In case of trab with 5-Fluorouracil diffuse elevated and more avascular blebs were formed because single intraoperative 5–Fluorouracil application during Trabeculectomy caused reversible inhibition of fibroblast proliferation which resulted into absence of collagen which is formed fibroblast. Collagen was required for the process of angiogenesis. Hence due to absence of collagen new vessels are not formed at bleb site and avascularity is enhanced. While aqueous flow caused regression of remaining vessels adding to avascularity. Due to decreased amount of fibrosis there was less obstruction to flow of aqueous and the blebs tend to remained more diffuse with microcystic conjunctival changes, promoting the filtration of more aqueous in these cases for longer duration.

Our findings are consistent with the Shelat et al who observed diffuse avascular blebs with intraoperative use of 5–Fluorouracil [18]. Our findings correlate to Lachkar who noted consistently higher blebs with intraoperative use of 5–Fuorouracil than placebo [19].

Conclusion

To conclude, intraoperative use of 5–Fluorouracil in trabeculectomy is a safe and effective alternative to subconjunctival injections of 5–Fluorouracil. It is also useful in controlling the intraocular tension in high risk eyes.

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