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Original Research Article

Comparative Study between Non Penetrating Glaucoma Surgery with and without Implant

Sudhir S Pendke[1], Ravi A Chauhan[1], Rahul V Gokhale[1], Sanchit S Bhalgat[2]

[1]MS (Ophthalmology), [2]MBBS, Diploma in Ophthalmology,
Indira Gandhi Government Medical College, Nagpur, Maharashtra University of Health Sciences, Nasik, INDIA.

ABSTRACT

Objective: Analysis of safety and efficacy of Self engineered polymethylmethacrylate (Acry C) implants in Non-Penetrating Glaucoma surgery (NPGS) as compared to NPGS without implants for control and maintenance of Intraocular pressure in Primary Open Angle Glaucoma (POAG) patients.
Design: A Hospital based Randomized study
Participants: 70 eyes of 70 POAG patients, divided in 2 groups based on whether implants were used in NPGS
Materials: NPGS was done in 35 patients with poly-methyl methacrylate implants made from haptics of intraocular lenses and without the implant in the remaining 35. All patients were followed up after 1 week, 1 month, 3 months, 6 months and 12 months. Post-operative success was defined as IOP <21 mm Hg at 1 month in absence of additional anti glaucoma medication or other treatment.
Results: A significant reduction in intraocular pressure was observed post-surgery in both groups, changing from a preoperative mean of 31.09±7.37 mm of Hg and 29.26 ±7.10 mm of Hg to a postoperative mean of 15 ±3.06 mm of Hg and 14.85 ±4.22 mm of Hg respectively (P<0.001) at 12 months. It was observed that intraocular pressure was significantly controlled in both groups and that between two groups the difference was insignificant. It was however seen that Failure rates were higher with NPGS without implant as compared to with implant (p<0.05). For both procedures, the only significant complication was failure of surgery.
Conclusion: NPGS with Acry - C implants is a safe, non-invasive and cost effective (less than one U.S. dollar) procedure for control of Intraocular pressure in POAG patients and results in lower failure rates as compared to NPGS without implants and should therefore be preferred as the first line surgical treatment in Primary Open Angle Glaucoma.

Keywords: NPGS, Acry C implant, Primary Open Angle Glaucoma, Non-invasive.

***Correspondence to:**
Dr. Sudhir Sudhakar Pendke, 17, Shastri Layout, Subhash Nagar, Nagpur.
Email: sudhirpendke@rediffmail.com

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INTRODUCTION

Glaucoma, a serious sight threatening optic Neuropathy, is marked among ophthalmic disorders by the variability of its presentations and the variability of the array of treatment options available. Among the most recent forms of surgical treatment in Glaucoma is the Non Penetrating Glaucoma Surgery with the use of implants being a further advancement in this safe and efficacious procedure. Our study is a pilot study that unbiasedly tests whether the economically advantageous self engineeredAcry C plants are necessary to successfully serve the primary aim of controlling intraocular pressure.

MATERIALS AND METHODS

This Hospital based Randomised Prospective study included 70 eyes with Primary Open Angle Glaucoma in 35 of who Non-penetrating Glaucoma Surgery with Acry C plants was performed and the remaining underwent the same procedure without an implant and patients were followed up.

INCLUSION CRITERIA: Patients with Primary Open Angle Glaucoma who gave consent.

EXCLUSION CRITERIA: All patients with any other type of glaucoma

Preoperative data included Ocular complaints, BCVA, Intraocular tensions by Perkins applanation tonometer, Diurnal variation test, Slit lamp examination, gonioscopy, perimetry and fundus examination. The above parameters were reassessed postoperatively after 1 week, 1 month, 3 months, 6 months and 1 year. Success of surgery was considered as postoperative intraocular pressure less than 21 mm hg in the absence of antiglaucoma medication or other intervention.

Complications such as hyphaema, flare, hypotony, shallow or flat anterior chamber, bleb leak, blebitis, macular edema, maculopathy, choroidal effusion were also looked for.

Surgical Procedure: (Figures 1 to 10) All surgeries considered in this study were performed by a single experienced senior surgeon. The surgery was preceded by systematic preoperative preparation and was done under peribulbar anesthesia.

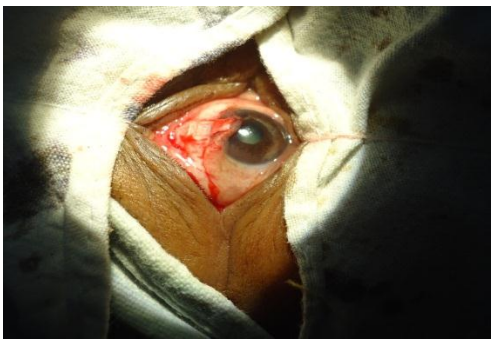

Fig 1: Preparation of superficial scleral flap

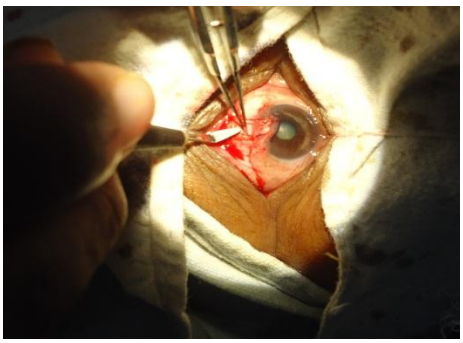

Fig 2: Preparation of deep scleral flap

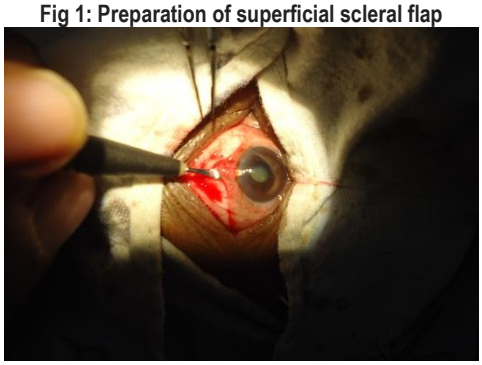

Fig 3: Preparation of sclero corneal tunnel

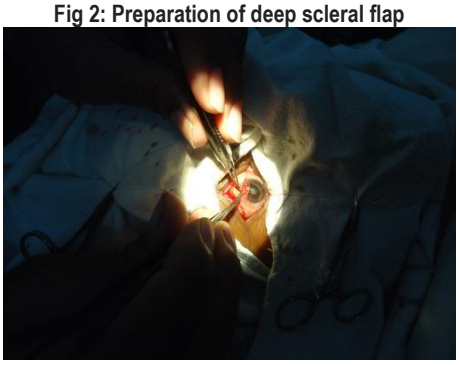

Fig 4: Excision of deep scleral flap

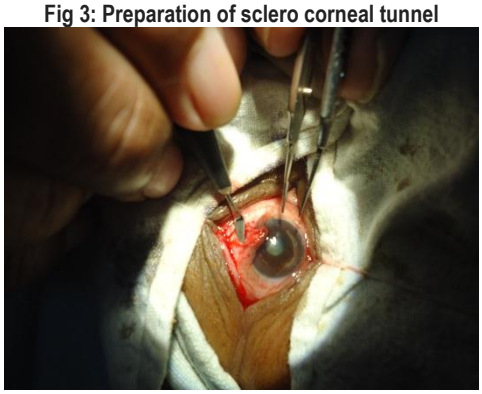

Fig 5: Preparation of side pocket to fix the implant

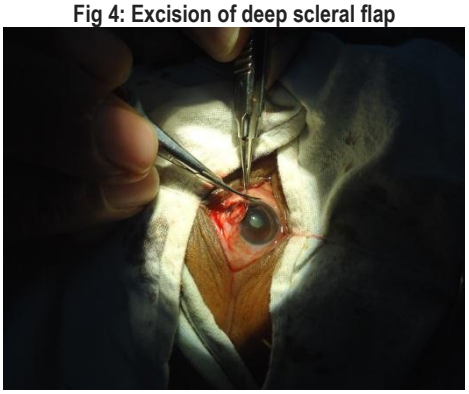

Fig 6: Preparation of implant

Fig 7: Prepared implant for NPGS

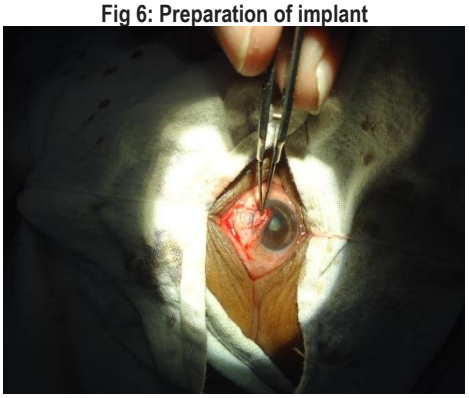

Fig 8: Fixation of implant

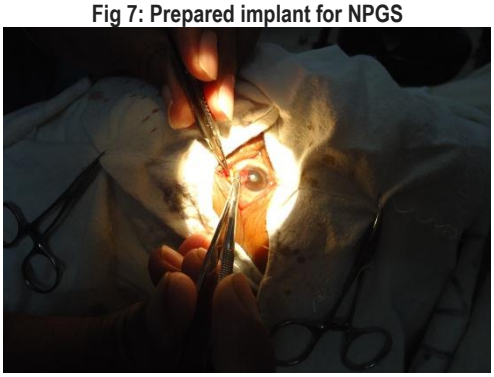

Fig 9: Suturing of scleral and conjunctival flaps

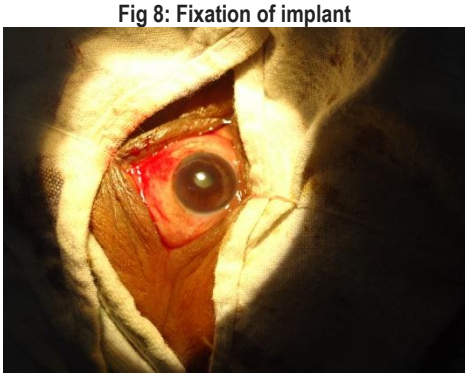

Fig 10: Successful NPGS implant

7 mm of limbus based conjunctival flap is made in the upper quadrant. Superficial scleral flap – 5x5 mm square scleral flap of 40% depth is dissected upto clear cornea followed by a second 3x3 mm deep scleral flap of 90 % depth of sclera using a crescent blade. At the level of the scleral spur, the Schlemm's canal is deroofed and a corneoscleral lake is formed to facilitate the diffusion of the aqueous humor. The deep scleral flap is excised along its base 0.5 mm anterior to Schwalbe's line to create the deep sclerectomy space. Scleral pockets are made on both lateral sides of the deep groove.

The Acry C plant: This non absorbable C shaped implant is made by cutting one of the haptics of the Polymethylmethacrylate Intraocular lens regularly used for cataract surgery. Thus, a 3-4 mm curved inert implant is created and can be directly placed in the scleral pockets for fixation. (Fig 1) Superficial scleral flap and conjunctival flap are sutured using 10 – 0 Nylon sutures.

The purpose of placing this implant in the deep scleral groove is to prevent the common complication of fibrosis to keep the space patent that often follows NPGS resulting in failure of filtration and ineffective control of IOP. NonPenetrating Glaucoma Surgery was performed in a similar manner without insertion of the implant and patients were similarly evaluated on followup.

From the study of 70 patients surgically treated, the following observations were made: 35 patients of Penetrating Glaucoma Surgery and 35 of Nonpenerating Glaucoma Surgery.

GROUPS DIVISION

The patients receiving the surgical procedure are divide in two groups.

GROUP A includes patients receiving Nonpenetrating Glaucoma Surgery With Acry C Implant.

GROUP B includes patients receiving Nonpenetrating Glaucoma Surgery (Deep Sclerectomy).

RESULTS

Table 1 gives age and sex distribution of patients taken up for the study along with average preoperative IOP of both the groups. No statistically significant difference was seen in any of the above data in the two groups.

Table 2 shows that Maximum number of patients had BCVA same as preoperative at 12 months of follow up postoperatively, out of 35 patients in group A 25(71.43%) patients and in group B 23(65.71%) patients has same visual acuity as preoperative and that there was no statistically significant difference observed between two groups (p>0.05).

Success of procedure was defined as postoperative IOP less than or equal 21 mmofHg without any use of local or systemic antiglaucoma medication.

As seen in Table 3, Postoperatively there is significant reduction of IOP as compared to preoperative by both the procedures in both the groups, At 1 month postoperatively, two patients in group B were having IOP >21mmofHg, requiring antiglaucoma medication and one among them required resurgery at 3 months due to non-control of IOP by antiglaucoma medication. At 12 months of follow up mean postoperative IOP in group A was 15 ±3.06mmofHg and in group B was 14.85± 4.22 mmofHg.No significant difference between two groups. It is seen that in postoperative IOP control between two groups no significant difference was seen between two groups (p>0.05).

As evidenced in Table 4 , for both groups difference was statistically significant i.e postoperative IOP significantly decrease from preoperative level (p<0.05).

As per table 5 in regard to failure rate, the difference was statistically significant i.e group A has significantly less failure rate than group B (p<0.05).

With regards to age and sex, there was no statistically significant data. In terms of visual acuity, maximum number of patients in both groups has same postoperative BCVA as compared to preoperative i.e 20(57.14%) patients in group A and 21(60%) patients in group B has same postoperative visual acuity as preoperative.

In postoperative BCVA at day one there was no statistically significant difference observed between two groups (p>0.05).

Maximum number of patients has BCVA same as preoperative at 12 months of follow up postoperatively, out of 35 patients in group A 25(71.43%) patients and in group B 23(65.71%) patients has same visual acuity as preoperative.

At 12 months of follow up In group A 7(20%) patients has decline by 1 line and 3(8.57%) patients has decline by 2 lines of snellen's V/A testing chart due to failure of surgery and postoperative cataract progression.

At 12 months of follow up in group B 8(22.86%) patients has decline by 1 line and 4(11.43%) patients has decline by 2 lines of snellen's V/A testing chart due to failure of surgery and postoperative cataract progression.

In Postoperative BCVA at 12 months there was no statistically significant difference observed between two groups (p>0.05).

Table 1: Age, Sex, Pre-Operative IOP Distribution

GROUPS	AGE IN YEARS(MEAN ± SD)	MEN	WOMEN	PREOPERATIVE IOP (MEAN± SD) in mm of Hg
GROUP A	61.03± 5.06	20	15	31.09± 7.36
GROUP B	61.66 ± 5.29	19	16	29.26± 7.09

p1= 0.61, p> 0.05, NOT SIGNIFICANT.X^2 = 0.057,p> 0.05, NOT SIGNIFICANTp2 =0.29, p>0.05, NOT SIGNIFICANT

Table 2: Shows preoperative and postoperative intraocular pressures in all three groups

Group	Mean ± SD for IOP						
	Pre-operative	Post-Operative					
		Day 1	Week 1	Week 4	Month 3	Month 6	Month 12
1	25.62 ±1.72	13.38 ± 1.72	13.24 ± 1.55	13.14± 2.19	13.44 ±1.99	13.27 ±1.55	13.27 ± 2.13
2	34.38 ±2.27	18.77 ±2.39	18.27 ± 3.47	18.05 ± 4.17	17.33 ±2.44	16.94 ±2.23	16.50 ± 2.74
3	41.66 ±1.15	23.33 ±1.15	23.66 ±3.78	24.00 ±2.00	17.33 ±1.52	17.33 ±0.57	17.66 ± 1.52

Table 3: Postoperative IOP Control Comparision between Two Groups

	GROUP A (MEAN IOP± SD)in mm of Hg	GROUP B (MEAN IOP ± SD) in mm of Hg	P VALUE	S/NS
PREOPERATIVE	31.09± 7.37	29.26± 7.10	0.29	NS
POST OP DAY 1	11.23± 3.35	12.03± 4.64	0.41	NS
POST OP DAY 3	11.23± 3.34	12.03± 4.64	0.41	NS
POST OP DAY 7	11.37± 3.61	12.77± 4.72	0.15	NS
POST OP DAY 15	13.37± 3.65	14.29± 4.50	0.35	NS
POST OP 1 MONTH	14.2± 3.51	15.2± 5.23	0.35	NS
POST OP 3 MONTH	15.31± 4.03	16.23± 6.55	0.48	NS
POST OP 6 MONTH	15.17± 3.54	16.11± 6.08	0.43	NS
POST OP 9 MONTH	14.97± 3.10	14.86± 4.22	0.89	NS
POST OP 12 MONTH	15± 3.06	14.85± 4.22	0.87	NS

p>0.05,NOT SIGNIFICANT.

Table 4: Preoperative And Postoperative IOP Chart

GROUPS	PREOPERATIVE IOP (MEAN± SD)	POSTOPERATIVE IOP AT 12 MONTHS (MEAN±SD)	P VALUE	S/NS
GROUP A	31.09± 7.37	15± 3.06	1.39024E-15	S
GROUP B	29.26± 7.10	14.85± 4.22	1.66064E-14	S

p <0.05,SIGNIFICANT.

Table 5: Efficacy of Procedure

GROUPS	SUCCESS RATE n(%)	FAILURE RATE n (%)	TOTAL n (%)
GROUP A	33(94.29%)	2(5.71%)	35(100%)
GROUP B	25(71.43%)	10(28.57%)	35(100%)

X^2= 6.43, p<0.05, SIGNIFICANT

DISCUSSION

Studies including those by Ates H et al[1], Bonilla R et al[2], Dahan et al[3], Devloo et al[4], Hamel et al[5], Sanchez et al[6] and most others indicate that the preoperative IOP taken for our study falls in the same range as that taken in other similar studies. Also the average age range in our study vs similar studies and within the three groups in our study are statistically insignificant.

Postoperatively there is significant reduction of IOP as compared to preoperative by both the procedures in both the groups.

Postoperative on day 1 mean IOP in group A was 11.23± 3.35 mm ofHg which is 63.87% reduction in preoperative IOP, while in group B it was 12.03 mmofHg which is 58.88% reduction in preoperative IOP there was no statistical significant difference between the two groups.

At 1 month, mean postoperative IOP in group A was 14.2±3.51 mmofHg and in group B was 15.2±5.23 mmofHg and two patients in group B were having IOP >21mmofHg, requiring antiglaucoma medication and one among them required resurgery at 3 months due to non-control of IOP by antiglaucoma medication.

At 6 months of follow up , mean postoperative IOP in group A was 15.17±3.54 mmofHg while in group B mean postoperative IOP was 16.11±6.08 mmofHg and four patients has IOP >21 mmofHg failure of surgery required postoperative antiglaucoma medication, No significant difference in two groups.

At 12 months of follow up mean postoperative IOP in group A was 15 ±3.06mmofHg and in group B was 14.85± 4.22 mmofHg.No significant difference between two groups

It is seen that in postoperative IOP control between two groups no significant difference was seen between two groups (p>0.05).

For group A mean preoperative IOP was 31.09±7.37 mmofHg and postoperative mean IOP at 12 months of follow up was 15 ±3.06 mmofHg there was statistically significant difference between preoperative and postoperative IOP control.

For group B mean preoperative IOP was 29.26 ±7.10 mmofHg and postoperative mean IOP at 12 months was 14.85 ±4.22 mmofHg ,difference was statistically significant i.e postoperative IOP significantly decrease from preoperative level (p<0.05).

For group A according to IOP range 20-30 mmofHg mean preoperative IOP was 25.17 ±2.43mmofHg and mean postoperative IOP was 12.5 ±1.81mmofHg there is 50.34% reduction in IOP postoperatively.

In range 31-40, preoperative mean IOP was 34.09± 3.05 mm of Hg and postoperative IOP was 17.18± 2.90mmofHg with 49.60% reduction in IOP.

In range 41-50, preoperative mean IOP was 43.33± 2.25 mmofHg and postoperative IOP was 20.67± 3.88 mmofHg with 52.32% reduction.

From the chart it is seen that there is approximately constant reduction in all ranges of IOP in group A and there is significant reduction of postoperative IOP from preoperative level (p<0.05).

For group B according to IOP range 20-30 mmofHg mean preoperative IOP was23.74 ±2.26 mmofHg and mean postoperative IOP was 12.26± 4.03 mmofHg with 48.36% reduction in IOP.

In range 31-40 mmofHg mean preoperative IOP was 33.09± 2.98mmofHg and mean postoperative IOP was 19.64± 5.07 mmofHg with 40.65% reduction in IOP.

In range 41-50 mmofHg mean preoperative IOP was 41.8 ±1.10 mmofHg and mean postoperative IOp was 29.17± 2.86 mmofHg with 30.14% reduction.

It is seen from the IOP chart that for group B there is better postoperative IOP control in lower preoperative ranges as compared to higher preoperative range which has only 30.14% of reduction in IOP. There is significant reduction in postoperative IOP from preoperative level ($p<0.05$).

In Both Groups, no intraoperative complications were seen.

Postoperative complication- In both groups,the only significant complication encountered was failure of filtration seen in 6 (18%) cases. Ravinetet al[7] in their study diagnosed surgery related complication including positive seidel test, hyphema, choroidal detachment and iris incarceration. Ates H et al[1] in their study showed no anterior segment complications and as a complication one case of self-limited shallow choroidal detachment was seen. Bonilla R et al[2] noted the only intraoperative complication was the microperforation of trabeculodescemetic membrane in four patients. Drosum L[8] in their study noted that there were no complications related to hypotony or other significant complications. Thus the safety of both these procedure as compared to other similar procedures is evident.

Failure rate in group B was 10(28.57%), the difference was statistically significant i.e group A has significantly less failure rate than group B($p<0.05$)

Another very important consideration is the cost effectiveness of the Acry C plant. Tan JC and Hitchings RA[9] state that in deep sclerotomy, the adjunctive implant is priced at approximately £120. Wang NL[10] et al have documented that cost of NPTS remains a serious concern. Guedes RAP et al[11] reported that cost of Non penetrating deep sclerotomy cost between US $305.25 to US $ 390.09 depending on the severity of glaucoma.

Thus, in comparison to the above expenses the PMMA implant is considerably inexpensive since it has to be constructed from a PMMA lens which is freely available at low costs. The cost of the implant was estimated to be between Rs. 50 to Rs. 100 i.e $1 - 2.

CONCLUSION

Non Penetrating Glaucoma Surgery is an effective modality for control and maintenance of Intraocular pressure in patients with primary open angle glaucoma which is better achieved with insertion of Acry C implants which helps avoid surgical failures. With the exception of failure of filtration seen in few cases, no major complications are noted related either to the surgery or the implant. The procedure is thus cost effective without a compromise in safety. However further wider and long term research in this area is required.

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