Self-engineered Acry C plants in nonpenetrating glaucoma surgery

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Abstract:
BACKGROUND: Analysis of safety and efficacy of self-engineered polymethylmethacrylate (Acry C) implants in nonpenetrating glaucoma surgery (NPGS) for control and maintenance of intraocular pressure (IOP) in primary open angle glaucoma (POAG) patients.

MATERIALS AND METHODS: This was a hospital-based randomized study. Fifty eyes of 50 POAG patients were divided into 3 groups based on preoperative IOP range. NPGS was done with polymethylmethacrylate implants made from haptics of intraocular lenses. All patients were followed up after 1 day, 1 week, 1 month, 3 months, 6 months, and 12 months. Preoperative IOP range was from 25.62 ± 1.72 to 41.66 ± 1.15 mmHg. Postoperative success was defined as IOP <21 mmHg at 1 month in the absence of additional antiglaucoma medication or other treatment.

RESULTS: A significant reduction in IOP was observed postsurgery in all three groups, changing from a preoperative mean of 25.62 ± 1.72 mmHg, 34.38 ± 2.27 mmHg, and 41.66 ± 1.15 mmHg to a postoperative mean of 13.27 ± 2.13 mmHg, 16.50 ± 2.74 mmHg, and 17.66 ± 1.52 mmHg, respectively (P < 0.001) at 12 months. No significant difference was seen with change in position of the implant, i.e., convexity facing limbus or fornix. No intraoperative complications were observed. The main postoperative complication was failure of filtration in 1 case (3.44%) from Group 1, 5 cases (27.78%) from Group 2, and all 3 cases (100%) from Group 3 at 1 month postoperatively. Thus, 9 eyes (41%) required postoperative antiglaucoma medications following which the IOP was controlled.

CONCLUSION: NPGS with Acry-C implants is a safe and cost-effective (<1 US dollar) procedure for control of IOP in POAG patients especially those with moderately elevated IOPs.

Keywords: Acry C implants, cost-effective, noninvasive, self-engineered

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 nonpenetrating glaucoma surgery (NPGS) with the use of implants being a further advancement in this safe and efficacious procedure. Our study is a pilot study that unbiassedly tests whether the economically advantageous self-engineered Acry C plants successfully serve the primary aim of controlling intraocular pressure (IOP).

Materials and Methods

This hospital-based randomized prospective study included 50 eyes with primary open angle glaucoma (POAG) on whom NPGS with Acry C plants was performed and patients were followed up.

Ethics committee

The Indira Gandhi Government Medical College Nagpur Ethics Committee approval

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was taken. Written informed consent was taken from all individuals.

**Inclusion criteria**
Patients with POAG who gave consent.

**Exclusion criteria**
All patients with any other type of glaucoma including normal tension glaucoma (NTG).

Preoperative data included ocular complaints, best-corrected visual acuity, 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 day, 1 week, 1 month, 3 months, 6 months, and 1 year.

The success of surgery was considered as postoperative IOP <21 mmHg at 1 month in the absence of antiglaucoma medication or other intervention.

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

Surgical procedure is shown through Figures 1-10. All surgeries considered in this study were performed by a single experienced senior surgeon – Dr. S. S. Pendke. The surgery was preceded by systematic preoperative preparation and was done under peribulbar anesthesia.

7 mm of limbus-based conjunctival flap is made in the upper quadrant. Superficial scleral flap – 5 mm × 5 mm scleral flap of 40% depth is dissected up to clear cornea followed by a second 3 × 3 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 is a nonabsorbable C-shaped implant which 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 [Figure 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.
The implant is placed either with its convexity toward the fornix or the limbus, the position remaining constant, i.e. in the deep scleral groove. The implant does not need to be sutured to ensure it stays in the scleral pockets of the groove. In our study, 25 (50%) implants were placed with convexity toward the limbus and the rest were placed with convexity toward the fornix and the results compared.

All statistical analyses in this study were done using STEM and the statistical method used was the Chi-square test.
Table 1 gives age-wise and sex-wise distribution of patients in all three groups along with direction of placement of implants. No statistically significant difference is seen in these preoperative values.

Table 2 is a numeric representation of statistically significant reduction of preoperative IOP in all three groups at all postoperative follow-ups.

Table 3 shows complication rates in all three groups, and \( P < 0.0001 \) by Chi-square test indicates significance between the baseline IOP and efficacy of the procedure.

**Discussion**

The above statistics indicate that NPGS is effective in controlling IOP independently in cases with mild to moderately elevated IOPs and in combination with antiglaucoma medication in eyes with highly elevated IOPs.

The preoperative baseline IOPs in our study population resemble those included in previous similar studies.\[^1\]-\[^4\] Moreover, the average age range in our study versus similar studies and within the three groups in our study is statistically insignificant.

The mean percentage reduction in IOP at 12 months for the three groups is 48.14% ±7.85%, 52.00% ±7.59%, and 57.52% ±4.72% as shown in figure 11.

The only significant complication encountered in our study was failure of filtration seen in 9 (18%) cases; no other significant complications were seen. Ravinet et al., 2004[^7] in their study diagnosed surgery-related complication including positive Seidel test, hyphema, choroidal detachment, and iris incarceration. Ates et al., 2001[^1] in their study showed no anterior segment complications, and as a complication, one case of self-limited shallow choroidal detachment was seen. Bonilla et al., 2012[^2] noted the only intraoperative complication was the microperforation of trabeculodescemetic membrane in four patients. Drolsum 2003[^8] in their study noted that there were no complications related to hypotony or other significant complications. Thus, the safety of this procedure as compared to other similar procedures is evident.

Another very important consideration is the cost-effectiveness of the Acry C plant. Tan and Hitchings 2001[^9] state that in deep sclerotomy, the adjunctive implant is priced at approximately ≤120. Wang et al. 2005[^10] have documented that cost of NPTS remains a serious concern. Guedes et al., 2011[^11] reported that cost of nonpenetrating 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 polymethylmethacrylate (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 and Rs. 100 i.e., $1–$2.

One other aspect the study considered was the position of the implant in the deep scleral groove, and no significant difference was seen in postoperative results based on whether the convexity of the implant was toward the limbus or the fornix.

Conclusion

NPGS with implant is an effective modality for control and maintenance of IOP in patients with POAG with its greatest efficacy being in patients with a preoperative IOP between 20 and 30 mmHg. With the exception of failure of filtration seen in few (9%) cases, no major complications were 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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Conflicts of interest
There are no conflicts of interest.

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