Comparative Study between Non Penetrating Glaucoma Surgery with and without Implant

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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.

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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 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 engineered Acry 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, perimeter 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
The deep scleral flap is excised between two groups. 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 group A and 35 patients in group B were having IOP >21mmHg, 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 ±3.06mmHg and in group B was 14.85± 4.22 mmHg.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).

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

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

<table>
<thead>
<tr>
<th>GROUPS</th>
<th>AGE IN YEARS(MEAN ± SD)</th>
<th>MEN</th>
<th>WOMEN</th>
<th>PREOPERATIVE IOP (MEAN± SD) in mm of Hg</th>
</tr>
</thead>
<tbody>
<tr>
<td>GROUP A</td>
<td>61.03± 5.06</td>
<td>20</td>
<td>15</td>
<td>31.09± 7.36</td>
</tr>
<tr>
<td>GROUP B</td>
<td>61.66 ± 5.29</td>
<td>19</td>
<td>16</td>
<td>29.26± 7.09</td>
</tr>
</tbody>
</table>

p1= 0.61, p> 0.05, NOT SIGNIFICANT, X2 = 0.057,p> 0.05, NOT SIGNIFICANT, p2 =0.29,p>0.05, NOT SIGNIFICANT

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

<table>
<thead>
<tr>
<th>Group</th>
<th>Mean ± SD for IOP</th>
<th>Pre-operative Day 1</th>
<th>Week 1</th>
<th>Week 4</th>
<th>Month 3</th>
<th>Month 6</th>
<th>Month 12</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>34.38 ± 2.27</td>
<td>28.33 ± 1.72</td>
<td>18.77 ± 2.39</td>
<td>18.27 ± 3.47</td>
<td>18.05 ± 4.17</td>
<td>17.33 ± 2.44</td>
<td>16.94 ± 2.23</td>
</tr>
<tr>
<td>3</td>
<td>41.66 ± 1.15</td>
<td>23.33 ± 1.15</td>
<td>23.66 ± 3.78</td>
<td>24.00 ± 2.00</td>
<td>17.33 ± 1.52</td>
<td>17.33 ± 0.57</td>
<td>17.66 ± 1.52</td>
</tr>
</tbody>
</table>
DISCUSSION

Studies including those by Ates H et al., Bonilla R et al., Dahan et al., Devloo et al., Hamel et al., Sanchez et al. 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 of Hg which is 63.87% reduction in preoperative IOP, while in group B it was 12.03 mm of Hg 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 mm of Hg and in group B was 15.2±5.23 mm of Hg and two patients in group B were having IOP >21mmHg, 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 mm of Hg while in group B mean postoperative IOP was 16.11±6.08 mm of Hg and four patients has IOP >21 mm of Hg 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 ±3.06 mm of Hg and in group B was 14.85± 4.22 mm of Hg. 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 mm of Hg and postoperative mean IOP at 12 months of follow up was 15 ±3.06 mm of Hg there was statistically significant difference between preoperative and postoperative IOP control.

For group B mean preoperative IOP was 29.26 ±7.10 mm of Hg and postoperative mean IOP at 12 months was 14.85±4.22 mm of Hg 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 mm of Hg mean preoperative IOP was 25.17 ±2.43 mm of Hg and mean postoperative IOP was 12.5 ±1.81 mm of Hg 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±2.90 mm of Hg with 49.60% reduction in IOP.

In range 41-50, preoperative mean IOP was 43.33± 2.25 mm of Hg and postoperative IOP was 20.67±3.88 mm of Hg 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 mm of Hg mean preoperative IOP was 23.74 ±2.26 mm of Hg and mean postoperative IOP was 12.26±4.03 mm of Hg with 48.36% reduction in IOP.

In range 31-40 mm of Hg mean preoperative IOP was 33.09±2.98 mm of Hg and mean postoperative IOP was 19.64±5.07 mm of Hg with 40.65% reduction in IOP.
In range 41.50-50 mmHg mean preoperative IOP was 41.8 ±1.10 mmHg and mean postoperative IOP was 29.17± 2.86 mmHg 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. Ravinet et al in their study diagnosed surgery related complication including positive seidel test, hyphema, choroidal detachment and iris incarceration. Ates H et al 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 noted the only intraoperative complication was the microperforation of trabeculodescemetic membrane in four patients. Drosum L 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 state that in deep sclerectomy, the adjunctive implant is priced at approximately £120. Wang NL et al have documented that cost of NPTS remains a serious concern. Guedes RAP et al reported that cost of Non penetrating deep sclerectomy 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.

REFERENCES

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