Combined Surgery Versus Sequential Surgery In Patients With Primary Glaucoma And Senile Cataract: A Randomised Controlled Trial

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ABSTRACT:
BACKGROUND AND AIM: This prospective study was aimed to compare efficacy and safety of combined surgery and sequential surgeries in patients with primary glaucoma and visually significant senile cataract. MATERIALS AND METHODS: 50 consecutive patients having coexisting visually significant senile cataract with primary glaucoma were included in study. Patients underwent detailed history, ocular examination and routine pre operative investigations. Random distribution of patients into sequential surgery group (S) who underwent planned two staged surgeries and combined surgery group (C) who underwent combined surgery with 25 patients each was done with follow up of 3 months. Statistical analysis was done using chi-square test where p value <0.05 was considered statistically significant. RESULTS: The mean IOP achieved at 12 weeks postoperatively was 2 mm of Hg lower for group S compared to group C. Amount of IOP reduction was 10% more for group S. Overall intra-operative complication rate was higher in Group C (52%) compared to Group S (42%), post operative complications were higher in group S (64%) compared to group C (44%). Unaided visual acuity (>6/60) was more in group C (68%) compared to group S (60%). CONCLUSION: Both surgeries were found be statistically comparable in terms of safety and efficacy where sequential surgeries had lower intraoperative complication rate and preferred for more compromised ocular conditions with disadvantage of economic losses and relative visual deprivation until cataract surgery whereas combined surgeries had an advantage of faster visual rehabilitation and disadvantage being higher rate of intraoperative complications.

Key words: Combined surgery, Sequential surgery, Glaucoma, Cataract.

INTRODUCTION
Coexistence of cataract and glaucoma is encountered frequently in aged population. A wide variety of clinical entities exist within this spectrum [¹¹]. For this study we limited ourselves to the study of patients with primary open angle or narrow angle glaucoma with visually significant senile cataract which is most frequent in our setup. In the management of these patients 2 basic approaches were followed. 1. Planned two staged (sequential) surgeries - trabeculectomy followed by extracapsular cataract cataract extraction with IOL implantation in the same sitting³,¹². There are number extraction with IOL implantation. 2. One staged (combined) surgery- trabeculectomy along with extracapsular of studies evaluating these surgical approaches individually but results were conflicting and only few studies compared safety and efficacy of these approaches on Indian eyes. In this randomized controlled study we endeavored to study and compare these two surgical techniques with regards to control of IOP, complications and final visual outcome in this subset of patients.

MATERIALS AND METHODS
Approval was obtained from the ‘Institutional research and ethics committee’. Written and informed consents from all the participants of our study were obtained. 50 consecutive patients having coexisting visually
significant senile cataract with primary glaucoma either open angle or closed angle, admitted and treated surgically during the period 2003-2005 in Department of Ophthalmology of SSG Hospital were included in this study. Patients having secondary cataract or secondary glaucomas like lens induced, inflammatory (uveitis), post traumatic, steroid induced etc. were excluded from the study. Also those patients treated for glaucoma by Laser trabeculoplasty or anti glaucoma surgeries like trabeculotomy in the past and patients with active uveitis were excluded. Random distribution of patients into two groups (group S and group C) with 25 patients in each was done. All patients underwent detailed history, general and systemic examination and local examination which included visual acuity, slit lamp examination, tonometry, gonioscopy for anterior chamber angle grading, direct and indirect ophthalmoscopy (esp. Cup : disc ratio). Pre operative investigations included IOL power calculation by A scan Biometry, automated static perimertry (when possible), measurement of blood pressure for hypertension and blood sugar for diabetes and other routine pre operative investigations. Pre operative medications included topical and oral antibiotics with IOP lowering agents (like Tab. acetazolamide, oral glycerol) and injection mannitol when IOP was >25 mm of Hg just before surgery. Group S patients underwent two staged sequential surgery i.e. trabeculectomy initially followed by extracapsular cataract extraction with IOL implantation later as a second surgery; whereas group C patients underwent one staged surgery i.e. trabeculectomy along with extracapsular cataract extraction with IOL implantation at the same sitting. Post operative treatment was given in the form of systemic antibiotics and anti inflammatory drugs, along with local treatment in the form of antibiotic drops, steroid-antibiotic combination drops in tapering frequency, cycloplegics and mydritics (when inflammation was severe) and anti glaucoma drops when post operative IOP remained higher. Patients were discharged in 3-5 days and called for follow up at 1,2,4,8 and 12 weeks. During each follow up patients were examined for unaided visual acuity, IOP, slit lamp examination for anterior segment especially filtering bleb formation, anterior chamber depth, fundus examination and looked for any post operative complications like increased IOP, hypotony, shallow anterior chamber, keratitis, IOL decentration, synechiae formation, iritis (fibrin reaction) and pupillary distortion. When any complication was found it was treated either medically or surgically if required. The above data was collected and statistical data analysis was done using chi-square test where p value <0.05 was considered statistically significant.

RESULTS
In present study maximum patients were between 50-60 years of age with mean age being 55 years and 60 years in group S and group C respectively. The male: female ratio was 1.27 in group S and 0.92 in group C. Associated established risk factors for glaucoma like hypertension, diabetes positive family history and refractive errors were found in 44% of patients in group S and 48% in group C. Both groups had greater affection for left eye (56% in group S and 60% in group C). Visual acuity on presentation was poor in both the groups. Visual acuity was less than 6/60 in 84% of patients in group S and 72% of patients in group C. Mean pre operative IOP in group S was 27.46 mm of Hg and 27.68 mm of Hg in group C. The cup: disc ratio ranged from 0.5 to 1.0 in both the groups. Mean cup: disc ratio was 0.7 in group S and 0.73 in group C. Gonioscopically the average grading of anterior chamber angle was grade 2.0 in group S and 1.96 in group C. The minimum interim duration of 2 weeks was seen between two surgeries in group S with maximum of 1 year. The average duration was of 6 months.

Table 1: Intra operative complications

<table>
<thead>
<tr>
<th>Patients groups</th>
<th>Intra operative complications (no. of patients)(%)(n)</th>
<th>Absent</th>
<th>Present</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group S</td>
<td>10(40%)</td>
<td>15(60%)</td>
<td>25(100%)</td>
<td></td>
</tr>
<tr>
<td>Group C</td>
<td>5(20%)</td>
<td>20(80%)</td>
<td>25(100%)</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>15(30%)</td>
<td>35(70%)</td>
<td>50(100%)</td>
<td></td>
</tr>
</tbody>
</table>

Chi-square value: 2.40  p value: <0.5
Intra operative complications were found to be more common in group C (80%) compared to group S (60%) but it was clinically not significant (p value 0.5). Most common complication was incomplete removal of cortex, others included hyphaema, Descemet’s membrane stripping, vitreous loss, pigment dispersion, conjunctival button holing and refractive IOP.

### Table 2: Contingency table for post operative IOP control at 12 weeks

<table>
<thead>
<tr>
<th>Patients groups</th>
<th>Post op IOP control at 12 weeks (no. of patients)(%):</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>&lt;20 mm Hg</td>
<td>&gt;20 mm Hg</td>
</tr>
<tr>
<td>Group S</td>
<td>24 (96%)</td>
<td>1 (4%)</td>
</tr>
<tr>
<td>Group C</td>
<td>22 (88%)</td>
<td>3 (12%)</td>
</tr>
<tr>
<td>Total</td>
<td>46 (92%)</td>
<td>4 (8%)</td>
</tr>
</tbody>
</table>

Chi –square value: 0.751, p value : <0.5

Control of IOP at 12 weeks (<20 mm. of Hg) was found in majority of patients of both the groups (92%), but it was slightly better in group S compared to group C. IOP less than 20 mm of Hg was found in 24 patients (96%) in group S patients and 22 patients (88%) in group C patients.

**Figure 1, 2: Amount of IOP reduction (%) in Group C and group S**

Figure 3: Post-operative change in visual acuity group S and C at 12 weeks

The amount of improvement in the unaided visual acuity was found to be slightly more in group C compared to group S. 12% of group C patients did not have any discernible bleb 3 months postoperatively with control of IOP where as 32% patients of group S patients didn’t show any discernible bleb, of these 50% had absence of bleb following trabeculectomy. The remaining 50% showed a loss of an established filtering bleb following cataract surgery. 26% patients in group S
had reduction in bleb size. At the end of 12 weeks most ideal bleb (type II) was seen in majority of group C (40%) compared to group S which had only 20%. Over filtration was a there in 8% patients. Shallow anterior chamber was seen in 24% patients of group S and 32% patients of group C.

**Table 3: Contingency table for post operative complications at 12 weeks**

<table>
<thead>
<tr>
<th>Patients groups</th>
<th>Post op complications at 12 weeks (no. of patients)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Absent</td>
<td>Present</td>
</tr>
<tr>
<td>Group S</td>
<td>9(36%)</td>
<td>17(68%)</td>
</tr>
<tr>
<td>Group C</td>
<td>11(44%)</td>
<td>14(56%)</td>
</tr>
<tr>
<td>Total</td>
<td>19(38%)</td>
<td>31(62%)</td>
</tr>
</tbody>
</table>

Chi- square value: 0.764  p value: <0.5

Incidence of post operative complications at the end of 3 months follow up was 68% among group S and 56% among group C. Most common complication in both group S and C was synechiae formation 60% and 48% respectively. Higher incidence of transient hypotony was found almost double in group S (32%) compared to group C (16%). IOL decentration was more common in group S (28%) compared to group C (12%). Intra operative complications were more common in group C (80%) compared to group S (60%) whereas post operative complications were more common in group S (68%) compared to group C (56%). Re surgeries like conjunctival suturing, air injection, bleb revision and para ocular steroids were required more frequently in group C (36%) compared to group S (28%). Nearly 50% patients of group S showed excellent results as these patients had lower IOP, greater reduction in IOP and lower rate of complications but were associated with lower unaided visual acuity where in group C 36% showed excellent outcome and 40% having good outcome. The fair outcome was there in almost equal number of patients in both groups.

**DISCUSSION**

On statistical analysis of the data for both the groups of surgical techniques, the results were statistically comparable in terms of both efficacy (in terms of visual acuity and IOP achieved) and safety (incidence of intra operative and post operative complications). Analysis of data using chi square test results were found to be more in favor of sequential surgery than combined surgery in our study; which is different from study done by Casson RJ et al which concluded both them having similar outcome [1]. The mean IOP achieved at 12 weeks postoperatively was 2 mm of Hg lower for group S compared to group C. Amount of IOP reduction was 10% more for group S comparable to study by Naveh N et al [15]. The rate of uneventful surgery, for group S was nearly double to that of group C. this is because in S group cataract with IOL surgery was performed in the eye in which IOP was under control with quiet eye. In group C 2 surgeries (cataract removal with IOL implant and trabeculectomy) were performed at the same time, in the eye having relatively uncontrolled IOP, which was technically more demanding. These findings were found comparable with study done by Krupin T et al [7,8]. Intra operative complications were more common in group C due to higher IOP during surgery whereas IOP was controlled during cataract extraction surgery by previous trabeculectomy surgery in group S [13,14]. Post operative complications rate at the end of 12 weeks was higher in group S (68%) than in group C (56%), but the type of complications were different in both the groups. Incidence of transient hypotony was more in group S compared to group C as it was observed after both trabeculectomy and cataract surgeries. All the patients in group S after 12 weeks had controlled IOP (<20 mm Hg) without any anti glaucoma medication, while 5 patients in group C required 1-2 anti glaucoma medications to control the IOP. Incidence of transient IOP spikes was almost equal in both the groups, as also the incidences of complications like keratitis, pupillary distortion with capture of the IOL,
Complications like shallow anterior chamber, persistent corneal oedema, IOL surface deposits were found more common in group C. Decentration of PC IOL and formation of anterior and posterior synechiae were more common in group S compared to group C, which may be due to prolonged hypotony with shallow anterior chamber after trabeculectomy. Complications like synechiae formation and IOL decentration were more common in group S because of the previous trabeculectomy surgery as also mentioned by Steinert R F13. The improvement in visual acuity was more in group C compared to group S, this could be due to surgically induced corneal astigmatism which is more in group S because of the corneal incision for cataract to avoid filtration bleb. This was found to be comparable with study by Rockwood EJ et al10 and Percival SP et al9. In our study 26% patients in group S had reduction in bleb size post operatively which is similar to the results of study done by Dicken MA et al2 study of combined surgery. In this study if assessed clinically, sequential surgery would be preferential in certain situations especially in patients with advanced glaucoma, in which glaucoma contributed more to visual loss compared to cataract, for a surgeon at an early part of his learning curve and in patients with decompensated corneas4. Inadequate control of post operative IOP was more in group C due to secondary rise in IOP, favors sequential surgery but this had an added disadvantage of performing two surgeries with economic losses and relative visual deprivation until cataract surgery4,5. On the other hand combined surgery has the advantage of short hospital stay, undergoing surgical insult only once and faster visual rehabilitation, disadvantage being higher rate of complications6 because it was a demanding surgery with two procedures being done at once and its associated with higher intraocular manipulations and inflammation5.

CONCLUSION
Both surgeries were found statistically comparable with a few clinically differences in favor of sequential surgery. Efficacy in terms of control of IOP was better in group S while in terms of improvement in unaided visual acuity was better in group C. The choice of procedure should thus be individualized. Those patients having advanced cataract, mild to moderate glaucoma and not willing to come for the second surgery should be considered for combined surgery while patients with advanced glaucoma, immature cataract and willing to come back for the second surgery should be considered for sequential surgery. The limitation of this study is the lack of long term follow up. A multicentric study with long term follow up would throw light on future course and complications in these patients.

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