SUCCESS OF COMBINED SICS AND TRABECULECTOMY BY SUTURELESS TECHNIQUE VS. ‘W’ SHAPED INCISION TECHNIQUE

Shikha Agarwal¹, Priyanka Jain², Santosh Kumar³, Rakesh Sharma⁴, Mahesh Prasad Tandon⁵

¹Assistant Professor, Department of Ophthalmology, Mayo Institute of Medical Sciences, Lucknow.
²Assistant Professor, Department of Ophthalmology, Mulyam Singh Medical College, Meerut.
³Assistant Professor, Department of Ophthalmology, Regional Institute of Ophthalmology, Allahabad.
⁴Professor, Department of Ophthalmology, Mayo Institute of Medical Sciences, Lucknow.
⁵Ex. Professor, Department of ophthalmology, Regional Institute of Ophthalmology, Allahabad.

ABSTRACT

BACKGROUND
Cataract and glaucoma are first and second leading causes of blindness worldwide. Combined surgery has the advantage of treating two distinct co morbidities by a single surgery. To increase the success rate and minimize complication rate of this surgery different modification have been tried both in superficial scleral flap formation as well as in fistulising technique and also in the incision shape, size and sites. This study is done to compare the results of combined manual small-incision cataract surgery (SICS) and posterior chamber intraocular lens (PCIOL) implantation with trabeculectomy by sutureless versus combined SICS with 'W'-shaped incision technique.

MATERIALS AND METHODS
In a randomized, prospective, interventional study of 1 year duration, 39 eyes with senile cataract and primary open-angle glaucoma were divided into 2 groups; patients in group A (n=19) underwent SICS with sutureless trabeculectomy and those in group B (n=20) underwent SICS with trabeculectomy using 'W'-shaped incision with one suture. Group A Kelly’s punch was used to punch out a piece of trabecular meshwork at the posterior limbus within the scleral tunnel. Group B The central triangular part of the 'W' shaped scleral flap was lifted and a block of deep sclera (1.5 × 2 mm) was excised using a razor blade fragment and conical scissors. The superficial triangular scleral flap was sutured by one 10 - 0 nylon suture at the apex of the flap.

RESULTS
Mean pre-operative IOP without medication was 32.68 (±4.95) mmHg in group A and 32.15 (±5.15) in group B (p value= 0.53). At 6th month, mean postoperative IOP was 16.42(±2.50) mmHg in group A and 14.87(±2.46) mmHg in group B (p=0.04). 84.21% patients of group A and 90% of group B achieved complete success. The mean number of antiglaucoma medications reduced postoperatively in group A from 1.84±0.83 to 0.42±1.01 while in group B from 1.85±0.875 to 0.10±0.30 (p value= 0.003).

CONCLUSION
Combined SICS with trabeculectomy using 'W' shaped incision is more effective approach for IOP control. It also reduces antiglaucoma drug dependency in comparison to SICS with sutureless trabeculectomy.

KEYWORDS
Trabeculectomy, Cataract, Glaucoma, SICS, Intraocular Pressure, Sutureless, 'W' Shaped Incision.


BACKGROUND
Cataract and glaucoma are first and second leading causes of blindness worldwide.¹² The prevalence of both diseases is increasing with aging population and either one affects the treatment and prognosis of the other condition. Combined glaucoma/cataract surgery lowers IOP more; with fewer postoperative pressure spikes.³ Combined surgery has the advantage of treating two distinct co morbidities by a single surgery and long term control of IOP with glaucoma surgery and quick visual recovery from removal of a significant cataract.

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Corresponding Author:
Dr. Shikha Agarwal,
#10/403, Malhar Deluxe,
Sahara Grace Apartment,
Jankipuram, Lucknow-226021.
E-mail: shikha.agarwal.dp@gmail.com
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Currently manual small-incision cataract surgery with trabeculectomy is most suitable option for the surgical management of combined cataract and glaucoma, uncontrolled with maximum tolerated medical therapy. It has even more important role where phacoemulsification has a limitation.⁴ To increase the success rate and minimize complication rate different modification have been tried both in superficial scleral flap formation as well as in fistulising technique and also in the incision shape, size and sites and few of them found to be more useful in comparison to conventional surgery, sutureless trabeculectomy is one of them. Another modification described to have control on IOP was 'W' shaped incision trabeculectomy. Not many studies have been done previously on 'W' shaped incision technique thus we carried out the present study with the aim to compare the results and complications of combined manual Small-Incision Cataract Surgery (SICS) and posterior chamber intraocular lens (PCIOL) implantation with Trabeculectomy by sutureless versus combined SICS and PCIOL implantation with trabeculectomy using 'W' shaped incision technique.
MATERIALS AND METHODS
A randomized, prospective, interventional and comparative clinical trial carried out on 39 eyes of 39 patients attending outpatient department and glaucoma clinic at Mayo institute of medical sciences, Lucknow during the period of July 2015-July 2016.

Inclusion Criteria
Patients with primary open angle glaucoma (POAG) with coexisting cataract.

Exclusion Criteria
The patients with any other associated ocular disease, with previous ocular surgery or trauma and with diagnosed cases of angle closure and secondary glaucoma.

Detailed history regarding diminution of vision, headache or eye ache, coloured haloes, dark spots in the field of vision, redness, and photophobia, family history of glaucoma and history of drug intake was recorded. Any systemic illness and past history in relation to any ocular trauma, surgery, laser treatment or medications were enquired about.

Ocular examination, including Best Corrected Visual Acuity (BCVA) measurement, slit-lamp examination, applanation tonometry, gonioscopy, automated perimetry, keratometry & biometry.

The patients were randomly divided into two groups (A & B). Group A (n = 19) included patients who underwent combined SICS with sutureless trabeculectomy. Group B (n=20) included the patients who underwent combined SICS with W-shaped incision trabeculectomy with one suture.

Surgical Procedure
1. A fornix-based conjunctival flap was made at the limbus from 10 o’clock to 2 o’clock.
   
   **Group A** - A partial thickness ‘V’ shaped sclera groove of 6 mm size was made superiorly 2 mm away from the limbus. & a scleral tunnel was dissected followed by routine SICS with PCIOL implantation.
   
   **Group B** - a partial thickness ‘W’-shaped scleral groove was made superiorly 2 mm away from the limbus. A triangular flap was lifted with base towards the limbus followed by routine SICS with PCIOL implantation.

2. **Group A** - Kelly’s punch was used to punch out a piece of trabecular meshwork at the posterior limbus within the scleral tunnel.
   
   **Group B** - The central triangular part of the W shaped scleral flap was lifted and a block of deep sclera (1.5 x 2 mm) was excised using a razor blade fragment and corneal scissors. A peripheral iridectomy was done. The superficial triangular scleral flap was sutured by one 10-0 nylon suture at the apex of the flap.

3. The conjunctival flap was repositioned back and sutured with 10-0 nylon suture in both the groups.

Post-operative assessment of the Patients was done on day 1, 3, 7; then at 2nd week, 4th week, 8th week and then monthly till the end of study, i.e. July 2016. Bleb was scored objectively using Migdal and Hitchings Classification, 1983.

Criteria for Success for Surgery included mainly of Intraocular Pressure (IOP).
1. Complete success- IOP ≤ 21 mm of Hg without the use of any antiglaucoma medication.
2. Qualified success- IOP ≤ 21 mmHg with use of antiglaucoma medications.
3. Qualified failure- IOP > 21 mm of Hg with use of antiglaucoma medication, but there is no need for further filtration surgery.
4. Complete failure- Patient needed further filtration surgery or PL become negative.

Statistical Analysis
Student’s unpaired ‘t’ test and chi square test were used to analyse data with the help of SPSS 21 software.

RESULTS
Mean age of the patient in group A was 63.74±5.94 years and in group B was 64.30±6.02 years (p value= 0.77) with maximum patient in 60-69 years age group in both the groups. In the whole sample, M: F ratio was 1.78:1. The mean follow up time for group A was 8.42±2.01 months and for group B was 8.47±2.01 months (p= 0.93). From previous records, we calculated the mean pre-operative IOP without medication was 32.68 (±4.95) mmHg in group A and 32.15 (±5.15) in group B (p value= 0.53) while the mean pre-operative IOP with medication was 23.68 (±3.69) mmHg in group A and 23.60 (±3.52) in group B (p value= 0.99). Post operatively in the 2 groups at 1st week no significant difference was found in mean postoperative IOP. The mean post-operative IOP was having significant difference in both groups in 2nd week onward follow up (Table 1). This indicates lower mean post-operative IOP in group B. The mean number of antiglaucoma medication taken preoperatively was 1.84±0.83 in group A and 1.85±0.875 in group B (p value= 0.97). The mean number of antiglaucoma medication taken post operatively was 0.42±1.01 in group A and 0.10±0.30 in group B. (p value=0.003). Overall success rate is 94.74% in group A and 100% in group B. Rate of qualified failure was higher in group A (5.30%) in comparison to 0% in group B (Table 2). In our study 13 patients in group A and 15 patients in group B had bleb score of 5 while 6 patients in group A and 5 patients in group B had bleb score of 6. Mean bleb score in group A was 5.31±0.48 and in group B 5.25±0.44. The difference was not significant (p value 0.44) (table 3). Preoperative mean C:D ratio in group A was 0.61±0.15 in group B 0.58±0.14 (p value=0.6025) and postoperatively mean C:D ratio in group A was 0.61±0.13 in group B 0.59±0.12 (p value=0.6239). Similarly, field charting of both groups showed comparable results.
combined SICS with trabeculectomy using ‘W’-shaped incision offers better prospective in terms of glaucoma control than sutureless combined surgery. Kelly's Descemet's membrane punch was used in group A to create a small sclerostomy. There is evidence that a small sclerostomy (0.5 mm) is easy to perform, enough to control IOP and may curtail the chance of limbal aqueous flow, and maximize the likelihood of controlling outflow. \(^{10}\) In group B with ‘W’ shape incision surgery the better IOP control could be attributed to good quality posterior aqueous outflow which was more efficient probably because of the side incision of ‘W’ shape which acted as a barrier to lateral flow. We kept the anterior limit of incision 2.0 mm behind the limbus to prevent the anterior misdirection of aqueous towards limbus. This led to a low but diffuse bleb with an adequate and controlled filtration. Moreover, in Group B a triangular flap with one suture provided a more guarded filtration as well as prevented hypotony. We can attribute poor IOP control in subsequent follow ups after 1st postoperative week in Group A, to rapid fibrosis of the fistula in due course of time with closure of fistula. In the present study, surgical success rate was higher in group B as compared to group A. Overall success rate, in group A and in group B was 94.7% and 100% respectively. In a range of formerly done studies, earlier presented facts are also supported by Michielsen & Hennel\(^{14}\) 1994 who said that the W incision can be regarded as a self-sealing incision with an additional posterior flap. For cataract surgery, the flap can be used to add further stability to the incision whilst for combined

<table>
<thead>
<tr>
<th>Group</th>
<th>1st Day</th>
<th>3rd Day</th>
<th>7th Day</th>
<th>2nd Week</th>
<th>4th Week</th>
<th>8th Week</th>
<th>3rd Month</th>
<th>6th Month</th>
</tr>
</thead>
</table>

**Table 1. Post-operative IOP**

<table>
<thead>
<tr>
<th>Success</th>
<th>Group A (n=19)</th>
<th>Group B (n=20)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Complete success</td>
<td>16 (84.21%)</td>
<td>18 (90.00%)</td>
<td>&gt;0.05</td>
</tr>
<tr>
<td>Qualified success</td>
<td>2 (10.53%)</td>
<td>2 (10%)</td>
<td>&gt;1.0</td>
</tr>
<tr>
<td>Qualified failure</td>
<td>1 (5.3%)</td>
<td>0 (0%)</td>
<td>&gt;0.05</td>
</tr>
<tr>
<td>Complete failure</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td>-</td>
</tr>
</tbody>
</table>

**Table 2. Success rate**

<table>
<thead>
<tr>
<th>Bleb Score</th>
<th>Group A (n=19)</th>
<th>Group B (n=20)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>2</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>3</td>
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<td>5</td>
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<td>15</td>
</tr>
<tr>
<td>6</td>
<td>6</td>
<td>5</td>
</tr>
<tr>
<td>Mean</td>
<td>5.31±0.48</td>
<td>5.25±0.44</td>
</tr>
<tr>
<td>Test of significance</td>
<td>p=0.44</td>
<td></td>
</tr>
</tbody>
</table>

**Table 3. Bleb scoring**

**DISCUSSION**

The prevalence of both diseases, Cataract and glaucoma increases in aging (Geriatric) population\(^{1,2}\) so the application of various management modalities to manage these diseases effectively plays an important role, and further research experiments and clinical trials are being continuously performed all over the world for effective modifications in the present surgical modalities. Researchers have proved Combined surgery is better than trabeculectomy alone because it manages both diseases at the same time and gives desirable results in terms of IOP control and visual outcome.\(^{3}\) Of the various glaucoma surgeries trabeculectomy is the best technique to be used in association with cataract extraction.\(^{7}\) The protective scleral flap over a limbal fistula reduces the chances of an early postoperative flat anterior chamber and also makes the guarded filtering operation particularly desirable for combined procedures. In the present scenario especially in the past two decades, SICS and trabeculectomy (conventional or sutureless) has become more and more popular specially in developing countries like India where availability of required infrastructure as well as trained surgeons who are able to perform phacoemulsification are limited.\(^{8}\) In our study it was found that mean post-operative IOP was lower in group B throughout the follow up except initial 7 days which shows that there was better IOP control postoperatively in group B. Similar results were found in the study done by Khurana A K et al\(^{9}\) in which
glaucoma surgery it can also be used to "cover" a trabeculectomy located underneath which controls leakage and over-filtration.

In our study, postoperatively no significant disc changes and visual field progression were seen which could be explained due to short duration of study. The time required to detect visual field defect progression and the pattern of the progression are influenced by factors including underlying rate and type of progression, degree of variability, frequency of examinations and position of visual field within the time series.15 Progression rate is influenced by numerous additional factors which possibly include both visual field measurement dependent factors, such as variation in threshold, accuracy and precision of measurement dependent factors, such as differential structural vulnerability to damage and current treatment, type and effectiveness mainly in control of IOP.16 IOP control in our study had no correlation with bleb morphology.

Several morphologic classification systems of filtration blebs were developed to improve communication. We used Migdal and Hitchings Classification, (1983)17 for objective scoring of bleb. Although group B had better IOP control but bleb score showed no significant difference in 2 groups. It could be due to the fact that IOP control in group B was not due to better bleb morphology and it could be due to difference in surgical techniques but further investigations in future needed to be done to confirm the fact. According to previous literature bleb morphology serves as an indicator of function and a clinical predictor of success and bleb-related complications such as leak, blebitis, or endophthalmitis. However, there is no single bleb configuration that guarantees long-term intraocular pressure control.17

CONCLUSION
Combined surgery done with W-shaped incision is more effective in controlling IOP in comparison to combined SICS with sutureless trabeculectomy in post-operative follow up and it is because of better filtration by W-shape incision in combined trabeculectomy which in turn is due to restricted lateral flow and anterior flow with controlled posterior flow of aqueous. Not only poor IOP control but the failure rate was also higher in combined SICS with sutureless trabeculectomy in comparison to W-shaped incision trabeculectomy combined with cataract extraction as there is significant difference is seen in number of patient who had not achieved IOP of 21 mmHg or below even with antiglaucoma medication. Combined SICS with W-shaped trabeculectomy also offers advantage in regards to reduction of antiglaucoma drug dependency postoperatively. Thus, our study concludes that in coexisting glaucoma and cataract combined small incision cataract surgery with trabeculectomy using W-shaped incision is a safer and more effective approach for IOP control in comparison to combined small incision cataract surgery with sutureless trabeculectomy.

As our study had short term follow up further studies including large number of patients, more stringent criteria and long term follow up are warranted

REFERENCES