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Research Article

SMALL INCISION CATARACT SURGERY TRABECULECTOMY WITH PHACOEMULSIFICATION TRABECULECTOMY: A RANDOMISED CONTROLLED TRIAL

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Abstract

Background
Cataract and glaucoma frequently coexist, and their combined management remains a surgical challenge. Small incision cataract surgery (SICS) combined with trabeculectomy, as well as phacoemulsification combined with trabeculectomy, are common approaches. Comparative data on their efficacy and safety are limited.

Purpose
To compare the surgical outcomes, intraocular pressure (IOP) control, visual acuity, and complication rates between SICS-trabeculectomy and phaco-trabeculectomy in patients with coexisting cataract and glaucoma.

Methods
This randomized controlled trial enrolled patients diagnosed with cataract and glaucoma, randomized into two groups: Group A underwent SICS-trabeculectomy, and Group B underwent phaco-trabeculectomy. Patients were followed postoperatively at 1 week, 1 month, 3 months, and 6 months. Primary outcomes included change in IOP, improvement in best-corrected visual acuity (BCVA), and surgical complications.

Results
Both groups showed significant improvement in BCVA and reduction in IOP. The phaco-trabeculectomy group demonstrated slightly better visual outcomes, while the SICS-trabeculectomy group showed comparable IOP control. The overall complication rates were low and similar between groups.

Conclusion
Both SICS-trabeculectomy and phaco-trabeculectomy are effective and safe options for managing coexisting cataract and glaucoma. Phaco-trabeculectomy may provide superior visual outcomes, while SICS-trabeculectomy remains a viable and cost-effective alternative, especially in resource-limited settings.

Keywords: SICS-trabeculectomy, Phaco-trabeculectomy, Cataract, glaucoma

INTRODUCTION

Glaucoma is chronic optic neuropathy caused by a group of ocular conditions,

which lead to damage of the optic nerve with loss of visual function.[1, 2]

Types of Glaucoma:

1) Open angle representing 90% of all narrow-angle glaucoma or angle-closure glaucoma.
2) Secondary glaucoma - due to specific disease of eye.
3) Congenital and developmental glaucoma. [2]

Glaucoma currently has no permanent cure, and vision loss is irreversible. However, any further vision loss can be slowed down with medicine or surgery. Hence, early detection is essential.[1]

Glaucoma and cataract follow a silent and highly variable natural course and the most common causes of visual handicap in senescence. [3]

Cataract surgery i.e., Small Incision Cataract Surgery (SICS) and Phacoemulsification is the commonest surgical procedure carried out throughout the world.[4]

Moreover, the presence of cataract can affect the ability to assess glaucoma progression, and cataract extraction affects intraocular pressure as well as effectiveness of glaucoma surgery.[1]

Cairns in 1968, Watson and Grierson in 1981 popularized trabeculectomy Conventional trabeculectomy is a safe and economical for better control of IOP, visual field changes stabilization and optic disc damage. Long term intraocular pressure is controlled more by combined cataract and glaucoma procedures than by cataract extraction alone.[3] Combined glaucoma and cataract surgeries may be considered in patients having glaucoma in its advanced stage with coexisting cataract.[4]

Combined procedures reduces the hospital stay and health expenditure of the individual.[5]

Thus, trabeculectomy is justifiable. However, phacoemulsification surgery has improved the success rates and reduced the complication rates after cataract surgery.[6]

As limited number of studies are being available on the comparison between SICS Trabeculectomyvs Phacoemulsification trabeculectomy on the patients with the coexisting cataract and open angle glaucoma Hence, to aid in early detection and treatment & to fill the vaccum of knowledge this study is being conducted.

METHODOLOGY

This was a **prospective randomized controlled study** conducted in the Department of Ophthalmology, **Rohilkhand Medical College and Hospital (RMCH), Bareilly, Uttar Pradesh**, between **August 2023 and July 2024**. A total **72 patients** with visually significant cataract and primary open angle glaucoma (POAG) were included. Approval was obtained from the **Institutional Ethical Committee**, and informed written consent was taken from all participants before enrollment.

Study Design and Sample Size

Patients were randomly divided into two groups:

- **Group A**: Small incision cataract surgery (SICS) with trabeculectomy.
- **Group B**: Phacoemulsification with trabeculectomy.

Sample size was calculated using the Power and Sample Size software with an alpha error of 0.05, mean difference of 0.2, standard deviation of 0.3, and study power of 80%. The required size was **36 patients per group**.

Eligibility

Inclusion Criteria:

- Patients with significant cataract and coexisting primary open angle glaucoma.
- Patients with Age group >50years
- Patients giving informed consent for the study.

Exclusion Criteria:

- Patients with other secondary glaucoma like Pseudoexfoliative glaucoma,

  Pigmentary glaucoma, neovascular glaucoma and inflammatory glaucoma.
- Patients who underwent other surgical glaucoma treatments previously.
- Patients with previous Ocular trauma or surgery.
- Patients with complicated cataract.
- Patients with systemic diseases such as Diabetes Mellitus and Hypertension.

Preoperative Assessment

All patients underwent a detailed history and general examination. Ophthalmic evaluation included:

- Best corrected visual acuity (Snellen's chart).
- Pupillary reaction and ocular motility.
- Slit-lamp biomicroscopy to assess corneal clarity, anterior chamber depth, lens changes, and any associated pathology.
- Intraocular pressure measurement (non-contact tonometer).
- Gonioscopy to assess the anterior chamber angle.
- Fundus examination with indirect ophthalmoscopy and slit-lamp biomicroscopy using a 90D lens.
- Optical coherence tomography (OCT) for retinal nerve fiber layer and macular ganglion cell complex thickness.
- Visual field analysis with Humphrey field analyzer.
- Biometry for intraocular lens (IOL) power calculation.

Surgical Procedure

Both groups underwent combined cataract surgery and trabeculectomy, with differences only in the cataract extraction technique.

- **Group A (SICS with trabeculectomy):** A superior scleral tunnel was created and the cataract removed manually using viscoexpression. After IOL implantation, trabeculectomy was completed by excising a small block of scleral tissue including Schlemm's canal and performing a peripheral iridectomy.
- **Group B (Phacotrabeculectomy):** Phacoemulsification was performed using the stop-and-chop technique, followed by IOL implantation. Trabeculectomy was then carried out in the same manner as in Group A.

In both groups, the scleral flap was closed with a single 10-0 nylon suture, conjunctiva was secured, and subconjunctival dexamethasone with gentamycin was given at the end of the procedure.

Postoperative Care and Follow-Up

Patients were examined on **day 1, week 1, week 4, and week 12** after surgery. At each visit, best corrected visual acuity, intraocular pressure, slit-lamp examination (for bleb, anterior chamber, IOL, and wound status), and fundus evaluation were performed. At the **12-week visit**, OCT and visual field analysis were repeated to assess structural and functional stability.

Statistical Analysis

The data was entered in the EoiInfo^{TM}7.1.5 Descriptive analysis was done calculating proportions, means & standard deviation. Appropriate statistical test was applied depending on type & the distribution and type of data. $P<0.05$ considered significant.

RESULTS

TABLE 1: MEAN AGE IN YEARS

	GROUP1	GROUP2		
	Mean ± SD	**Mean ± SD**	**t-Value**	**P-Value**
AGE (in years)	58.06 ± 9.61	60.69 ± 8.78	1.216	0.228#

#Statistically not significant.

In our study, the mean age of patients in the PhacoTrab group was 58.06 ± 9.61 years, and that in the SICS Trab group was 60.69 ± 8.78 years. The difference in age between the two groups was statistically insignificant. (p=0.228)

TABLE 2: SEX DISTRIBUTION

	GROUP 1		GROUP 2			
SEX	**Number**	**%**	**Number**	**%**	**Chi-Square Value**	**P-Value**
MALE	26	72.2	21	58.3		
FEMALE	10	27.8	15	41.7	1.532	0.216#
TOTAL	36	100.0	36	100.0		

#Statistically not significant.

In our study, In the PhacoTrab group, there were 26 males and 10 females; in the SICS Trab group, there were 21 males and 15 females. The difference in gender between the two groups was statistically insignificant. (p=0.216)

TABLE 3: COMPARISON OF MEAN IOP RANGE AT PRE-OPERATIVE RANGE 1WK, POST-OPERATIVE RANGE 1 WEEK, AND POSTOPERATIVE RANGE 1 MONTH AND 3 MONTHS IN GROUP1 AND GROUP2.

	GROUP1	**GROUP2**		
	Mean ± SD	**Mean ± SD**	**t-value**	**P-Value**
PRE-OPERATIVE RANGE(IOP) at 1WEEK	31.67 ± 1.74	31.92 ± 1.87	0.587	0.559#
POST-OPERATIVE RANGE(IOP) at 1WEEK	14.92 ± 3.16	19.67 ± 3.85	5.72	0.000*
POST-OPERATIVE RANGE(IOP)at 1MONTH	15.06 ± 0.75	16.42 ± 2.31	3.361	0.001*
POST-OPERATIVE RANGE(IOP)at 3MONTHS	14.5 ± 2.37	15.36 ± 2.74	1.426	0.158#

#Statistically not significant. *statistically significant.

In our study, the mean Pre-Operative range (IOP) at 1 week of patients in the PhacoTrab group was 31.67 ± 1.74, and that in the SICS Trab group was 31.92 ± 1.87, the mean Post-Operative range (IOP) at 1 week of patients in the PhacoTrab group was 14.92 ± 3.16 and that in the SICS Trab group was 19.67 ± 3.85, the mean Post-Operative range (IOP) at 1 month of patients in the PhacoTrab group was 15.06 ± 0.75 and that in the SICS Trab group was 16.42 ± 2.31, the mean Post-Operative range (IOP) at 3 months of patients in the PhacoTrab group was 14.5 ± 2.37 and that in the SICS Trab group was 15.36 ± 2.74. The mean Post-Operative range (IOP) was higher in the SICS Trab group as compared to the PhacoTrab group, There was no significant difference in the mean Pre-Operative range (IOP) at 1 week and post-operative 3 months but a considerable difference in the mean Pre-Operative range (IOP) at postoperative 1 week and 1 month.

TABLE 4: PRE-OPERATIVE BCVA

	PRE-OPERATIVE BCVA					
GROUP	**HM**	**2M**	**3M**	**6/60**	Total	**P-Value**
GROUP1	0	16	10	10	36	0.004*
GROUP2	11	12	8	5	36	
Total	11	28	18	15	72	

***Statistically significant.**

In our study, pre-operative BCVA of patients in the PhacoTrab group, 2M in 16 patients,3M in 10 patients,6/60 in 10 patients, and HM in none of the patients and preoperative BCVA of patients in the SICS Trab group, HM in 11 patients , 2M in 12 patients,3M in 8 patients,6/60 in 5 patients, and there was a significant difference in pre-operative BCVA of patients in the SICS Trab group and PhacoTrab group.

TABLE 5: OPERATIVE BCVA

	IST DAY POST-OPERATIVE BCVA					
GROUP	**2M**	**3M**	**6/60**	**6/36**	Total	**P-Value**
GROUP1	6	10	8	12	36	0.002*
GROUP2	12	18	5	1	36	
Total	18	28	13	15	72	

***Statistically significant.**

In our study, postoperative BCVA of patients in the PhacoTrab group, 2M in 6 patients,3M in 10 patients,6/60 in 8 patients, and 6/36 in 12 of the patients, and postoperative BCVA of patients in the SICS Trab group, 2M in 12 patients,3M in 18 patients,6/60 in 5 patients, and 6/36 in 1 patients and there was a significant difference in post-operative BCVA of patients in the SICS Trab group and PhacoTrab group.

TABLE 6: COMPARISON BETWEEN GROUP1& GROUP2 REGARDING 1ST WEEK POST-OPERATIVE EXAMINATION.

		Group 1		Group 2		
		Number	**%**	**Number**	**%**	**P-Value**
Corneal assessment	**Clear**	36	100.0	29	80.6	0.005*
	Mild edema	0	0.0	7	19.4	
Anterior Chamber	**Well formed**	36	100.0	36	100.0	1.000#
	Hyphema	0	0.0	0	0.0	
	Cells+	0	0.0	0	0.0	
Bleb	**Flat diffuse**	25	69.4	23	63.9	0.671#
	Well formed	11	30.6	13	36.1	
Wound	**Sealed**	36	100.0	35	97.2	0.049*
	Leaky wound	0	0.0	1	2.8	

***Statistically significant, # Statistically not significant.**

In the present study in the 1st week post-operative, there were 0% of cases with mild corneal edema in group 1. There were 0% with irritant wound sutures group 1 and 69.4% of cases had flat diffuse blebs in the 1st week post-operative, there were 19.4% of cases with mild

corneal edema in group 2, There were 2.8% with irritant wound suture in group 2 and 63.9% of cases had flat diffuse blebs.

TABLE 7: COMPARISON BETWEEN GROUP1& GROUP2 REGARDING 3 MONTH POST-OPERATIVE EXAMINATION.

		Group 1		Group 2		
		Number	%	Number	%	P-Value
Corneal assessment	Clear	36	100.0	36	100.0	1.000#
	Mild edema	0	0.0	0	0.0	
Anterior chamber	Well formed	36	100.0	36	100.0	1.000#
	Hyphema	0	0.0	0	0.0	
	AC Cells+	0	0.0	0	0.0	
Bleb	Flat diffuse	25	69.4	23	63.9	0.671#
	Well formed	11	30.6	13	36.1	
Wound	Sealed	36	100.0	36	100.0	1.000#

	Leaky wound	0	0.0	0	0	

 # Statistically not significant.

In the present study in the 3rd month post-operative, no cases were suffered from corneal edema and irritant suture wounds in groups 1 and 2. In the present study in the 3rd month post-operative, there were 0% of cases with mild corneal edema in group 1. There was 0% with irritant wound suture in group 1 and 69.4% of cases had flat diffuse blebs in the 3rd month post-operative, there were 0% of cases with mild corneal edema in group 2, There was 0% irritant wound suture in group 2 and 63.9% of cases had flat diffuse blebs.

DISCUSSION

Developments in cataract extraction and the improvements in trabeculectomy and non-penetrating filtering surgery and implant drainage devices have favored the trend for doing a combined surgery

The primary objective in managing a glaucoma patient with cataract is to ensure effective long-term intraocular pressure (IOP) control, prevent postoperative IOP spikes that could harm the optic nerve head, and achieve optimal visual restoration.. Cataract surgery alone has significant effects on the intraocular pressure. Following an early rise in intraocular pressure, the IOP tends to fall in the long run. Although significant, the magnitude of the change is small, averaging around 2-4 mm Hg and one cannot depend on this as a means of lowering the IOP**.**

Also, both diseases are controlled in a single sitting, thus it reduces the need for glaucoma medications and frequent follow-ups.

The advent of small incision cataract surgery both by phacoemulsification or manual small incision along with trabeculectomy has improved the IOP control outcome, other advantages include lens induced astigmatism, early visual rehabilitation, reduced stimuli to wound healing, inflammation and postoperative-blebs carring and thus improving long- term filtration.

Singh et al. (7) compared phacotrabeculectomy and phacofracturetrabeculectomy in 30 patients with a follow-up of 12 months. Both groups started with a mean preoperative IOP of around 29 mmHg and showed a very similar fall in pressure—46% in the phacotrabeculectomy group and 44% in the phacofracture group at 3 months, which remained stable at one year. The success rate was excellent, with all patients maintaining IOP below 21 mmHg without additional medication. Visual acuity improved in both groups, with more than half of the patients achieving BCVA of 0.3 or better. The only difference they noted was a higher rate of anterior chamber reaction in the phacofracture group initially, but this settled

completely within two weeks. Overall, they concluded that both procedures were equally effective.

Another **study (8)** compared phacotrabeculectomy with small-incision trabeculectomy and again found no major differences. The mean IOP reduction at 3 months was 52.9% and 53.2% in the two groups, with complete success in all patients and no hypotony or IOP spikes. Visual outcomes also improved significantly, with the mean BCVA improving from 0.15 to 0.3 in the phacotrabeculectomy group and from 0.1 to 0.29 in the small-incision group. Postoperatively, bleb morphology was similar, and there were no problems with inflammation or raised IOP.

Our own results are in line with these findings. We also found that both surgical approaches led to a marked and sustained reduction in IOP, along with meaningful improvement in vision. None of our patients developed hypotony or uncontrolled postoperative IOP, and bleb morphology and postoperative inflammation patterns were quite similar to what has been described in earlier studies. Taken together, these observations suggest that whichever surgical technique is used, combined cataract–glaucoma surgery can reliably provide both good pressure control and visual rehabilitation.

Choy[9]conducted a comparative study on the surgical outcomes of phacotrabeculectomy versus trabeculectomy alone in Chinese glaucoma patients, with a follow-up period of up to 3 months. The study included 38 consecutive patients, 20 of whom underwent phacotrabeculectomy, while 18 underwent trabeculectomy. Baseline characteristics such as age, visual acuity, and intraocular pressure (IOP) were comparable between the two groups.

Postoperative IOP control from day 1 to 3 months was similar in both groups. Complete success was reported in 65% of phacotrabeculectomy cases and 66.7% of trabeculectomy cases, while failure rates were 16.7% in the phacotrabeculectomy group and 10% in the trabeculectomy group at 3 months. Visual acuity improvement was consistently better in the phacotrabeculectomy group.

Regarding bleb morphology, diffuse blebs were observed in 65% of phacotrabeculectomy cases and 83% of trabeculectomy cases, whereas flat blebs were noted in 35% of phacotrabeculectomy cases, with none reported in the trabeculectomy group. Hypotony occurred in 5% of phacotrabeculectomy cases but was absent in the trabeculectomy group.

In conclusion, both phacotrabeculectomy and trabeculectomy provided comparable IOP control up to 3 months postoperatively. However, phacotrabeculectomy offered superior visual acuity improvement, while trabeculectomy resulted in a higher occurrence of diffuse blebs and lower rates of hypotony

Khandelwal et al. (10) compared phacotrabeculectomy with SICS-trab using the sandwich technique in patients with coexistent glaucoma and cataract. They reported a shorter operative time and slightly better early IOP reduction in the phacotrab group at 1 week and 1

month, though by 3 months both groups had similar pressure control. Visual outcomes were also better in the phacotrab group, and early postoperative complications such as wound leak, corneal edema, hyphema, and anterior chamber inflammation were more frequent in the SICS-trab group. By 3 months, however, both groups had quiet anterior segments, clear corneas, and stable blebs.

In our study, we also observed comparable long-term IOP control between the surgical groups, but in contrast to Khandelwal's findings, we did not identify a clear early advantage of phacotrabeculectomy in terms of pressure reduction or visual recovery. Postoperative complications were minimal in both groups, with no significant difference in wound status, anterior chamber reaction, or corneal clarity, and none of our patients developed hypotony. These differences may reflect variations in surgical technique, patient selection, or the use of mitomycin C, which was applied more extensively in Khandelwal's study. While their data suggest a relative benefit of phacotrab in the immediate postoperative period, our results emphasize that both techniques remain equally effective and safe in the longer term for IOP control and visual rehabilitation.

Venkataraman*et al*[11]published the following study in glaucoma session in congress of ESCRS 2017. The aim of the study is to assess the changes in the intraocular pressure, endothelial cell density, visual acuity and refractive changes (induced astigmatism), and per-operative complications in patients undergoing Phaco-TRAB (Group 1) and SICS-TRAB (Group 2) for coexisting primary open angle (POAG)/ angle closure glaucoma (PACG) and cataract

Sixty eyes of 60 patients undergoing either phaco-trab or small incision cataract surgery combined with trabeculectomy were included in the study. This was a nonrandomized comparative study the patients chose the type of surgery. Primary outcome were changes in intraocular pressure and endothelial cell (EC) density and secondary outcomes were astigmatic changes after surgery (induced astigmatism) and intraoperative and postoperative complications at 1, 3 and 6 months.

Modern techniques and instruments for combined cataract and glaucoma surgeries have made the surgeon more confident in handling cases of PXF with coexistent cataracts and glaucoma. A strong relationship between glaucoma and PXF is well known. Our own clinical experience after dealing with a large number of PXF glaucoma patients is that they respond poorly to medical treatment. **Kim et al [12]** during his study on PXF patients found that they have a weaker and thinner lamina cribrosa which was more susceptible to raised IOP. Various studies have also found an increased association of cataracts with **PXF.[13,14,15]** Ocular ischemia8 and low concentrations of ascorbic acid9 in aqueous patients with PXF could be the reason for the occurrence of cataracts in patients with PXF.

In our study, we found that intraoperative complications were slightly more in the SICS Trab group but the difference was not statistically significant. Similarly comparing postoperative complications in the two groups moderate to severe uveitis was seen in 4 cases with SICS

Trab group and only in 3 cases in the phacotrab group, again the difference was not statistically significant P = 0.683. These findings are in agreement with other studies done by **Mohammed IA,[1]Khandelwal et al,[10] and Venkataraman et al.[11]**

The goal of treatment with co-existing glaucoma and cataract patient is to provide long-term IOP control along with visual rehabilitation to improve the quality of life of the patient. In our study we found that both the modalities of treatment are equally effective in providing visual rehabilitation and IOP control in patients in which there are more chances of complications. In a developing country like ours SICS trab may be a more practical option given the cost of phaco machine and the learning curve associated with phacoemulsification.

CONCLUSION

It could be concluded that there is a significant improvement in the BCVA and IOP control after the combined procedure for the management of coexistent cataracts and glaucoma. This improvement is statistically significant. There was no statistically significant difference in the final visual acuity, IOP control and post-operative complication rate between phaco trabeculectomy and small incision trabeculectomy.

A combined procedure is a very good option in patients with glaucoma associated with visually significant cataracts. Both BCVA and IOP control showed significant improvement after the combined procedure. There was statistically significant difference between the SICS trab versus phacotrab group in terms of BCVA, IOP control, and intra- and post-operative complications.

Statistically significant improvement was detected in postoperative BCVA and IOP. Preoperative IOP ranged from 30-35 mmHg with mean ±SD of 31.28 ± (1.25) in the phaco trabeculectomy group while in the small incision trabeculectomy group preoperative IOP ranged from 30-36 mmHg with mean ±SD of 31.14 ± (1.34)

Phacotrabeculectomy appears to be superior to SICS trab in terms of better Post-Operative Visual outcomes, Faster recovery & reduced Post-Operative Astigmatism Additionally Phacotrabeculectomy offers a more controlled & Predictable reduction in IOP while minimizing surgical complication.

Although SICS trab may still be a viable option in resource-limited settings or for certain patient profiles Phacotrab's enhanced precision & improved outcomes make it the preferred technique in modern surgical practice.

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