International Journal of Science and Healthcare Research
Vol.5; Issue: 1; Jan.-March 2020
Website: ijshr.com
Original Research Article *ISSN: 2455-7587*

Comparison of Intraoperative and Postoperative Complications of Phacoemulsification and Small Incision Cataract Surgery in Central India

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ABSTRACT

Purpose: To compare the incidence of intraoperative and early postoperative complications, and visual outcomes of small incision cataract surgery (SICS) and phacoemulsification in immature cataracts at a secondary eye care hospital.
Methods: A hospital-based prospective study from January 2016 till October 2016 in 500 patients undergoing SICS and phacoemulsification groups (250 patients each). Intraoperative and early postoperative complications were noted and best corrected visual acuity was assessed at regular intervals postoperatively. Statistical analysis was performed using JMP Pro version 12.0.1, © SAS Institute Inc and Microsoft Excel 2013.
Results: The incidence of iris prolapse was found to be higher in the SICS group (0.8%) than the phaco group (3.6%) (P=0.03). There was no significant difference in the occurrence of PCR with vitreous loss (P=0.67) and PCR without vitreous loss (P=0.99) between the two groups. In early postoperative period corneal edema was found in 18 patients of phaco group and 7 patients of SICS (P=0.04) which cleared off later.
Conclusion: Phacoemulsification and SICS are safe and equally efficacious procedures with low complication rates and excellent visual outcomes.

Keywords- Cataract, Phacoemulsification, visual acuity, SICS, aphakia

INTRODUCTION

An estimated 670 million people [1,2] worldwide are visually impaired, 39 million of which are blind and 269 million have low vision. [3] Cataract, one of the most common eye diseases [4] and a leading cause of blindness worldwide [5] accounts for 50% of the global burden of blindness, representing more than 20 million people worldwide. [6] Subsequently cataract presents a significant public health challenge and is responsible for a visual acuity of 6/60 or worse in more than 100 million eyes. [7]

In most developing countries, blindness carries considerable economic and social implications, especially for those who reside in under-served areas. [8] An estimated 90% of people who are affected with cataracts reside in developing countries which have limited capacity, infrastructure and technology to care for the visually impaired. [7] Thus, these countries exhibit the largest backlog of cataract surgeries, most of which are intumescent, mature and hyper-mature lenses (white cataracts). [9]

Near normal vision can be restored through the surgical removal of the opacified lens facilitated by the implantation of an intraocular lens (IOL) or occasionally using spectacles. [10-12] To overcome the burden of cataract blindness, there must be sufficient surgical coverage and good surgical outcomes [7] viz. safety, early visual rehabilitation and postoperative emmetropia. [12]

Phacoemulsification (Phaco) has emerged, in recent years, as the most popular procedure to treat cataracts in patients in the developing world [9,13] as it is

safe [12]and gives better visual outcomes [7] such as early visual rehabilitation and emmetropia. However, several studies have shown that despite Phaco surgery being popular in developing countries, [9,12]it is not suitable for developing countries that have a significant backlog of patients requiring surgery, as the technique is associated with high costs, including the cost of the Phaco machine, maintenance and upgrades of the machine and facilities, staff wages and the cost of consumables.

Therefore the Phaco technique is often unaffordable to disadvantageous individuals and communities. [14-17] Driven by the need for more cost effective options, an increasing trend in developing countries is the use of manual sutureless Small Incision Cataract Surgery (SICS), which some have claimed is comparable to Phaco in terms of obtaining excellent visual outcomes, is faster, less costly and has fewer complications. [7]

Postoperative better quality of vision and early visual rehabilitation are the important parameters which determine the success of modern cataract surgery. These two parameters are in turn dependent upon complications associated with the surgical procedure.

Studies have individually evaluated outcomes of Phacoemulsification and MSICS separately. However, only few studies compare both the modalities in terms of intraoperative and postoperative complications. Most of the studies are either cross-sectional or retrospective, where there were no standard protocols for evaluation of patient pre and post operatively.

In our study, we aim to compare the surgical outcomes of both the techniques postoperatively.

METHODS

A hospital-based prospective, randomized, comparative study was carried out from January 2016 to October 2016 in 500 patients undergoing SICS and phacoemulsification groups (250 patients each). Ethical clearance for the study protocol was obtained from the institutional ethics committee and informed consent was obtained from patients who were willing to participate.

Primary outcomes were intraoperative and early postoperative complications, while best corrected visual acuity was assessed at day 1 and week 6 postoperatively.

Patients with senile immature cataract, willing for cataract surgery and fit for local anesthesia were included in the study. Exclusion criteria were patients with any other type of cataract except senile cataract, patients with ocular trauma or any other intraocular surgery in the same eye, patients with any anterior segment problems other than senile cataract like glaucoma, uveitis, corneal opacity or vascularization, any posterior segment pathology (retinopathy/maculopathy) and hard cataracts of more than grade III on Lens Opacity classification system III (LOCS III). [18]

Demographic data of patients was collected including name, age, sex, occupation and personal details. Detailed history of patients complaining of diminution of vision was taken including duration and relevant past history Proper ocular examination including visual acuity (aided and unaided), slit lamp examination of anterior segment, pupillary reaction, size of the pupil and its dilating capacity was evaluated and fundus examination was carried out after pupillary dilatation to rule out other causes of diminution of vision. Subjective examination in the form of grading of Nucleus was done using Lens Opacity Classification System III (LOCS III). [18]

The unit of randomization was an individual patient. Research coordinator used randomization allocation software to generate 500 numbers randomly into two groups, SICS and Phaco. As per the allocation done, each of the 500 opaque, numbered envelopes was filled with a paper containing the surgery to be done for that case. The envelopes were sealed and kept in

the custody of research coordinator. Each envelope was opened serially at the beginning of surgery, after the patient was placed on the operating table. The participating surgeons were not involved in the care of or the opening of the envelopes and were informed of the treatment assignment in the operating room immediately before surgery.

All surgeries were performed by senior surgeons who had 5 or more years of experience in both SICS and Phacoemulsification.

Peribulbar anaesthesia with 2% Lignocaine along with Hyaluronidase was used as local anaesthetic. After taking all aseptic precautions, painting and draping was done. Eye speculum was applied. Betadine (5%) wash was given twice for 3 minutes. All surgeries were performed under Zeiss operating microscope. Phacoemulsification surgeries were performed with Appasamy Associates Galaxy pro Phaco machine.

All cases were followed up for 6 weeks after surgery, with regular intervals and Best Corrected Visual acuity (BCVA) recorded 6 weeks after surgery.

Statistical analysis was performed using JMP Pro version 12.0.1, © SAS Institute Inc and Microsoft Excel 2013. Descriptive statistics are presented as means, percentages and standard deviations. Visual acuity was converted from Snellen's to Logarithm of the Minimum Angle of Resolution (LogMAR) for statistical evaluation. To assess significant statistical differences in outcomes between two surgery groups, Fisher's exact test was used for categorical variables and non-parametric Wilcoxon Rank sums test was used for continuous variables, as it precludes any assumption about normal distribution of data. Univariate odds ratios were calculated using nominal logistic regression. P values were considered statistically significant at <0.05 level.

RESULTS

Majority of patients were in the range of 61 to 70 years (298 i.e. 59.6 %); with a mean age of 66.6 years and median 66 years. 24 % patients were between 51 to 60 years of age. In phacoemulsification group there were total of 134 males and 116 females while in SICS group there were 141 males and 109 females.

Maximum patients 357 were in category B i.e. visual acuity between 6/24 to 6/60. Of these, 181 were in the phaco group and 176 were in the SICS group. As only immature cataracts were selected for this study the number of patients in category C i.e. vision below 6/60 were low (31 in the phaco group and 43 in the SICS group). There were total of 69 patients in category A i.e. vision better than 6/18.

All patients taken in this study were senile immature cataracts out of which maximum were in the category of Nuclear sclerosis III with posterior subcapsular cataract i.e. 110 (44%), followed by Nuclear sclerosis grade II with posterior subcapsular cataract i.e. 92 (36.8%), Nuclear sclerosis grade II i.e. 68 (27.2%), and Nuclear Sclerosis grade III i.e. 66 (26.4%) respectively.

At 6 weeks post-operative follow up, 98.6% achieved a best corrected vision of 6/18 or better. 99.6% patients from the Phaco group achieved BCVA 6/18 or better as compared to 97.6% in SICS group.7 out of 500 patients had visual acuity of 6/24 to 6/60 out of which 1 was in the phaco group and 6 were in the SICS group. No patient had vision less than 6/60 in our study.By Fisher's exact test, the difference in BCVA at 6 weeks between the phaco and SICS groups was not statistically significant ($p = 0.12$).

Mean Best corrected visual acuity in the Phaco group was 0.12 ± 0.12 while in the SICS group it was 0.15 ± 0.15 at 6 weeks. At day 1 post operatively 145 (58.00%) patients in the phaco group had visual acuity better than 6/18 while only 122 (48.80%) patients in SICS group had visual acuity of 6/18 or better. The difference was

statistically significant by the Wilcoxon Rank sums test with p-value- 0.001. (Table 1).

Table 1: Comparison of visual acuity at different postoperative days and Visual Rehabilitation

	Phacoemulsification	SICS	*P-value
Visual Acuity at postop day 1	0.52 ± 0.21	0.59 ± 0.24	0.001
Visual Acuity at postop day 28	0.30 ± 0.19	0.35 ± 0.14	<.0001
Visual Acuity at postop week 6	0.12 ± 0.12	0.15 ± 0.15	0.05

*Wilcoxon Rank sums test

Of 500 patients, 371 were free of both intra- and post-operative complications. On 6thweek followup, all 371 patients had BCVA of 6/18 or better.

Table 2: Intraoperative complications in both groups

Complication	Phaco-emulsification		SICS		
	N	%	N	%	P value*
Premature Entry	0	0	4	1.6	0.12
Posterior capsule rupture with vitreous loss	13	5.2	10	4	0.67
Posterior capsule rupture without vitreous loss	5	2	5	2	0.99
Zonular Dialysis	5	2	3	1.2	0.72
Irido-Dialysis	0	0	4	1.6	0.12
Descemet's Membrane Detachment	4	1.6	6	2.4	0.75
Iris Prolapse	2	0.8	9	3.6	0.03
Capsulorrhexis Extension	3	1.2	6	2.4	0.50
Broken Haptic	1	0.4	2	0.8	0.99
Failure to implant lens	3	1.2	7	2.8	0.34

*Fisher's exact test

PCR to be maximum in the phacoemulsification group i.e. 18 out of 250 patients (7.2%) and 15 out of 250 patients (6.0%) in the SICS group, however difference between 2 groups was not statistically significant (P-Value - >0.05) (Table 2).

Table 3: Postoperative complications in both groups

Complication	Phaco-emulsification		SICS		
	N	%	N	%	P value*
Wound Leak	6	2.4	8	3.2	0.79
Corneal edema	18	7.2	7	2.8	0.04
Epithelial defect	5	2	3	1.2	0.72
Hyphema	3	1.2	6	2.4	0.50
Retained cortical matter	1	0.4	2	0.8	0.99
Decentered IOL	2	0.8	2	0.8	0.99
Secondary Glaucoma	8	3.3	4	1.6	0.38

*Fisher's exact test

Total post-operative complications in the phaco group were 43 (17.2%) and 32 (12.8%) in the SICS group. Out of which maximum i.e. 25 cases were of corneal edema. (Table 3)

Difference in incidence of aphakia in both the groups was not statistically significant (p-value 0.34). (Table 4).

Table 4: IOL and failure to place IOL (surgical aphakia) in both groups

	Phaco	SICS
PCIOL	247	243
Failure to place IOL	3	7

P = 0.34*

*Fisher's exact test

There were total of 79 (31.6%) complications that occurred in Phaco and 88 (35.2%) in SICS group (P=0.44) (Table 5).

Table 5: Total Intraoperative + Post-Operative complications

	Phaco	SICS
Total intraoperative complications	36 (14.4%)	56 (22.4%)
Total postoperative complications	43(17.2 %)	32 (12.8%)
Total Intraoperative + Post - Operative complications	79 (31.6%)	88(35.2%)

Denominator is total surgeries in that group = 250.

P–value for total intra-operative & post-operative complications = 0.44*

*Fishers exact test

DISCUSSION

Our findings were comparable with the study carried out by Gogate PM et al [19] who found out that at 6 weeks post operatively, 81.1% patients in the phacoemulsification group and 71.1%

patients in the SICS group had UCVA of better than or equal to 6/18. There was no statistically significant difference in both the groups and the BCVA was comparable in the two groups. Ruit et al [16] found visual outcomes of manual SICS and phacoemulsification to be comparable (98% of both groups had UCVA and BCVA of 20/60). Venkatesh et al., [9] showed that Phaco and SICS surgery both achieved excellent visual outcomes with low complication rates. Singh S.K.et al [20] reported that on first postoperative day, more than two thirds of the patients from the Phaco group and more than three quarters of the patients from the SICS groups had good visual outcome. Poor visual outcome was noted for 6% of Phaco patients and 1% of SICS patients. Mean visual acuity was 0.43 ± 0.27 in phacoemulsification group and 0.47 ± 0.24 in SICS group. R. Husain et al [21] concluded that there was very little difference between Manual SICS and Phacoemulsification surgeries visual outcome at 4-11 weeks visit (89.50% vs 88.20%).In our study all the results with respect to best corrected visual acuity were comparable to other studies mentioned above. Hence as per the observation in our study, the visual outcome of both phacoemulsification and SICS is comparable at 6 weeks proving both to be equally efficacious.

There were total of 79 (31.6%) complications that occurred in Phaco and 88 (35.2%) in SICS group which was not statistically significant as was the case seen with Gogate et al., [19] Haripriya A. et al, [22] Venkatesh R. et al [9] and Singh et al. [20] who concluded that incidence of complications in Phaco and SICS are comparable.

Of the 500 cases in our study, 5 cases of the phaco group (2%) and 3 cases of the SICS group (1.2%) had zonular dialysis which was managed in time and there were no sequelae seen to this complication. Similar study by Gogate et al [19] observed 1 case of zonular dialysis in both phaco and SICS group each which was not statistically significant, same finding repeated in the study by Haripriya A. et al. [22]

Iridodialysis occurred in 4 cases of SICS (1.6%) and none was seen in the phaco group. All cases were related to difficulty while delivering the nucleus. The higher incidence was probably because of the larger size of the incision in SICS, but the difference was not statistically significant. Gogate et al [19] and Singh et al [20] carried out a comparative study and found out that incidence of Iridodialysis is comparable in both the groups. Haripriya A.et al [22] suggests that Iridodialysis though rare, occurred statistically more often with manual SICS than in phaco groups.

Capsulorhexis extension was seen in 3 cases of the phaco group (1.2%) and 6 cases of the SICS group (2.4%), however the difference was not statistically significant. The study conducted by Gogate et al [19] reported only 2 cases of capsulorrhexis extension in the phaco group while none was seen in SICS, however overall the difference was not statistically significant as in our study.

Descemet's Membrane Detachment was seen in 4 cases of phaco (1.6%) and 6 cases of SICS (2.4%), though the difference was not statistically significant. Haripriya et al [22] found that the difference between the two groups was also not statistically significant though more cases were reported in the SICS group.

In our study the incidence of PCR was 33/500 patients (6.6 %) out of which 23 required vitrectomy. This incidence was comparable with incidence of PCR and vitreous loss in academic hospitals that has been mentioned in literature. Kothari M et al [23] reported an incidence of vitreous loss 7.63 % in their institute; the incidence was significantly lower in patients undergoing phacoemulsification as compared to SICS group. Balent LC et al [24] found little difference in complication rates among sutureless SICS, phacoemulsification and standard ECCE techniques performed in a public eye camp in India. As per a study by

Venkatesh et al, [9] posterior capsule rupture occurred in 2 eyes (1.4%) in the manual SICS group and in 3 eyes (2.2%) of the Phaco group.

Cook et al [25] reported incidence of PCR to be 0.1% in the SICS group and 0.04% in the phaco group. While there was a higher incidence of posterior capsule tear, both with and without vitreous loss, in the eyes having manual small-incision surgeries, this difference was not statistically significant (P=0.34).

Ghosh et al [26] reported the incidence of vitreous loss to be 1/112 (0.89%) in the SICS and 4/112(3.5%) in the phaco group (not statistically significant). Gogate et al [19] reported in their study the incidence of PCR to be 12/201(5.9%) in the SICS group and 7/199(3.5 %) patients in the phaco group. Venkatesh et al [9] reported incidence of PCR to be 2/137(1.4%) in SICS group and 3/133(2.2%) in phaco group. Singh et al [20] found out that in the phaco group, two patients out of 93 patients had posterior capsule rupture (PCR) with vitreous loss. No PCR was seen in 89 patients operated with SICS. Haripriya A. et al [22] concluded that posterior capsule rupture accounted for two-thirds (519 of 771 eyes, 67%) of all complications. Vitreous loss occurred in 374 of 519 (72%) of these eyes. The overall PCR or vitreous loss rate was 0.87% for phacoemulsification and 0.64% for manual SICS.

The overall rate of aphakia at 1.8 % in our study is higher than that of reported by Venkatesh R et al [9] and Singh et al. [20]

Corneal edema in early post-operative difference between SICS and phaco group was statistically significant (p-value 0.04) on the day 1 post op, it did not remain till 6 weeks and had no impact on final visual outcome at 6 weeks. The findings were comparable with other studies like Ruit et al [16] who reported on postoperative day 1, the groups had comparable uncorrected visual acuity (UCVA) (P = 0.19) and the SICS group had less corneal edema (P = 0.004).Venkatesh R et al [9] reported that on the first postoperative day, there were fewer cases of significant corneal edema in the manual SICS group (10.2%) than in the phacoemulsification group (18.7%) (P value=0 .047). Singh et al [20] reported the incidence of corneal edema in 4.3%(4 out of 93) of phacoemulsification cases but none in SICS. Gogate et al [19] reported the incidence of corneal edema to be higher in Phaco group (9.7%) than in SICS group (4.8%).

Post-operative hyphema was seen in 3 cases of phaco (1.2%) and 6 of the SICS group (2.4%).This is little higher than quoted by Venkatesh R. et al. [9] The results of our study were comparable with studies by Gogate et al (19) and Sharaf et al. [15] The increased occurrence of hyphema in SICS points out that scleral tunnel incision is subject to unpredictable hemorrhage, and that the incision must be closed carefully with sutures if indicated. Clear corneal surgery reduces the risk of bleeding from limbal vessels since the cornea in its healthy state is avascular.

Decentered IOL occurred in 2 cases each of SICS and Phaco group with an overall incidence of 0.8%. Decentration of a posterior chamber IOL can occur after complicated cataract surgery; and according to Gimbel HV et al [27] the incidence ranges from 0.2-0.8% which was comparable to our study. In our study out of 4 decentered IOL cases 2 were associated with PCR.

CONCLUSION

Phacoemulsification and SICS are safe and equally efficacious procedures with low complication rates and excellent visual outcomes. MSICS can thus be an alternative to phacoemulsification wherever the requisite equipment and expertise are not available.

Conflict of Interest- No

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How to cite this article: Wairagade N, Deshmukh M, Pande C et.al. Comparison of intraoperative and postoperative complications of phacoemulsification and small incision cataract surgery in central India. International Journal of Science & Healthcare Research. 2020; 5(1): 120-127.

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