A clinical study on phacoemulsification versus manual small incision cataract surgery in rural hospital setting

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Abstract

Introduction and Objectives: A prospective randomized control study was conducted to compare the manual small incision cataract surgery with phacoemulsification in hospital with objectives to study main out come measures uncorrected visual acuity on post operative day 1, best corrected visual acuity post operative day 6 weeks and study secondary outcome in terms of complication rates, effect of ocular and systemic co –morbidity on visual acuity out comes and operative time taken.

Materials and Methods: 100 patients with age related cataract were randomly assigned Phacoemulsification and SICS groups [group A (n=50) and group B (n=50) respectively] with written informed consent and ethical clearance.

Results: There was no significant difference between techniques regarding uncorrected visual acuity on post operative day 1 and best corrected visual acuity on post operative day 6 weeks. However visual acuity on post operative day 1 showed suggestive significance of "p" value 0.064 between the two groups. Greater proportion of patients had good outcomes in both the groups as regards to final visual acuity at the end of 6 weeks showing "p" value 0.310 with Fisher Exact test. Both comorbidities showed no difference in term of events. Mean surgical time was in group. A 15.97 +/-2.02 and in group B 8.40 +/- 1.34 showing a significant "p" value of less than 0.001 using student t test.

Conclusion: Manual small incision cataract surgery is similar to phacoemulsification as regards to intra and post operative outcomes, decreased complication rates final visual acuity with minimal effect of co existing comorbidities on events.

Keywords: Co-morbidity, Complication rates, MSICS, Phacoemulsification, Operative time, Visual acuity.

Introduction

Cataract is the chief cause of avoidable blindness in India and throughout the world. The national survey on blindness (2006-2007) shows an estimated 1.0 per cent prevalence of blindness in general population. With 62.6 percent share, cataract continues to be the main cause of blindness.[1] The use of smaller incision with advantages of faster rehabilitation, less astigmatism, early stabilization of refraction and visual acuity with better post operative vision without spectacles led to phacoemulsification being preferred technology where resources are available.[2] Cataract surgery with phacoemulsification is standard care today. Manual small incision cataract surgery claims to have similar advantages of phacoemulsification. In both cases associated co-morbidity, surgical techniques, visual outcome, complication rate vary between them specially in age related cataracts.[3] Our study is to compare both procedures.

Objectives of Study

1. To analyse post-operative visual acuity achieved in the two procedures.
2. To document complication rates of the two procedures.
3. To assess co-morbidity associated with age related cataract and their influence on final visual out come.
4. Compare the operative time taken for the procedures in high volume cataract unit.

Materials and Methods

The material for the study was collected from the patients presenting themselves to the department in the time period December 2014- May 2016. 100 consecutive patients with age related cataracts were assigned randomly to receive either phacoemulsification or manual small incision cataract surgery after obtaining ethical clearance and written informed consent. Outcome measures noted was in form of visual acuity, surgical complications, posterior capsule opacity, operative time, effect of co-morbidity on visual prognosis. In phacoemulsification group (group A) stop and chop nucleotomy done using Alcon Laurette and timed.

In manual small incision cataract surgery group (group B) was done and timed. Patients in the both groups received post-operative medication. Follow up 1st day, 1 week, 3 weeks, 6 weeks, 3 months, 6 months.

Main outcome measure were implantation of intra ocular lens in the capsular Bag and determination of visual acuity POD 1st day, 6 weeks.

Keratometry was done to measure the pre-operative corneal astigmatism and intraocular lens (IOL) power was calculated using SRK-II formula. On the day of surgery, pupil was dilated with tropicamide with phenylephrine eye drops were instilled thrice to maintain intra-operative mydriasis. All the surgeries were performed under peribulbar anesthesia. A Zeiss microscope (OPMI 1 FR pro) was used to perform both MSICS and phacoemulsification procedures.

Plan for Data Analysis: Statistical tests used were percentage, proportion, chi square test, student t-paired test and Fisher exact test.

Inclusion Criteria
1. Both sexes
2. Age above 50 years
3. Age related cataracts
4. Associated co-morbidity

Exclusion Criteria
1. Age less than 50 years
2. Intra-ocular pressure>21 mm of hg
3. Open globe injury
4. Scleral thinning
5. Corneal scarring
6. Fuchs dystrophy
7. Active uveitis
8. Poor pupillary dilatation less than 5 mm
9. Complicated cataracts
10. Subluxation
11. Pseudo exfoliation
12. History of ocular surgery
13. Laser treatment
14. High astigmatism
15. Retinal detachment

Keratometry was done to measure the pre-operative corneal astigmatism and intraocular lens (IOL) power was calculated using SRK-II formula. On the day of surgery, pupil was dilated with tropicamide with phenylephrine eye drops were instilled thrice to maintain intra-operative mydriasis. All the surgeries were performed under peribulbar anesthesia. A Zeiss microscope (OPMI 1 FR pro) was used to perform both MSICS and phacoemulsification procedures.

Results

There were no difference between groups in terms of gender ("p"=0.695), age ("p"=0.368), pre operative visual acuity ("p"= 0.803).

In the present study post-op visual acuity assessment had good outcome (6/6 – 6/18) was found in 84 patients (84%) in the first post-op day, 89 patients (89%) at 6 weeks which showed comparable results in about 88 patients (88%) at 6 months follow up. Representing 87% change from the pre-op values. Further borderline outcome (6/24 - 6/60) in post-op visual acuity was seen in 16 patients (16%) 1st day, 6 weeks 11 patients (11%),6 months 11 patients (11%) However poor outcome as defined <6/60 by Snellens visual acuity was not present in any patient [Table 1].

In the present study VA assessment according to ocular co-morbidity in group A (n=37) pre operative VA of less than 6/60 was seen in 20 patients (62.5%) and VA 6/24 -6/60 was seen in 12 (37.5%).

Among the 5 patients in group A (n=37) who had ocular co-morbidity VA less than 6/60 was seen in 1 patient (20%), where as majority 4 patients (80%) had VA 6/24 -6/60 necessitating cataract surgery.

Overall 21 patients (56.8%) had VA less than 6/60 and 16 patients (43.2%) had preoperative visual acuity between 6/24 – 6/60 in group A (n=37).

UCVA on POD 1 in range of 6/6-6/18 was achieved in 26 patients (70.2%) and UCVA 6/24 -6/60 was achieved in 6 patients (16.21%) among 32 patients who did not had ocular co-morbidity and UCVA 6/6 – 6/18 was achieved in 4 patients (80.0%), UCVA 6/24-6/60 achieved in 1 patient (20%) out of 4 patients in who had ocular co-morbidity in group A (n=37).

Overall BCVA on POD 6 weeks between 6/6 -6/18 was achieved in 33 patients (89.2%), 6/24 – 6/60 was achieved in 4 patients (10.8%) in group A(n=37) [Table 2].

VA assessment in relation to systemic co-morbidity in group A (n = 37) showed systemic co-morbidity absent in 26 patients, present in 11 patients of the total 37 patients in group A.

Overall in group A (n=37) at POD 6 weeks 33 patients (89.2%) achieved BCVA 6/6-6/24 and 4 patients (10.8 %) achieved BCVA of 6/24 – 6/60 [Table 3].

In the present study VA assessment according to ocular co-morbidity in group B (n=49) showed ocular co-morbidity absent in 39 patients present in 10 patients.

Among the 39 patients in group B (n=49) who had ocular co-morbidity VA less than 6/60 was seen in 24 patient (61.5%), where as 14 patients had VA 6/24 -6/60, and 1 patient (2.6%) had VA 6/6-6/18 out of 39 patients pre operatively necessitating cataract surgery.

In 10 patients having ocular co-morbidity in group B(n=49) 6 patients (60%) had VA less than 6/60, and 4 patients (40%) had VA in the range of 6/24-6/60.

Overall 30 patients (61.2%) had VA less than 6/60 and 18 patients (36.7%), had visual acuity between 6/24 – 6/60, 1 patient (2%) had VA 6/6-6/18 in group A (n=37) preoperatively.

UCVA at POD 1 showed UCVA in range of 6/6-6/18 in 30 patients (76.9%), 6/24-6/60 in 9 patients (23.1%) among 39 patients who did not have ocular co-morbidity in group B (n=49).

UCVA at POD 1 in 10 patients who had ocular co-morbidity showed all 10 patients (100%) achieved UCVA 6/6-6/18.

Overall of 49 patients in group B (n=49) 40 patients (81.6%) achieved UCVA 6/6-6/18, 9 patients (18.6%) achieved UCVA 6/24 -6/60 on POD 1.

BCVA at POD 6 weeks of 39 patients who did not had ocular co-morbidity in group B (n=49) 32 patients (82.1%) achieved BCVA of 6/6 -6/18 and 7 patients (17.9%) achieved BCVA 6/24-6/60.

Where as all 10 patients (100%) who had ocular co-morbidity in group B (n=49) BCVA of 6/6 -6/18 at POD 6 weeks [Table 4].

In relation of VA to systemic co-morbidity in group B (n=50) 32 patients had no systemic co-morbidity and 18 patients had systemic co-morbidity.

Overall pre operative assessment of UCVA in group B (n=50) showed 31 patients (62%) had UCVA less than 6/60, 18 patients (36%) UCVA 6/24-6/60, 1 patient had UCVA of 6/6-6/18.

UCVA at POD 1 in 32 patients who did not had systemic co-morbidity in group B (n=50) showed 27 patients (84.4%) showed UCVA of 6/6-6/18, 5 patients (15.6%) had UCVA of 6/24-6/60.

However of 18 patients who had systemic co-morbidity in group B (n=50) UCVA on POD 1 showed 16 patients (88.9%) had UCVA of 6/6-6/18, 2 patients (11.1%) had UCVA of 6/24-6/60.

Overall UCVA in POD 1 in group B (n=50) showed 43 patients (86%) had UCVA 6/6-6/18, 7 patients (14%) had UCVA of 6/24 -6/60.

In the present study BCVA at 6 weeks POD in 32 patients who did not had systemic co-morbidity in group B (n=50) showed BCVA 6/6-6/18 was present in 16 patients (88.9%), and BCVA 6/24 – 6/60 was present in 2 patients (11.1%) [Table 5].

In the present study in group A (n=37) 17 patients (45.9%) had operative time with in 15 minutes. whereas all the patients in group B (n=50) had operative time with in 15 minutes. Overall of the total (n=87) 67 patients (77%) had operative time of less than 15 minutes.

However in group A (n=37) 20 patients (54.1%) had operating time varying 16-30 minutes. In group A mean operative time achieved 15.97 +/- 2.02 minutes. Where as in group B (n=50) mean operative time was 8.40+/-1.34 minutes having a significant "p" value of <0.001% [Table 6].

In the present study group A (n=37) only 5 patients (13.5%) had intra operative complications, where as 3 patients (6%) in group B (n=50) had intra operative complications. Overall 8 patients (9.2%) had some degree of intraoperative complications.

Post operative complications were seen in 4 patients (10.8%) in group A (n=37), in group B (n=50) 3 patients (6%) had varying degree of Post operative complications.

Overall 8% had some degree of Post operative complications

In our study ocular morbidity was associated in 5 patients (13.5%) of group A (n=37) versus 10 patients (20%) in group B (n=50). Overall 15 patients (17.2%) of the total (n=87) had co-existent ocular morbidity [Graph 1].

In the present study distribution of ocular risk factors in individual groups was absent in 32 patients (86.5 %) in group A (n=37) where as in group B (n=50) 40 patients (80 %) had no ocular co-morbidities. Overall 15 patients (17.2 %) had various ocular co-morbidities [Graph 2].

In the present study distribution of systemic risk factors in individual groups was absent in 26 patients (70.3%) in group A (n=37) where as in group B (n=50) 32 patients (64%) had no systemic risk factors. Overall 29 patients (33.3%) had various systemic co-morbidities [Graph 3].

In the present study VA in relation to overall ocular morbidity in the total group recruited in the study (n=99) ocular co-morbidity seen in 15 patients; the following range of visual acuity was documented. UCVA range between 6/6-6/18 was achieved on POD 1 in 68 patients (80.95%) out of 84 subjects who had no ocular co-morbidity, however UCVA 6/6- 6/18 was achieved in all 15 patients (100%) having ocular co-morbidity UCVA on POD 1 between 6/24-6/60 was achieved in 16 patients (19.04%) out of 84 patients who had no ocular co-morbidity.

Overall of the total patients (n=99) recruited in the both study groups UCVA 6/6-6/18 on POD 1 achieved in 83 patients (83.83%) UCVA 6/24-6/60 on POD 1 was achieved in 16 patients (16.16%). In the present study BCVA at POD 6 weeks ranging between 6/6-6/18 was achieved in 73 patients out of 84 representing 86.9% of the total patients in the study who did not have any ocular morbidity. However those who had ocular co- morbidity achieved BCVA in the range of 6/6-6/18 in all 15 patients(100%) who had ocular co108 morbidity. None of the ocular co-morbidity group achieved BCVA less than 6/24 at POD 6 weeks. However BCVA in the range of 6/24 -6/60 was achieved in 11 patients (13.09 %) out of 84 patients who did not had ocular co-morbidity. Overall BCVA 6/6-6/18 on POD 6 weeks was achieved in 88 patients (88.88%) of the total (n=99) where as 6/24 -6/60 was achieved in 11 patients (11.11%) out of total 99 patients [Graph 4].

Among the total patients included under study 66 had no systemic comorbidity where as 34 patients had various systemic co morbidity. In the present study UCVA at POD 1 among patients who achieved VA in range of 6/6-6/18 was achieved in 54 patients (18.18%) out of 66 patients who did not had systemic co morbidity.

However UCVA 6/6 -6/18 on POD 1 was achieved in 30 patients (88.23%), UCVA 6/24-60 was achieved in 4 patients (11.76%) out of 34 patients who had systemic co morbidity.

Overall UCVA on POD 1 between 6/6 -6/18 was achieved in 84 patients (84%), 6/24 – 6/60 was achieved in 16 patients (16%) bout of total 100 patients. In the present study BCVA at post op 6 weeks ranging between 6/6-6/18 was achieved in 58 patients (87.87%) and 6/24 -6/60 was achieved in 8 patients (12.12 %) out of 66 patients who did not had systemic co morbidity [Graph 5].

Table 1: Visual acuity: Assessment from pre-op to 6 months

Visual Acuity	Pre op	POD 1	POD 1 week	POD 3 weeks	POD 6 weeks	POD 3 months	6 months	% change
6/6 – 6/18	1(1%)	84(84%)	89(89%)	89(89%)	89(89%)	88(88%)	88(88%)	87.0%
6/24 – 6/60	39(39%)	16(16%)	11(11%)	11(11%)	11(11%)	12(12%)	11(11%)	--28.0%
Less than 6/60	60(60%)	0(0%)	0(0%)	0(0%)	0(0%)	0(0%)	1(1%)	-59.0%
Total	100(100%)	100(100%)	100(100%)	100(100%)	100(100%)	100(100%)	100(100%)	-

Table 2: Visual Acuity assessment according to ocular morbidity in Group A

Visual acuity in Group I	Ocular Morbidity		Total (n=37)	P value
	No (n=32)	Yes (n=5)		
Pre op				
6/6 – 6/18	0(0%)	0(0%)	0(0%)	0.144
6/24 – 6/60	12(37.5%)	4(80%)	16(43.2%)	
Less than 6/60	20(62.5%)	1(20%)	21(56.8%)	
POD 1				
6/6 – 6/18	26(70.2%)	4(80%)	30(81.1%)	0.104 ?
6/24 – 6/60	6(16.21%)	1(20%)	7(18.91%)	
Less than 6/60	0(0%)	0(0%)	0(0%)	
POD 6 weeks				
6/6 – 6/18	28(87.5%)	5(100%)	33(89.2%)	1.000
6/24 – 6/60	4(12.5%)	0(0%)	4(10.8%)	
Less than 6/60	0(0%)	0(0%)	0(0%)	
6 months				
6/6 – 6/18	28(87.5%)	5(100%)	33(89.2%)	1.000
6/24 – 6/60	4(12.5%)	0(0%)	4(10.8%)	
Less than 6/60	0(0%)	0(0%)	0(0%)	

Table 3: Visual acuity assessment in relation to systemic morbidity in group A

Visual acuity in Group I	Systemic Morbidity		Total (n=37)	P value
	No (n=26)	Yes (n=11)		
Pre op				
6/6 – 6/18	0(0%)	0(0%)	0(0%)	0.475
6/24 – 6/60	10(38.5%)	6(54.5%)	16(43.2%)	
Less than 6/60	16(61.5%)	5(45.5%)	21(56.8%)	
POD 1				
6/6 – 6/18	20(76.9%)	10(90.9%)	30(81.1%)	0.649
6/24 – 6/60	6(23.1%)	1(9.1%)	7(18.9%)	
Less than 6/60	0(0%)	0(0%)	0(0%)	
POD 6 weeks				
6/6 – 6/18	23(88.5%)	10(90.9%)	33(89.2%)	1.000
6/24 – 6/60	3(11.5%)	1(9.1%)	4(10.8%)	
Less than 6/60	0(0%)	0(0%)	0(0%)	
6 months				
6/6 – 6/18	23(88.5%)	10(90.9%)	33(89.2%)	1.000
6/24 – 6/60	3(11.5%)	1(9.1%)	4(10.8%)	
Less than 6/60	0(0%)	0(0%)	0(0%)	

Table 4: Visual Acuity assessment in relation to Ocular Morbidity in group B

Visual acuity in group II	Ocular Morbidity		Total (n=49)	P value
	No (n=39)	Yes (n=10)		
Pre op				
6/6 – 6/18	1(2.6%)	0(0%)	1(2%)	1.000
6/24 – 6/60	14(35.9%)	4(40%)	18(36.7%)	
Less than 6/60	24(61.5%)	6(60%)	30(61.2%)	
POD 1				

6/6 – 6/18	30(76.9%)	10(100%)	40(81.6%)	0.173
6/24 – 6/60	9(23.1%)	0(0%)	9(18.4%)	
Less than 6/60	0(0%)	0(0%)	0(0%)	
POD 6 weeks				
6/6 – 6/18	32(82.1%)	10(100%)	42(85.7%)	0.319
6/24 – 6/60	7(17.9%)	0(0%)	7(14.3%)	
Less than 6/60	0(0%)	0(0%)	0(0%)	
6 months				
6/6 – 6/18	31(79.5%)	10(100%)	41(83.7%)	0.457
6/24 – 6/60	7(17.9%)	0(0%)	7(14.3%)	
Less than 6/60	1(2.6%)	0(0%)	1(2%)	

**Table 5: Visual Acuity assessment in relation to Systemic Morbidity in group B**

Visual acuity in group II	Systemic Morbidity		Total (n=50)	P value
	No (n=32)	Yes (n=18)		
Pre op				
6/6 – 6/18	0(0%)	1(5.6%)	1(2%)	0.500
6/24 – 6/60	12(37.5%)	6(33.3%)	18(36%)	
Less than 6/60	20(62.5%)	11(61.1%)	31(62%)	
POD 1				
6/6 – 6/18	26(81.3%)	15(83.3%)	41(82%)	1.000
6/24 – 6/60	6(18.8%)	3(16.7%)	9(18%)	
Less than 6/60	0(0%)	0(0%)	0(0%)	
POD 6 weeks				
6/6 – 6/18	27(84.4%)	16(88.9%)	43(86%)	1.000
6/24 – 6/60	5(15.6%)	2(11.1%)	7(14%)	
Less than 6/60	0(0%)	0(0%)	0(0%)	
6 months				
6/6 – 6/18	26(81.3%)	16(88.9%)	42(84%)	1.000
6/24 – 6/60	5(15.6%)	2(11.1%)	7(14%)	
➢ Less than 6/60	1(3.1%)	0(0%)	1(2%)	

**Table 6: Op time distribution in two groups of patients studied**

Op Time	Group I	Group II	Total
1-15	17(45.9%)	50(100%)	67(77%)
16-30	20(54.1%)	0(0%)	20(23%)
31-45	0(0%)	0(0%)	0(0%)
Total	37(100%)	50(100%)	87(100%)
Mean ± SD	15.97±2.02	8.40±1.34	11.62±4.11

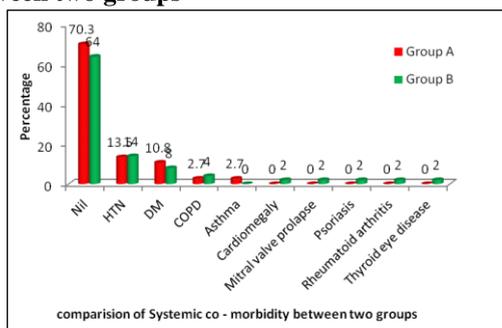P<0.001**, significant, student t test

**Graph 1: Intra operative complications occurred in patients having ocular co-morbidity**
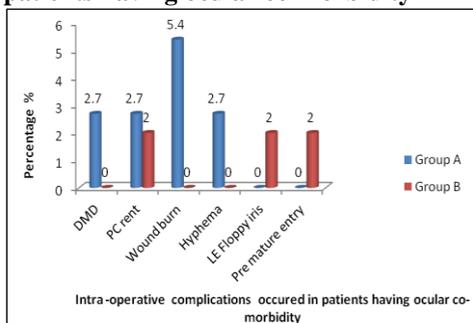
**Graph 2: Comparison of ocular co-morbidity between both groups**
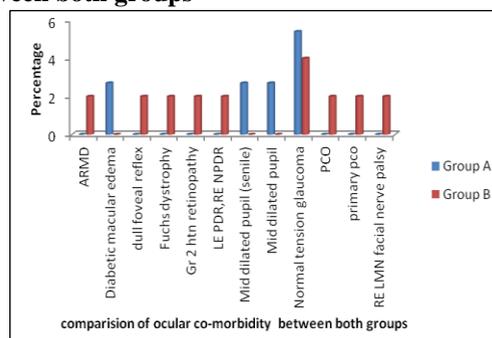
Graph 3: Comparison of systemic co-morbidity between two groups

comparision of Systemic co - morbidity between two groups

Graph 4: Comparison of BCVA at POD 6 weeks between patients had ocular co-morbidity and not had ocular co-morbidity

Comparison of BCVA at POD 6 weeks between patients had ocular co-morbidty and not had ocular co-morbidity
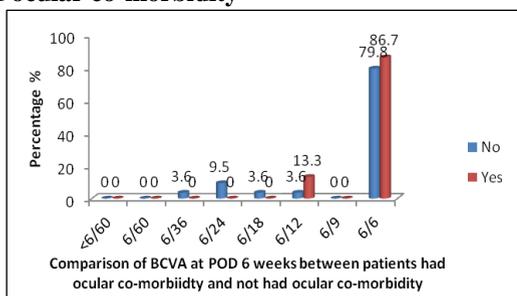
Graph 5: Visual acuity - Post operative 6 weeks

VA- POD 6 weeks
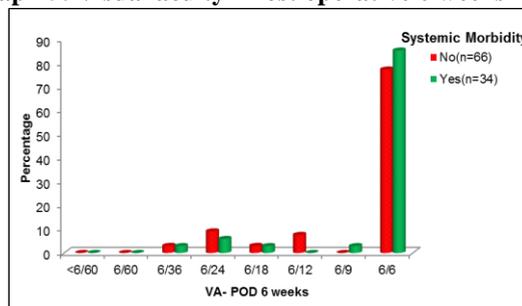
Discussion

POD 1 UCVA comparison in both groups showed "p" value of 0.064 which was of suggestive significance by using chi square test or fisher exact test. In other studies done at one day postoperatively, UCVA of 6/18 or better was found in 77.7% of participants in the MSCIS group and 68% of participants in the phacoemulsification group (P = 0.0655) (Singh 2009).[55] At six weeks, Gogate 2005 a reported UCVA of 6/18 or better in 133/187 (71%) of MSICS participants compared to 150/185 (81%) of phacoemulsification participants (risk ratio (RR) 0.88, 95% confidence interval (CI) 0.78 to 0.98).(55) However in our study follow up regarding BCVA at 6 weeks revealed comparable outcomes which was not significant, "p" value 0.857, indicating similarity of efficacy of both procedures in both groups respectively.

In study by Gogate 2005, 2/199 cases allocated to the phacoemulsification groups were converted to MSICS; in Gogate 2010 this was 5/ 100 cases (three due to zonular dialysis and two due to posterior capsule tears), in Cook 2012 8/100 cases (due to hard nucleus) and in Venkatesh 2010 3/137 cases.[4,5]

Postoperative inflammation was reported in three studies (11 cases in total). In the Ruit 2007 study, no events occurred in either group.[7]

Surgical time was reported in two studies, and was shorter in the MSICS group in both. Singh 2009 reported surgical time was less than six minutes in 11.2% of phacoemulsification and 84.9% of MSICS cases.[8] Venkatesh 2010 reported mean surgical time of 8.8 +/- 3.4 minutes in the MSICS group and 12.2 +/- 4.6 minutes in the phacoemulsification group.[4,6]

Among 50 patients in group A 13 could not complete the procedure and had to be converted to MSICS with successful implantation of IOL due to various reasons like wound leak, rhexis break, floppy iris, abdominal distress with respiratory distress on table, positive vitreous pressure, shallow anterior chamber, hyphema, severe chemosis, lid edema, tight orbit and eye pain, due to failure of anesthesia, posterior capsular rent, corneal thinning due to wound burn, chronic obstructive pulmonary disease occurred each in 1 patient respectively. However all were successfully converted to MSICS.

Conclusion

Short term and long term visual acuity are almost same in both procedures with decreased complication rates. MSICS is appropriate for fast turnover of cases specially in advanced cataracts thereby resulting in economic benefit both to the patient and hospital. Our study found usefulness of both procedures, however due to conversion of few cases from group A to group B (13 cases) we find MSICS dependable in such situations due to increased effectiveness in controlling complications, less cost, less maintaince and less technology dependent.

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