

Original article



Phacoemulsification versus small incision cataract surgery (SICS): which one is a better surgical option for immature cataract in developing countries?

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Abstract

Background: Several studies have shown comparable visual outcomes of SICS and phacoemulsification (Gogate et al 2007, Ruit et al 2007).

Objective: To compare the safety and efficacy of different types of surgical procedures (phacoemulsification versus SICS) for cataract surgery in immature cataract.

Material and methods: A prospective randomized controlled trial was carried out involving 93 and 89 patients with immature senile cataract selected for phacoemulsification and SICS respectively.

Statistics: Mean values with standard deviations were calculated. P value of less than 0.05 was considered significant.

Results: There was no difference between the groups in terms of gender, age and pre-operative visual acuity ($p = 0.09$). In phacoemulsification group ($n=93$) more than two thirds and in SICS group ($n=89$) more than three quarters of the patients had good visual outcome (6/6-6/18) on first postoperative day ($p=0.065$). Poor outcome ($<6/60$) was recorded in 6% (phacoemulsification group) and 1% (small incision cataract surgery group). Mean visual acuity was 0.43 ± 0.27 in phacoemulsification group and 0.47 ± 0.24 in SICS group. Mean surgery time was significantly shorter in SICS group ($p=0.0003$).

Statistics: Data were computed and analyzed using the SPSS software program vs 10. The p value of < 0.05 was considered significant.

Conclusion: There was no significant difference in visual outcome on first post operative day in between phacoemulsification and SICS technique. However, performing SICS was significantly faster. Small incision cataract surgery with implantation of rigid PMMA lens is a suitable surgical technique to treat immature cataract in developing countries.

Keywords: phacoemulsification, small incision cataract surgery (SICS)

Introduction

Cataract is the leading cause of blindness in the world causing more than 18 million bilateral blindness (Foster and Resnikoff, 2005; Ceklic et al 2005). Most of these blind people reside in developing countries (Ladnyi and Thylefors, 1983). Insufficient financial resources,

inaccessibility and lack of awareness about existing eye care facilities are some of the barriers underprivileged people face in utilizing available eye care services in these countries (Melese et al 2004, de Lima et al 2005, Sapkota et al 2004). Phacoemulsification is the standard surgical procedure for cataract in developed countries whereas the technique of cataract extraction varies in developing countries (Tabin et al 2008, Ellwein and Kupfer, 1995). Since the last decade small incision cataract surgery (SICS) has become a popular technique of cataract surgery in Nepal (Hennig et al 2003) and other developing countries. Anecdotally, it is believed that SICS is the appropriate technique for

Received: 13.07.2009

Accepted: 25.08.2009

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mature cataracts and phaco emulsification is more suitable for immature cataracts. Several comparable studies have shown similar visual outcome of the two surgical techniques (Ruit et al 2007; Schwab, 2007; Gogate et al 2007; Spencer, 2006) but none of those previous studies had compared the surgical procedures on phaco suitable immature cataracts. This prospective randomized controlled trial was done to compare the efficacy of these two methods of cataract extraction on phaco suitable immature cataract in developing countries.

Materials and methods

Study design

A randomized clinical trial was conducted at Biratnagar Eye Hospital (BEH) for a period of two months (1 May 2007 to 29 June 2007).

Inclusion and exclusion criteria

All patients underwent slit lamp examination. Phacosuitable immature senile cataracts were included for this study. Immature cataract was defined as nucleus sclerosis up to 2+, cortical cataract 2+ and posterior sub-capsular cataract of any grade. All other types of cataracts were excluded from this study.

An informed consent was obtained from all the patients before including them in the study. Ethical clearance was obtained from the Institutional Research Committee.

Randomization

The patients with immature senile cataract were divided into two groups before receiving retrobulbar anesthesia. Randomization was done with the help of random number tables. All patients were operated by a single surgeon (SKS) well experienced in performing cataract surgery with both techniques for more than ten years.

Masking

As the surgeon was the only ophthalmologist available at BEH at the time of this study, masking did not seem practical. All cases were operated and examined in the postoperative period by him. However, the visual acuity recording person was not aware of the study and masking could be achieved.

Intervention

An automated keratometer was used for the purpose of keratometry and a A-Scan ultrasound (Nidek) for

the purpose of axial length measurement. The power of the intra-ocular lens was calculated with the modified SRK II formula.

After pupil dilatation with tropicamide and phenylephrine eye drops, a retrobulbar injection was given in sitting position and the patient requested to press the eye ball with the palm of the hand over a piece of a cotton gauge to soften the eyeball. Preoperative povidone iodine 5 % solution was used for disinfection of the periocular skin area. The surgeon performed the operations in sitting position on two alternate tables using a single microscope. Some of the surgical steps, such as fornix based conjunctival flap and cauterization of bleeding vessels, were performed by an operation theatre assistant in order to minimize the surgical time.

All the surgeries were done via the temporal approach. A phacoemulsification machine (Swisstech Catarrhex) with tubings, hand pieces and phaco tips, irrigation and aspiration cannulas was used for performing phacoemulsification surgery in this study.

A standard phacoemulsification using phaco chop technique was performed. The rigid Poly Methyl Metha Acrylate intraocular lens with a 5 mm optic was implanted after enlarging the incision to 5 mm. The SICS was performed using the "fish hook technique" (Hennig et al 2007) wherein the tunnel had to be enlarged up to 6 mm for IOL insertion. In all SICS cases, a large capsulorrhexis was made before nucleus delivery to ensure the placement of the intraocular lens in the bag. The operation was completed with an intracameral injection of cefuroxime. The surgical time was measured from the preparation of the sclerocorneal incision to the end of the intracameral cefuroxime injection.

Study variables

Study variables included surgeon's time, intraoperative/ postoperative complications, postoperative uncorrected visual acuity and surgery-induced astigmatism on the first postoperative day. Postoperative uncorrected visual acuity was taken with a Snellen chart at a 6 meter distance and was converted into decimals.

Results

182 patients consented for the study, 93 were operated with the phacoemulsification technique (Group A) and 89 were operated with the SICS technique (Group B).

Table 1
Baseline characteristics

Variables	Phacoemulsification (Group A) n=93	SICS (Group B) n=89	P value
Age(Mean ± SD)	58.2±12.7 yr	58.7±11.3yr	
Male	60.2 %	50.6 %	0.0968
VA (HM or worse)	12.9 %	7.7 %	0.2236
Mean VA (remaining patients)	0.076±0.11	0.11±0.05	

Baseline characteristics were similar in both groups as shown in table 1.

Mean intraocular lens power was similar in both groups, phaco group: 22.02 ± 1.31 D and SICS group: 22.2 ± 1.8 D.

Table 2
Intra-operative findings

Parameters	Phaco surgery (Group A)	SICS (Group B)	
Mean IOL power	22.02 ± 1.31 D	22.2 ± 1.8 D	
Intra-operative complications	PCR + vitreous loss: 1 PCR + Nucleus drop: 1	Zonular dialysis during hydrodissection: 1	
Mean surgery time > 6 min	84.9%	11.2%	p value <0.00003

In group A, two patients had posterior capsule rupture (PCR) with vitreous loss. One patient underwent anterior vitrectomy and PCIOL was placed in the ciliary sulcus. The other patient, who had a nucleus drop, was referred to the Retina Unit of our hospital. Dropped nucleus was removed and PCIOL was implanted in ciliary sulcus by the vitreo-retina surgeon.

In group B, one patient had zonular dialysis during hydro-dissection procedure.

Mean time spent by the surgeon per surgery was 7 minutes in group A and 5 minute 18 seconds in group B. In group A, 84.9 % patients and in group B 11.2 % had surgery time of more than 6 minutes (p value < 0.00003).

Table 3
Visual outcome on the first postoperative day

Parameters	Phacoemulsification (Group A) n=93	SICS (Group B) n=89	P value
Good (6/6-6/18)	68%	77.7%	0.0655
Borderline (6/24-6/60)	26%	22%	
Poor (<6/60)	6%	1%	

Postoperatively, uncorrected visual acuity was measured on the first postoperative day at 7 a.m. immediately after removal of the eye pad. In group A, nearly two thirds and in group B nearly three quarters (68% and 78% respectively) of patients had good visual outcome (6/6-6/18). Mean visual acuity was 0.43 ± 0.27 D in group A and 0.47 ± 0.24 in group B. Poor outcome (unaided visual acuity <6/60) was noticed in 6% patients from group A and in 1% patients from group B.

Table 4
Postoperative findings on the first post-operative day

Parameters		Group A	SICS Group B
Postoperative complications	Corneal edema	4	0
	AC reaction	0	1
Mean visual outcome		0.43 ± 0.27	0.47 ± 0.24
Mean induced K astigmatism (diopter)		0.11 (SD 0.74)	0.09 (SD 0.82)

Postoperatively, four patients had corneal edema in group A and one patient had increased anterior chamber reactions due to postoperative uveitis in group B (Table 4). All patients with corneal edema responded to treatment with antibiotic and steroid (Ciprofloxacin and Dexamethasone) containing eye drops and were discharged on the third post operative day.

Discussion

Only immature cataracts were included in this study, so the outcomes cannot be generalized for all types of cataract. Operated patients were advised to apply antibiotic and steroid containing (Ciprofloxacin and Dexamethasone) eye drops regularly on a tapering regime for six weeks. Most of the patients included in this study had traveled long distances from India to Biratnagar Eye Hospital. It is a common tendency that though we advise our patients to review after six weeks, almost all patients who have good vision do not come for follow-up. Due to this, long-term follow-up outcome could not be evaluated in this study.

All surgeries were performed by a single surgeon (SKS), who is experienced in both the techniques. Phacoemulsification surgery could be performed on all but one case who had nucleus drop during hydrodissection. Dropped nucleus was removed and the patient had a good visual outcome (visual acuity 6/18) in the post-operative period. SICS could be performed on all randomly selected cases for SICS.

After the phacoemulsification procedure a 5 mm optic PMMA lens was implanted and after the fish hook SICS surgery a 6 mm optic PMMA lens was implanted. Usually in SICS surgery, the internal opening of the sclero-corneal wound is larger than the outer opening, but as all the surgeries were performed on immature cataract, nucleus could be removed through the 6 mm internal opening. So, the size of internal and external openings for SICS was the same in this study.

On the first post-operative day, more than two thirds of the patients in group A and more than three quarters of all the patients in group B had a good visual outcome. Mean visual outcome and mean induced keratometric astigmatism were comparable in both groups on the first post operative day. A frown shaped temporal incision of 1 mm size difference with phaco (5mm incision) and with SICS (6 mm incision) techniques resulted in almost similar visual outcome with equal amount of postoperative astigmatism.

Mean surgery time was 7 minutes in group A and 5 minutes and 18 seconds in group B. Mean surgery time of more than 6 minutes was observed in 85% of patients in group A and 11 % of patients in group B (P value <0.00003). Shorter in toto nucleus extraction time compared to phacoemulsification of nucleus, faster

epinucleus removal and faster cortex aspiration by simcoe cannula compared to irrigation and aspiration cannula resulted in faster surgery by the SICS method. In the present study, in one-hour surgical time, 4 additional SICS could have been performed by the surgeon.

Though the cost difference between the phaco and SICS with rigid lens is very low (Gogate et al, 2007) in high volume set up, consumable cost of phaco surgery with a rigid PMMA lens is higher due to increased use of viscoelastics and irrigating solution. A hospital based study done by Hennig et al (2007) in similar setting at Sagarmatha Choudhary Eye Hospital, Nepal showed a consumable cost difference of USD 0.50 between SICS and phaco with rigid lens. The fixed cost associated with the establishment of a phaco set-up is much higher compared to SICS. The cost of the phaco machine used in this study was Euro 20,000. The depreciation of the phaco machine and the running cost associated with the consumables and tips make phaco surgery expensive as compared to SICS.

Phacoemulsification has a long learning curve, requires expensive equipments, has a high consumable cost and needs expensive foldable lenses to maximize the benefit associated with the small incision (Thomas, 2009). Despite these facts, there is a growing demand for phaco surgery in the developing world and many patients are willing to pay more for it (Thomas et al, 2008). To meet the demand and to make it affordable to the people of all socioeconomic levels, phacoemulsification is being performed with implantation of foldable and rigid IOLs as well in the developing countries.

In the high volume set-up of the BEH where a single surgeon operates on two tables, six surgical sets of instruments, hand pieces, phaco tips, sleeves and irrigation-aspiration cannulas are required to perform phacoemulsification faster. The cost associated with phaco hand pieces, phaco tips, sleeves, irrigation and aspiration cannulas are high and increase the fixed cost and consumable cost associated with phacoemulsification. Reusable tubings, cassettes, phaco tips and hand pieces can help to lower the cost of phacoemulsification surgery. There are certain guidelines given by the company about the maximum number of autoclaving cycles for the tubings, tips and

hand pieces. Often these accessories are autoclaved and reused many more times than recommended (Thomas, 2008). Only in a very few ophthalmic theatres in developing countries do they change phaco hand pieces, phaco tips, sleeves and tubings for each surgery (Thomas, 2009). Various practices like changing only the tips and sleeves between surgery and dipping phaco tips and cannulas in antiseptic solution after each surgery are common practices in developing countries to cut down the cost. But none of the above-mentioned procedures meet the recommended sterilization standards and therefore, should be avoided (Thomas, 2009). Easily available, inexpensive surgical instruments allow surgeons to follow standard recommended procedures of sterilization for SICS whereas the same is not true for phacoemulsification.

This study clearly shows that there is no additional visual and surgical benefit on the first postoperative day with phaco technique with rigid IOLs as compared to SICS with rigid IOLs.

Limitations of this study

In this study a single surgeon well-experienced in both techniques performed all the surgeries. This has reduced the surgeon's factor associated with the study but at the same time the result may vary in another setting.

Due to practical problems and seeing the follow-up behavior of patients in our hospital, follow-up was limited to the first post operative day. This study does not show the changes in astigmatism and visual outcome in long-term follow-up. A study with a longer follow-up is recommended.

The definition of immature cataract surgery suitable for phaco varies with the experience of surgeons. Many phaco surgeons may disagree with the definition of phaco-suitable immature cataract used for this study. At the same time, the result of this study cannot be applied to all types of cataract.

Conclusion

There is no significant difference in visual outcome on the first postoperative day between phaco and SICS techniques. Performing SICS is significantly cheaper and faster. SICS with implantation of rigid PMMA lens is a suitable alternative option for the treatment of immature senile cataracts.

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Source of support: nil. Conflict of interest: none