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EVALUATION OF FEASIBILITY OF BINOCULAR MAGNIFYING LOUPES IN SMALL INCISION CATARACT SURGERY AND ITS COMPARISON WITH OPERATING MICROSCOPE WITH RESPECT TO COMPLICATIONS AND POSTOPERATIVE INFLAMMATION- A PROSPECTIVE RANDOMIZED STUDY

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ABSTRACT

Purpose: To evaluate feasibility of a binocular loupe in performing small incision cataract surgery (SICS) and to compare the intraoperative complications and postoperative inflammation of surgeries performed using operating microscope and binocular loupe. **Setting:** District government hospital in Western India. **Design:** Prospective, randomized controlled study. **Methods:** Three hundred and twenty-six patients undergoing SICS were randomly allocated to microscope (158 eyes) or loupe (168 eyes) magnification. Intra- and post-op complications and signs of inflammation were evaluated on day 1 and day 30. **Results:** With similar baseline characteristics, postoperative congestion (p 0.05) and reaction in anterior chamber (p 0.53) were comparable in both the groups. The overall incidence of striate keratopathy (SK) was statistically significantly higher in group B (p 0.003), but visually significant SK (grade 3 and 4) was similar in both the groups. Intra operative complications were comparable in both groups (p 0.74). Mean surgery time with loupe magnification was shorter, but not statistically significant (p 0.14). **Conclusions:** The complications and handling of intraocular tissues using magnifying loupes is comparable to that using a microscope. Loupe is a cheap and effective tool to perform cataract surgery in a camp set up; so, it can play a role in reducing cataract blindness in developing countries of the world.

KEYWORDS: Loupe; Microscope; Cataract.

INTRODUCTION

Cataract is the main and biggest cause of curable blindness in India and worldwide. It has been estimated that 3.8 million people develop blinding cataract every year in India as against 2.7 million cataract surgeries done every year. [1,2] Cataract extractions are one of the most cost-effective procedures of all surgical interventions in terms of quality of life restored. [3,4] The only treatment option for cataract is the surgical removal of the opaque lens and the implantation of an artificial lens. The state-of-the-art technique is phacoemulsification with the insertion of a foldable intraocular lens (IOL) through a self-sealing incision. The cost considerations and the steep learning curve associated with the phacoemulsification procedure makes it a less feasible procedure for high-volume surgery needed in developing countries, especially in a camp set up. Hence, MSICS becomes the surgery of choice in such circumstances. [5] Conventionally, operating microscope is used to provide magnification while performing MSICS. However, it is difficult to carry an operating microscope in rural hilly areas without the risk of getting damaged. A binocular loupe, on the other hand, is easy to carry and cost effective. This study was designed to evaluate feasibility of a binocular loupe in performing MSICS and to compare the intraoperative complications and postoperative inflammation (which usually indicates handling of tissues intraoperatively) of surgeries when performed using operating microscope and with binocular loupe.

MATERIAL AND METHODS

This was a prospective camp based randomized study conducted at different camps in Ahmednagar,

Maharashtra over a period of 4 months (July 2018 to October 2018). Approval for the study was obtained from the institutional review board, and the study was conducted within the Declaration of Helsinki. A written informed consent was taken from the patients. Patients with uncomplicated cataracts who gave consent for the study were included. Those with complicated cataract, congenital cataract, developmental cataract and cataract associated with other diseases or those who didn't complete a month of follow-up were excluded from this study.

All patients who met the inclusion criteria were divided into two groups before receiving peribulbar anesthesia. Randomization was done with the help of random number tables. Patients with odd numbers were selected for microscope magnification and even numbers were selected for loupe magnification. All patients were screened at different camp sites but operated at a common operation theatre at a district hospital in Ahmednagar. All patients underwent slit lamp examination to assess the anterior segment, with special consideration to pupillary dilatation and grade of cataract; and indirect ophthalmoscopy for evaluation of posterior segment, wherever possible. All patients were operated by a single surgeon. The patients were evaluated for signs of inflammation by another surgeon on day 1 and day 30. Masking was achieved by assigning a different person for randomization, surgery and postoperative evaluation.

Pupillary dilatation was achieved with Tropicamide and Phenylephrine eye drops. Preoperative povidone iodine 10% solution was used to disinfect the periocular skin area. A peribulbar injection was given in lying down position by ophthalmic assistants. The surgeon performed the surgery in either sitting position with the operating microscope [Carl Zeiss microscope (OPMI -1 FR)] or standing position using a magnifying loupe [Carl Zeiss EyeMag Pro F with 4 times magnification and 450 mm working distance with attached Carl Zeiss EyeMag Light II LED for illumination]. The surgical time was measured from the time the patient lied down on the table to the end of procedure after patching the eye.

Surgical steps: The eye was painted and draped. After inserting the wire speculum, superior rectus bridle suture was taken. A fornix based conjunctival flap was made and the bleeding vessels were cauterized. Side port entry was made with 3 mm keratome. With the help of trypan blue and viscoelastic, a continuous curvilinear capsulorrhexis (CCC) was performed. In cases CCC was smaller than desired, few nicks were given in it. Sclerocorneal tunnel was made superiorly or temporally (depending on the case) using a crescent knife and a keratome. The nucleus was brought out in the anterior chamber using hydroprocedures and prolapsed with viscoexpression. With a Simcoe cannula the remaining cortex was aspirated. PMMA posterior chamber intraocular lens was implanted and anterior chamber was filled with ringer lactate solution. A subconjunctival injection of gentamycin and dexamethasone was given and the case closed.

Data was entered in MS excel format and descriptive statistics with frequency, mean and standard deviation were computed. The statistical analysis was done with the SPSS version 22 software package (IBM Corporation, SPSS Inc. Chicago, IL, USA). Chi-square was used to find out association between qualitative data and Mann-Whitney U test was used to find the difference between mean. p value less than 0.05 was considered to be significant. Study variables included surgeon's time, intraoperative and postoperative complications and postoperative inflammation on first postoperative day and a month later.

RESULTS

Out of 326 patients included in the study, 158 were operated under microscope (Group A) and 168 with magnifying loupe (Group B). Baseline characteristics were similar in both groups (table 1). In group A 34.8% (55 out of 158) and 35.11% (59 out of168) in group B had vision of perception of light while the remaining patients had visual acuity ranging from finger counting 3 meters to 6/24.

Mean surgical time in group A was 10 minutes 18 seconds (9.78±3.86) and 9 minutes 20 seconds (9.19±3.29) in group B (p value 0.14). Intraoperatively complications (Table 2) were seen in 17 patients (10.75%) in group A and 7 patients (4.17%) in group B. Tunnel related complications were most common (6 in group A and 3 in group B) which included premature tunnel entry, requiring tunnel suture and tunnel bleed. Posterior capsular rupture was seen in 3 patients in group A and 2 patients in group B. They went anterior vitrectomy and implantation of intraocular lens in the bag/ sulcus, depending on the case. However, 1 patient in each group had to be kept aphakic.

On day 1, postoperative complications were noticed among fifteen patients in group A and sixteen patients in group B (Table 2). Two patients from each group had to undergo surgical revision on the first postoperative day; (1 Tunnel suture and 1 PCIOL repositioning). Some degree of corneal edema was seen in 35.44% of patients in group A in contrast to 51.78 % in group B (p value 0.003). Visually significant complications in group A included hyphema (4 patients), increased anterior chamber reactions (9 patients) and Descemet's membrane (DM) detachment (1 patient) and in group B hyphema (2 patients), increased anterior chamber reactions (11 patients) and DM detachment (1 patient). After one month of follow up none of the patients in either group showed any corneal edema, AC reaction or IOL related complications.

Table 1: Baseline features of the two groups.

Variables	Treatment method		P value
	Microscope (Group A)	Magnifying Loupe (Group B)	
Gender			
Male	69	69	
Female	89	99	0.63
Age (mean)	65.6	66.4	0.85
Eye			
Right	74	77	
Left	84	91	0.85
Grade			
Soft	49	50	
Hard	54	59	
Mature	55	59	0.96
System			
BP	28	35	
DM	64	55	
IHD	18	20	0.14
Pupil (mm)	7.77±1.08	8.05±0.94	0.06

Table 2: Intra- and post-operative complications.

Variables		Treatment method		P value
		Microscope	Loupe	
Intraoperative				
Tunnel related		06	03	
Premature entry		3	2	
Tunnel bleed		3	1	
Iris related		06	02	
Iridodialysis		2	0	0.74
Sphincterotomies		4	2	
Lens-bag related		05	02	
Zonular dialysis		2	0	
Posterior Capsular rent		3	2	
Aphakia		01	01	
Postoperative (day 1)				
Congestion	1	63	83	0.05
	2	80	63	
	3	13	22	
Subconjunctival hemorrhage		36	37	
Cornea				
Striate keratopathy		56	87	0.003
DM detachment		1	1	
AC reaction	1	01	0	
	2	72	69	
	3	74	89	0.53
	4	9	11	
Tunnel leak		01	01	
Visually significant complications				
Cornea (DMD)		01	01	
AC		13	13	
Hyphema		4	2	
Severe reaction		9	11	
Aphakia		01	01	

DISCUSSION

Preoperatively the patients in both the groups were similar to each other with respect to age, gender, grade of cataract and pupillary size. Intraoperative complications were seen more in surgeries with microscope, tunnel related being more common (6 in group A and 3 in group B). But 3 out of 6 in group A and 1 out of 3 in group B were due to bleeding from the scleral tunnel; requiring cotton soaked with adrenaline in the tunnel to control bleeding. Post-operatively on day 1, other than striate keratopathy (SK), rest of the complications were similar in both the groups. The overall incidence of striate keratopathy was statistically significantly higher in group B, but visually significant SK (grade 3 and 4) was similar in both the groups.

PubMed search showed only one study comparing loupe magnification with microscope magnification in small incision cataract surgery. [6] Singh et al in their study concluded that comparatively equivalent good surgical outcome was achieved with loupe as well as with microscope magnification and that performing SICS with loupe magnification was significantly faster. Intraoperative complications were comparable in both groups and similar results were achieved by Singh et al.[6]

Surgical time included the time taken to prepare the patient after lying down in addition to all the surgical steps performed during the surgery. Though the surgeries with loupe was faster to perform, the difference wasn't statistically significant. In their study, more patients in loupe group had mean surgical time less than 4 minutes as compared to microscope group.

Surgeries with microscope were performed in the sitting position whereas with the magnifying loupe the standing position was more practical. The main advantage with loupe magnification is the flexibility in judging intraocular structures from different angles during surgery. Change in head posture of patient during surgery requires vertical and horizontal adjustment of optical part of the microscope to remain in good focus of the operation site whereas with the magnifying loupe the surgeon can adjust immediately by just moving his head as required. [6] Hence, surgery with magnifying loupe was easier in patients who could not lie down straight, those with deep set eyes and thick neck. These results in a shorter time needed for focus adjustment with loupe magnification.

Our study is more practical in its aspect as we have included all grades of cataract, operated over varied pupillary size, population from different parts of the entire district and replicated the actual scene at peripheral camp site where a single surgeon with a single nursing staff has to perform the surgeries.

A good quality operating microscope is expensive equipment for many private eye clinics and eye units in developing countries. Compared to the most basic model of Zeiss operating microscope, Zeiss magnifying loupe with illumination source is much cheaper, easy to transport and almost maintenance free. Since we used Carl Zeiss EyeMag Light II LED attached to the loupe to provide illumination, we were able to eliminate the need of an additional external light source. The total cost of the equipment was 3227 USD/ 2836 Euros, which costs less than one-third when compared to OPMI-1 FR. This not only increases the efficacy of the surgeons without compromising on the results but also reduces the cost of surgery.

With the "at-risk" population for blinding cataract increasing exponentially and majority of our population still living in rural areas, [7] surgical eye camps are still common and acceptable means of reducing the burden of cataract blindness in these communities. [8]

Using a magnifying loupe has its own disadvantages as well. There is a learning curve to perform CCC, however very brief. The surgeries have to be performed in standing position which might not be convenient to all surgeons. It is not possible to demonstrate the surgical steps to a trainee as no imaging device can be attached to it which can be done with an operating microscope.

CONCLUSION

Magnifying loupe is a cheaper and convenient option to perform small incision cataract surgeries at a relatively faster rate and also with comparative complication rate. In developing countries where cataract blindness is a major cause of avoidable blindness, the trainees should also have access to magnifying loupes while performing small incision cataract surgeries which will help us to provide good surgical outcome with increased output.

What was known:

- Comparatively equivalent good surgical outcome can be achieved with loupe
- Performing SICS with loupe magnification is significantly faster

What this paper adds:

- Magnifying loupe can be used to perform SICS in all grades of cataract (soft/ hard/ mature) and pupillary size ranging from 6-10 mm
- Post-op inflammatory response is comparable with loupe and microscope.

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