Sunt FOR RESERACE	Research Paper	Medical Science			
Internationed	Assessment of Visual Outcome of Post-Operative Cataract Surgery in Paying Versus Non-Paying Patients				
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INTRODUCTION

Cataract remains the leading cause of blindness in India 1-4. The targeted patients are from remote and rural areas where there is limited access, lack of resources and affordability of eve care services, as also lack of knowledge and understanding about diseases. Superstitious practices are often carried out and patients usually present late to the concerned medical personnel. Thus the Government of India, under the National Programme for Control of Blindness (NPCB) has launched various schemes to conduct free cataract surgeries, so as to reduce the burden of avoidable blindness in India, under VISION 2020 launched by WHO⁵. As a result, the number of cataract surgeries performed per year has increased from 1.2 million in 1992 to 3.86 million in the year 2003.6 However, in most of the countries, phacoemulsification is not affordable, while extracapsular cataract extraction (ECCE) is still routinely performed on a large scale. In 2000, Ruit et al 7 described the technique for "sutureless" ECCE or manual small incision cataract surgery (MSICS), and since then, this technique has grown in popularity in developing countries. In several randomized prospective trials, MSICS has been a successful technique to produce visual outcomes, superior to ECCE and also when compared to Phacoemulsification^{8.}

People residing in urban areas usually have adequate knowledge about availability and resources, are capable of paying and thus get treated under paying packages at an appropriate time, in order to procure maximum and the best possible visual outcomes, post operatively. This study is thus a novel approach to compare the visual outcome indices among patients, who get operated under non-paying and paying schemes for cataract extraction in rural hospitals of central India, taking into consideration the various pre-operative, intra operative and post-operative variables.

AIMS AND OBJECTIVES

To compare the visual outcome indices among cataract patients operated under non-paying schemes (NPS) versus paying schemes (PS).

To evaluate pre-existing ocular morbidity in both groups

To assess intra-operative complications in both the groups

Materials and methods Study duration: 1 year

Study site : Acharya Vinoba Bhave Rural hospital, Sawangi (Meghe), Wardha.

Study design : Prospective Randomized Controlled Trial (RCT)

Study sample : 400 patients requiring cataract surgery were selected for the study. They were further divided into 2 groups- Group A included 'Non-Paying' patients (NP=200) and Group B included 'Paying' patients (P=200).

This study was approved by the Institutional Ethics Committee and was performed in accordance with the tenets of the Declaration of Helsinki. Written informed consent was obtained from eligible subjects. All subjects underwent a complete ophthalmic examination. Examination consisted of measuring the best-corrected visual acuity (BCVA) using the modified ETDRS chart, applanation tonometry, gonioscopy, grading of lens opacities using LOCS II⁹, stereoscopic evaluation of the optic nerve head and macula at the slit-lamp using a +78 diopter lens, and a detailed retinal examination with a binocular indirect ophthalmoscope.

Pre operatively, pupils were dilated and sensitivity to local anesthetics was tested with 2% lignocaine test dose. To reduce bias and disparity in both the surgical techniques (manual small incision cataract surgery and phacoemulsification), all surgeries were performed by a single surgeon.

Pre, intra and post-operative complications were observed by the same surgeon for both the groups.

Post operatively patients were assessed 4 times (day 1, week 1, week 4 & week 6)

INCLUSION CRITERIA

Patients aged > 50 years

Patients with non-traumatic, non-developmental immature (BCVA <6/18) and mature cataracts who visited ophthalmology OPD and planned to undergo cataract surgery.

EXCLUSION CRITERIA

Patients with glaucoma, previous ocular trauma, ocular surgery, those who were unable to co-operate and communicate during surgery (due to dementia, hearing impairment, etc.) and who were not willing were excluded from the study.

STASTICAL ANALYSIS: Data analysis was carried out using SPSS (SPSS Inc., Chicago, IL). Significance was assessed at the *P*, 0.05 level for all parameters.

OBSERVATIONS

Table 1 & Table 2: Out of 400 patients maximum patients who underwent cataract surgeries were from 61-70 years. The mean age was 65.73 years for group A while for group B it was 63.26 years. Maximum number of cataract patients were males- 54.5% in group A and 51% in group B. There were no differences between the paying and the non-paying groups in terms of gender distribution.

Table 3: 69% of patients in group A and 73% in group B underwent

phacoemulsification surgery while 31% in group A and 26% in group B underwent $\ensuremath{\mathsf{MSICS}}$

Table 4: Based on preoperative BCVA (Table 4), there was a significant difference between Group A and Group B. A BCVA of 6/12 - 6/36 was recorded in 34% patients in group A and 64% in group B. <6/60 BCVA was observed in 66% of patients in group A and 36% in group B. This shows that group B patients presented early for diminution of vision compared to Group A. Similar observations have been made in other parts of rural India, China and USA which is attributable to the fact that patients who were more concerned, sought early opinion for their visual problem¹⁰⁻¹².

Table 5: Anterior segment abnormalities such as corneal pathologies, pseudoexfoliation were found to be more in Group A patients (23.5%) compared to group B (9%). Identification of the risk factors that have a causal effect on cataract development may provide means for cataract prevention. There are few risk factors that satisfy the criteria for causal effect: smoking, which increases the risk of nuclear cataract, excessive UV-B exposure and diabetes that increase the risk of cortical cataract, and steroidal treatment, diabetes and ionizing radiation that lead to the formation of posterior subcapsular opacity. The working pattern leads to trauma to cornea⁹⁻¹².

Table 6: 21% of group A patients had posterior segment changes compared to 10.5% in group B. (Diabetic Retinopathy 10%, Hypertensive Retinopathy 5%, Age Related Macular Degeneration 6% In Group A compared to DR 6%, HTNR 2%, ARMD 3.5% in group). It showed that the incidence of posterior segment disease was more in group A compared to Group B. Ederer F¹⁹ also showed similar findings and this occurs because poor control of Diabetes and Hypertension leads to retinopathy and thus compromises post-operative visual outcome.²⁰

Table 7: Comparison of grade of cataract: In Group A, 97 patients had Grade 3 cataract followed by 53 patients who had Grade 2 cataract while in Group B, 91 patients had Grade 2 cataract while 49 patients had Grade 3 cataract, which was statistically significant. Kevin M Mundy ^(11,21,22) showed similar observation in their study.

Table 8: Comparison of intra op complications: In Group A, the incidence of hyphema was 1%, Posterior Capsular Rupture (2.5%) and Zonular dailysis (2%) whereas in group B it was hyphema (1%), however these results were not statistically significant²³.

Table 9: Post op BCVA of 6/6 after 6 weeks in group B (84%) was found to be better than in group A (69.5%) because in this group patients had more anterior and posterior segment abnormality which resulted in subnormal vision.

Pre-op assessment in terms of visual acuity, anterior segment and fundus pathology, and grading of cataract between non-paying (A) and paying (B) showed variations & was significant (p < 0.0001).

No significant difference was noted in intra-operative complications.

Significant difference was observed in post op BCVA which was found to be better in patients operated under paying scheme as compared to non-paying scheme, when assessed postoperatively in the 6th week (p<0.0001).

DISCUSSION

Principal findings & Interpretation and comparison with other research studies:

Implications for clinicians and policymakers

Strengths and limitations of the study

Principal findings & Interpretation and comparison with other research

In most other studies, cataract surgery was associated with older age. Paying patients who mostly belonged to urban areas and were more literate have been found to be associated with better post op visual outcome in other studies in India and Nepal. With respect to visual outcome, education/ literacy, it was significant in all surveys. Gender was not a significant predictor of surgical outcome in the present study. This is in general contrast with a meta-analysis of various population-based surveys showing that surgical coverage among genders was 1.2–1.7 times higher among males compared to females. This is a positive trend as women in India, like in most of South Asia face social discrimination. If cataract surgical coverage is similar among males and females, it would mean that women also have equal access to surgical services as men.

In our study, cataract surgery produced much better visual outcomes compared with those in non-paying patients in China (both Shunyi and Doumen). The proportion of eyes with pre op VA of > 6/18 was 3% in non-paying patients as compared to 19% in paying patients. This rate in paying patients was lower than those in Doumen (36.2%) and Shunyi (42.1%), Bangladesh (58.7%), Hong Kong (59.6%), Beijing Eye Study (79.7%, 106/133 eyes, had a PVA of > 6/18). This result could in part be explained by differences in the study population and quality of eye care service.

Implications for clinicians and policymakers

To further increase access to cataract surgery services and thus eventually improve visual outcome, the addition of outreach free clinic screening points, in distant districts and addressing hidden costs by providing transportation may prove effective. Low health awareness in non-paying patients may be a barrier to seeking healthcare and use of services, including cataract surgery. Programme policies should focus on providing intensive counselling and improving the understanding of cataracts through community-based education opportunities to increase the likelihood of seeking surgery.

Strengths and limitations of the study

Strengths of our study include its access to detailed preoperative, perioperative and postoperative medical data for all patients. Among its limitations is the fact that information regarding the participants' knowledge of cataract and cataract surgery and awareness of local eye care services was not obtained. These factors may have influenced the uptake of cataract surgery in ways we are unable to measure. These results likely reflect the case scenario in a rural tertiary care hospital, and may be applied to other populations only with care.

CONCLUSION AND IMPLICATIONS

In our study, the visual outcomes after cataract surgery were better in Group B. Anterior segment and posterior segment abnormalities were the major causes for subnormal outcomes in group A.

Due to better awareness, literacy, occupational constraints, paying patients presented early with least associated features (i.e. pterygium, PXF, corneal degenerations, opacities, higher grade & maturity of cataract, lens induced glaucoma etc.) and they were capable of paying for treatment at an appropriate time and also followed-up regularly, which ultimately resulted in best possible post-op visual outcome.

While non-paying patients being ignorant, illiterate, with increased exposure to UV rays and lack of adequate follow-up, have more associated features leading to guarded visual prognosis.

There is a need to enhance the cataract surgery program to include adequate infrastructure for postoperative monitoring and appropriate management. By improving this facility, the prevalence of visual impairment in non-paying group can be minimized.

Cataract outcomes can be definitely improved with a good follow-up component in the cataract blindness program that results in elimination of the treatable causes for poor outcomes.

Blindness prevention programs targeting the rural elderly should be expanded, particularly in areas with limited access Special emphasis should be given to reaching women and those without education. Greater attention should also be given to correction of refractive errors.

Cataract surgery has been shown to have significant positive functional, social, and economic implications for patients.

This information is crucial for improving and expanding the management of cataract surgery programmes in rural areas of Wardha District.

RESULTS

Table 1: Age wise distribution of patients

Age(years)	Group A	Group B	v2-value	p-value	
41-50	2(1%)	1(0.5%)			
51-60	50(25%)	77(38.5%)			
61-70	112(56%)	97(48.5%)			
71-80	33(16.5%)	21(10.5%)			
>80	3(1.5%)	4(2%)	9.96	0.05	
Total	200 (100%)	200 (100%)	5.50	NS,p>0.05	
Mean Age	65.73	63.26			
SD	7.17	7.38			
Range	50-85	50-86			

Table 2: Gender wise distribution of patients

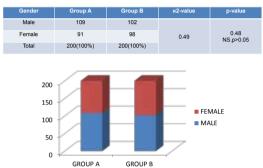
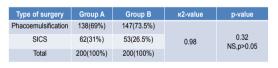


Table 3: Type of surgery



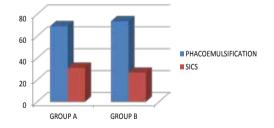


Table 4: Pre operative BCVA

p-value	א2-value		Group B		Group A	V/A
0.0001, S, p<0.05		5.5	11	1	2	6//12
		13.5	27	2	4	6//18
		15	30	6	12	6//24
		30	60	25	50	6//36
	54.83	26	52	53.5	107	6//60
		7.5	15	6	12	3/60
		2.5	5	6.5	13	PL
		100	200	100	200	Total

Table 5: Comparison of pre op anterior segment examination

Exam	Group A	%	Group B	%	א2-value	p-value	
CD	17	8.5	4	2	9.78		
со	12	6	2	1		0.044, S, p<0.05	
PXF	6	3	4	2			
Posterior synechiae	12	6	8	4			
Normal	153	76.5	182	91			
Total	200	100	200	100			

Table 6: Comparison of pre op fundus examination

Fundus	Group A	%	Group B	%	א2-value	p-value	
Mild NPDR	7	3.5	10	5	25.82		
Moderate NPDR	10	5	2	1			
Severe NPDR	3	1.5	0	0		0.0001, S, p<0.05	
Grade 2 HR	8	4	4	2			
Grade 3 HR	2	1	0	0			
ARMD	13	6.5	7	3.5			
Not visible	38	19	19	9.5			
Normal	119	59.5	158	79			
Total	200	100	200	100			

Table 7: Comparison of post op fundus examination

Fundus	Group A	%	Group B	%	v2-value	p-value	
Mild NPDR	7	3.5	11	5.5	17.65	0.0072, S,	
Moderate NPDR	11	5.5	2	1			
Severe NPDR	3	1.5	0	0			
Grade 2 HR	9	4.5	4	2			
Grade 3 HR	2	1	0	0			p<0.05
ARMD	15	7.5	8	4			
Normal	153	76.5	175	87.5			
Total	200	100	200	100			

Table 8: Comparison of post op Visual Acuity at 6 weeks

Post Op V/A	Group A		Group B	%	א2-value	p-value	
6/60	2	1	0	0	17.92	0.0064 S, p<0.05	
6/36	10	5	2	1			
6/24	6	3	4	2			
6/18	4	2	1	0.5			
6/12	7	3.5	1	0.5			
6/9	32	16	24	12			
6/6	139	69.5	168	84			
Total	200	100	200	100			

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