

Cost-effectiveness analysis should continually assess competing health care options especially in high volume environments like cataract surgery

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Context: Cost-effectiveness analysis should continually assess competing health care options especially in high volume environments like cataract surgery. **Aims:** To compare the cost effectiveness of phacoemulsification (PE) versus manual small-incision cataract surgery (MSICS). **Settings and Design:** Prospective randomized controlled trial. Tertiary care hospital setting. **Subjects and Methods:** A total of 52 consenting patients with age-related cataracts, were prospectively recruited, and block randomized to PE or MSICS group. Preoperative and postoperative LogMAR visual acuity (VA), visual function-14 (VF-14) score and their quality-adjusted life years (QALYs) were obtained, and the change in their values calculated. These were divided by the total cost incurred in the surgery to calculate and compare the cost effectiveness and cost utility. Surgery duration was also compared. **Statistical Analysis Used:** Two group comparison with Student's *t*-test. Significance set at $P < 0.05$; 95% confidence interval (CI) quoted where appropriate. **Results:** Both the MSICS and PE groups achieved comparative outcomes in terms of change (difference in mean [95% CI]) in LogMAR VA (0.03 [-0.05-0.11]), VF-14 score (7.92 [-1.03-16.86]) and QALYs (1.14 [-0.89-3.16]). However, with significantly lower costs (INR 3228 [2700-3756]), MSICS was more cost effective, with superior cost utility value. MSICS was also significantly quicker (10.58 min [6.85-14.30]) than PE. **Conclusions:** MSICS provides comparable visual and QALY improvement, yet takes less time, and is significantly more cost-effective, compared with PE. Greater push and penetration of MSICS, by the government, is justifiably warranted in our country.

Key words: Cost-effectiveness, manual small incision cataract surgery, phacoemulsification, quality adjusted life year, visual function-14

Undoubtedly, better health services improve health. It is often the available resources that become the limiting factor when one has to choose between competing options. To maximize health outcomes, vis-à-vis the costs, decision makers use health economics to compare and rate different programs.^[1]

Various methods to compare the relative costs as well as health gains of different health interventions such as cost-benefit analysis (CBA), cost-effectiveness analysis (CEA), cost utility analysis (CUA), cost efficiency analysis and cost minimization analysis exist.^[2] CBA compares both the costs and benefits that accrue in monetary terms. CUA assesses both technical and allocative efficiency within the health care sector: The basic outcome is "healthy years." The years of life in states less than full health can be converted to healthy years by the use of various techniques like quality-adjusted life years (QALYs) and disability-adjusted life years DALYs.^[1] The idea behind QALY is that it assumes that a year of life lived in perfect health is worth 1 QALY (1-year of life \times 1 utility value = 1 QALY) and that a year of life lived in a state of less than this perfect health is worth <1 .

The weight values are usually determined in three common ways: In time-trade-off,^[3] the individual is asked to choose between remaining in a state of ill-health for a period of time, or being restored to perfect health but with a shorter life expectancy; standard gamble requires a respondent to trade

off the certainty of being in an intermediate health state for his remaining life expectancy with a "treatment" which offers a chance of regaining full health for his remaining life expectancy but that also entails a risk of immediate death;^[4] finally, an individual is asked to rate a state of ill health on a visual analog scale (VAS) from 0% to 100%, with 0 representing death and 100 representing perfect health. The last has the advantage of being easiest to ask but is the most subjective.^[5]

Quality adjusted life years can be incorporated with medical costs to reach a final common denominator of cost/QALY which can be used to develop a CEA of any intervention. CEA concentrates on one major desired outcome or benefit in terms of effectiveness rather than valuing it in terms of money. It is particularly useful to evaluate different interventions for the same disease to identify which one is better both in terms of cost and health gain, and is an important aid to public health decision making.

The WHO also recommends the CEA approach to evaluate a range of health interventions,^[6] especially when confronted with competing alternatives in the face of scarce resources. CEA

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has been extensively used in all fields of health care, including ophthalmology. Cataract surgery is a routine intervention, the demand for which is expected to increase strongly as the population is ageing.^[7,8] Phacoemulsification (PE) is considered the standard of care for cataract surgery in the developed world.^[9] Costs, in terms of equipment, consumables, and training, has limited its use in the developing world, in contrast to manual small incision cataract surgery (MSICS).

We evaluated the cost-effectiveness of PE (with foldable intraocular lenses [IOLs]) versus MSICS (with rigid IOLs), from the point of view of the limited finances available in the university's health scheme; and also because we found such studies to be few and far from our country.

Subjects and Methods

After obtaining clearance from the institutional review board, 52 consenting patients with age-related cataracts, were prospectively recruited and block randomized to PE group or MSICS group. We included patients of ≥ 40 years, with an operable cataract; and excluded those with ocular co-morbidity likely to impact vision, such as corneal opacity, maculopathy or macular edema; also excluded were patients who failed to comprehend our questionnaire or those refusing participation. Detailed biomicroscopy and ophthalmoscopy were undertaken, including dry and wet retinoscopy and LogMAR visual acuity (VA). Preoperatively, the patients were scored on the visual function-14 (VF-14) questionnaire (served in colloquial Hindi),^[10] and their QALYs were calculated as the product of the VAS and life expectancy.^[11] A similar exercise was carried out at 4–6 weeks postoperatively, to obtain a change in score on the VF-14 and in QALYs.

The costs of surgery were calculated using 2012–2013 as the base year: And included the combined costs incurred by the hospital (capital costs) and the patient. Capital costs included the cost of building, equipment (surgical microscopes, PE machine, and surgical instruments) and running-overtime (OT) costs (i.e., the cost of the personnel and electricity). Costs of building, personnel and electricity were aggregated and divided by the total available OT table time (in hours) to calculate the cost of OT table time/h (overhead rate). Total time of surgery was calculated from the time at an entry to exit from the OT: To which we added 1-h, assuming this would cover pre- and post-operative time in the OT environs. This was multiplied by the overhead rate to get the overhead costs. Cost of the equipment per patient was calculated by dividing the depreciated cost of the equipment by the average number of patients being operated in a year.

Salient details about the cost-calculations

Annual cost of OT building was INR 108,464.76 (using the PWD manual, and based on covered area). This cost for the whole year was divided by the product of 260 days (the average number of working days in a year) and 8 h (the average working hours in a day) to arrive at cost/h: $108,464.76 / (260 \times 8) = \text{INR } 52.14/\text{h}$.

Similarly, the hourly cost of electricity (INR 98.93/h) and manpower or personnel (INR 1320.98/h) was calculated.

Combined hourly cost of the building electricity and manpower was thus the sum of: $52.14 + 98.93 + 1320.98 = \text{INR } 1472.05/\text{h}$, now referred to as hourly overhead cost.

The cost of the equipment was calculated as the purchase price depreciated linearly over the life span of the equipment as suggested by Asimakis *et al.*^[12] The cost of the equipment per patient was calculated by dividing the cost for 1-year by the number of patients operated in 1-year. In the case of the PE machine, the annual cost was divided by the number of patients undergoing PE only: We obtained values of INR 435.3 in MSICS and INR 1602.98 in PE group.

Patient costs included hospital fees, laboratory charges, consumables and transportation costs and included cost due to loss of wages of the patient and accompanying attendant; with the last being nil in the case of unemployed. Patient costs were split into direct costs (IOL cost + cost of other consumables + investigation and admission charges) and indirect costs (travel costs + loss of wages); since we were interested in the former, because that is, the amount reimbursed by our university.

Our main outcome measures thus were costs per unit change in QALYs, VF-14 scores and LogMAR VA, which were compared between PE and MSICS groups using *t*-tests, with significance set at $P < 0.05$.

Results

Age distribution, LogMAR best corrected VA (BCVA), VF-14 scores, life expectancy and QALYs were similar in the two groups at baseline [Table 1]. Gender-wise distribution was similar: Females were 57.69% (15 of 26) in MSICS and 50% (13 of 26) in PE group ($\chi^2 P = 0.78$).

Postoperative LogMAR BCVA, QALYs, and VF-14 scores are depicted and compared between groups in Table 2.

Between groups, comparison of change of LogMAR BCVA, QALYs, and VF-14 scores, from preoperative to postoperative values, are shown in Table 3.

In our study, PE (duration in minutes: Mean [standard deviation (SD)]: 45.35 [6.39]) took significantly longer, compared to MSICS (34.77 [6.98] min): Mean difference (10.58 min, 95% confidence interval [CI] for difference: 6.85–14.30 min; $P < 0.001$).

The group-wise comparative cost of surgery, rounded off to the nearest rupee, is presented in Table 4.

Cost for one unit gain in LogMAR BCVA, VF-14 scores and QALYs in both the groups is shown in Table 5.

Discussion

In our study, both the MSICS and PE groups achieved comparable outcomes [Table 2]. The mean change in LogMAR BCVA at 6 weeks was 0.7 (SD = 0.11) in MSICS and 0.67 (SD = 0.17) in PE group ($P = 0.46$) [Table 3]. The mean postoperative LogMAR BCVA was 0.17 (SD = 0.07) in MSICS group and 0.15 (SD = 0.05) in PE group ($P = 0.30$) [Table 2]. Gogate in a randomised controlled trial (RCT) in Nepal found no significant differences in proportion with BCVA $> 6/18$ at 6 weeks postoperatively: 184 of 187 (98.4%) in MSICS and 182 of 185 (98.4%) in PE group ($P = 0.549$).^[13] Khanna reported equivalent proportion of patients with BCVA $> 6/12$ Snellen in the two groups: 84.3% (440 of 522) in MSICS and 88% (446 of 507) in PE group ($P = 0.09$).^[14]

Table 1: Baseline characteristics of patients in MSICS (n=26) and PE (n=26) groups

Variable	MSICS		PE	
	Mean (SD)	Median (minimum-maximum)	Mean (SD)	Median (minimum-maximum)
Age in years	60.46 (11.79)	60.00 (40-84)	59.50 (8.72)	60.00 (40-77)
Life expectancy in years	17.82 (7.71)	16.60 (6.40-34.60)	17.63 (6.60)	15.50 (7.90-34.60)
Preoperative LogMAR BCVA	0.87 (0.15)	0.92 (0.60-1.00)	0.82 (0.17)	0.78 (0.48-1.00)
Preoperative QALYs*	7.44 (5.97)	5.82 (1.00-23.33)	8.52 (4.63)	7.15 (2.50-20.76)
Preoperative VF-14 [†] score	44.67 (21.39)	39.28 (16.66-81.81)	53.57 (15.37)	55.63 (22.22-75.00)

*QALYs: Quality adjusted life years, [†]VF-14: Visual function-14 questionnaire, MSICS: Manual small incision cataract surgery, PE: Phacoemulsification, SD: Standard deviation, BCVA: Best corrected visual acuity

Table 2: Comparison of postoperative LogMAR BCVA (VA), QALYs and VF-14 core between MSICS and PE groups

Variable	Mean (SD)		Mean difference (95% CI)	P
	MSICS	PE		
Postoperative LogMAR BCVA	0.17 (0.07)	0.15 (0.05)	0.02 (-0.02-0.05)	0.30
Postoperative QALYs	15.25 (6.34)	15.19(6.10)	0.05 (-3.41-3.52)	0.97
Postoperative VF-14 score	88.04 (6.63)	89.01 (6.01)	-0.97 (-4.50-2.55)	0.58

QALYs: Quality adjusted life years, VF-14: Visual function-14, MSICS: Manual small incision cataract surgery, PE: Phacoemulsification, SD: Standard deviation, BCVA: Best corrected visual acuity, CI: Confidence interval, VA: Visual acuity

Table 3: Comparison of gains in LogMAR BCVA, QALYs and VF-14 scores following surgery in MSICS (n=26) and PE (n=26) groups

Variable	Mean (SD)		Difference in mean change (95% CI)	P
	MSICS	PE		
Change in LogMAR BCVA	0.70 (0.11)	0.67 (0.17)	0.03 (-0.05-0.11)	0.46
Change in QALYs	7.81 (4.19)	6.67 (2.97)	1.14 (-0.89-3.16)	0.26
Change in VF-14 score	43.37 (19.38)	35.45 (11.85)	7.92 (-1.03-16.86)	0.08

QALYs: Quality adjusted life years, VF-14: Visual function-14, MSICS: Manual small incision cataract surgery, PE: Phacoemulsification, SD: Standard deviation, BCVA: Best corrected visual acuity, CI: Confidence interval

Table 4: Comparison of the costs (in INR) incurred in MSICS and PE groups

Type of costs in INR (per surgery)	Mean (SD)		Mean difference (95% CI)	P
	PE	MSICS		
Patient costs				
Direct	3638 (574)	2235 (185)	1404 (1166-1641)	<0.001
Indirect	2931 (669)	2534 (845)	397 (27-822)	0.066
Capital costs				
Overhead	2584 (157)	2325 (171)	259 (168-351)	<0.001
Equipment	1603 (0.00)	435 (0.00)	1168 (1168-1168)	<0.001
Total costs	10756 (1001)	7528 (893)	3228 (2700-3756)	<0.001

MSICS: Manual small incision cataract surgery, PE: Phacoemulsification, SD: Standard deviation, CI: Confidence interval

Likewise, Ruit *et al.* in his RCT found no difference in the proportion of patients with BCVA $\geq 20/60$ in the two groups: 98% in each.^[15] Similarly Jongsareejit *et al.*, Ang *et al.* and Venkatesh *et al.* in their respective studies found MSICS to be safe and effective.^[16-18]

By 4–6 weeks, there was a similar gain in QALYs in both our groups: A mean change of 7.81 (SD = 4.19) in MSICS group and 6.67 (SD = 2.97) in PE group ($P = 0.26$) [Table 3]. There was also increment in VF-14 score with a nonsignificant difference in mean change of 43.37 (SD = 19.38) in MSICS group and 35.45 (SD = 11.18)

in PE group ($P = 0.08$) [Table 3]. Manaf *et al.* in an RCT in Malaysia reported a significant, but comparable increase in VF-14 scores 6 weeks postcataract surgery, in both extracapsular cataract extraction (ECCE) and PE: A mean increase in VF-14 scores of 32.71 in ECCE and 27.03 in the PE ($P = 0.225$).^[19] Unlike us, their study had ECCE as the comparator, while we had MSICS.

In our study, time-wise, PE duration was significantly longer compared to MSICS by on average 10.58 min (95% CI: 6.85–14.30). Ruit *et al.* and Venkatesh *et al.* in their respective studies also found that MSICS was quicker than PE.^[15,20]

Table 5: Comparison of cost per unit gain in LogMAR BCVA, VF-14 score and QALYs in MSICS (n=26) and PE (n=26) groups

Variable	Mean (SD)		Mean difference (95% CI)	P
	MSICS	PE		
Cost per gain in LogMAR BCVA	10995 (2038)	17170 (5199)	-6175 (-8375 to -3975)	<0.001
Cost per QALY gained	1372 (1150)	2062 (1263)	-691 (-1363 to -18)	0.04
Cost per VF-14 score increment	235 (162)	345 (138)	-110 (-194 to -26)	0.01

QALYs: Quality adjusted life years, VF-14: Visual function-14, MSICS: Manual small incision cataract surgery, PE: Phacoemulsification, SD: Standard deviation, BCVA: Best corrected visual acuity, CI: Confidence interval

The direct costs to the patients were significantly more for PE compared to MSICS, by on average INR 1404 ($P < 0.001$) [Table 4]. This is largely on account of differences in cost of IOLs. Ruit *et al.* in their study also found similar results.^[15] Given an average of 775 cataract cases (on the basis of average of the last 3 years (2011–2013) data at our institution) being operated in a year, if all the cases were to undergo PE, the total direct costs would be INR 2,819,450 (775×3638 i.e., average number of cases operated annually \times direct costs in PE). Similarly, the total direct costs would be INR 1,732,125 if all the cases would undergo MSICS. In such a hypothetical situation, if everyone opted for MSICS instead of PE, in terms of direct costs (which are the costs funded by sponsoring agencies) there would be a net saving of INR 1,087,325 annually. These direct costs are usually reimbursed by the health scheme resources. We believe these resources could be directed toward more cost effective alternatives not only in the field of ophthalmology but other medical treatments too. Likewise, the overhead cost was significantly higher in the PE group by INR 259 ($P < 0.001$). Furthermore, the cost of the equipment was significantly greater by INR 1168 ($P < 0.001$) in the PE group, essentially due to the inclusion of the cost of the PE machine. Ruit *et al.*, Gogate *et al.* and Muralikrishnan *et al.* in their studies also found the cost of equipment to be higher in PE group.^[15,21,22] In our study, the total cost per surgery was found to be significantly higher in the PE group by INR 3228 ($P < 0.001$).

Comparison of cost per unit increment in VF-14 score gained in the two groups showed it to be higher in the PE group by INR 110.0 ($P = 0.01$), implying that MSICS is a more cost effective option. Manaf *et al.* in his RCT also calculated cost per VF-score gained, and found it to be US \$14 for ECCE as compared to US \$20 for PE, and like us, concluded that ECCE was more cost effective than PE.^[19] Our study also showed the cost per gain in LogMAR BCVA to be significantly higher in PE group by INR 6175 ($P < 0.001$) [Table 5]. It makes for more intuitive understanding if we compare costs per line LogMAR gained (each line being equivalent to 0.1 LogMAR): Thus PE was costlier by an average of INR 618 for each line VA gained on the LogMAR chart compared to MSICS.

The cost-utility was significantly ($P = 0.04$) superior in MSICS (INR 1372 per QALY gained) compared to PE (INR 2062 per QALY gained).

In health programs, where there is chronic scarcity of funds, as evidenced by a 20% reduction in health from the annual national budget (India Today December, 2014), interventions which are cheaper and yet provide equally good outcomes should be adopted and actively propagated. Our study shows that MSICS is comparably as effective as PE in terms of visual rehabilitation and increasing the quality of life in cataract

patients. However, MSICS is significantly less expensive and does not require the capital expenditure and maintenance of PE machine which requires a dependable source of energy, which is usually a limiting factor in developing countries. Training in PE also has a steeper learning curve.^[13] The foldable IOLs used in PE are also far more expensive than the rigid polymethyl methacrylate IOLs used in MSICS. Treating cataract in the developing world is a formidable challenge with significant barriers like cost, lack of awareness and shortage of trained personnel. MSICS with its shorter surgical time and its requirement for less expensive and less technology dependent equipment can help in overcoming this challenge. Health care expenditures are continuously rising throughout the world. Regular cost-effectiveness studies should be carried out in various fields to look for the best intervention amongst the alternatives. This will ensure proper channelization of resources for a sustainable growth in the medical field.

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Conflicts of interest

There are no conflicts of interest.

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