



Outcome Report

On

“Health Technology Assessment of Intraocular Lenses for treatment of Age-related Cataracts in India”

**Health Technology Assessment in India (HTAI) Secretariat,
Department of Health Research,
Ministry of Health and Family Welfare**

**July-2018
New Delhi**

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On**

**“Health Technology Assessment of intraocular lenses for
treatment of age-related cataracts in India”
(July 2018)**

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List of Abbreviations

AIIMS	All India Institute of Medical Sciences
BCVA	Best Corrected Visual Acuity
DALY	Disability Adjusted Life Years
DHR	Department of Health Research
ECCE	Extra-capsular Cataract Extraction
FLACS	Femtosecond Laser-Assisted Cataract Surgery
GGSGH	Guru Gobind Singh Government Hospital
HRQoL	Health-related Quality of Life
HTA	Health Technology Assessment
ICCE	Intra-capsular Cataract Extraction
ICER	Incremental Cost Effectiveness Ratio
IND-VFQ-33	33 Item Indian Visual Function Questionnaire
INR	Indian Rupee
IOL	Intra Ocular Lens
LHMC	Lady Hardinge Medical College
MSICS	Manual Small Incision Cataract Surgery
OOP	Out of Pocket (expenditures)
PCO	Posterior Capsular Opacification
PGIMER	Post Graduate Institute of Medical Education & Research
Phaco	Phacoemulsification
PMMA	Poly Methyl Methacrylate
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
QALY	Quality Adjusted Life Years
QoL	Quality of Life
RAAB Survey	Rapid Assessment of Avoidable Blindness Survey
RCT	Randomized Controlled Trial
RSBY	Rashtriya Swasthya Bima Yojna
SECH	Shroff Eye Care Hospital
SICS	Small Incision Cataract Surgery
UCVA	Uncorrected Visual Acuity
USD	United States Dollar
VA	Visual Acuity
VF	Visual Function
VRQoL	Vision-related Quality of Life
WHO	World Health Organization

Introduction

Background: According to World Health Organization (WHO) definition, cataract is clouding of the lens of the eye, which impedes the passage of light. As per WHO estimates 285 million people are visually impaired worldwide: 39 million are blind and 246 have low vision (1). Cataract is the leading cause of blindness (51%) and low vision (33%) worldwide(1). About 90% of the World's visually impaired live in low-income settings(1,2). Of the disability-adjusted life years (DALY) due to cataract more than 90% are in the developing world(3).

The prevalence of blindness in India is around 1% where cataract contributes for almost 60-70%(4,5). According to rapid assessment of avoidable blindness survey (RAABs) done in 2006 in India the prevalence of blindness (vision,3/60 in the better eye presenting vision) among those aged 50 years and over was 3.6%(4).This is significantly lower than the prevalence reported in a national survey over the period 1999–2001 where a detailed eye examination was undertaken (5.3%; 95% CI: 5.1–5.6)(5)and a rapid assessment in 1998 which covered most of the highly populated states in India (5.24%; 95% CI: 4.98–5.62)(6). Prevalence of severely visually impaired (vision,6/60 to 3/60 in the better eye) was found to be 4.4% and low vision (6/18 to 6/60 in the better eye) was 16.8% (4).As per the ongoing national blindness survey 2017-2018, the prevalence of blind people above age 50 Years is coming around 2% whereas the overall prevalence of blindness has reduced to almost 0.25% but cataract is still as prevalent as 65% (Personal communication with the survey coordinator Dr Praveen Vashisht, AIIMS, New Delhi).

Rashtriya Swasthya Bima Yojana (RSBY): Government of India has introduced RSBY, a Health Insurance Scheme in early 2008, for the Below Poverty Line families with the objectives to reduce out of pocket (OOP) expenditure on health and increase access to health care(7). Under RSBY, cataract is one of the most utilized packages in most of the states with a utilization rate from 16% to 36 %. RSBY offers four different packages for cataract ranging from 4000 to 7000 Indian Rupees (INR) (table 1) where cataract package “Cataract with foldable IOL by Phacoemulsification tech. Unilateral” of INR 7000 is most utilized cataract package.

Table 1. Cataract packages available under RSBY scheme

Cataract packages under RSBY	Package Rates
Cataract Unilateral	4000
Cataract with foldable IOL by Phacoemulsification tech. Unilateral	7000
Cataract surgery (SICS) Unilateral	6000
Cataract with IOL Unilateral	5000

Cataract Surgery: The surgical options available in India are intracapsular cataract extraction (ICCE), extracapsular cataract extraction (ECCE), manual small-incision cataract extraction (MSICS) and phacoemulsification (8). Cataract surgery by ICCE is declining rapidly(9). ECCE is still being performed for certain cases of cataract where other techniques are either not feasible or not available. However, the most commonly performed surgeries in India are Phacoemulsification and Small Incision cataract surgery.

Intraocular Lenses: Currently 90% of all the cataract surgeries are performed with Intraocular lenses (IOLs)(10).The devices can be classified as monofocal, multifocal or accommodative(11). Traditionally, monofocal (e.g., fixed focusing power) IOLs are available as replacement lenses. IOLs can be made up of a range of different materials. PMMA IOLs are inflexible, require a larger incision for implantation (5-7 mm requiring sutures) compared with newer foldable silicone (hydrophobic) and acrylic (hydrophobic or hydrophilic) lenses (2.8-3.5 mm and not requiring sutures). Most commonly implanted IOLs in India are rigid PMMA lenses and Acrylic foldable lenses.

Rationale of the study: Choice of cataract surgery and lenses in India are made depending upon the clinical, economic and social conditions of patients and surgeon's expertise, infrastructure available at clinic etc. It is quite evident that there is a lack of evidence in Indian context in comparative effectiveness and cost-effectiveness of various surgeries and IOLs for the treatment of age-related cataracts(12).Therefore rigorous and relevant research evidence is essential for planning cost-effective and scalable approaches. In order to bridge this gap in evidence base and inform the policy, a comprehensive Health Technology Assessment (HTA) study was undertaken to examine the comparative effectiveness and cost-effectiveness of various cataract surgeries and intraocular lenses (IOLs) for the treatment of age-related cataracts.

AIM AND OBJECTIVES

Aim: To assess the cost-effectiveness of benefit packages for treatment of age related cataract using various types of intra-ocular lenses over a lifetime horizon for the Indian population using a health sector as well as societal perspective.

Objectives:

- To assess clinical efficacy of different Intra ocular Lenses for cataract surgeries in term of their impact on Health related Quality of life. (QoL study)
- To compare cost of different lens with surgery (Costing study).
- To evaluate the cost effectiveness of different cataract surgeries including lenses.
- To evaluate the level of Visual Acuity for performance of Cataract Surgery in India.

Table2: Framework of the study including PICOT

Population	Age Related Cataract patients for whom IOL implantation will be performed after cataract extraction.
Intervention(s)	Cataract surgeries with Intraocular Lens implantation
Comparators	Cataract Surgery: MSICS/Phacoemulsification Intraocular Lens: Rigid PMMA Lenses, Foldable Acrylic Lenses
Outcomes	The outcome measures to be considered may include: Primary Outcomes: <ul style="list-style-type: none">• Effectiveness measure: Incremental Cost Effectiveness Ratio (ICER) and Net Health Benefit Secondary Outcomes: <ul style="list-style-type: none">• surgical complications• health-related quality of life<ul style="list-style-type: none">• Cost
Time horizon	<ul style="list-style-type: none">• Lifetime

Chapter 1
Clinical Effectiveness
Literature Review

Background: Cataract surgery is performed in India by using various techniques. Some of these techniques include intracapsular cataract extraction (ICCE), extracapsular cataract extraction (ECCE), manual small-incision cataract extraction (MSICS), phacoemulsification (Phaco) and femtosecond laser-assisted cataract surgery (FLACS). Two most commonly used techniques in India are Manual small-incision cataract extraction (MSICS) and Phacoemulsification. Phacoemulsification is more popular and easily available in urban areas while on the other hand, MSICS is a technique of choice in suburban and rural areas.

Similar to the choices available in case of surgical method for cataract extraction, there are choices available for type of intraocular lenses (IOLs) to be implanted after cataract extraction. IOLs available are be made up of a range of different materials. IOLs are also available with different focussing power such as monofocal, multifocal or accommodative.

Aim: To examine the comparative clinical effectiveness of various types of cataract surgeries and intraocular lenses (IOLs) for the treatment of age-related cataracts.

Methods:

Identification of studies: Strategies were designed to identify all relevant studies for comparing clinical effectiveness of various types of cataract surgeries and intraocular lenses. A list of comparators undertaken are given below. (Table 1)

Table 1. List of Comparators

S No.	Comparator
Comparison of Different types of Surgeries	
1	ECCE vs. MSICS
2	ECCE vs. Phaco
3	MSICS vs. Phaco
Comparison of Different types of Lenses	
4	Monofocal vs. Multifocal Lens
5	Accommodative vs. Monofocal Lens
6	Rigid vs. Foldable Lens
7	Hydrophobic Acrylic vs. Hydrophilic Acrylic

Literature Search: The databases searched for published studies and ongoing research were: The Cochrane Library including the Cochrane Database of Systematic Reviews (CDSR), Cochrane Central Register of Controlled Trials (CENTRAL), the NHS Economic Evaluation Database (NHS EED), and the Health Technology Assessment (HTA) database, MEDLINE, ClinicalTrials.gov, Current Controlled Trials, and World Health Organization International Clinical Trials Registry Platform (WHO ICTRP). Searches were limited to Systematic Reviews, Meta-analysis, randomised controlled trials (RCTs) for the assessment of clinical effectiveness. The electronic databases were last searched on 30 September 2017.

Inclusion Criteria: The studies were included based on the following criteria:

- Population: Adult patients with age-related cataracts.
- Comparators: as given in Table 1.
- Intervention: Cataract surgeries and Intraocular Lenses.
- Outcomes: distance visual acuity (best corrected distance visual acuity), near visual acuity (best distance corrected near visual acuity) , contrast sensitivity, depth of field, glare, quality of life, visual function, spectacle dependence, posterior capsule opacification and other surgical complications, cost.

Study design:

- Latest, published, systematic reviews and meta-analysis relevant to each comparison of interest were considered as first priority.
- For the comparison of interest where no relevant systematic review or Meta-analysis was available, randomised clinical trials were searched and were eligible for inclusion.

Critical appraisal strategy: The methodological quality of included systematic reviews was assessed using revised AMSTAR (R-AMSTAR) tool(13). The risk of bias of the included RCT was assessed using criteria devised by the Cochrane Collaboration(14).

Method of data synthesis: Clinical effectiveness data were synthesised through narrative review that included critical appraisal of study methods and tabulation of the results of included studies.

RESULTS:

Results of the search: The electronic searches yielded a total of 268 citations. After de-duplication, titles and abstracts of 112 references were screened. Of these, 58 were excluded after inspection of the full article. Main reason for exclusion of articles was either the

comparators or the outcomes were not relevant to the review. Some records were excluded on the basis of study design. RCTs where randomization and allocation concealment were not described clearly and the data was insufficient for analysis were also excluded. We obtained and screened full-text copies of 54 references and finally 11 studies were included in our evidence based analysis (Figure 1).

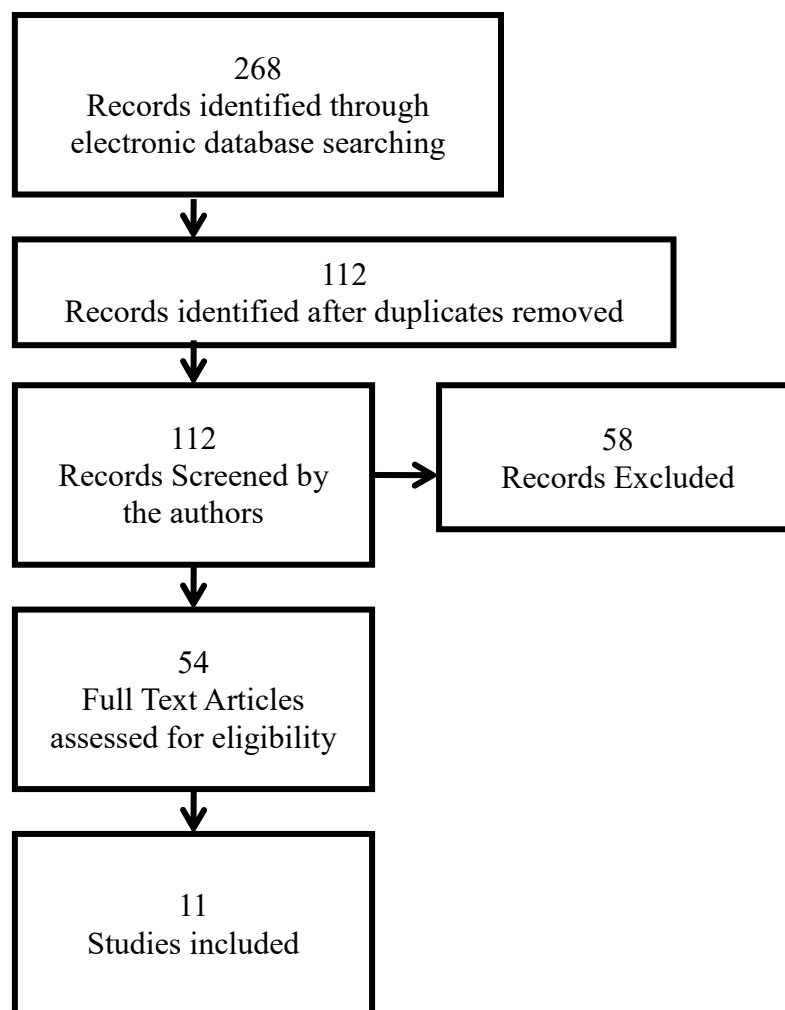


Figure1. Flow chart for the identification of studies

Overview of the included studies: Systematic reviews and meta-analysis were available for all comparison of interest except for rigid vs. foldable lenses. However, one RCT comparing rigid vs. foldable lens met the inclusion criteria and was thus included in this review. Following are the details of evidences available related to each comparison of interest(Table 2).

Table 2. Details of evidences available related to each comparison of interest.

S.No	Reference	Type of Study	Comparing what
Comparison of Different types of Surgeries			
1	Ang et al 2014 (15)	Cochrane Systematic Review	ECCE vs. MSICS
2	Silva et al 2014 (16)	Cochrane Systematic Review	ECCE vs. Phacoemulsification
3	Riaz et al 2013(17)	Cochrane Systematic Review	MSICS vs. Phacoemulsification
4	Gogate et al 2015(18)	Meta-analysis	
5	Ye Z et al 2015(19)	Meta-analysis	
6	Zhang et al 2013(20)	Meta-analysis	
Comparison of Different types of Lenses			
7	Silva et al 2016(21)	Cochrane Systematic Review	Monofocal vs. Multifocal
8	Ong et al 2014 (22)	Cochrane Systematic Review	Accommodative vs. Monofocal
9	Hennig et al 2014(23)	Randomised controlled trial	Rigid vs. Foldable Lens after Phacoemulsification
10	Findl et al 2010(24)	Cochrane Systematic Review	Different properties of IOLs for preventing PCO
11	Ying L et al 2013(25)	Meta-analysis	Hydrophobic vs. Hydrophilic Acrylic Lens for PCO Reduction

Main Findings:**Comparison of different types of cataract surgeries (ECCE, MSICS, and Phacoemulsification):**

1. In terms of post-operative visual acuity and post-operative complications both MSICS and Phaco stands out to be better as compared to ECCE(15,16). MSICS and Phaco results in almost similar outcomes in terms of post-operative visual acuity (both UCVA and BCVA) and post-operative complications (astigmatism, endothelial cell loss, post-operative capsular rupture, and corneal oedema) (17).
2. Phaco is costlier than ECCE and MSICS (18).

3. The average time for MSICS was lower than phaco and cost was less than that of phaco (19,20).

Comparison of different types of Intraocular Lenses:

Monofocal vs. Multifocal Lenses: Both monofocal and multifocal lenses provides almost similar distant vision. A better near vision and less spectacle dependence may be achieved with multifocal as compared to monofocal lenses. Adverse events like glare and haloes are more prevalent and more troublesome with multifocal as compared to monofocal lenses(21).

Accommodative vs. Monofocal Lenses: A superior clinical effectiveness of accommodative lenses over standard monofocal lenses was not proven (22).

Rigid vs. Foldable Lenses after Phacoemulsification: Cost of the foldable IOL was many times higher than the PMMA IOL with no additional clinical benefit when implanted after phacoemulsification (23).

Posterior capsule opacification: There are no clear differences in PCO scores between the different IOL optic materials (PMMA, hydrophilic acrylic, hydrophobic acrylic, silicone)(24,25).

Quality assessment of included studies:

Total 11 studies were included in the current review consisting of Cochrane Systematic Review 6, Non Cochrane Systematic Review 4, and one Randomized Clinical Trial.

Quality assessment of Systematic Review/Meta-analysis: The methodological quality of included systematic reviews and meta-analysis were assessed using revised *AMSTAR* (*R-AMSTAR*) tool (13).*R-AMSTAR* checklist contained eleven questions with regard to the quality of the review. Each question was answered based on 3 to 5 criteria defined with each question. Every question was assigned a score from one to four. The sum of all scores was the overall quality score of the systematic review. Table 3 shows the total score assigned to individual reviews.

Table 3: Quality assessment of Systematic Review/Meta-analysis using *R-AMSTAR* checklist

S.No.	Reference (Comparators)	Type of Study	Total Score
1	<i>Ang et al 2014</i> (15) (ECCE vs. MSICS)	Cochrane Systematic Review	42
2	<i>Silva et al 2014</i> (16) (ECCE vs. Phaco)	Cochrane Systematic Review	43
3	<i>Riaz et al 2013</i> (17) (MSICS vs. Phaco)	Cochrane Systematic Review	41
4	<i>Silva et al 2016</i> (21) (Monofocal vs. Multifocal)	Cochrane Systematic Review	40
5	<i>Ong et al 2014</i> (22) (Accommodative vs. Monofocal)	Cochrane Systematic Review	36
6	<i>Findl et al 2010</i> (24) (Different properties of IOLs for preventing PCO)	Cochrane Systematic Review	38
7	<i>Gogate et al 2015</i> (18) (MSICS vs. Phaco)	Non Cochrane Meta-analysis	30
8	<i>Ye Z et al 2015</i> (19) (MSICS vs. Phaco)	Non Cochrane Meta-analysis	33
9	<i>Zhang et al 2013</i> (20) (MSICS vs. Phaco)	Non Cochrane Meta-analysis	37
10	<i>Ying L et al 2013</i> (25) (Hydrophobic versus Hydrophilic Acrylic Lens for PCO Reduction)	Non Cochrane Meta-analysis	36

Quality assessment of randomized clinical trial: Overall, the methodological quality of the trial (23) was judged to be good with a low risk of bias. Table 4 shows the judgements of risk of bias in the various domains. Figure 2 represents risk of bias assessments for this trial study.

TABLE 4: Assessment of risk of bias (adapted from Higgins and Altman)(26)

Cochrane criteria for assessment of risk of bias in RCTs		
	Judgement	Support for judgement
Selection bias <ul style="list-style-type: none"> • Random sequence generation • Allocation concealment 	Low Risk Low risk	“Computer generated using Microsoft Excel random function.” “The allocation was delivered in serially numbered, sealed opaque envelopes, each containing an adhesive label with the study number and allocation.”
Performance bias <ul style="list-style-type: none"> • Blinding of participants and personnel 	Low risk	Patients were blinded. The surgeons were not blinded. This is not possible to mask the operating surgeon; we judge that this would not have important effect on risk of bias.
Detection bias <ul style="list-style-type: none"> • Blinding of outcome assessment 	Low risk	All patients were examined on the HS not involved in the surgery. HS was not masked to treatment status as the type of surgery was clear on examination. They could make out the type of operation but were unaware of the hypothesis being tested. Since outcome of visual acuity is an objective outcome, it would not lead to detection bias
Attrition bias <ul style="list-style-type: none"> • Incomplete outcome data 	High risk	Low proportion of withdrawals and participants not receiving allocated treatment. Outcome was assessed in 81.7% and 84.3%. 102 and 87 patients were not tracked. This could result in a small attrition bias.
Reporting bias <ul style="list-style-type: none"> • Selective reporting 	Low risk	Outcomes were clearly mentioned and reported in same way.
Other bias		

<ul style="list-style-type: none"> Anything else, ideally pre-specified 	Low risk	None evident.
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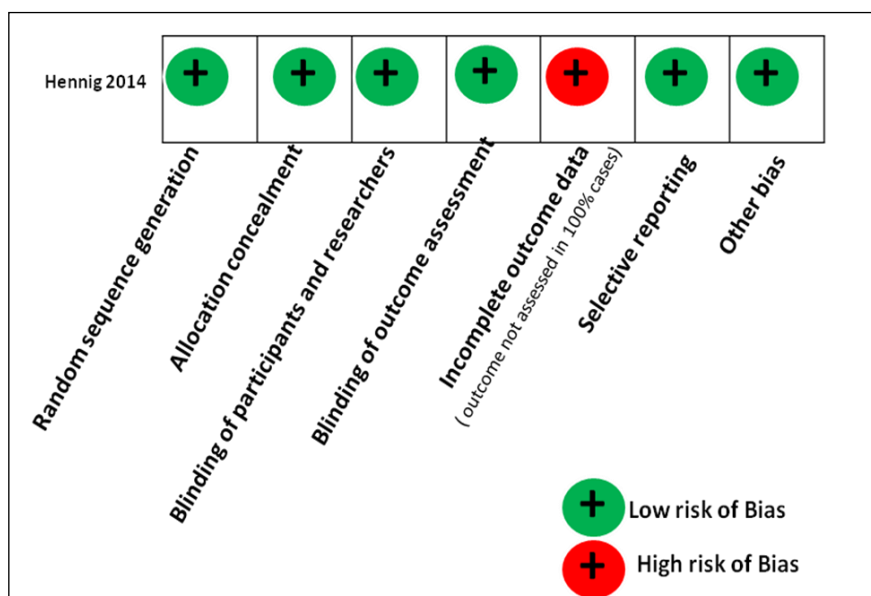


Figure 2. Representation of risk of bias assessments for trial *Hennig et al* 2014.

Conclusion:

- The available evidences clearly indicate superiority of Phaco and MSICS over ECCE.
- Phaco and MSICS results in comparative clinical efficacy in terms of visual acuity and complications.
- There are comparable clinical benefits with rigid and foldable lenses when implanted after a Phaco surgery with foldable lens being costlier to rigid PMMA lenses.
- There are no enough evidences suggesting superiority of multifocal lens over monofocal lenses.
- There are no evidences suggestive of role of IOL material in developing PCO.
- With a view of above mentioned points which emerged from evidence based analysis of comparative clinical efficacy of different type of cataract surgery and IOLs, providing MSICS with rigid monofocal lenses sounds a wise strategy to cater the huge backlog of cataract patients in India without compromising the quality of healthcare.

Chapter 2

Health Related Quality of Life

Literature Review

Background: Cataract surgery is one of the most cost-effective interventions worldwide though cost and clinical effectiveness of different surgical techniques and intraocular lenses (IOLs) vary a lot (1). In clinical decision-making, interventions are primarily assessed based on efficacy and safety. However, it is also important to monitor the impact that treatments have on utility i.e., health-related quality of life (HRQoL) using validated instruments (27,28). Utility is a measure of health preference anchored around a value of “1” for perfect health and “0” for dead that is used in calculations of quality-adjusted life years (QALY) (29).

Preference based measures are used to value HRQoL and these measures could be either generic or condition specific. Condition-specific instruments are useful tools that provide information on specific domains relating to the disease of interest. General quality of life measures, however, are important when one wishes to make comparisons across health states for policy decisions.

Aim: This systematic review aims to evaluate health related quality of life evidences on effects of cataract surgery and intraocular lens implantation on vision function and quality of life in age related cataract patients. This review also attempts to bring together all the cataract related HRQoL evidences pertaining to different cataract surgical techniques, different intraocular lenses, and cataract related complications.

Methods: The systematic review was registered with International prospective register of systematic reviews (PROSPERO). Registration number assigned from PROSPERO was CRD42018092377 (30).

Literature Search: Strategies were designed to identify all relevant studies for HRQoL among age related cataract patients. The databases searched were: The Cochrane Library including the Cochrane Database of Systematic Reviews (CDSR), Cochrane Central Register of Controlled Trials (CENTRAL), EMBASE, SCOPUS, the NHS Economic Evaluation Database (NHS EED), Health Technology Assessment (HTA) database, MEDLINE, ClinicalTrials.gov, Current Controlled Trials, and World Health Organization International Clinical Trials Registry Platform (WHO ICTRP). All studies reported and conducted till 8 January 2018 were considered.

The studies were included based on the following criteria:

- **Population:** Adult patients with age-related cataracts without any other ocular comorbidity

- **Interventions:** Phacoemulsification, SICS, ECCE, ICCE, Rigid lens, foldable lens, monofocal lens, multifocal lens.
- **Comparative studies:** Phacoemulsification/ECCE, Phacoemulsification/SICS, Phacoemulsification/ ICCE, ICCE/ECCE, ECCE/SICS, Rigid Lens/Foldable IOL, Monofocal/Multifocal IOL, unilateral/bilateral cataract.
- **Outcomes:** Generic Quality of life, Health Related quality of life, Vision Related quality of life, Visual function, Cataract surgery related Complications
- **Study Design:** Review articles containing new data/analyses, Meta-analysis, RCT, Original observational studies, Case Control Studies, Cohort Studies, Cost effectiveness studies.

Inclusion screening process: Studies were selected for inclusion through a two-stage process. First stage was to screen the literature search results (titles and, if present, abstracts) identified by the search strategy to identify all citations that potentially met the inclusion/exclusion criteria. Second stage was a ‘preliminary’ data extraction to aid in the study selection process.

Critical appraisal strategy: The quality of included studies was assessed by using a modified checklist recommended by Ara et al (31). Three main criteria considered while quality assessment were:

1. Relevance to the study in terms of population and health states
2. Quality assessment in terms of sample size, response rates to the measure used, loss to follow-up and missing data
3. Utility values used.

Results: The electronic searches yielded a total of 2389 titles and abstracts. After de-duplication, the title and abstracts of 1624 references were screened. 1403 abstracts were rejected as not eligible for inclusion in the review. Full-text copies of 221 references were obtained and screened through preliminary data extraction by using prefixed criteria. Studies (42) were excluded as irrelevant after preliminary data extraction. Finally, 179 full text studies were assessed for inclusion where 114 studies were excluded with reasons and 65 of them were included in the review (Figure 1).

Overview of the included studies: Out of 65 included studies, there were three distinct studies, which each had one more, similar, somewhat duplicate study by same author. These

three studies were therefore merged with their respective similar studies in order to avoid any duplication in reporting results. After merging the studies, total number of studies were 62.

For the ease of review process, the studies were classified under following categories depending upon the main aim of the study (Table 1, Figure 1).

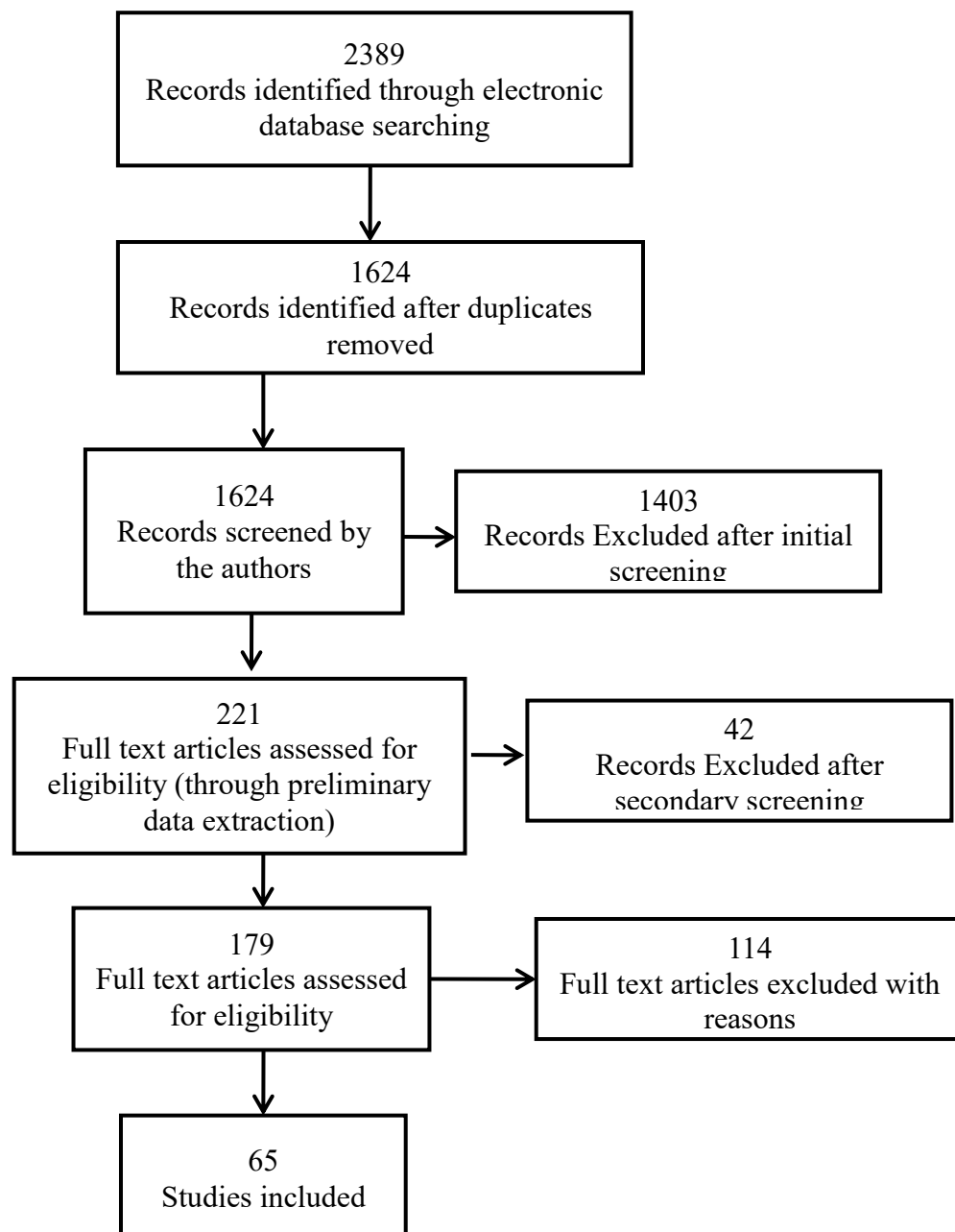


Figure 1. Results from searching for studies for inclusion in the review.

Maximum studies were those (n=38) where main aim of the study was to analyse the HRQoL of cataract patient before and after the surgery. These studies were not meant to compare surgical techniques or type of lenses implanted but provided the effectiveness of cataract surgery overall in terms of QoL improvement, QALY gained, and visual function scores.

Table 1. Studies included under different categories

S No.	Category	Number of studies	Number of studies after merging
1	Cataract surgery	38	37
2	Unilateral/Bilateral Cataract	7	7
3	Multifocal Lenses	9	8
4	Phacoemulsification	3	3
5	Extracapsular/Intracapsular cataract surgery	3	2
6	Phacoemulsification/ Extracapsular cataract extraction	2	2
7	Phacoemulsification/Small Incision manual cataract surgery	1	1
8	Complication Related	2	2
	Total studies included	65	62

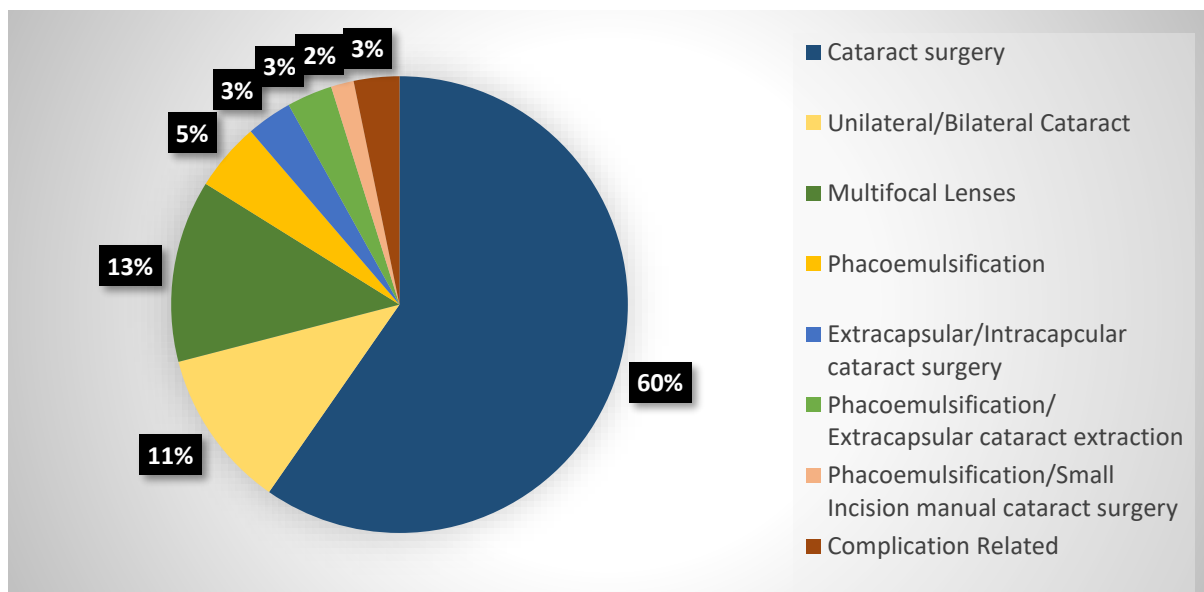
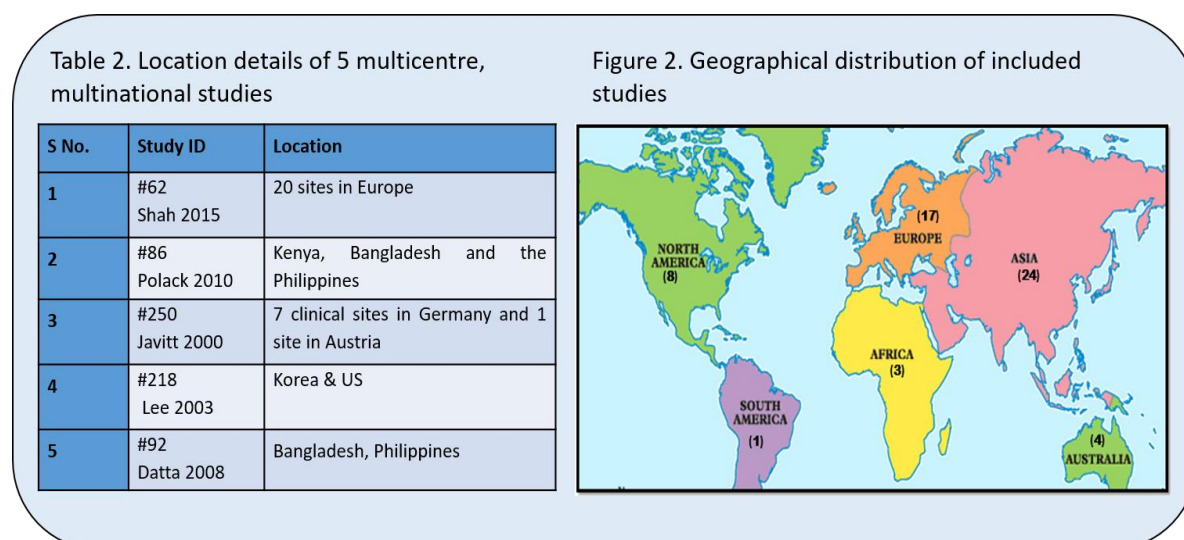


Figure 1. Studies included under different categories

Location of the included studies: Out of 62 studies there were five multicentre studies where different centres belonged to different countries across the globe (Table 2). Rest of 57 studies were conducted within a country as either single centre or multi-centre study. The studies included were from all across the globe with maximum studies from Asian countries (n=24).

Figure 2 describes the distribution of included studies across geographical zones.



Category wise Findings:

Table 3: Main findings of included studies category wise-

S. No.	Category	n*	Results
1	Cataract surgery	37	<ul style="list-style-type: none"> • Clear indication of QoL improvement and QALY gain with the cataract surgery and IOL implantation(32–34). • Cost-utility values for cataract surgery (first eye) varied from \$245 to \$22,000/QALY in Western countries and from \$9 to \$1,600 in developing countries(38). • Significant improvement in visual function demonstrated by many studies (35–37). • Cataract surgery had a positive impact on reducing economic poverty as patients more likely to be engaged in income earning activities one year after surgery(38,39).

2	Unilateral/Bi-lateral Cataract	7	<ul style="list-style-type: none"> Both unilateral and bilateral visual impairment was associated with poorer SF-36 profiles as compared to the unimpaired group (40,41). Second-eye surgery generated 0.68 additional quality-adjusted life years (QALY) with an incremental cost-effectiveness ratio of £1,964 per QALY gained (42). Second-eye cataract surgery was found as not being cost-effective in the short term for those with mild visual dysfunction pre-operation (43). <p>Pre and post-surgery visual function score differ significantly between unilateral and bilateral cataract, with more improvement observed after second eye surgery(44–46).</p>
3	Multifocal Lenses	8	<ul style="list-style-type: none"> Multifocal lens implantation after cataract surgery tends to increase VRQoL of the patients post operatively as compared to before the surgery(47,48). Overall quality of life was better in patient groups implanted with multifocal lens as compared to those with monofocal lens (49–51). The incremental cost-effectiveness ratios of monofocal versus multifocal IOLs indicated that it cost an additional \$57 to \$58 (US dollars) to increase each 1% of the spectacle-independence rate (50).
4	Phacoemulsification	3	<ul style="list-style-type: none"> Significant improvement in quality of life and visual function was observed after Phacoemulsification surgery (52,53).
5	Extracapsular/Int racapsular cataract surgery	2	<ul style="list-style-type: none"> Patients who received ECCE reported larger benefits as compared to ICCE post 12 months of surgery (54–56).
6	Phacoemulsification/ Extracapsular cataract extraction	2	<ul style="list-style-type: none"> VF 14 scores not significantly different between Phaco and ECCE groups (62). ECCE more cost effective after six months post-operation with USD 458 (\pm USD 72) as compared to Phaco with USD 528 (\pm USD 125) (63).
7	Phacoemulsification/Small Incision manual cataract surgery	1	<ul style="list-style-type: none"> QALYs and VFQ Scores for both the MSICS and Phaco groups achieved comparable outcomes in terms of change in LogMAR VA, VF-14 score and QALYs. However, with significantly lower costs (INR 3228 [2700–3756]), MSICS was more cost effective, with superior cost utility value (64).

8	Complication Related	2	<ul style="list-style-type: none"> • Endophthalmitis after cataract surgery negatively affected self-perceived vision-related quality of life, resulting in poorer psychological well-being and ability to maintain a role in daily life (57). • Patients for posterior capsule opacification showed significant improvements in binocular visual acuity, VF-14 index, satisfaction with vision, and EQ-5D measures after capsulotomy as compared to before capsulotomy (66).
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n* total number of studies

Conclusion:

- There are very few studies reporting quantitative QALY data. Most of the studies provided narrative HRQoL results in terms of improvement in performing visual activities, daily routine activities, social wellbeing etc. There are many studies where QoL results were given for different dimensions, e.g. it is given on mobility, self-care, usual activities, pain/discomfort and anxiety/depression if EQ5D is used as an instrument but utility weights were not assigned against the overall health state and therefore QALYs were also not estimated.
- Most of the HRQoL studies on Cataract were done under the category of “Cataract surgery (60%)”, where main aim of the study was to analyse the HRQoL of cataract patient before and after the surgery. These studies were not meant to compare surgical techniques or type of lenses implanted but provided the effectiveness of cataract surgery overall in terms of QoL improvement, QALY gained, and visual function scores.
- There is only one study comparing SICS with PMMA lenses vs. Phacoemulsification with rigid lenses (this is most relevant to the present HTA study) and found QoL and VFQ scores comparable in these two groups.
- Overall, the review suggests there were not enough studies comparing HRQoL between different type of surgeries and the studies available were highly heterogeneous in terms of study design, population, instruments used for measuring the health states, value sets used for assigning utility weights, and reporting results.

Chapter 3
Cost effectiveness
Literature Review

Background: Cataract surgery is reported to be a globally cost effective intervention, the cost of which varies dramatically by setting in a country(58). Standards of cost–effectiveness also vary depending on the resources available to the health system. Cost-effectiveness studies should be carried out to assess the best intervention amongst the alternatives available for efficient resource allocation especially in developing countries like India where resources are scarce.

Aim: This systematic search aims to assess the availability of cost effectiveness evidence for different types of cataract surgeries and different type of intraocular lens’ for undertaking Health Technology Assessment in India.

Methodology

SearchStrategy: A search strategy was designed to identify all relevant articles in English related to cost effectiveness studies comparing different types of cataract surgeries/ intraocular lenses.

Literature Search: A systematic search was performed in databases EMBASE, The Cochrane Library, Cochrane Database of Systematic Reviews (CDSR), PubMed, Google Scholar, NHS EED, and the INAHTA HTA database.

The studies were included based on the following criteria:

- **Population:** Adult patients with age-related cataracts without any other ocular comorbidity
- **Interventions:** Phacoemulsification, SICS, ECCE, ICCE, Rigid lens, foldable lens, monofocal lens, multifocal lens.
- **Comparators:** Phacoemulsification/SICS, ECCE/Phaco, MSICS/ECCE, Rigid Lens/ Foldable IOL, Monofocal/Multifocal IOL
- **Primary outcome:** distance visual acuity (best corrected distance visual acuity), near visual acuity (best distance corrected near visual acuity)
- **Secondary outcomes:** Cost, quality of life, posterior capsule opacification, complications. Contrast sensitivity, depth of field, glare, visual function, spectacle dependence.

Exclusion Criteria:

- Cost effectiveness of cataract surgery in general, comparing with no surgery at all or not comparing types of cataract surgeries or type of lenses are excluded
- IOL implantation for non-age related cataracts like congenital cataracts or paediatric cases.
- Ophthalmic diseases other than cataract like Glaucoma, macular degeneration, diabetic retinopathy, uveitis.
- Economic evaluations comparing first eye with second eye cataract surgery.
- Economic evaluations comparing immediate v/s sequential cataract surgery.
- Cost effectiveness studies of cataract for avoiding falls and fractures.

While comparing the intervention herein, we have explicitly excluded the cost effectiveness studies/economic evaluations comparing ICCE or FLACS as number of centres and number of surgeries being performed using these two techniques is quite limited in public health settings presently.

Study Design: Systematic reviews of economic evaluations/Economic Evaluations / Health Technology Assessments of age related cataract comparing different type of cataract surgeries or different type/ material of intraocular lenses

Inclusion Screening Process: Studies were selected for inclusion through a two-stage process. Literature search results identified by the search strategy were screened independently by two reviewers to identify all citations. Full manuscripts of selected citations were assessed by one reviewer and checked independently by a second reviewer. At each stage any disagreements were resolved by discussion, with the involvement of a third reviewer whenever necessary. Findings were reported based on the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guide.

Critical Appraisal: Characteristics of identified economic evaluations were recorded, and included studies were appraised for reporting quality using the Drummonds 2015 checklist.

RESULTS

Search Strategy:

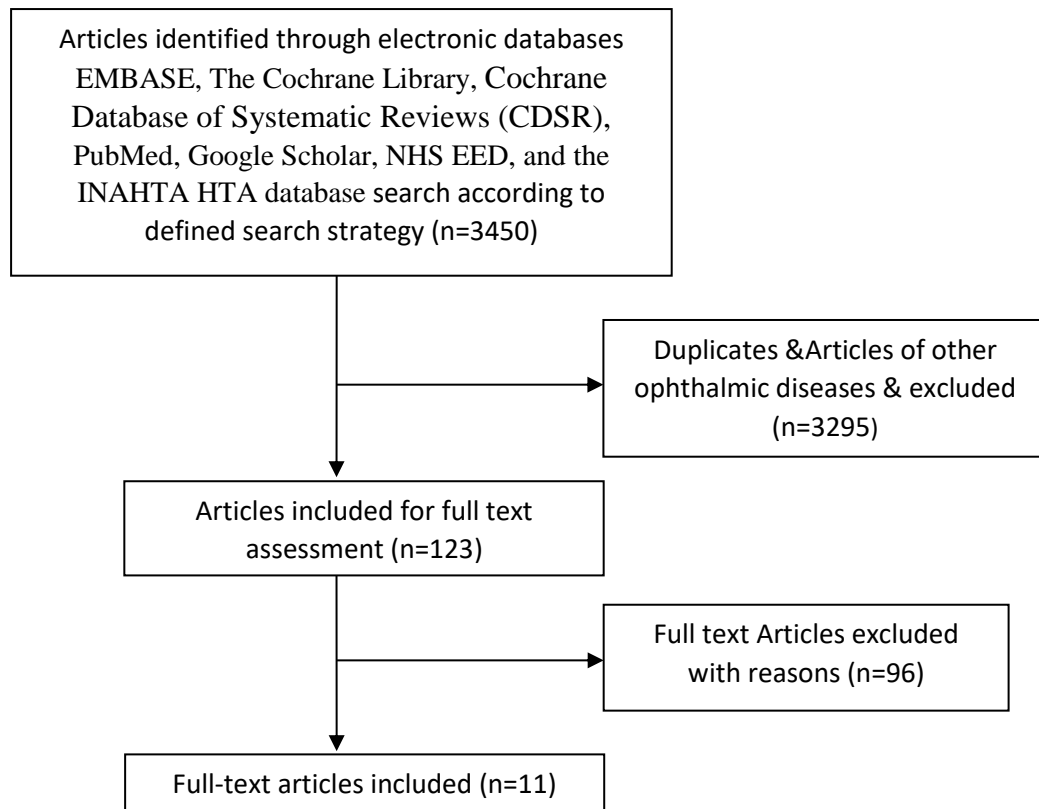


Figure 1. PRISMA CHART FOR 'COST EFFECTIVENESS' OF CATARACT SURGERY

Overview of included articles: Among the 11 articles included, 10 were identified as economic evaluations in that they included both costs and benefits associated with an intervention measured against a comparator. And one is a Health technology assessment which compares different type of cataract surgery/ different type of lens. Most of the studies were clinical trials based economic evaluations. Though majority of the studies are economic evaluations, except for two articles, none of the studies were based on modelling where inputs for all the key parameters including the effect size are either drawn from published datasets, existing literature or based on expert advice.

Two articles deserve a special mention though they do not get included as per our inclusion criteria- An abstract which is a cost utility analysis comparing Phacoemulsification and MSICS from Thailand (no full text available and hence excluded) and the other is a cost

utility analysis from India(59) which takes into account only Phacoemulsification without any comparators thus not making it a true economic evaluation and hence excluded.

The following results could be deduced from the studies included.

Table 1. Summary of studies included

S. No.	Category	No of articles	Key Points of Results
1	Phaco/MSICS	2	<ul style="list-style-type: none"> The cost-utility was significantly ($P = 0.04$) superior in MSICS (INR 1372 per QALY gained) compared to PE (INR 2062 per QALY gained).Patients were scored by VF-14 and QALY was calculated by product of VAS and life expectancy.(60) The effectiveness of MSICS and Phaco methods was not significantly different, but Phaco method had higher costs. MSICS was reported to have better cost-effectiveness than Phaco from the hospital's perspective(61)
2.	Phaco/ECCE	2	<ul style="list-style-type: none"> ECCE technique is more cost effective than phacoemulsification based on the cost per one unit increment of VF-14 score after six months (62) whereas Loo et al(63) reported that there was no significant difference in cost effectiveness between ECCE and phacoemulsification

3.	MSICS/ECCE	0	No articles obtained
4.	Rigid /Foldable	2	<ul style="list-style-type: none"> For hydrophobic acrylic, one of materials with the lowest rate of PCO complication, the multifocal IOL implantation for age-related cataracts was found to have an ICER of about \$8,000/QALY which was well below the threshold indicating its cost effectiveness in Canada as compared to the monofocal IOL(64) Cost-effectiveness ratios of hydrophobic acrylic (Acrysof®) were better and was shown to be a highly cost effective option than those of PMMA, Silicone & hydrophilic acrylic used in Germany, Spain, Italy &France. (65)
5	Monofocal/Multifocal	5	<ul style="list-style-type: none"> In Taiwan the incremental cost-effectiveness ratios of monofocal versus multifocal IOLs indicated that it cost an additional \$57 to \$58 (US dollars) to increase each 1% of the spectacle-independence rate and suggested that multifocal IOLs can be highly cost effective for patients who prefer to be spectacle free.(66)

			<ul style="list-style-type: none"> Three studies reported that the multifocal lens was more cost effective than the monofocal lens in terms of cost per patient(spectacle free)in developed countries(67–69)contrasting to a study(70) which reported that both mono and multifocal lenses are equally cost effective.
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As is evident from the results, except for the RCT based economic evaluation by (60), which compares Phaco/SICS there is no economic evaluation reported from India which compares Phaco/ECCE or SICS/ECCE or Rigid/Foldable lens or Monofocal / Multifocal lens.

Conclusion: Despite a large number of economic evaluations from different countries describing the cost effectiveness of cataract surgery in general, this review identified relatively few economic evaluations which compared different type of cataract surgeries or different type of material/intraocular lens. There is only one RCT based economic evaluation, without a model, reported from India which compares different type of cataract surgeries Phacoemulsification &MSICS. A RCT based economic evaluation, in most situations is reported to lead to a partial and limited analysis to inform decision making. Hence the more appropriate framework for economic analysis is evidence synthesis and decision modelling where all available data are brought to bear on fully specified decision problems. Hence this review serves to synthesise evidence and lays ground for decision modelling to identify the most cost effective cataract surgery in the Indian context.

Chapter 4

Cost Data Evidence

Literature Review

Background: Cataract is reported to be a cost effective intervention globally(58,71). In health economic evaluations, the outcome of a medical intervention is associated with the cost parameter to create a basis for higher-level allocation decisions under limited financial resources. In case of cataract surgery, cost is still a barrier to higher rates of cataract surgery especially for people in lower socioeconomic levels(58).

Aim: This Systematic search aims to assess the availability of cost data for different types of cataract surgeries and different type of intraocular lens' in India and other developing countries (using both Phacoemulsification and MSICS) for undertaking Health Technology Assessment in India.

Methodology

SearchStrategy for cost of cataract surgery: A search strategy was designed to identify all relevant articles in English related to cost of cataract surgery and cost of different type of intraocular lenses in India and from other developing countries using both Phacoemulsification and MSICS for treating cataract. The databases searched for relevant published studies were The Cochrane Library including the Cochrane Database of Systematic Reviews (CDSR), PubMed, SCOPUS, EMBASE and Google scholar. Searches were done till Feb 2018. MeSH Search terms were used wherever appropriate.

The studies were included based on the following criteria:

- **Population:** Adult patients with age-related cataracts without any other ocular comorbidity
- **Interventions:** Phacoemulsification, SICS, ECCE, ICCE, Rigid lens, foldable lens, monofocal lens, multifocal lens.
- **Comparators:** Phacoemulsification/SICS, Phacoemulsification/ECCE, ICCE/ECCE, ECCE/SICS, Rigid Lens/Foldable IOL, Monofocal/Multifocal IOL
- **Outcomes:** Cost of different type of cataract surgery, Cost of Rigid/Foldable IOL, Cost of Monofocal/Multifocal IOL, Cost of cataract surgery related complications

Exclusion Criteria: Research Articles with cost of IOL implantation for non-age related cataracts like congenital cataracts or paediatric cases and with cost of ophthalmic diseases other than cataract like Glaucoma, macular degeneration, diabetic retinopathy, uveitis were excluded.

Study Design adopted: Relevant Systematic reviews of economic evaluations / Economic Evaluations / Health Technology Assessments, Randomised Clinical Trials, Observational studies & Narrative Reviews, Letter and Reports reporting cost of cataract surgery/lens from India and other developing countries (using Phacoemulsification and MSICS) were searched.

Inclusion Screening Process: Studies were selected for inclusion through a two-stage process. Literature search results identified by the search strategy were screened independently by two reviewers to identify all citations. Full manuscripts of selected citations were assessed by one reviewer and checked independently by a second reviewer. At each stage any disagreements were resolved by discussion, with the involvement of a third reviewer whenever necessary. Findings were reported based on the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guide.

Results

Search: The electronic searches yielded a total of 1187 titles and abstracts. 239 duplicated articles were removed. After de-duplication, the title and abstracts of 948 references were screened. 730 articles pertaining to other ophthalmic diseases were omitted. Full-text copies of 218 articles were assessed for eligibility. 188 articles were excluded as no cost data was found and finally 30 research articles were included in the review (Figure 1).

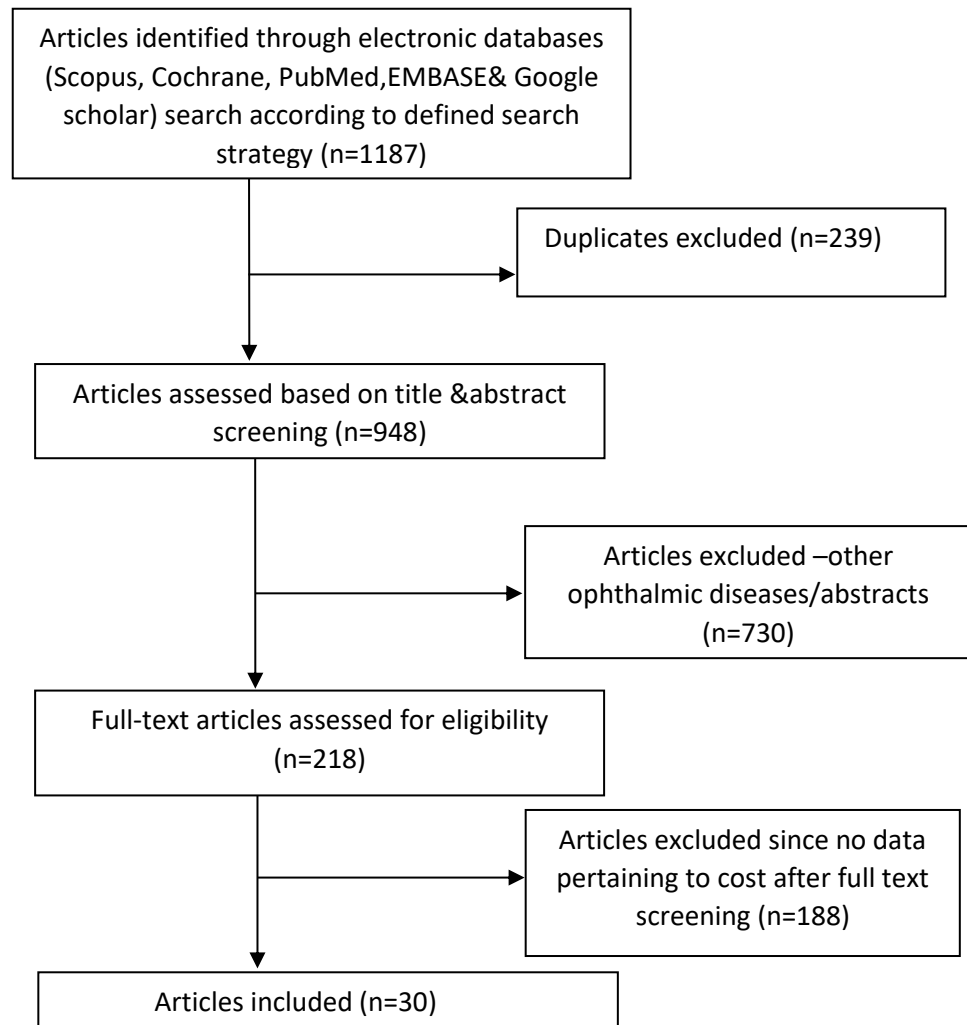


Figure 1. PRISMA CHART FOR 'COST' OF CATARACT SURGERY

Results:

Table 1. Type of Included Articles

S.No	Type	No of articles
1	Narrative Review	6
2	Economic Evaluation	8
3	Meta-Analysis/Systematic Review	4
4	RCT	4
5	Observational Study	3
6	Cost Analysis	3
7	Letter	2
	TOTAL	30

The critical appraisal of the studies were done by Fukuda and Imanaka (2009) checklist (72) based on:

- a) The type of the study included
- b) Cost reported

Table 2. Results deduced from the studies included

S. No.	Category	No of articles	Cost of cataract surgery/complications (in Rs /US \$)
1	Cataract Surgery	5	<p>Cost of cataract surgery (73)from camps reported (74)(75)(76)(77)</p> <ul style="list-style-type: none"> • Cost of cataract surgery reported as US\$ 23 in comprehensive makeshift camps • Cost of ECCE cataract surgery per patient from peripheral eye camps (Rs 390.50) and base hospitals(Rs497.10) excluding IOL was reported
2	Phaco/MSICS	14	<p>Cost of Phacoemulsification and SICS reported in various studies (59,60,86–89,78–85) cost of phacoemulsification reported to be more than MSICS in all of the studies</p> <ul style="list-style-type: none"> • The provider cost of cataract surgery\$25.55(Phaco) and \$17.03(MSICS) reported from an eye care programme of an NGO in India. (80) • The average cost per procedure for phacoemulsification was reported to be Rs 1978.89 (US\$42.10), and for SICS it was Rs 720.99 (\$15.342)in a hospital setting in India.(82) • Cost of Cataract Surgery consumables reported as \$70 (Phaco) and \$15(MSICS)from a RCT in Nepal(81)

			<ul style="list-style-type: none"> The cost of Phaco & MSICS \$113 was reported in a RCT from a tertiary hospital setting in Uttar Pradesh.(60)
3	Phaco/ECCE	3	<p>Costs of Phaco & ECCE reported and ECCE reported to be cheaper than Phaco((80)(90)(91):</p> <ul style="list-style-type: none"> The provider cost of Phaco \$25.55 and ECCE \$16.25 reported from an eye care programme in a high volume NGO in India.
4.	MSICS/ECCE	3	<p>Costs of ECCE & MSICS reported (92)(83)(80).</p> <ul style="list-style-type: none"> The provider cost of ECCE \$15.82 & that of MSICS \$15.68 was reported from an eye care programme in a high volume NGO from India and \$11.34 was the fixed facility cost common to both(80) The cost of both MSICS & ECCE was reported to be economical in community eye care settings, but MSICS was economical and gives better UCVA in patients.(92)
5	ICCE/ECCE	3	<p>Different costs of ECCE & ICCE reported (93)(94)(95).</p> <ul style="list-style-type: none"> NPCB provider cost from India Rs 769 ECCE & Rs 519 ICCE(93) ECCE is more cost effective cataract surgery than ICCE in India,& Nepal
6.	Rigid /Foldable	3	<p>Cost of Rigid and foldable lens reported from a high volume cataract surgery performing NGO in India (96)(97)&Nepal (84)</p> <ul style="list-style-type: none"> Cost of rigid and foldable IOL was found to be \$1.4 & \$13 respectively and \$120 reported to be

			average cost of foldable lens in India (Eight times higher than the PMMA IOL)(96,97)
6	Monofocal/ Multifocal	1	Costs of cataract surgery using monofocal/multifocal IOL reported(66) <ul style="list-style-type: none"> The total costs of bilateral cataract surgery using monofocal IOLs (SA60AT), aspheric multifocal IOL (ZM900), and aspheric multifocal IOL (ReSTOR IQ) were \$1928.7, \$5319.3, and \$5319.3, respectively in Taiwan(66)
7	Complication Costs	1	Cost of complications reported(98) <ul style="list-style-type: none"> Cost of Spontaneous Follow-up Visit for Patient Total costs \$ 9.60.Costs of Treatment for Complications and Glasses- Medicine costs \$8.00, laser costs \$21.10,and surgery costs \$ 41.20(98)

From the above literature search it is evident that the costs of cataract surgery reported are from other developing countries or are a decade old / are representative of only a particular type of health facility from India which cannot be generalised for undertaking a health technology assessment.

Conclusion

Variation in costs between different providers of cataract surgery exists in the Indian Healthcare system. In the absence of a country wide costing database in India, some of these variations need to be researched and addressed so that a true picture of the cost of different type of cataract surgeries and intraocular lenses at different levels of healthcare can be elucidated and considered by the policy maker for making policy decisions.

Chapter 5
Quality of Life
Primary Study

Background: A systematic review conducted for health related quality of life (HRQoL) evidences suggested there were not enough studies comparing HRQoL between different type of cataract surgeries and lenses. Moreover, the studies available were highly heterogeneous in terms of study design, population, instruments used for measuring the health states, value sets used for assigning utility weights, and reporting results. Therefore, a primary study was planned and conducted to assess the differences in generic quality of life and vision related quality of life, different types of cataract surgeries (ECCE, SICS, Phacoemulsification) and lenses (rigid and foldable lenses) having on age related cataract patients of Indian origin.

Aim: Main aim of this study was to compare the QoL differences after having SICS with rigid lenses and Phaco with foldable lenses as these two are the most commonly performed cataract procedures in India.

Methodology

Study Centres: This longitudinal, observational study was conducted in three ophthalmology centres. Details of centres are as given in Table 1. Dr. Rajendra Prasad Centre for Ophthalmic Sciences, AIIMS, New Delhi is an apex tertiary care institute of India which caters to patients coming from all over the country and provides mostly phacoemulsification surgeries. Hence, this centre was selected to ensure we get a mixed population sample representing different regions of the country. Another centre selected for the study was Dr. Shroff's Charity Eye Hospital, New Delhi (Shroff Delhi). Shroff Delhi is a non-government organization catering mainly to poor patients and provides both SICS and Phaco surgeries. Third centre selected was another branch of Dr. Shroff's Charity Eye Hospital, located in a small town Vrindavan (Shroff Vrindavan) in Uttar Pradesh and provides mostly SICS. The centre was selected to ensure the patient sample also represent rural population of India.

Table 1: Details of Study Centres

S No.	Centre	Facility	Healthcare	Cataract surgeries	Lenses implanted
1	Dr. Rajendra Prasad Centre for Ophthalmic Sciences, AIIMS, New Delhi	Tertiary care	Public	Phacoemulsification, ECCE	Rigid PMMA, Foldable
2	Dr. Shroff's Charity Eye Hospital, New Delhi	Secondary care	Private non-profit organization	Phacoemulsification and SICS	Rigid PMMA, Foldable
3	Dr. Shroff's Charity Eye Hospital, Vrindavan, UP	Secondary care	Private non-profit organization	Phacoemulsification and SICS	Rigid PMMA, Foldable

Subjects: A total of 814 patients admitted for age-related cataract surgery were prospectively recruited in the study after getting Institutional ethics committee approval from both AIIMS and Shroff centres. Written informed consents were obtained from each patient to participate in the study. Details of the patients recruited are given in table 2.

Table 2: Distribution of recruited patients

	Number (%)			
	Overall	AIIMS	Shroff Delhi	Shroff Vrindavan
Total	814	395	209	210
Males	386 (47.4%)	171 (43.3%)	89 (42.6%)	126 (60%)
Females	428 (52.6%)	224 (56.7%)	120 (57.4%)	84 (40%)

All data were collected on standardised proforma. Clinical data (on the process of care provided and related clinical outcomes) were collected by the ophthalmologists concurrently with routine preoperative assessments and at dedicated postoperative follow up 4 weeks after the surgery. Data pertaining to visual function and quality of life were obtained from a standardised administered interview preoperatively and at 4 weeks after surgery.

Generic Quality of Life: The instrument used for measuring generic QoL was Euroqol's EQ5D-5L questionnaire. The EQ-5D consists of a descriptive system and the EQ visual analogue scale (VAS). The descriptive system comprises five dimensions: mobility, self-

care, usual activities, pain/discomfort and anxiety/depression. The EQ VAS records the patient's self-rated health on a vertical visual analogue scale. (99)

Quality adjusted life years (QALYs) were estimated by using age adjusted life expectancy rates for India from Sample Registration Survey (SRS) life tables for 2012-16 (100) whereas Indonesian EQ5D-5L value sets were used to assign quality weights against each health state.(101)

Visual Function Scores: The vision related QoL was measured by using 33-item Indian Vision Function Questionnaire (IND-VFQ-33).(102)(103)This scale has been developed from focus group discussions with Indian patients; has a concise format; is easy to administer; and has been validated using traditional validation techniques such as classical test theory (CTT), and modern psychometric methods such as Rasch analysis.(102–104)IND-VFQ-33 has three independent subscales for general functioning, psychosocial impact and visual symptoms therefore individual composite scores were generated for each of the three parts of the questionnaire during the analysis.

Visual Acuity Scores: The visual acuity scores of the patients were measured before and after the surgery and the patients were categorized as having good, poor or borderline visual acuity in terms of visual outcomes of patients with no surgical complications as a good outcome (visual acuity $\geq 6/18$), a borderline outcome (visual acuity 6/24 - 6/60) and a poor outcome (visual acuity $\leq 6/60$) (5). The post-surgical visual acuity was correlated with the QALY gains. Pre and post-surgical visual acuity differences were also analysed.

Results: A total of 814 patients were recruited for the study where 52.6% patients were females. Average age of patients was 60.58 years at the time of surgery. (Table 3) Out of 814 patients recruited for the study, follow up data were available for 519 (63.8%) patients at 4 weeks after surgery. (Figure 1) Details of patients who completed both pre and post-surgery questionnaire are given in table 4.

Table 3: Sample Characteristics

	Average Age (in years)			
	Overall	AIIMS	Shroff Delhi	Shroff Vrindavan
Overall	60.58	60.04	60.55	61.65
Males	60.96	60.13	61.04	62.2
Females	60.25	59.97	60.22	60.95

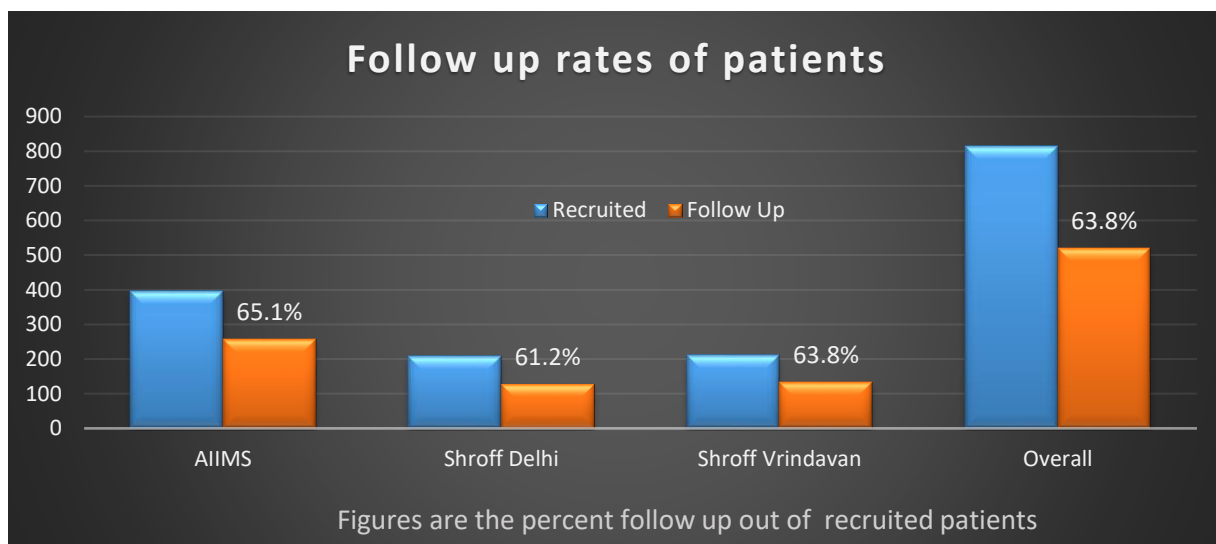


Figure 1: Graph representing the follow up rates of patients

Table 4: Distribution of patients-questionnaire wise

Category	EQ5D	VFQ
	Number (% of total patients recruited)	
Patients followed up	517 (63.5%)	519 (63.8%)
Category	Number (% of followed up patients)	
Type of Surgery		
1. ECCE	31 (6%)	31 (6%)
2. Phaco	360 (70%)	361 (70%)
3. SICS	126 (24%)	127 (24%)
Type of IOL		
1. Foldable	333 (64%)	335 (65%)
2. PMMA	184 (36%)	184 (35%)
Surgery & IOL		
1. ECCE & Foldable	3 (<1%)	3 (<1%)
2. ECCE & PMMA	28 (5%)	28 (5%)
3. Phaco & Foldable	327 (63%)	330 (64%)
4. Phaco & PMMA	33 (6%)	31 (6%)
5. SICS & Foldable	3 (<1%)	2 (<1%)
6. SICS & PMMA	123 (24%)	125 (24%)

EQ5D Results: The overall changes were positive with all patients showing an improved QoL score after a month of the surgery. Highest change in QoL were observed in patients undergoing ECCE with rigid PMMA lens implantation. This result however was inconclusive due to the lesser sample size relative to other categories. Patients undergoing phacoemulsification with a foldable lens implantation and those undergoing SICS with a rigid PMMA lens implantation had a good increase in QoL scores (0.11 and 0.09 respectively). Difference in QoL scores between Phacoemulsification and SICS was very small (a meagre 0.02) with both procedures having closely comparable increase in quality of life of the patients. (Figure 2) There is a marked increase in the VAS scores as compared to the EQ5D scores with the increase in VAS being about 30-40% post-surgery whereas those in the quality weights are around 10-15%. (Figure 3) Pre and Post surgery differences in QALY values were highly significant for combinations of Phaco with foldable lens and SICS and ECCE with rigid PMMA lens. QALY differences were statistically not significant for ECCE and SICS with foldable lens and Phaco with rigid PMMA lens, which might be due to insignificant sample size relative to other categories.

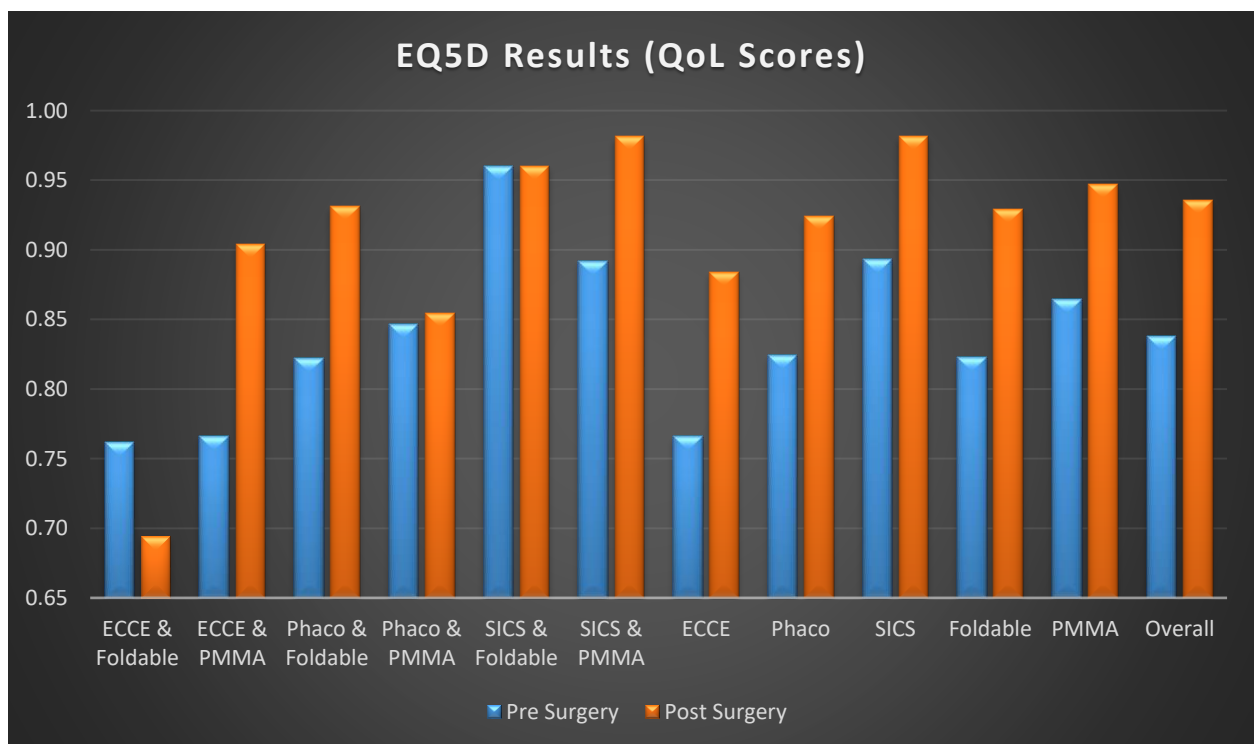


Figure 2: Graph representing Pre and Post surgery QoL scores for EQ5D

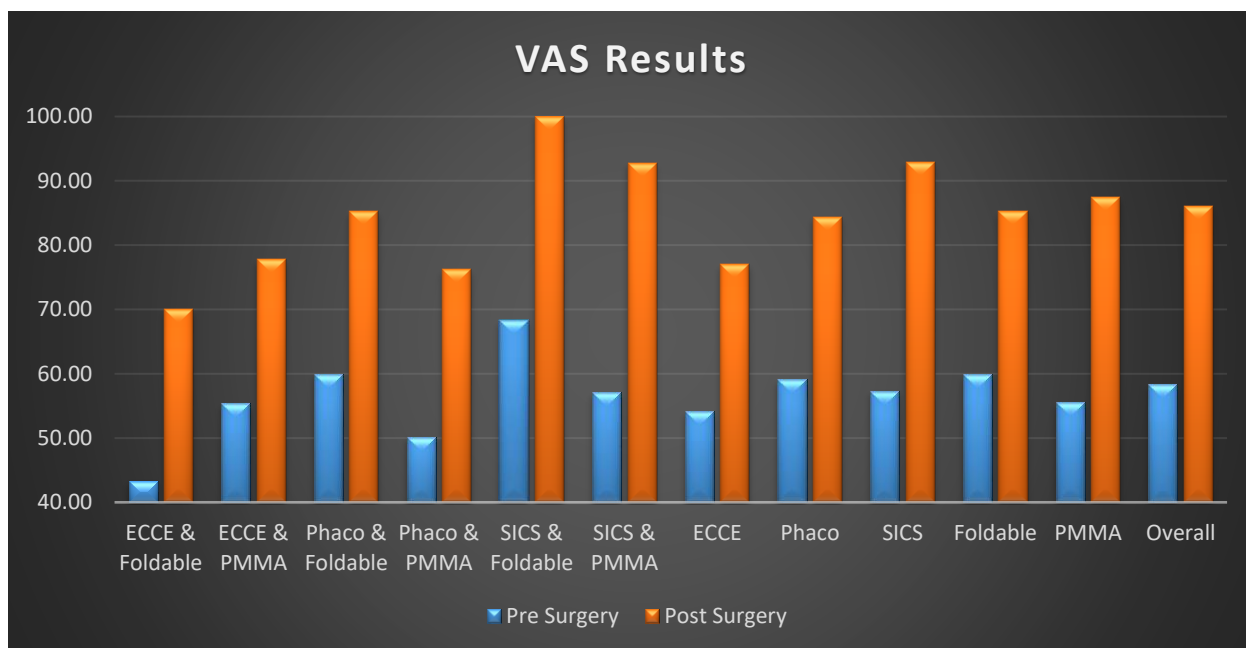


Figure 3: Graph representing Pre and Post surgery EQ5D visual analogue scale results

Table 5: Category-wise Change in Quality Adjusted Life Years (QALYs)

Category	N	Average Age (years)	QALY Gain	p-value (by t test)
ECCE & Foldable	3	59	-1.18	0.88
ECCE & PMMA	28	60	2.50	0.006
Phaco & Foldable	327	60.04	2.25	<0.01
Phaco & PMMA	33	61.18	0.23	0.75
SICS & Foldable	3	55.67	0.00	0.42
SICS & PMMA	123	62.07	1.68	<0.01
ECCE	31	59.9	2.15	0.03
Phaco	360	60.15	2.06	<0.01
SICS	126	61.91	1.64	<0.01
Foldable	333	50.99	2.20	<0.01
PMMA	184	61.59	1.55	<0.01
Overall	517	60.56	1.97	<0.01

IND-VFQ-33 Results: IND-VFQ-33 results indicated a marked increase in the scores of all three subscales including general functioning, psychosocial impact and visual symptoms of the questionnaire for each type of surgery and lenses. On comparison of the three subscales, visual symptoms had the worst presentation before surgery. The improvements seen in this subscale were relatively higher than those seen in the general and psychosocial subscales but even after surgery the lowest scores were recorded for the visual symptoms on comparison with other parameters (Table 6, Figures 4 & 5).

Table 6. Table representing change in the IND-VFQ-33 scores pre and post-surgery

Category	N	Change in General Functioning (p-value)	Change in Psychosocial Symptoms (p-value)	Change in Visual Symptoms (p-value)
ECCE & Foldable	3	15.48 (<0.01)	8.33 (0.19)	8.33 (<0.05)
ECCE & PMMA	28	6.7 (<0.01)	7.14 (<0.01)	21.43 (<0.01)
Phaco & Foldable	330	15.4 (<0.01)	16.64 (<0.01)	37.76 (<0.01)
Phaco & PMMA	31	4.22 (<0.01)	6.94 (<0.05)	25.69 (<0.01)
SICS & Foldable	2	40.48 (<0.01)	15 (0.07)	30.36 (<0.01)
SICS & PMMA	125	53.34 (<0.01)	54.05 (<0.01)	41.7 (<0.01)
ECCE	31	7.55 (<0.01)	7.26 (<0.01)	20.16 (<0.01)
Phaco	361	14.44 (<0.01)	15.8 (<0.01)	36.72 (<0.01)
SICS	127	53.13 (<0.01)	53.43 (<0.01)	41.52 (<0.01)
Foldable	335	15.55 (<0.01)	16.55 (<0.01)	37.45 (<0.01)
PMMA	184	37.95 (<0.01)	38.96 (<0.01)	35.91 (<0.01)
Overall	519	23.49 (<0.01)	24.5 (<0.01)	36.91 (<0.01)

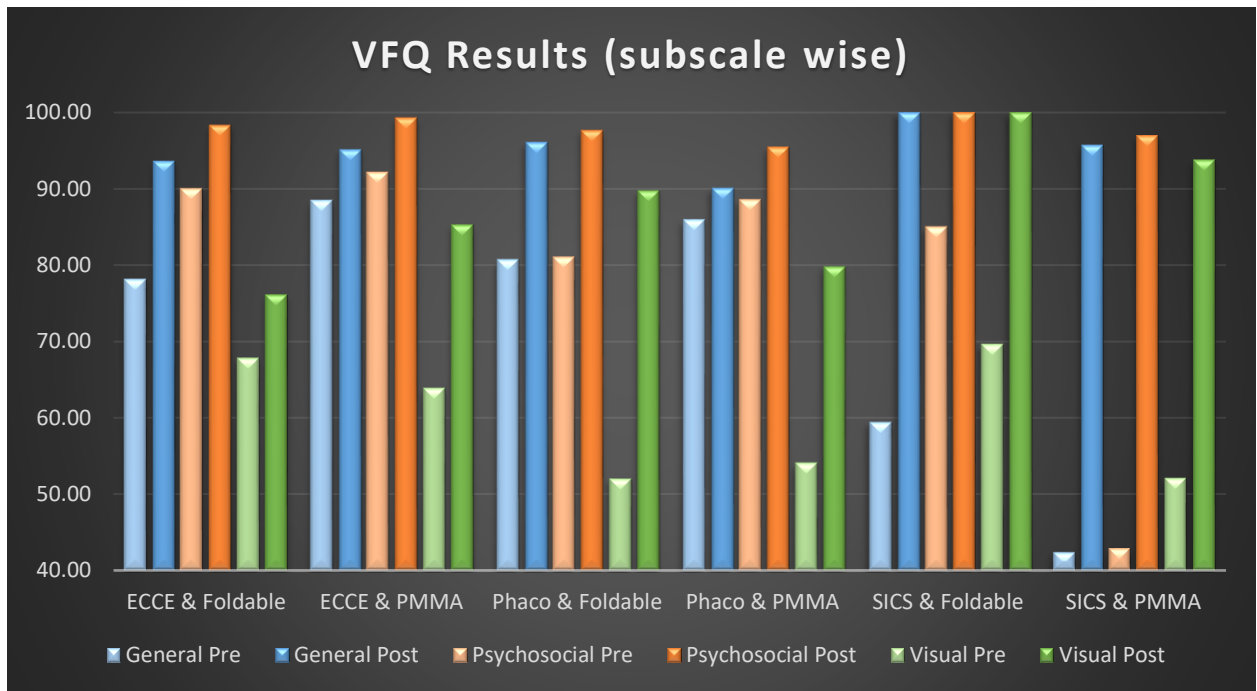


Figure 4: Pre and Post surgery scores for IND-VFQ-33 subscales for different combinations of surgery and IOLs

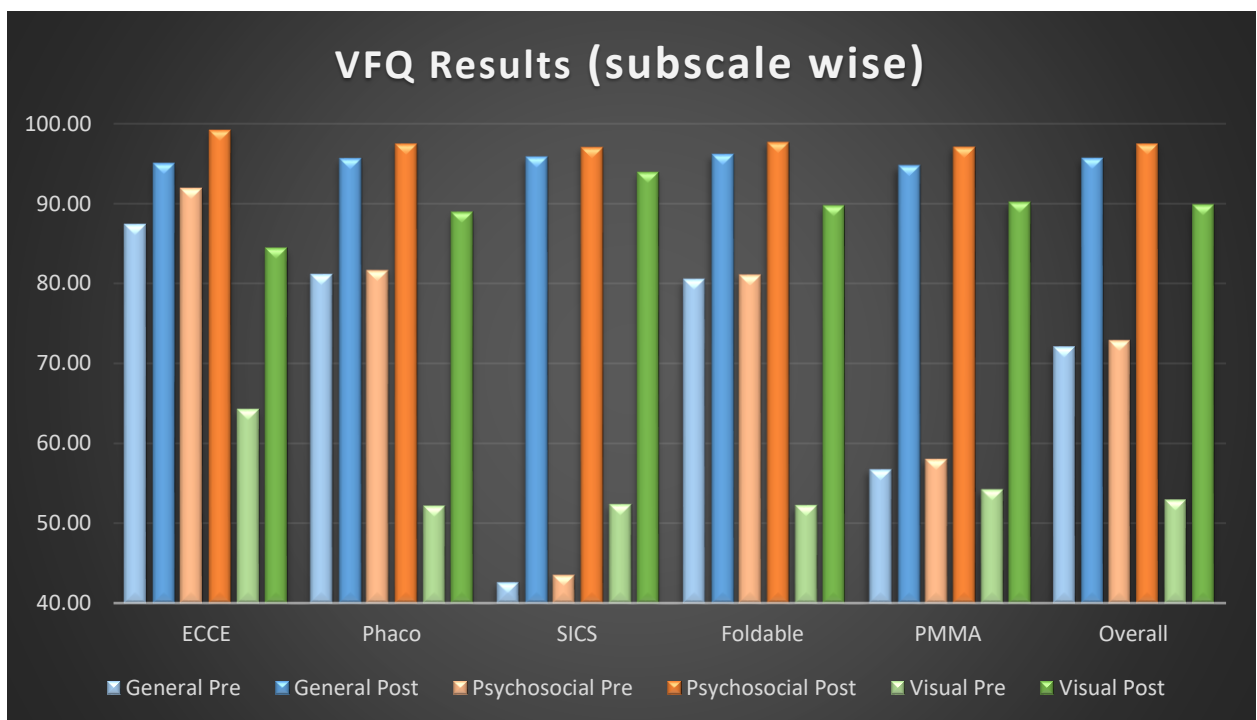


Figure 5: Pre and Post surgery scores for IND-VFQ-33 subscales for different surgeries and lenses

Visual Acuity Results: The data for visual acuity was available for only AIIMS institute (n = 257). A total of 257 eyes were analysed of which 122 patients had their left eyes operated while 135 had their right ones. Table 7 shows the correlation between visual acuity and QALY gain. The above results show that maximum QALY gain is observed in people where surgical outcomes are borderline (VA 6/24-6/60), followed by people where surgical outcomes are good (VA $\geq 6/18$).

Maximum number of patients (73.2%) have achieved good outcome post-surgery (VA $\geq 6/18$) which comprised of a majority of patients who had similar visual acuity pre surgery. Another key point observed was that about 60-75% of the patients falling in the categories of borderline and poor visual acuity pre-surgery have achieved good outcomes post-surgery (Table 8).

Table 7: Patients characteristics regarding visual acuity after surgery

Surgery Outcomes (Visual Acuity)	Average Age (in years)	Number of patients post-surgery	QALY Change (<i>p</i> value)
Good outcome VA $\geq 6/18$	59.08	188	2.31 (<0.001)
Borderline Outcome VA 6/24-6/60	64.35	29	3.26 (<0.001)
Poor Outcome VA $\leq 6/60$	61.48	40	1.08 (0.4)

Table 8: showing the movement of patients among the VA categories after surgery

Pre-Surgery VA Category	Number of patients before surgery	Post-Surgery VA Category	Number of patients after surgery
VA $\geq 6/18$	112	VA $\geq 6/18$	188
VA 6/24-6/60	44		
VA $\leq 6/60$	38		
VA $\geq 6/18$	7	VA 6/24-6/60	29
VA 6/24-6/60	8		

VA $\leq 6/60$	10		
VA $\geq 6/18$	17	VA $\leq 6/60$	40
VA 6/24-6/60	8		
VA $\leq 6/60$	13		

Conclusion: The present study confirms that both Phacoemulsification and small incision cataract surgery leads to comparable gains in terms of health related quality of life (both generic as well as vision related) where phacoemulsification leading to an extra QALY gain of 0.57 Years over small incision cataract surgery.

Chapter 6
Costing
Primary Study

Aim: The study aimed to estimate the unit cost of providing cataract surgery, both Phacoemulsification and MSICS across different levels of healthcare facilities in India including the Non-Governmental organisations, secondary healthcare centres and tertiary centres in India from the healthcare perspective.

Methodology: A micro-costing/ bottom up approach was done from the health system perspective to calculate overall costs of cataract surgery on one eye, including pre- and postoperative care.

Study Centres: A bottom up economic costing was conducted in four centres providing cataract surgery representing different levels of healthcare provision. Details of centres are as given in Table 1. Guru Gobind Singh Hospital (GGSGH), New Delhi is a 100 bedded secondary care hospital in a Tier 1 city providing phacoemulsification and MSICS surgeries to a mixed population of urban, semi urban & to people from low socioeconomic strata from nearby Delhi. This centre was selected to have a true representation of a public secondary hospital where majority of the cataract surgeries take place. Another centre selected for the study was Dr Shroff's Charity Eye Hospital, New Delhi (SEC Delhi). Shroff Delhi is a non-government organization catering mainly to poor patients and provides both SICS and Phacoemulsification surgeries. Third centre selected was a branch of Dr Shroff's Charity Eye Hospital, located in a small town Vrindavan (SEC, Vrindavan) in Uttar Pradesh providing majorly SICS surgeries along with phacoemulsification. This centre was selected so as to have a representation of a healthcare facility in a small town providing cataract surgery. The fourth centre selected was a public funded tertiary care hospital, Lady Hardinge Medical College (LHMC) situated in a Tier 1 city Delhi. The centre provides majorly phacoemulsification cataract surgery along with MSICS. This centre was chosen so as to have a representation of a normal tertiary care hospital as opposed to the super speciality tertiary care hospitals.

Table 1: Details of Study Centres chosen for the study.

S No.	Centre	Facility	Healthcare
1	Guru Gobind Singh Hospital	100 bedded secondary care	Public

2	Dr Shroff's Charity Eye Hospital, New Delhi	Secondary care	Private non-profit organization
3	Dr Shroff's Charity Eye Hospital, Vrindavan, UP	Secondary care	Private non-profit organization
4	Lady Hardinge Medical College	Tertiary Care	Public

Data collection: Primary cost data was collected from four different health care facilities using a costing data collection questionnaire adapted for cataract surgery and a time allocation sheet for personnel performing cataract surgeries and undertaking multiple duties.

Data was primarily collected from the Out Patient Department - where doctors are consulted and patients are tested & diagnosed for cataract, In Patient Department - where people are treated for cataract by Phacoemulsification or MSICS surgery and Ward - where the operated person is admitted for a check-up the next day.

Cost data of all resources used for cataract surgery for a patient was divided into the following categories: Human Resource (HR) /labour, Non Consumables including Equipment, Furniture & fixtures, Infrastructure, Consumables including drugs & medicines and Overhead (Electricity and water bills, dietetics and laundry and maintenance charges).

Human resource data of those healthcare providers who are directly involved (like Surgeons, Anaesthetists, Consultants, Senior and Junior Residents, Interns, nursing and OT Technicians, Optometrists) and indirectly involved (Registration Counter Personnel, Data Entry Operator in the OT/OPD/Ward & Ancillary staff) in healthcare and cataract surgical procedures were collected. Time allocation of all those healthcare givers undertaking multiple duties were also collected by a short 10-15 minutes interview.

The stock of non-consumables and consumables indented monthly from the Eye OPD/OT and Ward was taken and the procurement price of the same was collected from the store of the respective hospitals. The overhead charges of electricity, water consumption, maintenance charges, diet charges per day for inpatient stay from the dietetics department and laundry charges for the eye OPD/OT /Ward was also collected from respective departments of the hospitals. The infrastructure cost of land of the hospitals in Delhi was determined by market rental prices and was kept constant for all hospitals in determining the unit cost of cataract surgery.

Cost Data Analysis: Cost data collected for capital and recurrent costs was analysed using standard methods available in literature. Health system costs are usually shared in nature i.e. being used for more than one program or activity. Hence apportioning was done for the cost of phacoemulsification and MSICS cataract surgeries being evaluated using apportioning statistics.

Infrastructure costs like buildings rented or space utilized at health facility level was estimated using prevailing market rental prices. Annualized costs of capital goods like equipments and furniture with useful life of more than a year was calculated. A standard discounting rate of 3% was applied to convert the costs to current value. Besides capital costs, recurrent costs was also analysed for the previous one year to arrive at the overall estimates for providing cataract surgery at different level of facilities. Overhead costs were calculated and allocated per cataract surgery.

Out of Pocket (OOP) Expenditure in Cataract: The out of Pocket Expenditure in Cataract at different levels of healthcare facilities of both self-reported cases and hospitalisations was determined from NSSO data (2014).

RESULTS: The results of costs were calculated based on information about resource use and surgical volume from the all four mentioned centres. Details about number of services delivered like- total OPD visits, total cataract surgeries-both phacoemulsification and MSICS surgeries done was also collected in order to obtain unit cost of conducting cataract surgery. Following are the results of the primary cost data analysis done: Table 2 Represents the cost of OPD and surgeries in GGSGH, New Delhi. *Table 3 Represents the cost of OPD and surgeries Shroff Eye Care, Vrindavan. Table 4 Represents the cost of OPD and surgeries Shroff Eye Care, Delhi.*

Table 2: Resource distribution of cost of OPD and surgeries in GGSGH, New Delhi

Cost head	GGSGH, Delhi		
	OPD	OT+WARD	
		Phaco	MSICS
Infrastructure	6	320	320
Furniture	1	1167	1167
Equipment	56	3375	929
Overheads	2	307	307
Consumables	15	1918	1653
Human Resource	354	3157	3394

Total Cost of OPD/Pt ,Phaco/Pt &MSICS /Pt(INR)	433	10245	7771
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Table 3. Resource distribution of cost of OPD and surgeries in Shroff Eye Care, Vrindavan.

Cost head	Shroff Eye Care, Vrindavan		
	OPD	OT+WARD	
		Phaco	MSICS
Infrastructure	117	814	847
Furniture	6	116	121
Equipment	110	2561	1462
Overheads	5	1002	1043
Consumables	2	1797	871
Human Resource	193	1064	820
Total Cost of OPD/Pt ,Phaco/Pt &MSICS /Pt(INR)	433	7354	5164

Table 4. Resource distribution of cost of OPD and surgeries in Shroff Eye Care Hospital, Delhi

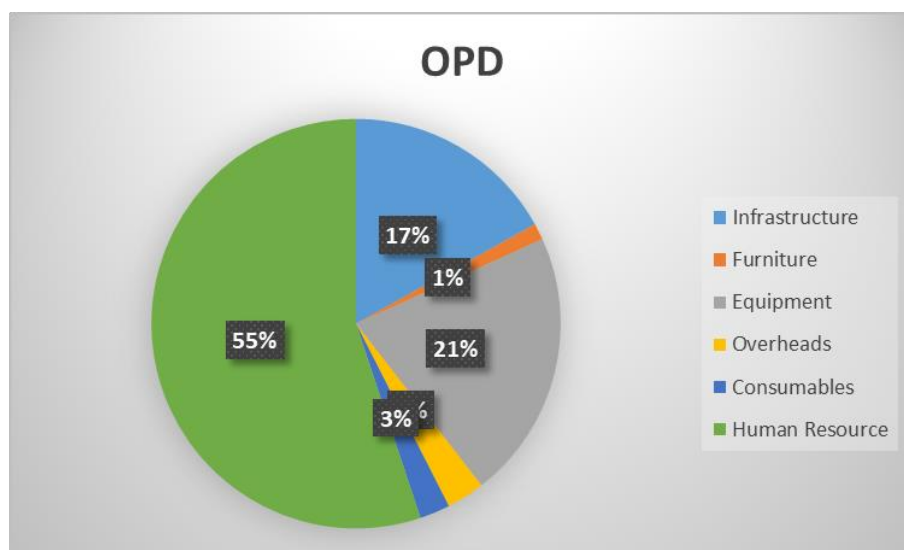
Consumables	Shroff Eye Care, Delhi		
	OPD	OT+WARD	
		Phaco	MSICS
Infrastructure	68	1174	1174
Furniture	8	219	212
Equipment	74	555	250
Overheads	27	1633	1633
Consumables	10	2660	1342
Human Resource	74	2185	1874
Total Cost of OPD/Pt, Phaco/Pt &MSICS /Pt (INR)	261	8426	6485

The Average Cost of Cataract Surgery with package cost and individual resource head divisions from all three centres for calculation of ICER to determine cost effectiveness of cataract surgery is given as below:

Table 5. Average Cost of Cataract Surgery from three secondary centres

Cost head	Average			Package cost*	
	OPD	OT+Ward		PHACO	MSICS
		Phaco	MSICS		
Infrastructure	64	769	780		
Furniture	5	501	500		
Equipment	80	2164	880		
Overheads	11	981	994		
Consumables	9	2125	1289		
Human Resource	207	2135	2029		
Average Cost of OPD/Pt, Phaco/Pt & MSICS /Pt(INR)	376	8675	6473	Package Cost Phaco 9606	Package Cost MSICS 7405
Standard Deviation-UL	475	10136	7777	11068	8708
Standard Deviation-LL	276	7214	5170	8145	6101

Package Cost includes initial OPD consultation, diagnostic tests (optometry, vision test etc.), counselling, pre-surgery/anaesthetics, surgery, ward, drugs, medical consumables, lens, food for patient and one attendant and one follow-up visit cost.



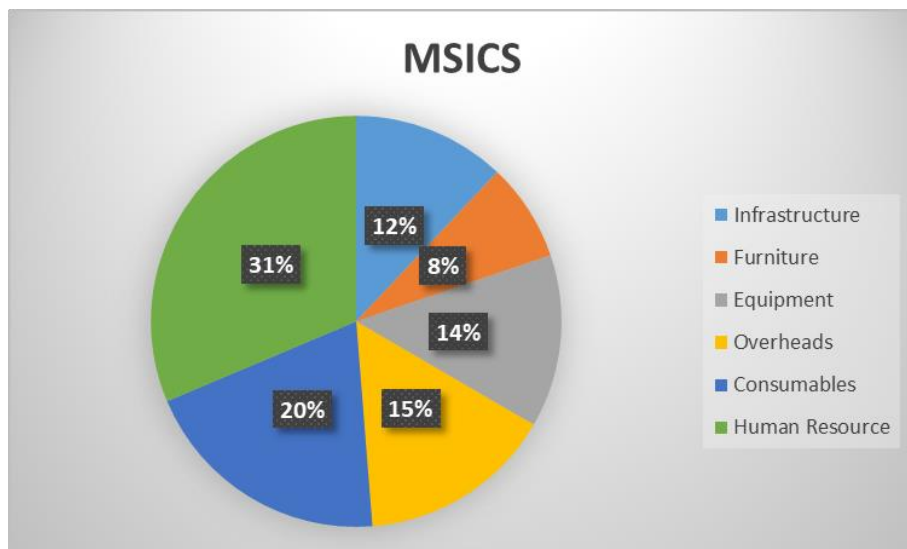
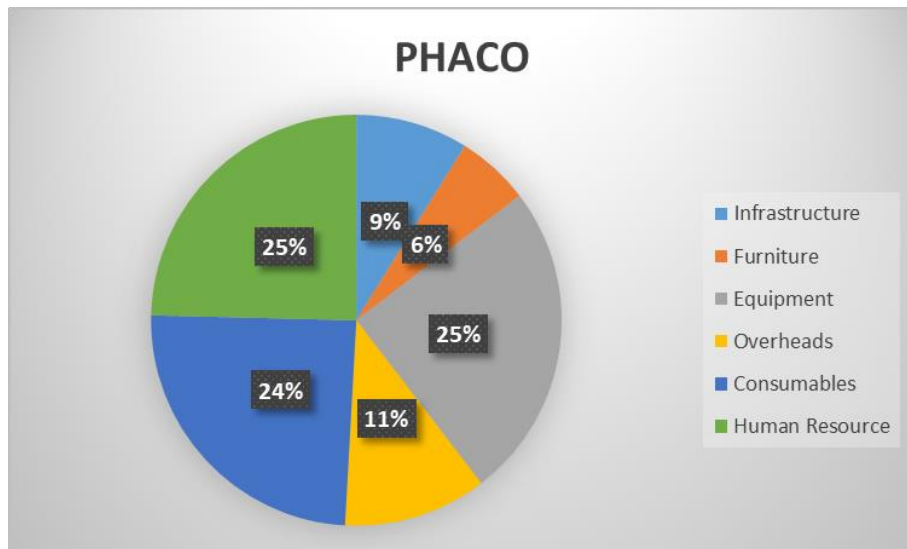


Figure 1: Pie charts of Average Cost of Cataract Surgery from three secondary centres for OPD, Phacoemulsification & MSICS Cataract Surgeries.

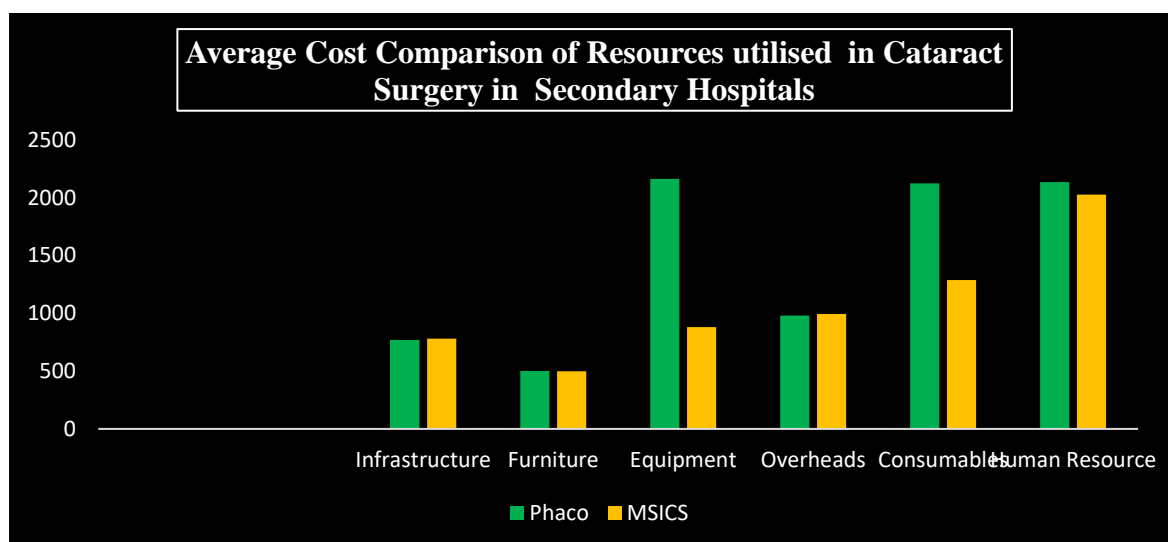


Fig2: Comparison of Cost of Average resources utilized for Phacoemulsification and MSICS Cataract Surgeries in Secondary Hospitals

The cost of Lady Hardinge Medical College Hospital, a tertiary care centre was also estimated. Being a tertiary care centre, which is involved in teaching also (unlike the other centres included in the study) LHMC is not included along with the other secondary centres in determining the average cost of cataract surgery for calculating the ICER for determination of cost effectiveness of cataract surgery.

Table 6. Resource distribution of cost of OPD and surgeries in LHMC, Delhi

LHMC, Delhi					
Cost head	OPD	OT+WARD		Package Cost	
	OPD	Phaco	MSICS		
Infrastructure	13.78	522.34	522.34		
Furniture	7.82	765.11	765.11		
Equipment	28.51	4820.9	3304.65		
Overheads	5.30	262.79	262.79		
Consumables	8.1	2320.67	980.67		
Human Resource	384.81	3314.65	2369.32		
Total Cost of OPD/Pt, Phaco/Pt & MSICS/Pt(INR)	448.32	12006.5	8204.88	Package* Cost PHACO 13017.5	Package* Cost MSICS 9215.89

Package Cost includes initial OPD consultation, diagnostic tests (optometry, vision test etc.), counselling, pre-surgery/anaesthetics, surgery, ward, drugs, medical consumables, lens, food for patient and one attendant and one follow-up visit cost.

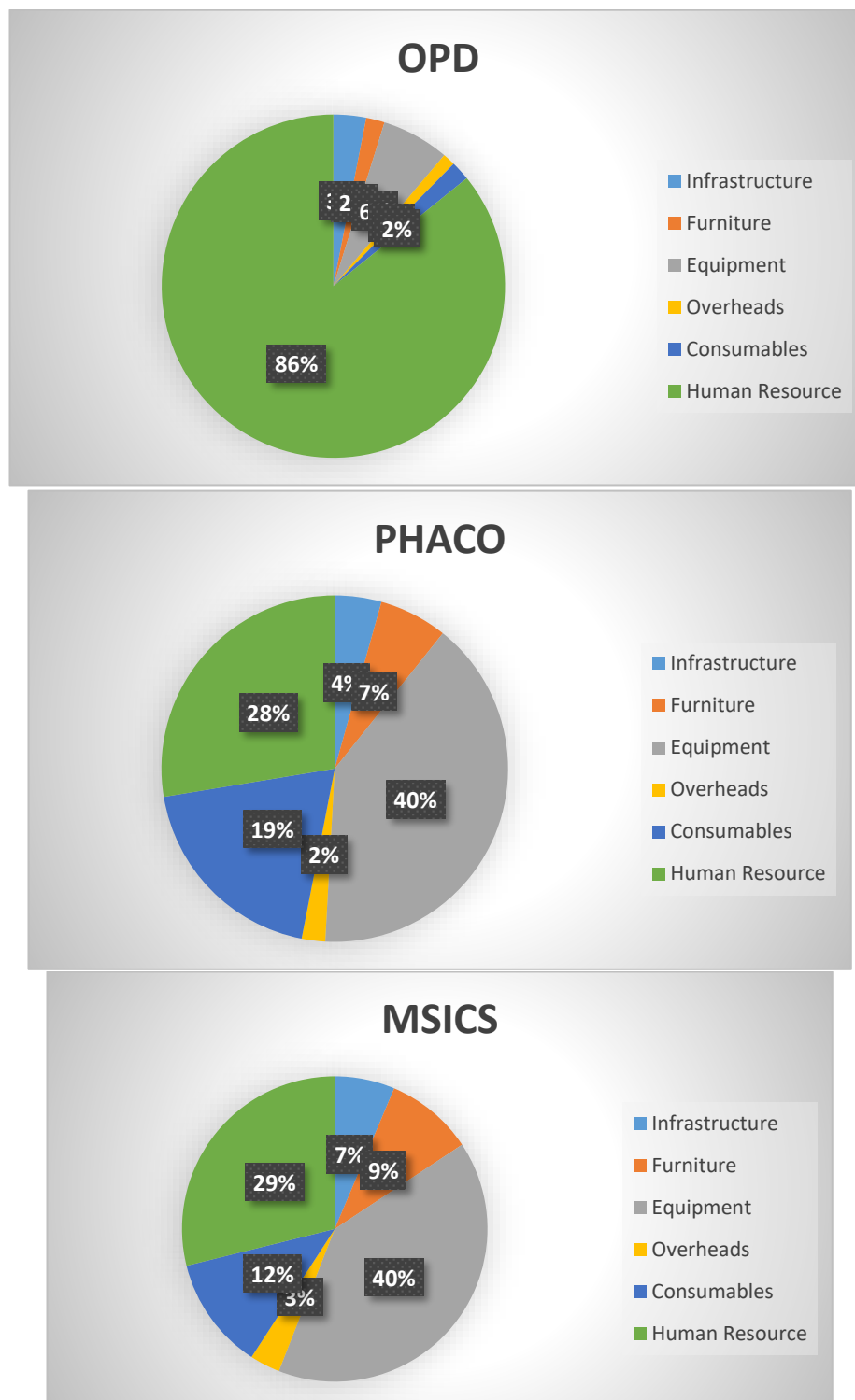


Fig3: Pie chart of Average Cost of Cataract Surgery from Tertiary hospital for OPD, Phacoemulsification & MSICS.

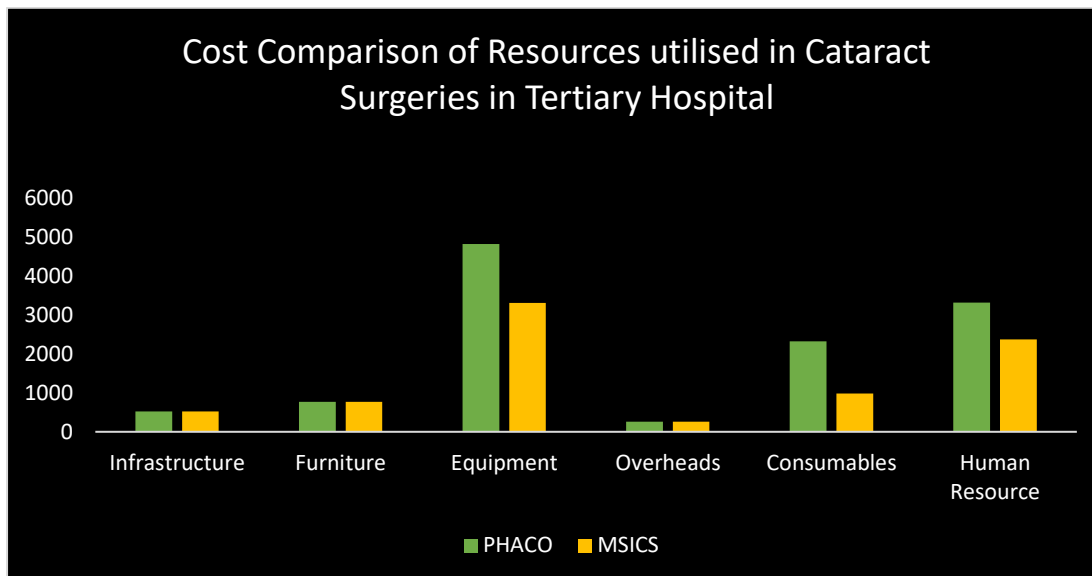


Fig4: Comparison of Cost of resources utilized for Phacoemulsification and MSICS Cataract Surgeries in Tertiary Hospital

Out of Pocket (OOP) Expenditure: The out of pocket expenditure of cataract –of self-reported cases and hospitalisations in different levels of healthcare was determined from NSSO data (2014) and is as given below.

Table 7. OOP expenditure and number of self-reported cases of cataract in India (NSSO, 2014)

Self-reported	Frequency	Percent	OOP expenditure (Rs.)
PHC/dispensary/CHC/mobile medical unit	9	7.1	145
Public Hospital	34	26.8	361
Private Doctor clinic	31	24.4	750
Private hospital	53	41.7	665
Total	127	100.0	585

Figure 5. OOP expenditure and number of self-reported cases of cataract in India (NSSO, 2014)

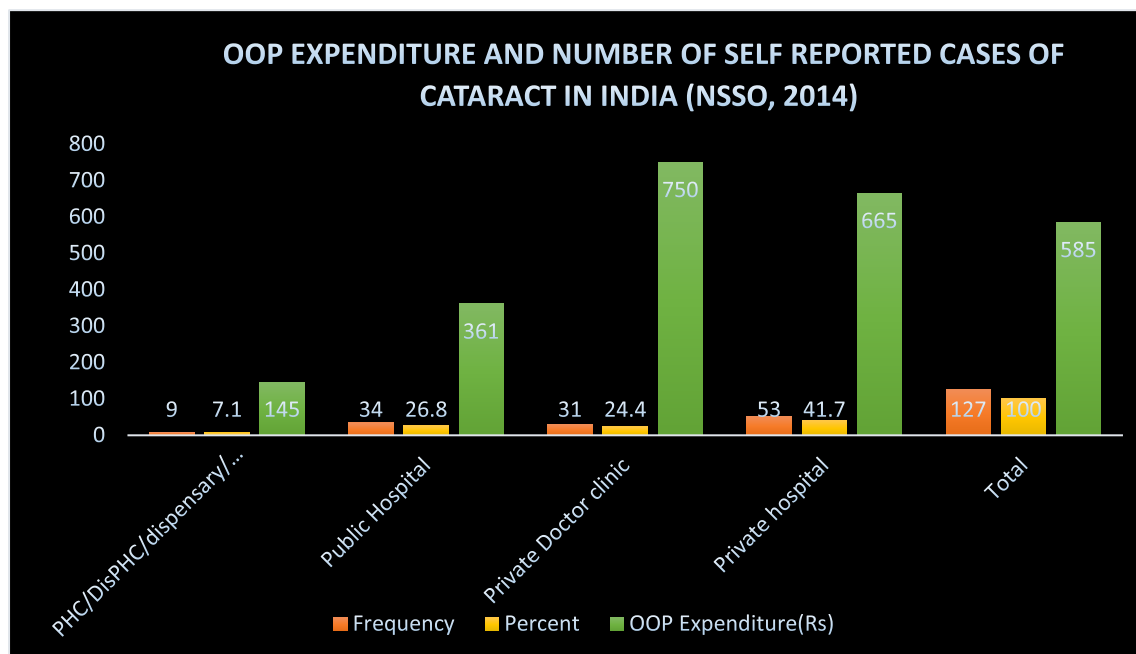


Table 8. OOP expenditure and number of hospitalization cases of cataract in India (NSSO, 2014)

Hospitalization	Frequency	Percent	OOP Expenditure (INR)
PHC/dispensary/CHC/mobile medical unit	21	1.9	2577
Public Hospital	375	34.7	4263
Private Hospital	685	63.4	16514
Total	1081	100.0	11993

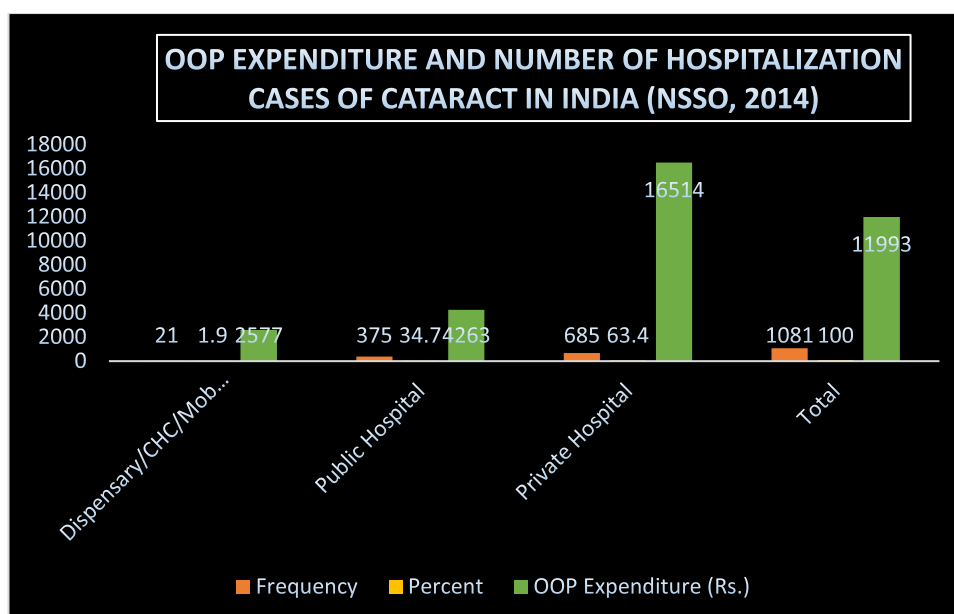


Figure 6. OOP expenditure and number of hospitalization cases of cataract in India (NSSO, 2014)

Conclusion

The Average Cost of Cataract Surgery from the health system perspective reported after primary cost data collection from three secondary centres

Cost of Phacoemulsification Cataract Surgery Package* Rs 9606/-

Cost of MSICS Cataract Surgery Package* Rs 7405/-

Cost of Cataract Surgery from the health system perspective reported after primary cost data collection from a tertiary hospital setting

Cost of Phacoemulsification Cataract Surgery Package* Rs 13017.51/-

Cost of MSICS Cataract Surgery Package* Rs 9215.89/-

Out of Pocket Expenditure for cataract surgery in CHC hospitals

For self-reported cases Rs 145/-

For Hospitalisations Rs 2577/-

Out of Pocket Expenditure for cataract surgery in Public Hospitals

For self-reported cases Rs 361/-

For Hospitalisations Rs 4263/-

* Package Cost includes initial OPD consultation, diagnostic tests (optometry, vision test etc.), counselling, pre-surgery/anaesthetics, surgery, ward, drugs, medical consumables, lens, food for patient and one attendant and one follow-up visit cost.

Chapter 7

Economic Evaluation

Background: Economic evaluation, most commonly in the form of cost-effectiveness analysis, has now become an established tool of overall health financing policy (105). It establishes the relative costs and impacts of health interventions, with the underlying objective of maximising population health for the available resources (105). While performing an economic evaluations priority is given to those treatments which provide the greatest benefit per unit of cost (106). Although economic evaluations approach costs in a common format, they differ in the way they approach benefits (106). These differences leads to different ways of performing economic evaluations like cost effectiveness analysis, cost utility analysis, cost benefit analysis and cost minimization analysis. Cost utility analysis is an adaptation of cost effectiveness analysis which measures an intervention's effect on both the quantitative and qualitative aspects of health using a utility based measure such as quality adjusted life years (QALYs) (107).

In the present analysis, an economic evaluation was undertaken to decide the most cost-effective cataract surgical technique along with intraocular lens implantation where Phacoemulsification with foldable lenses was compared against small incision cataract surgery with rigid lenses. These two interventions were finally selected for economic evaluation, based on our intensive consultations with expert ophthalmologists who suggest, these two are most commonly performed procedure in India. Besides this, there is a provision of only these two interventions in most of the public funded programs like NPCB and RSBY.

Aim: aim of this economic evaluation was to analyse the most cost effective cataract surgery with intraocular lens implantation for age related cataract, by performing a cost utility analysis.

Methods

Population: Age related cataract patients.

Intervention: Phacoemulsification with foldable lenses.

Comparator: Small incision cataract surgery with rigid lenses.

Estimation of cost: Unit costs for both the interventions were calculated using a bottom up costing approach by undertaking a primary costing study from a healthcare perspective (Chapter 6).

Estimation of health effects: QALY gains in both the interventions were estimated by a separate primary study on Quality of Life; (Chapter 5) to estimate quality of life, vision function and visual acuity scores of Indian cataract patients before and after the surgery using internationally accepted instruments EQ5D and IND VFQ 33.

Utilization rate of cataract packages in RSBY: Packages covering cataract were shortlisted from the RSBY scheme to get the share of total patients undergoing different cataract packages. The list used for reference was a package uptake list of the top 100 claimed RSBY packages of various states of India. As the study considers only age related cataract, all cataract related claims done for cataract patients above age 40 years were considered.

NET benefit analysis: As the health effects were measured in the form of quality adjusted life years, a cost utility analysis was performed to calculate the incremental cost effectiveness ratio (ICER). Cost per QALY was then used to calculate the net health benefit and net monetary benefit per patient treated. Cost effectiveness threshold was taken as gross domestic product (GDP) per capita of India 1,709.39 USD -2016 (108). The USD were converted into local currency which is Indian Rupees – 67.18 INR using the conversion rate of 2016. Exchange Rate of the Indian Rupee to US Dollar was taken as annual average (109).

Results:

Cost and QALY of selected interventions: Both the cost and QALY value were higher in phacoemulsification with foldable lens as compared to SICS with rigid lens. Cost and QALY values for the two interventions are as given in table 1.

Table 1. Cost and QALY values

Intervention	Unit Cost (INR)	QALY Gain (Years)
Phacoemulsification with Foldable lens	9606.3	2.25
SICS with rigid lens	7404.6	1.68

Utilization rate of cataract packages in RSBY: There were eight different cataract packages under RSBY (table 2). From these eight packages, unilateral cataract was most commonly utilized procedure (35.45%) and among the interventions most utilized was “Cataract with foldable IOL by Phacoemulsification tech. unilateral” (33.79% of total cataract packages).

Table 2: Cataract packages in the RSBY top 100 utilized package list (2013-14)

Package Name	Age 41-60 years	Age >60 years	Total (Age >40 years)	% of total
Cataract – Bilateral	4	8	12	0.01%
Cataract – Unilateral	32858	19508	52366	35.45%
Cataract + Pterygium	2986	3416	6402	4.33%
Cataract surgery (SICS) Unilateral	910	935	1845	1.25%
Cataract with foldable IOL by Phacoemulsification tech. unilateral	25008	24912	49920	33.79%
Cataract with IOL by Phaco emulsification tech. unilateral Inc. SICS	15222	19071	34293	23.21%
Cataract with IOL Unilateral	1122	1309	2431	1.65%
Cataract with IOL with Phaco emulsification Bilateral	175	294	469	0.32%
Overall Total	78285	69453	147738	100%

Incremental Cost Effectiveness Ratio (ICER)

$$\text{Incremental Cost effectiveness Ratio} = \frac{\text{Cost2} - \text{Cost1}}{\text{Effect2} - \text{Effect1}}$$

$$= \frac{\text{Cost(Phaco)} - \text{Cost(SICS)}}{\text{QALY(Phaco)} - \text{QALY(SICS)}}$$

$$= \frac{9606.36 - 7404.57}{2.25 - 1.68}$$

$$= \frac{2201.79}{0.57}$$

$$= \boxed{3862.79 \text{ INR/ QALY}}$$

Incremental Net Health Benefit:

Incremental Net Health Benefit

$$= (\text{Incremental QALY}) - \frac{\text{Incremental Cost}}{\text{Cost Effectiveness Threshold}}$$

$$= (\text{QALY(Phaco)} - \text{QALY(SICS)}) - \frac{\text{Cost (Phaco)} - \text{Cost (SICS)}}{\text{GDP per capita of India}}$$

$$= (0.57) - \frac{2201.79}{114836.82}$$

$$= \boxed{0.55 \text{ QALY}}$$

Incremental Net Monetary Benefit:

$$= (\text{Incremental QALY} \times \text{cost effectiveness threshold}) - \text{Incremental Cost}$$

$$= ((\text{QALY}(\text{Phaco}) - \text{QALY}(\text{SICS})) \times \text{GDP per capita of India}) - \text{Cost (Phaco)} - \text{Cost (SICS)}$$

$$= (0.57 \times 114836.82) - 2201.79$$

$$= \boxed{63255.2 \text{ INR}}$$

Conclusion: This economic evaluation depicts phacoemulsification with foldable lenses as being cost effective over small incision cataract surgery with rigid lenses with an incremental cost effectiveness ratio of **3862.79** INR /QALY, Incremental Net Health Benefit of **0.55** QALYs and Incremental Net Monetary Benefit of **63255.2** INR.

Chapter 8
Equity Issues
Literature Review

Background: Health inequity is defined as differences in health outcomes between population subgroups that are avoidable, unfair and unjust (110). The World Health Organization has operationally defined “equity in health” as “minimizing avoidable disparities in health and its determinants –including but not limited to health care-between groups of people who have different levels of underlying social attributes” (111). Cataract has many social implications like loss of productivity, breakdown of interpersonal relationships, depressive manifestations, loss of self-esteem and most patients lead an isolated humiliating life. Socio-economic inequities manifest in caste, class and gender differentials. Targeting the vulnerable groups belonging to lower socioeconomic focused programmes will be helpful in eliminating avoidable blindness as proposed strata through by the global initiative Vision 2020 (112).

This review expounds issues that constrict equity in cataract in India disaggregated by PROGRESS-Plus groups. The acronym represents **P**lace of residence; **R**ace/ethnicity/culture/ language; **O**ccupation; **G**ender/ sex; **R**eligion; **E**ducation; **S**ocio-economic status; **S**ocial capital/ networks. The 'Plus' component includes disability, sexual orientation and age. An attempt was made to compare MSICS and Phacoemulsification for their “suitability” (in terms of health service determinants, expertise, resources available, accessibility, cost, clinical outcomes and effectiveness etc.) in the Indian population from an equity point of view.

Methods

Identification of studies: Strategies were designed to identify all relevant studies to assess the equity issues in treatment of age related cataract for the Indian population.

Literature Search: Online databases (the Cochrane Library including the Cochrane Database of Systematic Reviews (CDSR), PubMed, Google scholar and other relevant reports on Government websites) were searched for published studies (Systematic reviews, Meta-analysis, RCTs, Case studies, Surveys, Observational studies and Grey literatures). Last search was done till 23 February 2018.

Inclusion/ Exclusion Criteria

Inclusion Criteria: The studies were included based on the following PICO criteria:

- **Patient or Population:** Adult patients with age-related cataracts from India or LMIC

- **Intervention:** Realization of health care needs (e.g. Information video and counselling about cataract and cataract surgery), Seeking health care services, health care resources, health care services utilization, offered health services {e.g. Free surgery + financial incentives and/ or Re-imbursement (of transport costs Low cost surgery)}
- **Comparison:** Standard care
 - a)Primary Outcomes* - Service utilization and accessibility (i.e. uptake of screening, referral and surgery), any measure of inequity (socioeconomic/ service-provider etc.), cataract surgical coverage (CSC), and change in the prevalence of cataract blindness.
 - b)Secondary Outcomes* - Cataract visual impairment, surgical outcome (visual acuity in the operated eye), unintended outcomes/ adverse events of the intervention.

Exclusion Criteria

- IOL implantation for non-age related cataracts like congenital, pre-senile or paediatric cataracts cases.
- Ophthalmic diseases other than cataract like glaucoma, macular degeneration, diabetic retinopathy, uveitis etc.
- Studies except equity/ inequity/ equality/ inequality for cataract surgical services available.
- Studies performed in countries other than India or LMIC.
- Language other than English.

Inclusion screening process: Studies were selected for inclusion through a two-stage process. First stage was to screen the literature search results (titles, abstracts) identified by the search strategy to identify all citations that potentially met the inclusion/exclusion criteria. Second stage was full text screening done by data extraction.

Critical appraisal: The methodological quality of included systematic review was assessed using revised AMSTAR (R-AMSTAR) tool.

Method of data synthesis: Data were synthesised through narrative review that included critical appraisal of the Cochrane systematic review.

Results

Results of the searches: The electronic searches yielded a total of 6855 articles out of which after removing the duplicates, articles not relevant to cataract and articles other than age related cataract, 172 articles were identified. Of these, on the basis of reading the title and abstract, 104 were excluded, the remaining 68 studies were screened by reading the full text and finally

50 studies were included for our analysis (Figure 1).

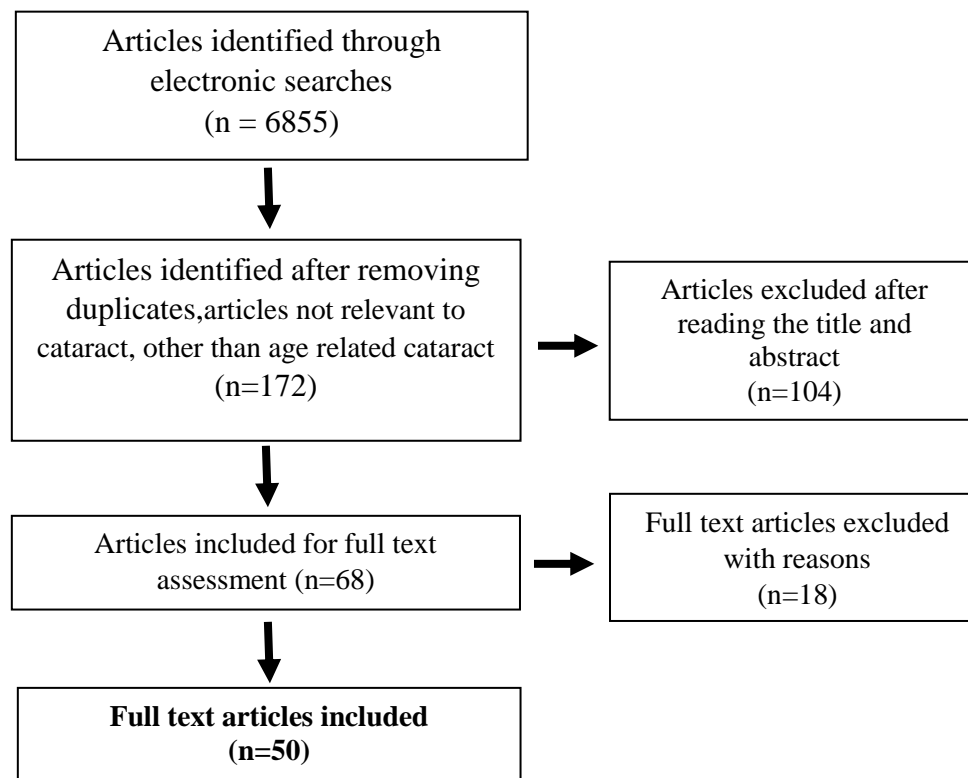


Figure 1. PRISMA flow chart for the identification of studies

Results of Cochrane systematic reviews: The evidence on the effect on equity of interventions (realisation of healthcare needs, seeking healthcare services, reaching healthcare resources, using healthcare services and being offered appropriate services) to improve access to cataract services in LMICs was limited. The only systematic review found reported two cluster randomized trials studies both conducted in rural China (113). The risk of bias was low or unclear. There was low-certainty evidence that providing information and counselling had no effect on uptake of referral to the hospital (OR 1.03, 95% CI 0.63 to 1.67, 1 RCT, 434 participants) and little or no effect on the uptake of surgery (OR 1.11, 95% CI 0.67 to 1.84, 1 RCT, 434 participants). There was low-certainty evidence that surgical fee waiver with/without transport provision or reimbursement increased uptake of surgery (RR 1.94, 95% CI 1.14 to 3.31, 1 RCT, 355 participants). On assessment, the level of evidence came out to be of low-certainty for both outcomes due to indirectness of evidence and imprecision of results. To assist with assessing generalizability of findings to other settings, robust data on contextual factors were also needed.

Quality Assessment: The methodological quality of the systematic review was assessed using PRISMA-E Checklist, which is a checklist of items for reporting Equity- Focused Systematic Reviews and also by revised *AMSTAR (R-AMSTAR)* tool. The included systematic review was in accordance with the PRISMA-E checklist. The total score assigned to the review is 34/44. Rest of the included studies were highly heterogeneous in terms of study design and reporting methods/ results therefore, quality assessment was done only for systematic review.

India specific studies reporting inequity in up taking cataract surgery

Studies from India reported that low uptake of cataract surgery services is mainly linked to service provider-related barriers such as financial reasons, distance from hospital or from a main road, no one to accompany, lack of transport, lack of service awareness, limited surgical manpower (114). Attitudinal/ behavioural barriers included perception such as immature cataract, manageable daily work due to vision in the other eye, busy schedule, female gender, lack of trust in service providers, fear of surgery causing blindness or death, old age that is event of aging so no need of the treatment, God's will, lack of social support in the family such as finding an escort or obtaining permission from other family members especially husbands for women patients and low literacy rates among women and old age patients.(115–118). The barrier no need and no one to accompany shows the attitude of the family members towards their older members as they are less functioning, non-productive people in context of work and income. Different types of barriers in cataract service utilization are discussed below.

Place of Residence: Availability, accessibility and affordability of health services are important determinants for improving population health and they are reflected in the location of the residence of the patient. Several studies reported higher prevalence of cataract in rural areas as compared to the urban areas probably due to a consumer-provider mismatch. It has been reported that 80% ophthalmologists are concentrated in urban areas whereas much of the blindness is in rural areas leading to inadequate service provision to the rural poor (119–121). To address the issue of this mismatch, incentives for ophthalmic personnel who are willing to work in rural underserved centres might be adapted (122). It is also very difficult to provide cataract services to the tribal population living in the remote areas such as mountain and forests. Elderly women from rural areas with cataract or poor vision prefer an attendant to be with them during their treatment. Reach in approach might be beneficial in

such conditions where “screening” camps identify eligible cataract patients especially vulnerable section (elderly women belonging to minorities or marginalised population may be tribal, older people, and people with disabilities) and refer them to a static base hospital for the treatment (120,123,124). Developing reasonable-quality sustainable infrastructure such as transportation, electricity and hospitals etc. in the underserved rural areas may serve the eye-care needs of the population in the long-term.

Race/ ethnicity/ culture/ language: In India, an important determinant of socio-economic inequities in nearly all spheres of well-being is caste. Scheduled Castes (SCs) and scheduled tribes (STs) suffer economic and social deprivation (125). Prevalence of blindness could be related to endogenous factors or because of difference in access to eye care services, which in turn could be due to lower socioeconomic status or racial discrimination (126). There is a need for building good relationships between receivers and providers in order to improve health communication and trust in geographical settings in which the population has a distinct culture and language and is facing conditions such as poverty, chronic hunger, low income, illiteracy and work pressure (127).

Occupation: Some studies suggested that the prevalence of cataract as well as tendency to uptake cataract surgery are related to the occupation of the patients (128). Farmers working in the fields or housewives working in the kitchen for long hours are exposed to UV light and fuel smoke, respectively and are more prone to develop cataract (129,130). Tendency of seeking cataract treatment also depends upon the “need and urgency” such as a driver or tailor who develop cataract will seek cataract treatment on urgent basis as compared to a farmer or a housewife or those who are not working at all. That’s why, the prevalence of productively employed individuals had lowest blind rates (131). Clean biofuels (LPG) to housewives and better farming technologies might help in reducing the cataract prevalence in India.

Gender/ Sex: Risk of cataract blindness between men and women are the same in the age of 50–54 years, but a higher prevalence of cataract was found in women that could be attributed to longer life expectancy, exposures to risk factors such as biomass cooking fuels or intrinsic differences such as hormonal factors (130). Pant et al (2017) describes the sex differentials in cataract blindness in India using data from the two large surveys conducted during 1999–2001 and 2006–2007 (132,133) in which prevalence of cataract blindness was found to be higher in females compared to males in both surveys. Under-utilization of

cataract treatment by women was found due to their poorer socioeconomic status (mainly due to financial dependency in the family), low literacy rate and lack of social support in the family (116–118). Innovative target based programmes for elderly female patient in poor settings and marginalised areas could be helpful to overcome these gender related issues. Creating awareness among women and counselling the males in the household through awareness programmes could be helpful in providing social support to the women in the family.

Religion: Limited studies discuss inequities with respect to religion in India but a significant proportion of people with eye problems reported reasons such as “God’s Will”, “too old”, “not needed”, and other “miscellaneous reasons” for non-utilization of eye care services (115). Interaction with patients who has undergone the operation could help reducing fear and abolishing fatalistic beliefs that blindness was an inevitable part of old age or God’s will (118). Social reforms and creating awareness among people in general and religious leaders in particular can reduce the under-utilization of cataract services.

Education: Studies report that lower educational levels were associated with higher prevalence of age related cataract. The highest risk of blindness was among those aged 70+ and the illiterate (132,134). Eye care programmes should find ways to include education about eye diseases/blindness in current literacy initiatives. A better quality information, education and communication on eye care for public is required.

Socioeconomic status; Social capital/networks: Global data on blindness suggest that the prevalence of blindness due to avoidable causes is higher in the countries with poor socioeconomic status (135–138). The lowest utilization rates of cataract treatment were due to the complex decision-making process in the family (often by male adults) (116) and also observed among those patients who were dependent on their spouses, relatives, or friends for economic sustenance (139). During a cataract surgery, a patient has to bear many indirect costs (out of pocket expenditure) like loss of wages, transportation, and accommodation for the attendant and drugs if not available in hospitals. The burden of expenditure is substantial even for the middle quintiles. Successful cataract surgery improved Vision Related quality of life (VRQoL) and enables previously visually impaired persons to restart work, leads to a higher monthly household income, and more members of the household being engaged in income earning activities. In addition, it makes remarriage amongst widowed elderly persons more likely (39). A study conducted in Kerala showed that state investment in social

development could achieve improvements in the health, even at low levels of per capita income (125). UP, on the other hand, has a persistence of high poverty levels and poor health services and social development. Families are more willing to invest in sight-restoring surgery when there is economic abundance in the home, and they do so more readily for men than women. Focused programmes targeting the vulnerable groups belonging to lower socioeconomic strata could be effective in addressing the social implication.

Disability and Age: The prevalence of cataract increased with increasing age. Respondents aged 60-69 years had a 2.74 times higher risk, while those aged 70 years+ had a 4.86 times higher risk of being blind, compared to those 50-59 years (131). Old age is reported as one of the barriers for not seeking cataract treatment in many studies (115,117,127,130,140–143). Another important barrier reported in many studies is lack of support systems (114,117,122,127,142,144–146).

MSICS vs Phacoemulsification

MSICS and Phacoemulsification were compared for their suitability, (in terms of health service determinants, resources availability, accessibility, perception, cost and clinical effectiveness etc.), for the Indian population from the equity point of view. In MSICS, the cataract nucleus is removed through a self-sealing sclero-corneal tunnel and this technique requires no sophisticated equipment, is machine-independent, cost-effective and efficient technique that gives rapid visual rehabilitation (147). A study reported that MSICS can remove difficult cataracts safely where phacoemulsification could be challenging, for example removal of mature and hard nucleus (148,149). It was also found that both MSICS and Phacoemulsification achieved equally good visual outcomes with low complication rates (147). In a study, the speed of surgery was significantly faster in case of MSICS and a better near vision was demonstrated in MSICS patient groups as compared to the Phacoemulsification group (150) but the speed of surgery depends on the expertise. MSICS has been shown to be the technique of choice in eye camps where hundreds of surgeries need to be performed in few hours with limited high-technology equipment (150,151). This is particularly important in remote settings where patients find it difficult to obtain refractions or spectacles after surgery. Another study reported similar results where MSICS was found to be advantageous for high-volume case-loads whilst maintaining excellent visual outcomes (152).

A Prospective Review of Early Cataract Outcomes and Grading (PRECOG) study was conducted in a geographically diverse range of large and small, urban and rural, and public and private hospitals in developing countries (China, India, Vietnam, Indonesia, Latin America and Africa) in which out of total hospitals selected 76% were public and 59 % situated in rural area. It was found in the study that out of total cataract surgeries conducted 63% were MSICS, 22% were Phacoemulsification and 15% ECCE (Extracapsular Cataract Extraction) (153). In India, 5 Aravind Eye Care System Centres were included in the study and it was found that in India 89% of total cataract surgeries were MSICS, 6% were Phacoemulsification and 5% were ECCE. 61% out of total patients were female and 82% were above 50 in age (153). As per the expert's opinion, 80% cataract surgery done in India are MSICS with rigid lens, followed by 15% of Phacoemulsification and only 5% ECCE and Phacoemulsification is done mainly in tertiary level hospitals and MSICS is mostly done in the secondary hospitals (some in tertiary).

Regarding the technologies used in these surgeries, the only expensive equipment needed in MSICS is an operating microscope, which can function on batteries or a diesel generator while Phacoemulsification requires capital investment and recurring expenditure of Phacoemulsification machine (costing GBP £9000-60000) as well as costs of surgical consumables (Phacoemulsification tips, sleeves, tubing). Moreover, rigid (PMMA) lens are produced locally in contrast to foldable IOLs that are imported from the United States (149). The provider cost of Phacoemulsification and MSICS reported by Muralikrishnan *et al.* (2004) were \$25.55 and \$17.03 respectively (80) while Gogate *et al.* (2005) reported \$42.10 for Phacoemulsification and 15.34 for MSICS (151) and Ruit *et al.* (2007) estimation was \$70 for Phacoemulsification and \$15 for MSICS respectively (147). All of these studies were done in similar geographic locations with comparable socioeconomic dynamics in India and Nepal. Within the Phacoemulsification group there was a wide variation in costs, ranging from \$25.50 to \$70 that was mainly due to different types of imported and expensive foldable IOLs used in Phacoemulsification while in case of rigid PMMA (used in MSICS) the cost of endogenous lens would be \$3. Even though rigid PMMA IOLs were used in both the arms, Phacoemulsification procedures were expensive because of the capital costs of the machine and the costs of the consumables (80). Besides the cost differences Phacoemulsification requires a constant source of reliable electricity and trained personnel to maintain its sophisticated instruments (80,147,154).

It was found in a study that the outcomes of the surgery were less good in an outdoor camp than when surgery is performed in the base hospital. In the long term, it is always better to develop a network of permanent static facilities, where high volume surgery is always available (155).

A study conducted in a rural eye centre, Bodhan, Nizamabad District reported more popularity of Phacoemulsification with IOL over MSICS. It was not clear whether the rural eye centre is public, private or NGO as no information is given about the centre in which the study was done. It suggested Phacoemulsification being minimally invasive and latest surgical technique with better recovery and increased awareness of people about the modern technique could be the reason of its popularity. However, the study also suggested Phacoemulsification to be less cost effective (156).

Information on health-seeking behaviour and utilization of the existing eye-care services is necessary to assist service providers in allocating existing resources and also setting up the priorities for provision of services. Service delivery and cost recovery methods like that of Aravind Eye Hospitals that subsidizes eye care to the poor by charging appropriate price from patients who can pay according to their paying capacities is a model worth looking into, to ensure fairness in financing and provision of services. Good quality outcomes and increased utilisation patterns can be consequential through standardized protocols and creation of accreditation bodies.

Conclusion: The MSICS technique has been shown to be advantageous for high-volume case-loads of age related cataract whilst maintaining excellent visual outcomes. It is less technology dependent, performed mostly at secondary level hospitals without any requirement of constant power supply or trained technical personnel. While, Phacoemulsification which is performed mostly at tertiary level, requires high capital investment and recurring expenditures of Phacoemulsification machine and surgical consumables, respectively. Phacoemulsification also requires trained technical personnel to handle the sophisticated machine. The lens (PMMA) used in MSICS is produced indigenously and thus it is less expensive in contrast to the foldable lens used in Phacoemulsification which is mostly imported and expensive.

In India most of the cataract cases are reported from rural underserved area and most of the cataract surgeries are done in secondary level hospitals. Surgeons in tertiary hospitals prefer to do Phacoemulsification as it is the advanced technique than MSICS. MSICS and

Phacoemulsification have similar clinical efficacy and complications. Therefore, for a public health programme in such a huge, populated and diverse country having enormous socio-economic differences and most of the old patient report to the hospital with a mature cataract, MSICS seems to be more appropriate intervention to address large backlog of cataracts cases. Given the present healthcare condition, an adequate supply of quality surgical and organizational trainers must be ensured so that not only high-quality but a cost effective and affordable eye care services could be provided to the patients that would be helpful in reducing the burden of OOP expenditures. Although direct cost is accounted in the study but indirect costs such as loss of wages, transportations and accommodation for the attendant pose significant burden on the patient. In the cataract package designed as a result of the whole costing study, the food (out of pocket expenditure) for attendant is covered along with the cost spent by healthcare system.

There are significant gaps in the availability of data regarding equity issues in cataract surgery from all the states in India. Hence, there is a pressing need for further high quality research on equity related factors. Another challenge is the value judgment for equity i.e. generating the relevant data regarding weight and trade-offs for equity parameters. Besides all these limitations, information that are available regarding the barriers in the utilization of cataract surgery are also important to better inform policy makers while making decisions.

Discussion, Results & Recommendations

DISCUSSION

Our study suggests that Phacoemulsification with foldable lens leads to more number of QALY gain (0.57 QALY) as compared to SICS with rigid lenses when EQ5D is used as an instrument to assess the generic QoL (Chapter 5). The descriptive system of EQ5D comprises five dimensions: mobility, self-care, usual activities, pain/discomfort and anxiety/depression. Each dimension has five levels: no problems, slight problems, moderate problems, severe problems and extreme problems (99). The limitations of using the EQ-5D is widely acknowledged for vision related disorders as the instrument lacks a particular domain in vision problems (157–160). Until a patient is not severally visually impaired, he or she could be quite well in terms of EQ-5D dimensions- mobility, self-care, usual activities, pain/discomfort and anxiety/depression.

Another issue with EQ-5D instrument is that the instrument is not specifically developed and validated for Indian population and there could be uncertainties in deciding how much Indian patients are able to relate with the instruments and how much their quality of life is being represented by the Eq5D dimensions. Besides this, the valuation of The index values, presented in country specific value sets, that is a major feature of the EQ-5D instrument, facilitating the calculation of quality-adjusted life years (QALYs) that are used to inform economic evaluations of health care interventions are also not available for India. In our study we have used Indonesian value sets for EQ-5D -5L, considering similarities between Indian and Indonesian population. However, we cannot be sure about degree of similarities between Indonesian preferences and preferences directly elicited from general population samples from India. Because of cultural and linguistic considerations, it is mandatory to use a questionnaire developed for a particular community and in the native language of that population, which is responsive to the experience of the population to be evaluated (161,162). The IND-VFQ 33 is much-detailed questionnaire as compared to EQ5D, with three scales, which are a 21-item section for general function, a five-item section for psychosocial impact and a seven-item section for visual symptoms (103). The items in the general function cover mobility, household performance, economic activity, and activities of daily living. The psychosocial scale have items concerning social, family and personal wellbeing. The visual symptoms have items like vision, photophobia and glare. A four-point response scale assesses visual symptoms and psychosocial impact: 1 (best score) to 4 (worst score). The general functioning questions have a five point scale from 1 (best score) to 5

(worst score) (162). For each scale, a composite score was calculated as the cumulative total of individual responses expressed as a percentage of the maximum score possible and then transformed such that 100 represented the best possible score (no difficulty with any of the items in that scale) and 0 the worst score (maximum difficulty in that scale). The results of our primary study clearly shows that SICS with rigid lenses leads to more improvements in all three subscales of IND VFQ33 as compared to Phaco with foldable lenses.

In some conditions (e. g. Vision related problems and paediatric cases), where EQ-5D lacks the sensitivity to capture the desired outcomes, it might be more appropriate to use the EQ-5D instrument to calculate the QALY gain linked with different interventions, but not using it for final decision making(163,164) . The results could be utilized later where priority setting is main objective and where we are comparing the diseases, which are much different in clinical outcomes. When our main objective is to make a choice within a given clinical condition (e.g. cataract for this study), it is better to use a condition specific instrument which is capturing the condition specific outcomes in much detail and far more informative both for clinicians and for patients(165–167).As far as the cost is concerned, it is evident from our primary study that SICS with rigid lens is cheaper than Phaco with foldable lenses, and the findings are true for both the secondary as well as for tertiary care settings in India (Chapter 6). If we look at the Indian settings in real world conditions, more than 95% of cataract surgeries are being conducted at secondary care centres and most of the cataract patient backlog belongs to the rural areas. It is also much evident that rural and semi-urban cities of India are provided with mostly secondary care facilities and tertiary care facilities are mostly located in bigger cities. Phacoemulsification, being an advance technique requires a proper infrastructure and expensive consumables which most of the district level hospitals are lacking at the current stage. Besides the infrastructure, Phaco machine and consumables, it requires surgeons who are specially trained in performing Phacoemulsification. Though the number of trained surgeons performing phaco is constantly increasing in India, they are most often practicing in urban area with bigger set-ups.

By looking at all the parameters viz. clinical effectiveness, Cost, affordability, accessibility, and availability, SICS with rigid lens seems to be more feasible in India in current scenario. Promoting an intervention, which is highly clinically effective, cheaper, available and accessible to larger population, will be best value for public money that will eventually help in reducing OOP expenditure, minimising inequities in healthcare and maximising health.

Results

Following major points emerged from literature review

- Both phacoemulsification and small incision cataract surgery results in comparable clinical efficacy in terms of visual acuity and cataract related complications.
- Though there is a dearth of literature on direct comparison between foldable and rigid PMMA lenses, some studies suggest both these lenses are equally clinically effective.
- There is only one study comparing “Small incision cataract surgery with rigid PMMA lenses” versus “Phacoemulsification with foldable lenses” and found Quality of Life and Vision Function Scores comparable in these two groups.
- The cost of “Small incision cataract surgery with rigid PMMA lenses” is lesser as compared to “Phacoemulsification with foldable lenses”.
- Target based strategies and creating awareness in people could be helpful in reducing the inequities in availing the cataract surgery in disadvantaged population.
- Over 85% of surgeries are currently done using small incision surgery with rigid PMMA lenses- and this is more suited for mature, hard cataracts as compared to phacoemulsification.

Following major points emerged from Primary studies.

- Patients undergoing phacoemulsification and small incision cataract surgery reported significant gains in terms of health related quality of life as measured by EQ-5D-5L instrument, after the surgery. The QALY gain is 0.57 Years over small incision cataract surgery. By using condition-specific instrument IND-VFQ-33, which measures the quality of life in much detail on three subscales including general functioning, psychosocial symptoms and visual symptoms, SICS with rigid lens stands out to be superior as compared to phacoemulsification with foldable lenses in all three subscales.
- The cost of SICS with rigid PMMA lenses is less as compared to Phacoemulsification with foldable lenses. Average cost for SICS with rigid lens is 7404.57 INR and that of Phacoemulsification with foldable lens is 9606.36 INR in

secondary care settings whereas the cost of SICS and Phacoemulsification is 9215.89 INR and 13017.5 INR respectively in tertiary care settings.

- Both Phacoemulsification with foldable lens and SICS with rigid PMMA lens are cost effective strategies for cataract treatment where we are gaining 2.25 and 1.68 QALYs by spending 9606.36 and 7404.57 INR respectively. On comparing Phacoemulsification with foldable lens with SICS and rigid lenses, Phacoemulsification with foldable lens is a cost effective strategy where the incremental cost effectiveness ratio (ICER) is 3024.6 INR only.
- SICS is clinically more effective (vision related Quality of life using IND VFQ 33), less expensive (primary costing), and with greater equity in access to larger number of target population, available in more number of secondary care settings as compared to Phacoemulsification. Increasing access to phaco-emulsification would require greater investment in equipment at peripheral hospitals and greater skill building, whereas SICS is more widely established.

RECOMMENDATIONS

- On the basis of clinical efficacy, cost, accessibility, availability and feasibility, SICS with rigid lens is most appropriate intervention to treat cataract patients in India in current scenario.
- Phacoemulsification cataract surgery can be provided in those areas where infrastructure and experts are available for Phacoemulsification surgery.
- The benefit packages for Phacoemulsification with foldable lens and small incision cataract surgery with rigid PMMA lenses may cost as 9606 INR and 7405 INR respectively.
- The package is inclusive of initial OPD consultation, diagnostic tests (optometry, vision test etc.), counselling, pre-surgery/anaesthetics, surgery, ward, drugs, medical consumables, lens, food for patient and one attendant and one follow-up visit cost.

Strengths of the study

- First comprehensive HTA study on management of age related cataract in India.
- Supported by five systematic reviews on different aspects including clinical effectiveness, quality of life, cost effectiveness, costing, and equity issues.
- Supported by primary study done specifically for this HTA analysis to estimate both quality of life and vision function scores of Indian cataract patients before and after the surgery using internationally accepted instruments EQ5D and IND VFQ 33.
- Supported by primary study done specifically for this HTA analysis to estimate the cost of resources utilized from secondary and tertiary care hospitals providing cataract surgery from the healthcare perspective.
- Various barriers for update of cataract surgery, specifically in Indian context are analysed separately by a thorough literature review.
- This study also considered highly valuable suggestions and key points that emerged after intensive stakeholder's consultation.

Limitations of the Study:

- Rigorous attempts were not made to retrieve unpublished literature and certain studies were not found as full text due to reasons like full study only available in languages other than English, access issues etc. this may also influence the literature review.
- Meta-analysis was not performed in any of literature review, as the ways in which outcomes were measured were too variable to be mathematically combined.
- Critical appraisal of included studies was not feasible in some of the literature reviews due to high variation in study designs and unavailability of set guidelines.
- There are assumptions taken during the primary costing study where getting the exact data was not feasible.
- The patients undergoing small incision cataract surgery with rigid lenses were quite lesser compared to patients undergoing phacoemulsification with foldable lenses and the follow up rate of patients after the surgery was almost 65% in primary study on quality of life. This may influence the exact values of health states after these two surgeries. The patients undergoing SICS with foldable lens was too few for comment.

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Annexures

Cost Data Collection Tool

Annexure - I

Cost data collection tool for Cataract Surgery

Facility type:

Information about the facility:

Interview Date	__/__/__
State name	
District Name	
Facility Type	
Facility Name	

This tool intends to collect information pertaining to following heads for the *financial year 2016-17*

	Different heads for cost data collection	Put tick mark at the end of interview
1.	Personnel	
2.	Record on services delivered/	
3.	Sources of revenue	
4.	Details regarding population covered and location of the facility	
5.	Equipment	
6.	Consumable drugs	
7.	Consumable Materials and Supplies/ Details on any other Kit/ Supplies as part of health programmes	
8.	Physical infrastructure	
9.	Stationary	
10.	Utility / Overheads	
11.	Laboratory test	
12.	Referral transport	
13.	Incentives paid	
14.	Grants utilised/ Amount spent under different schemes	

Cost Data Collection Tool

Table 1: Interview with the head of the facility or person In-charge

- A. Please tell me how many days per week this facility is closed? : _____ (Days per week)
- B. Please tell me how many hours per day this facility is open? : _____ (Hours per day)
- C. If the facility remains closed on Public holidays then mention total public holidays in last year: _____(Days in year)
- D. Average length of stay of IPD patients of the facility:

Mention the number of days of stay of 100 patients of facility of financial year 2016-17*

Exclude the following:

- Patients who were transferred to another hospital
- Patients for whom length of stay is not available
- Patients who left against medical advice or discontinued care

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[illegible][illegible]

For more than one person of a category use alphabetic prefixes. For e.g. if there are 2 Medical officers, use code: 1a, 1b

[illegible][illegible]

Cost Data Collection Tool

Table 4a: Annual services delivered (Record based for cataract)

<i>Codes</i>	<i>Services delivered</i>		<i>Actual services delivered in OPD during last year</i>	<i>Actual services delivered in IPD during last year</i>
1.	Routine OPD (over 5)	<i>Total at the facility</i>		NA
2.	Cataract Surgery done through outreach services(MSICS)	<i>Total at the facility</i>		
3.	Cataract Surgery done through outreach services(Phaco)	<i>Total at the facility</i>		
4.	Cataract Surgery(MSICS)-Daycare	<i>Total at the facility</i>		
5.	Cataract Surgery(Phaco)-Daycare	<i>Total at the facility</i>		
6.	YAG Laser Capsulotomy for PCO	<i>Total at the facility</i>		
7.		<i>Total at the facility</i>		
8.		<i>Total at the facility</i>		
9.				
10.				
11.				
12.				

Cost Data Collection Tool

Table 5: Sources of Revenue

		Amount collected during the period of data collection
1.	<i>Procedure fee</i>	
2.	<i>Referral Charges</i>	
3.	<i>Medical certificate for driving license</i>	
4.	<i>Any other (specify)</i>	
5.		
6.		
7.		
	<i>Total user fee from 2016-17</i>	

Table 6: Details regarding population covered at the facility

Total population under the Public Health Centre

Total=

Male=

Female=

Children (under 5 years)=

Children (5-10 years)=

Cost Data Collection Tool

Table 7a: Equipments (Observation cum record review of stock registers)

[illegible]

Cost Data Collection Tool

Table 8: Consumables. Drug (Review the stock- register and list the quantity and price of drugs in drug list sheets provided at the end of tool by using the sheets to photocopy index of drugs register and write quantity, price and utility against each drug as given below

<i>Name of drug(used for Cataract)</i>	<i>Quantity</i>	<i>Price</i>	<i>Utility (OPD=1, IPD=2, Out-reach=3,OPD+IPD=4, All= 5, OPD+OR=6, IPD+ OR=7)</i>	<i>List services for which it is used. Write serial number codes from Tables on time sheet allocation</i>

Table 9: Consumables. Material and Supplies(used for Cataract)

	<i>Quantity</i>	<i>Price</i>	<i>Utility (OPD=1, IPD=2, Out-reach=3,OPD+IPD=4, All= 5, OPD+OR=6, IPD+ OR=7)</i>	<i>List services for which it is used. Write serial number codes from Tables on time sheet allocation</i>
Bandages 4 meters* 5cm				
Bandages 5 meters*10cm				
Bandages 5 meters*15cm				
Biowaste polythene				
Blade 11 no.				
Cotton wool absorbent surgical 500g packet				
Crape bandage BP 3 mtr x 10cm				
Crape bandage BP 3 mtr x 15cm				
Crape bandage BP 3 mtr x 7.5cm				
Disinfectant fluids (Phenly-Ltr)				

Cost Data Collection Tool

[illegible]

Cost Data Collection Tool

Table 10: Physical infrastructure (Interview based)

Table 12 a: Particulars	Specify
Area of the building (Total area in Sq. ft.) (Covered + open space)	
What is the rental price of 100 sq ft place where this Public Health centre is located?	
Was there any expense on construction of building or renovation during the period of data collection	

Facility Check

Ask the head of the facility if you can make a tour of the facility to get some information on the building space, vehicles and equipment. Use the space below to draw a simple layout of the facility. Identify the type of service delivered in each room/space using the codes available. Specify a number for each room /space on the map.

Alternatively you can ask for map of the building with area measurements.

Thank the head of the facility and ask him if you can revisit the different rooms to complete measurements (if required) and make a closer observation.

Use the following table to fill in the required information for each room in the building(s)

You need to have a measuring instrument (used to calculate length and width of the room) with you to measure square meter surface area

You need to complete the following observations:

Record the measurements needed in Table 12b

Draw a sketch of the facility in the space available above

Complete Table 13 with the inventory of furniture and items available in each room.

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Facility space

N.B.

- _ Do not forget waiting areas (some of them can be for adult only or children only).*
- _ If any of the rooms are not used at the moment indicate this in the service/function column.*

Sketch of the facility:

Table 11: Services delivered in different rooms in facility (Put 1 if particular service is delivered in a particular room)

[illegible]

Table 12: Items in facility rooms (Observation and record review)

Do ask for any items that are there in stock register and are stored due to non-utilisation or non-functionality

[illegible]

[illegible]

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[illegible]

[illegible]

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[illegible]

Cost Data Collection Tool

[illegible]

Cost Data Collection Tool

Table 13: Signage/ IEC material on display in the unit (Observation cum record review in stock register)

Type of IEC material (Specify size)	Quantity	Price	Utility (OPD=1, IPD=2, Out-reach=3, OPD+IPD=4, All= 5, OPD+OR=6, IPD+ OR=7)	List services for which it is used. Write serial number codes from Tables on time sheet allocation
Flex board				
Paper Charts				
Wall paintings				
Handbills				
Pamphlets				
Booklets				

Table 14: Stationary and other miscellaneous items: (Record review for billed amounts of purchased stationary)

	Quantity	Price	Utility (OPD=1, IPD=2, Out-reach=3, OPD+IPD=4, All= 5, OPD+OR=6, IPD+ OR=7)	List services for which it is used. Write serial number codes from Tables on time sheet allocation
Article indent book				
Attendance register				
Bath soap				
Carbon paper				
Cash receipt book				
Disinfectant fluids (Phenly-Ltr)				
Harpic				
Health management info system subcenter Register				

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Indoor register				
Nirma				
OPD card				
OPD register				
Out-station dak book				
Pencil				
Broom				
Photostat paper				
Pocha				
Poly bags for biowaste				
Register IDSP				
Savlon solution				
Spirit				
Stamp ink				
Stamp pad				
Stock + OPD register				
Toilet brush				
Towels + dusters				
A-4 paper				
Vim powder				
Article indent book				
Attendance register				
Bath soap				
Carbon paper				
Cash receipt book				
Disinfectant fluids (Phenly-Ltr)				
Harpic				
Health management info system register				
Indoor register				
Nirma				
OPD card				

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OPD register				
Out-station dak book				
Pencil				
Broom				
Photostat paper				
Pocha				
Poly bags for biowaste				
Register IDSP				
Savlon solution				
Spirit				
Stamp ink				
Stamp pad				
ANY OTHER				

Table 15: Utilities/ Overhead (Annual)

	<i>Quantity</i>	<i>Price</i>	<i>Utility (OPD=1, IPD=2, Out-reach=3, OPD+IPD=4, All= 5, OPD+OR=6, IPD+ OR=7)</i>	<i>List services for which it is used. Write serial number codes from Tables on time sheet allocation</i>
1.Means of transport				
Maintenance				
Repairs				
Insurance				
Others				
Total (<i>If available</i>)				
2. Building				
Electricity				

Water				
Facility rent (if relevant)				
Maintenance				
Telephone				
Kerosene				
Other				
Total (If available)				
3. Equipment				
Maintenance				
Repairs				
Other				
Total (If available)				
4. Laundry				

Table 16: Laboratory/ Radiological investigation/Procedure fees

Type of tests	Quantity	Price	Utility (OPD=1, IPD=2, Out-reach=3, OPD+IPD=4, All= 5, OPD+OR=6, IPD+ OR=7)	List services for which it is used. Write serial number codes from Tables on time sheet allocation
Haemoglobin				
Complete Blood Count				
Blood Sugar				
Liver Function Test				
Kidney Function Test				

Diagnostic test (General)				
X-rays				
ECG				

Table 17: Details of referral transport

[illegible]

Table 18: Cash benefits paid to patients

[illegible]

Table 19: Utilisation of funds and grants

[illegible]

Time allocation sheet (Fill one sheet for each staff member)

Annexure - II

Staff Member Code (Enter Code as entered in Table 2 of Cost data allocation sheet):				
Code for services	Activities	Time per Patient (a)	Frequency ¹ (b)	Average number of patients during each session i.e. review records or ask the staff (c)
1.	Routine OPD (over 5)			
2.	Cataract Surgery done through outreach services(MSICS/Phaco)			
3.	Cataract Surgery(MSICS/Phaco)-Daycare			
4.	Capsulotomy for PCO			
5.	Laboratory Tests			
6.	Vision Tests			
7.	Ophthalmic Tests			
8.				
9.				
10.				

¹1' for once a year participation, '2' for twice a year, 3 for thrice a year participation, 4 for quarterly participation, 5 for once every two months, 6 for monthly participation, 7 for fortnightly participation, 8 for weekly participation, 9 for twice a week participation, 10 for thrice a week participation, 11 for daily participation.

Time allocation sheet (Fill one sheet for each staff member)

1' for once a year participation, '2' for twice a year, 3 for thrice a year participation, 4 for quarterly participation, 5 for once every two months, 6 for monthly participation, 7 for fortnightly participation, 8 for weekly participation, 9 for twice a week participation, 10 for thrice a week participation, 11 for daily participation.

Code for services	Activities that do not involve direct contact with single patient	Frequency	Number of hours on day of activity (a)	No. of days for single activity (b)	Hours spent (a*b)
11.	Meeting CHC				
12.	Health camps				
13.	Disease surveillance (Early detection of				
14.	Recording of vital events/HMIS				
15.	House to house surveys				
16.	Activities related to National Health programmes				
17.	Trainings conducted for staff at the facility				
18.	Water and Sanitation(Disinfection of drinking water source , Promotion of sanitation)				
19.	Support activities for all direct servicesLike cleanliness, sweeping, clerical work				



Health Questionnaire

English version for India

Under each heading, please tick the ONE box that best describes your health TODAY.

MOBILITY

- I have no problems in walking about ☐
- I have slight problems in walking about ☐
- I have moderate problems in walking about ☐
- I have severe problems in walking about ☐
- I am unable to walk about ☐

SELF-CARE

- I have no problems in bathing or dressing myself ☐
- I have slight problems in bathing or dressing myself ☐
- I have moderate problems in bathing or dressing myself ☐
- I have severe problems in bathing or dressing myself ☐
- I am unable to bathe or dress myself ☐

USUAL ACTIVITIES (e.g. work, study, housework, family or leisure activities)

- I have no problems doing my usual activities ☐
- I have slight problems doing my usual activities ☐
- I have moderate problems doing my usual activities ☐
- I have severe problems doing my usual activities ☐
- I am unable to do my usual activities ☐

PAIN / DISCOMFORT

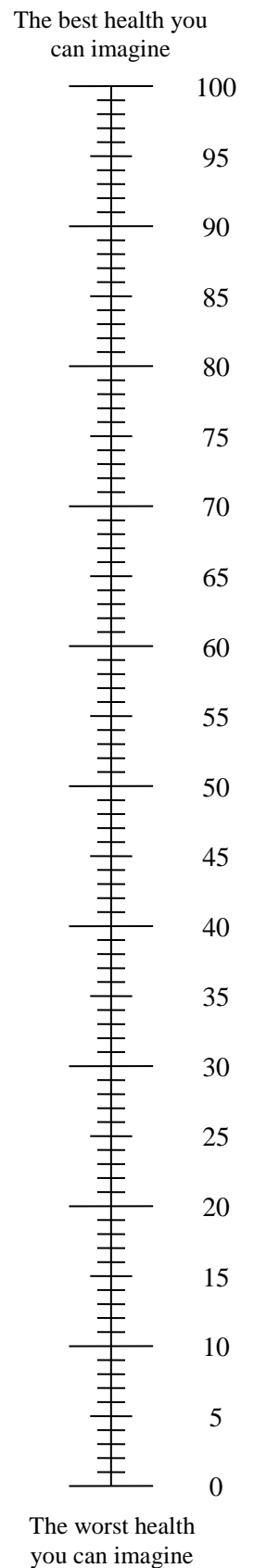
- I have no pain or discomfort ☐
- I have slight pain or discomfort ☐
- I have moderate pain or discomfort ☐
- I have severe pain or discomfort ☐
- I have extreme pain or discomfort ☐

ANXIETY / DEPRESSION

- I am not anxious or depressed ☐
- I am slightly anxious or depressed ☐
- I am moderately anxious or depressed ☐
- I am severely anxious or depressed ☐
- I am extremely anxious or depressed ☐

- We would like to know how good or bad your health is TODAY.
- This scale is numbered from 0 to 100.
- 100 means the best health you can imagine.
0 means the worst health you can imagine.
- Mark an X on the scale to indicate how your health is TODAY.
- Now, please write the number you marked on the scale in the box below.

YOUR HEALTH TODAY =



Indian Vision Function Assessment Questionnaire (33-item)

Encircle the appropriate response

In the first section, I am going to ask you how much your vision problem affects you in doing your daily activities. I will read out a choice of four answers and you will choose the one you feel describes you best. If you cannot do, or don't do this activity because of vision, or other reasons, please tell me. If someone helps you to do these activities please tell me.

Question Number		√ Appropriate Box						
		Not at all	A little	Quite a bit	A lot	Cannot do this because of my sight	Does some one help you? (Write Yes/No)	Don't do this for other reasons
1	Because of your vision how much problem do you have in climbing stairs							
2	Because of your vision how much problem do you have in making out the bumps and holes in the road when walking							
3	Because of your vision how much problem do you have in seeing if there are animals or vehicles when walking							
4	Because of your vision how much problem do you have in finding your way in new places							
5	Because of your vision how much problem do you have in going to social functions such as weddings							
6	Because of your vision how much problem do you have in going out at night							
7	Because of your vision how much problem do you have in finding your way indoors							
8	Because of your vision how much problem do you have in seeing the steps of the bus when climbing in or out							

9	Because of your vision how much problem do you have in recognising people from a distance							
10	Because of your vision how much problem do you have in recognising the face of a person standing near you							

Question Number		√ Appropriate Box						
		Not at all	A little	Quite a bit	A lot	Cannot do this because of my sight	Does some one help you? (Write Yes/No)	Don't do this for other reasons
11	Because of your vision how much problem do you have in locking or unlocking the door							
12	Because of your vision how much problem do you have in doing your usual work either in the house or outside							
13	Because of your vision how much problem do you have in doing your work up to your usual standard							
14	Because of your vision how much problem do you have in searching for things at home							
15	Because of your vision how much problem do you have in seeing outside in bright sunlight							
16	Because of your vision how much problem do you have in seeing when coming into the house after being in the sunlight							
17	Because of your vision how much problem do you have in seeing differences in colors							
18	Because of your vision how much problem do you have in making out differences in coins or notes							
19	Because of your vision how much problem do you have in going to the toilet							
20	Because of your vision how much problem do you have in seeing objects that may have fallen in the food							
21	Because of your vision how much problem do you have in seeing the level in the container when pouring							

In the next section, I am going to ask you how you feel because of your eye problem, I will read out a choice of four answers and you will choose the one you feel describes you best.

		√ Appropriate Box			
Question Number		Not at all	A little	Quite a bit	A lot
22	Because of your eye problem do you feel frightened to go out at night				
23	Because of your eye problem do you enjoy social functions less				
24	Because of your eye problem do you ashamed that you can't see				
25	Because of your eye problem do you feel you have become a burden on others				
26	Because of your eye problem do you feel frightened that you may lose your remaining vision				

In the next section, I am going to ask you to what extent do you have the following eye problems. I will read out a choice of four answers and you will choose the one you feel describes you best.

		√ Appropriate Box			
Question Number	<i>I am going to read out a list of eye problems that people report. For each problem please say to what extent you have the problem</i>	Not at all	A little	Quite a bit	A lot
27	Do you have reduced vision				
28	Are you dazzled in bright light				
29	Is your vision blurred in sunlight				
30	Does bright light hurt your eyes				
31	Do you close your eyes because of light from vehicles				
32	Does light seem like stars				
33	Do you have blurred vision				
		<i>Record as fully as possible the answer given by the patient</i>			
	Does your eye problem affect your life in any other way we have not mentioned? If YES, how?				