ORIGINAL ARTICLE

Incidence and Associated Factors of Posterior Capsule Opacification Formation in Pseudophakic Patients at Cipto Mangunkusumo Hospital : January - December 2010

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ABSTRACT

Objective: Posterior capsule opacification (PCO) is the most common postoperative consequence of cataract surgery which may cause visual acuity reduction. The incidence of PCO in Indonesia has not been reported yet. The objectives of this study were to evaluate three years cumulative incidence of PCO and factors associated with PCO formation at Cipto Mangunkusumo (CM) Hospital.

Methods: This was a retrospective descriptive study to patients with uneventful senile cataract surgery in year of 2010. All related data were retrieved from those medical records in year of 2013, which included patient demographics, type of surgery, time of PCO stated, IOL characteristics (material, optic edge design and diametere. Best corrected visual acuity (BCVA) pre operatively, when PCO was determined and Nd:YAG laser (Neodymium-doped yttrium aluminium garnet) was performed in decimal.

Result: A total of 578 eyes (485 patients) was involved in this study. Three years cumulative incidence of the PCO was 8.82% (51 eyes). Phacoemulsification surgery was conducted in 496 (85.8%) eyes. The median time to PCO was being determined was 21 months (range 1 to 34 months) with the mean of BCVA was 0.50 ± 0.26 . Age, gender, and type of surgery had no related factors to PCO, but higher evidence in using of hydrophilic acrylic IOL (10.7%) was found. After laser Nd:YAG laser was performed, BCVA was improved.

Conclusion: Three years cumulative incidence of PCO was 8.82% and there was no defined related factor to PCO reformation, but eye had been using hydrophilic acrylic IOL seem to be higher percentage

Keyword: incidence, posterior capsule opacification, intraocular lens

Posterior capsule opacification (PCO) is the most common postoperative consequence of cataract surgery.¹ Fong² et al in a cohort study, reported the three years cumulative incidence of PCO was 38.5% (95% confidence interval [CI] 36.1%-40.9%) among 1495 patients. PCO cause visual acuity and contrast sensitivity reduction, glare and monocular diplopia ^{1,3,4}, which might reduce the patient's quality of life and caused an economic burden to the healthcare system.⁵ Factors related to PCO formation mostly were type cataract surgery, IOL design and patient

with has sistemic diseases. To open blocked visual axis by using of Nd:YAG laser posterior capsulotomy will improve visual acuity. However in Indonesia, PCO patients should be referred to tertiary hospitals just for getting Nd:YAG laser posterior capsulotomy, while cataract surgery could be done in out-reach and primary health care. Laser procedure itself has risk of complications such as IOL damage, increase of intraocular pressure, cystic macular edema, anterior vitreous surface disruption, and retinal detachment.^{1,6}

Eventually, Opthtalmology Department-Cipto Mangunkusumo Hospital (CM-hospital) had done a retrospective study by Anggraini⁷ et al and found the incidence of PCO was 9,2% (47 of 513 eyes) in year of 2003 (unpublished data). Introducing by modern cataract machine, phacoemulsification have been performed increasingly with a better result regarding to visual acuity, small cornea incision, rapid wound healing and less complications. also varied better of IOL material and design had been used in our hospital. There was never been reported of PCO incidence since then. The objective of this study was to evaluate three years cumulative incidence of PCO and factors associated with PCO formation.

METHODS

This study was a retrospective descriptive study and conducted in year of 2013. All related data was retrieved from January to December 2010' medical records. The inclusion criteria was all patients who had uneventful senile cataract surgery at Ophthalmology Department, Cipto Mangunkusumo Hospital (CM hospital)-Indonesia. The exclusion criteria was patients with abnormalities other than PCO which influenced the visual acuity, incomplete medical records data and follow up less than 1 month post operatively. A total sampling method was used in selection of the subject and this study had been reported to CM hospital.

Alldatas were focused inpatient demographics, type of surgery which were extra capsular cataract extraction (ECCE), phacoemulsification and small incision cataract surgery (SICS), type of IOL characteristics on material, optic edge design and diameter, time to PCO of being stated (duration between cataract surgery and diagnosis of PCO in months). When PCO was determined, Nd:YAG laser posterior capsulotomy was performed. Best corrected visual acuity (BCVA) in decimal was noted at 1-month postoperatively and when PCO stated, and 2 weeks after Nd:YAG laser posterior capsulotomy. BCVA was classified based on ICD-10 CM revision.

The data was analyzed using SPSS 11.0 and Microsoft Excel 2011. The percentage was calculated with descriptive statistics and Chi- square test was used to compare PCO proportion within phacoemulsification group.

RESULTS

There were 1665 cataract surgeries performed during period January–December 2010 in Cipto Mangunkusumo Hospital. Ninety percent (1498 cases) had completed medical records, but only 1104 cases (73.7%) could be accessed. Finally, 852 eyes had met the inclusion criteria. Two hundred and seventy four cases (274) or 32.2% were excluded due to abnormalities other than PCO (138 cases) and 136 cases had incomplete related data. In a total of 485 patients or 578 eyes (67.8%) were analyzed in this study.

Demographics and clinical haracteristics of pseudophakic patients

There were 49.9% male with 80.8% unilateral eyes included in this study. The median age was 65 years old with ranging from 42-87 years old.

Median of pre operative BCVA was 0.07 (range 0.00 to 0.90). Visual acuity (VA) better than 0.5 was in 127 (22%) eyes, mild visual impairment in 48 (8.3%) eyes, moderate visual impairment in 102 (17.6%) eyes, severe visual impairment in 39 (6.7%) and 129 (22.3%) eyes with blind category 3 and 133 (23%) eyes was blind category 4, respectively. One month post operatively, VA was 1.00 (range from 0.30 to 1.20) , most of the eyes had VA better than 0.5 (99.8%), only one eye had VA less than 0.5. The most common type of surgery performed was phacoemulsification in 496 (85.8%) eyes followed by ECCE in 77 eyes (13.3%) and SICS in 5 eyes.

Table 1.	Patient	demographics
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Variable	Number of patients (pts) /eyes (%)		
Total subject	485 pts (578 eyes)		
Laterality			
Unilateral	392 pts (80.8%)		
Bilateral	93 pts (19.2%)		
Sex			
Male	242 pts (49.9%)		
Female	243 pts (50.1%)		
Age (median; range)	65 (42 - 87) years		

Table 2.	Clinical	characteristics	of	pseudo	phakic ev	/es

Variable	
Pre-op BCVA (decimal)	0.07 (0.00-0.90)
No visual impairment (> 0.5)	127 (22%)
Mild visual impairment	48 (8.3%)
$(\geq 0.3 - \leq 0.5)$	(0.570)
Moderate visual impairment	102 (17.6%)
$(\geq 0.1 - < 0.3)$	102 (17.070)
Severe visual impairment	39 (6.7%)
$(\geq 0.05 - < 0.1)$	
Blind category 3	129 (22.3%)
$(<0,05-\ge0,02)$	12) (22.370)
Blind, category 4	133 (23%)
(< 0.02 - light perception)	155 (2570)
Post-op BCVA at 1 month	1.00 (0.30;1.20)
(decimal)	1.00 (0.30,1.20)
No visual impairment (> 0.5)	577 (99.8%)
Mild visual impairment	1 (0.20/)
$(\geq 0, 3 - \leq 0, 5)$	1 (0.2%)
Type of surgery	
Phacoemulsification	496 (85.8%)
ECCE	77 (13.3%)
SICS	5 (0.9%)

Cumulative incidence of PCO and clinical characteristics of PCO patients

PCO is the most common consequence after cataract surgery. Among 578 eyes, only 51 eyes had PCO and the cumulative incidence of PCO formation was 14 (2.42%) eyes at first year, 34 (5.88%) eyes in second year and 51 (8.82%) eyes in the thirth year.

Table 3. Cumulative incidence of PCO

Period	Incidence
1 year	2.42% (14 eyes)
2 years	5.88% (34 eyes)
3 years	8.82% (51 eyes)

Table 4. Clinica	l characteristics	of PCO eyes ((n=51)
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Variable	
Age	63.57 ± 8.20 years old
Surgical technique	
Phacoemulsification	49 /496 (9.9%)
ECCE	1/77 (1.3%)
SICS	1/ 5 (20%)
BCVA at PCO stated (decimal)	0.50 ± 0.26
No visual impairment	34 (66.7%)
(> 0.5)	
Mild visual impairment	6 (11.8%)
$(\geq 0.3 - \leq 0.5)$	
Moderate visual	8 (15.7%)
impairment ($\geq 0.1 - < 0.3$)	
Severe visual impairment	3 (5.9%)
$(\geq 0.05 - < 0.1)$	
Symptoms of PCO	
Blurred vision	39 (76.5%)
Blurred vision and diplopia	2 (3.9%)
Foggy view	2 (2.0%)
Blurred vision and glare	1 (3.9%)
No symptoms	7 (13.7%)
Time of PCO stated	21 (1 - 34) months

The mean age of PCO patients was 63.57 ± 8.20 years old, younger than other pseudophakic patients. Formation of PCO was more common in SICS (20%) eyes, where as in phacoemulsification, PCO was found in 49/496 (9.9%) eyes. The most common symptoms of PCO was blurred vision in 39 (76.5%) eyes. BCVA decreased to 0.5 ± 0.26 , which included in normal range of VA in 34 (66.76%) eyes, mild visual impairment 6 (11.8%) eyes and severe visual impairment in 3 (5.9%) eyes, respectively. Median time to PCO was being stated was 21 months or 1.75 years, with ranging from 1 to 34 months.

Table 5 showed that Nd:YAG laser posterior capsulotomy was only performed in 72.5% of eyes. After Nd:YAG laser posterior capsulotomy was performed, the BCVA showed a better result that was 1.00 (range 0.70 - 1.00)]. No complications were found on 2 weeks follow up.

Variable	
Nd:YAG performed	37 (72.5%)
Nd:YAG not performed	14 (27.5%)
BCVA at PCO diagnosis	0.43 ± 0.24
(Nd:YAG performed, n=37)	
BCVA at PCO diagnosis	0.66 ± 0.24
(Nd:YAG not performed, n=14)	
BCVA at 2 weeks post Nd:YAG	1.00 (0.70- 1.00)

Intraocular lens characteristics

Since many efforts had been done to minimize PCO formation, several types of IOL material and design may be related factors in influencing the PCO formation¹. This study found hydrophilic acrylic IOL to be the most used (53.46%), then PMMA in 35.3%. The foldable design of this material is appropriate with the width of incision in phacoemulsification. In 2010, hydrophobic acrylic was still minimally being used due to the relatively expensive price. This material type of IOL was mainly used in patients who had certain health insurance in our hospital. Square optic edge was the majority of the optic edge design (65.4%) and all eyes had been used 1-piece IOL.

Phacoemulsification is the most common type of surgery performed. Cross tabulation of age and IOL characteristics only performed in phacoemulsification group in order to minimized bias due to different types of surgery. No significant difference was found in the proportion of PCO formation among type of IOLs on material, optic diameter and optic edge.

Table 6. IOL characteristics in pseudophakic eyes (n=578)
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Variable	Frequency(%)
IOL material	
Polymethylmethacrylate (PMMA)	204 (35.3%)
Acrylic	374 (64.7%)
Hydrophilic acrylic	309 (53.46%)
Hydrophobic acrylic	65
IOL design	
1-piece	578 (100%)
3-pieces	0 (0%)
Optic edge design	
Square	378 (65.4%)
Round	200 (34.6%)

Table 7. Cross tabulation of IOL characteristics with PCO incidence in phacoemulsification group (n=496)

Variable	PCO		No PCO		
variable	n	%	n	%	- p
Acrylic-PMMA					
Acrylic	37	9.9	337	90.1	NT
PMMA	12	9.8	110	90.2	
Acrylic					
Hydrophilic	33	10.7	276	89.3	NT
Hydrophobic	4	6.2	61	93.8	
Optic diameter					
5.25-5.50 mm	11	9.2	108	90.8	NT
6.00-6.50 mm	38	10.1	339	89.9	
Optic edge					
Square	37	9.8	339	90.2	NT
Round	12	10	108	90	

*Chi Square test NS: no significant difference

DISCUSSION

Our study revealed that modern cataract surgery with better quality of IOL design and material being used decreased the incidence of PCO formation from 9,2% in our previous unpublished data in year 2003, to 8.82% in year 2010. Using high technology mechine in cataract surgery showed less complication on long term of followed up pseudophakic eyes. Currently phacoemulsification become standard cataract surgery in our hospital since the results is amazing. This study also showed mostly our cataract patients condition in blind catagory 4 and relatively young. Shah⁸ et al in collaboration with World Health Organization (WHO) analyzed 11,408 patients who have had cataract surgery from 50 countries in 2008 also found the median age of 65 years with majority with severe visual impairment which was mostly related to senile degenerative cataract and strong correlation into ultraviolet exposure.

Phacoemulsification was the most common surgical technique performed in this study (85.8%) resemble as in Gollogly⁹ et al study which reported that 99.5% out of 8012 eyes cataract patients performed phacoemulsification from 2005 to 2011 in Minnesota, USA. That type of surgery has several advantages such as faster achievement of good visual acuity and wound healing, closed eye surgery and a safe surgical technique.¹⁰ It was showed in this study that postoperative BCVA achieved optimal target visual rehabilitation A regular follow up postoperatively is important to evaluate surgical success and to observe the possibility of further complication and PCO is the most common.

In three years cumulative incidence of PCO reported by Fong² et al was 38.5% (95% confidence interval [CI] 36.1%-40.9%) among 1495 patients that was higher to our study. This difference may be caused by larger sample size, different study design, and a long and equal follow up time in their study.

We found that PCO formation was found mostly in younger patients among all our pseudophakic patients. Age is one an important related factors to refom PCO according to Wormstone¹¹ et al study. They had conclution that younger age has potency of faster epithelial lens growth¹¹. Epithelial lens migration and proliferation from equator to centrally and block visual axis causing reduction of visual acuity.¹ Most of our PCO patients experienced blurred vision. Their visual acuity reduced into 0.5 ± 0.26 , but still in the category mild visual impairment. It was comparable with Van Bree³ et al study ($0.20 \pm$ $0.23 \log$ MAR or 0.64 ± 0.60) and Anggraini⁷ et al reported (0.47 ± 0.46). Decreasing BCVA into 0.5will significantlyt cause visual impairment to the patient. In this study, duration to PCO stated was 21 months or 1.75 years which comparable to Khan¹² et al and Khanzada¹³ et al had been reported in 23 months (2-24 months) and 2.06 years, respectively.

Variability of time period of follow up may produce a bias in determining the PCO incidence in our study. We assumed that patient with only 1 month duration of follow up suggested that they didn't have any visual problem, especially when we instructed patients to come back when having visual complaints. This condition could also influence our lower incidence than the actual incidence. We suggested, cohort study might provide a better study design in which all patients could have equal long term follow up.

Treatment with Nd:YAG laser posterior capsulotomy in PCO needed to clear the visual axis. In this study, not all patients having Nd: YAG laser which also showed not only weakness of our management but also patients refused to do a laser treatment due to accepted their BCVA or financial problem. During a posterior capsulotomy, by amplification and focusing of 1,064 nanometers (nm) infrared light, which electrons are ripped away from nuclei, forming energy plasma and corresponding shock wave. The plasma formation is known as optical breakdown and cut the targeta. When pressure wave created on the anterior vitreous side of the capsule, the laser breaks the posterior capsule.¹⁴ in this study, after the opening of visual axis, their BCVA achieved 1.00, which was the same as BCVA on 1 month postoperative. This result was similar to Van Bree³ et al (0.001 ± 0.12) logMAR or 1.0) and Khanzada¹³ et al studies (74.4% cases achieved 6/9 to 6/6).

Several studies related to risk factors of the formation of PCO had been done and some studies

had concluded that IOL material and design might associated with the PCO formation.^{1,13,15} In 2003, Anggraini⁷ et al reported that majority of patients used PMMA IOL (97%) and only 2.7% used acrylic IOL, at CiCM Hospital. In 2010, a transition into acrylic IOL has occurred. Acrylic IOL was used in majority of cases 374 (64.7%) whereas PMMA in 204 of cases (35.3%).

Other studies reported that surgical technique, including cortical cleaving hydrodissection and rotation, cortical clean up, in-the-bag fixation of IOL, and smaller capsulorhexis size than optic diameter of IOL seem to correlate with PCO formation. Those procedures factors could be minimized by doing phacoemulsification.^{5,16} In this study, the cross tabulation evaluated IOL factors in phacoemulsification group only. It was considered to minimize bias due to surgical technique difference and showed that no correlation on any type of IOL. p value was not analyzed because of the unequal sample size between groups of IOL characteristics. Acrylic material particularly hydrophobic has been identified as a preventing factor in PCO formation. Linnola17 found that acrylic had stronger adhesion with fibronectin and laminin compared to PMMA and silicone. It caused stronger adhesion of IOL and posterior capsule, therefore it would inhibit epithelial lens migration and proliferation. Hydrophobic acrylic had better capsular biocompatibility than hydrophilic. In this study, a higher proportion of PCO was found in hydrophilic acrylic than hydrophobic acrylic. Several studies also reported higher proportion of PCO in hydrophilic acrylic (42%-64.4%) compared to hydrophobic acrylic (8.9%-34.4%).^{2,18,19}

Optic diameter is still a mater of debate in the prevention of PCO formation. In this study, smaller optic diameter had lower proportion of PCO and Meacock²⁰ et al reported that optic diameter of 6 mm (1.5%) had lower proportion of PCO than 5 mm (6.9%). In contrast, Nishi²¹ et al reported that larger optic diameter inhibit IOL adhesion to posterior capsule and capsular bend formation.

Capsular bend formation is identified as an important factor in prevention of PCO. Square optic edge IOL may form a good capsular bend, which therefore inhibit epithelial lens migration to posterior capsule. In this study, a higher proportion of PCO was found in round optic edge IOL even in a very small difference. It was similar with proportion of PCO in PMMA and acrylic. Most of PMMA had round optic edge while most of acrylic had square optic edge. Several studies also reported higher proportion of PCO in round optic edge (13%-38.7%) than square optic edge (1.4%-3.4%).^{22,23,24}

In conclusion, three years cumulative incidence of PCO in CM hospital was 8.82%, with median time to PCO diagnosis on 21 months (1.75 years). A higher incidence of PCO was found in hydrophilic acrylic IOL. Nd:YAG laser posterior capsulotomy was performed in 72.5% of eyes and showed good results.

Conflicts of Interest

The authors affirm no conflict of interest in this study.

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