The Analysis of the Intraoperative Complications During the Transitional Period from In-patient Cataract Surgery to Ambulatory Day Surgery

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Abstract

Purpose: To report the incidence of posterior capsular rupture (PCR) of phacoemulsification and the contributing factors during the transitional period from in-patient model to ambulatory day surgery model.

Method: The medical records and intraoperative complication reports were systemically reviewed during the period of August 2015 to October 2020. The PCR rate was analyzed according to the following factors: type of surgery (day surgery vs. in-patient surgery), gender, age, surgery performed in the month containing long holiday (Chinese New Year and National day), surgery performed in the first month of the residents' rotation, increase of surgical volume comparing to the previous month, stage of the day surgery transition and whether it was before or after the implementation of safety recommendation based on clinical audit results in January 2018. The univariable logistic regression model was initially performed.

Results: Within the study period, 29 493 cases of phacoemulsification surgery were enrolled in the study, 14 451 of them were performed as day surgery while 15 042 of them were inpatient surgery. The overall incidence of PCR was 1.17% (346 cases) among the 29 493 planned phacoemulsification surgery. The increase incidence of PCR was associated with older age and male gender. The incidence of PCR decreased significantly after the implementation of safety recommendations.

Conclusion: The ambulatory day surgery for cataract patients could provide safe, efficient, and quality services. During the transitional period from in-patient to day surgery, careful planning and organization with dynamic clinical audit surveillance can further reduce the incidence of intraoperative complications, especially intraoperative PCR.

Introduction

Cataract remains to be one of the leading causes of blindness in China.[1] With the surgical and technical advancements, phacoemulsification with 2 to 3 mm corneal incision and the implantation of foldable intraocular lens (IOL) have been widely adopted as the standard clinical practice, which has been proven to be safe and effective. Since 1980s, the concept of ambulatory day surgery has been introduced and implemented in Europe and US because of the possible reduced risk of hospital-acquired infections, early rehabilitation, reduced waiting time for surgical appointment, enhanced patient satisfaction, and equal safety profile.[2–4] With the increasing demands of cataract surgeries due to the large number of population and increasing longevity, the clinical pathway of ambulatory day surgery for cataract has been promoted to increase the accessibility and efficiency of the ophthalmic facilities in China. In May 2015, the Guidelines on Comprehensive Reform Pilot of Urban Public Hospitals announced by General Office of the State Council stated that 20 types of day surgery including age-related cataract should be reimbursed by social medical insurance. Since then, many ophthalmic facilities commenced the transition from in-patient model to ambulatory day surgery for cataract procedures. The reported rate of

surgical complications and visual outcomes were consistent with previous reports showing the similar benefits in terms of cost-effectiveness and efficiency.[5]

However, the transition from traditional in-patient model to ambulatory day surgery is a complex process, which involves systemic changes in the medical, logistical, and other related workflow and the redesign of the functional areas within the hospital, as well as the changes of mind sets and training for the medical staff and the patients.[6–9] The intraoperative complications associated with cataract surgery during the transition period should be carefully monitored as the benchmarks to ensure the safety and quality during the transition. We reported our intraoperative complications rates and the associated risk factors during the transition period and to identify the related risk factors that could impact the safety and quality of the ambulatory day cataract surgery.

Materials And Methods

Ethical approval

was obtained from the Medical Research and Ethic Committee of Tianjin Medical University Eye hospital. The collection of data in the current study followed the guidelines of the Declaration of Helsinki. All the patients gave their informed consent after being fully explained about the procedure while the personal data remains anonymous. All intraocular surgical procedures in our hospital are videotaped as a routine practice for teaching and learning purposes. As one of the hospital policies, the attending surgeons are encouraged to report the occurrence of posterior capsular rupture and fill out the self-reporting form in the medical record. The clinical audit team reviewed the reported cases every month and provided a monthly report on the intraoperative complications in the staff meeting of the hospital. When the rate of intraoperative complications and PCR increases, the possible causes will be discussed during the staff meeting and the board meeting of safety and quality control of the hospital resulting in the implementation of safety guidelines and measures.

The current study retrospectively reviewed the cases of planned phacoemulsification over a period of 5 years, from August 2015 to October 2020. Eyes with combined trabeculectomy, vitrectomy and keratoplasty were excluded from the study. Demographic data, ocular comorbidities (such as pseudoexfoliation syndrome, angle closure glaucoma, diabetic retinopathy and age-related macular degeneration), intraoperative complications (such as: PCR, zonulysis, aqueous misdirection, iris prolapse, suprachoroidal haemorrhage, dehiscence of Descemet membrane, broken haptic, and amaurosis fugax) were documented for further analysis.

The staged implementation of ambulatory day care surgery units with the redesigning of the floor plan and re-organization of the day care medical team

As an academic tertiary eye hospital, our hospital commenced the implementation of ambulatory day surgery since 2015. The 2nd to 5th floor of the hospital building are in-patient wards which contain 50 beds on each floor as one independent unit with their designated operation rooms. The operating theatre

is located on the 6th floor. The transition of in-patient cataract surgery to ambulatory day surgery was staged to 3 consecutive periods. The first stage (stage 1, 2015.8 -2016.12) was the initial implementation of the day surgery for cataract, in which the day surgery patients share the same perioperative care units and the operation rooms with the in-patient surgery in their individual floor. The pre-admission tests including the blood work, EKG and biometry etc. were performed at least 3 days prior to the scheduled surgery. On the scheduled day of surgery, a designated staff nurse performed the preoperative preparation such as the irrigation of the conjunctival sac, vital signs taking and administration of antibiotic and mydriatic eye drops. The medical officer comes to meet the patients for the discussion of the cataract surgery to be done. Afterwards, the patients wait in the day surgery waiting room with their family for the porter to transfer them to the operating theatre. The second stage (stage 2, 2017.1-2019.12) of ambulatory day surgery launched because of the gradually increased numbers of day surgery patients. On each floor, a separated medical unit of nurses are designated to perform the perioperative care for the day surgery patients with the reconfigured reception counter and rooms for admission and pre-operative process. The waiting room remained as before. The third stage (stage 3, 2020.1-2020.10) commenced with two of the hospital floors (the 2nd and 5th floor) being renovated into independent day surgery centers exclusively for day surgery with their designated nursing staff and reception, which was also an adaptation for the prevention of the COVID-19.

The factors that could influence the incidence of intraoperative complications

We tested four non-medical factors that could influence the incidence of intraoperative complications. First, surgery performed in the month containing long holiday (Chinese New Year and National day could indicate the influence of the alteration of the human capital depreciation of the surgical team. Second, surgery performed in the first month of the residents' rotation may reflex the effect of cohort turnover that compromise the familiarity of the surgical team. The third factor we tested was whether the surgery perform in the month with a sudden increase of surgical volume by 30–50%, 50–100% and more than 100%, which could result in the overload for the workflow. The fourth factor was the stage of the transitional period of the day surgery. The PCR rates were analyzed according to these factors using univariable logistic regression.

Implementation Of Safety Recommendation Based On Clinical Audit Results

To further improve the quality of care provided to our patients, a clinical audit department was established in 2015 as part of the clinical service quality improvement project. The audit team extracts the data from electronic medical records as well as the medical documents to monitor certain benchmarks of the clinical service of various subspecialties, including the incidence of PCR, visual outcomes and surgical complications of phacoemulsification, vitrectomy, trabeculectomy and penetrating keratoplasty monthly. A full analysis of the clinical audit data and report was presented in the quality and safety meeting of the hospital in January 2018, including the increased PCR rate and the risk

factors of PCR. The audit team also shared the possible contributing factors that we hypothesized which could impact the intraoperative complication rate, including the age, the preoperative comorbidities, the inadequate communication between the team members and the incoming novice residents. The audit team also recommended the surgeons to be cautious on patient selection when they just came back from vacations more than 7 days. The surgeons were instructed to enhance the preoperative evaluation by filling up the pre-op check list to ensure the identification of the high-risk cases. Additionally, the residents received a more intensive course on the workflow and the perioperative management of cataract patients during the introduction courses before they started their new rotation. The PCR rate before and after the safety recommendation meeting was also analyzed.

Statistical analysis:

Datasets were analyzed using SPSS 22.0 for descriptive and comparative statistics. The frequency and percentage were used to describe the categorical variables. The PCR rate was analyzed according to the following factors: type of surgery (day surgery vs. inpatient surgery), gender, age, surgery performed in the month containing long holiday (Chinese New Year and National day), surgery performed in the first month of the residents' rotation, increase of surgical volume comparing to the previous month, stage of the day surgery transition and whether it was before or after the implementation of safety recommendation based on clinical audit results in January 2018. The univariable logistic regression model was initially performed. Variables that were statistically significant ($p < 0.01$) on the univariate model were then entered into multiple logistic regression model using stepwise regression method ($\alpha_{in} = 0.05$, $\alpha_{out} = 0.10$). Adjusted ORs indicating the effect of the risk factors on the occurrence of PCR and complications during cataract surgery were calculated and reported with 95% CI. The code of categorical variables showed in supplementary data (supplementary table 1).

Results

Within the study period, 29 493 cases of phacoemulsification surgery were enrolled in the study, 14 451 of them were performed as day surgery while 15 042 of them were inpatient surgery. The mean age of patients was 69.58 ± 10.05 (range 30 to 100), with a slight female preponderance (17 392, 59.0%). Over the 5-year period, the surgical volume of day case cataract surgery has been gradually increased from 28.2% of the total cataract surgeries during the first stage of transition to 47.6% during the second stage and 94.1% during the third stage of the transition (Table 1).

The incidence of PCR and intraoperative complications according to the coding system

The overall incidence of PCR was 1.17% (346 cases) among the 29 493 planned phacoemulsification surgery. The incidences of PCR of each month were shown in Fig. 1. The incidence of PCR of the day surgery was 1.08% (156 cases), while the incidence of PCR of the in-patient surgery was 1.26% (190 cases, Fig. 1). The incidences of PCR of each stage of the transitional period were shown in Table 1. The incidence of intraoperative complications and PCR according to the aforementioned factors including

type of surgery (day surgery vs. inpatient surgery), gender, age group, surgery performed in the month containing long holiday (Chinese New Year and National day), surgery performed in the first month of the residents' rotation, increase of surgical volume comparing to the previous month, stage of the day surgery transition and whether it is before or after the implementation of safety recommendation based on clinical audit results in January 2018 were listed in Table 2.

With the increased age, the incidence of intraoperative complications increased by 1.15 times (OR1.15), and the possibility of incidence after the implementation of safety recommendation was lower than before (OR = 0.53). After multiple logistic regression of the incidence of PCR, female was worse likely to have PCR (OR = 0.81), the increase of age was positively correlated with the incidence of PCR (OR = 1.14), and the incidence of PCR reduced after the implementation of safety recommendation (OR = 0.61) (Table 3).

Table 1
The incidence of PCR according to the type of admission and the stage of the transition

	The first stage of the transition (2015.8 -2016.12)		The second stage of the transition (2017.1-2019.12)		The third stage of the transition (2020.1-2020.10)		Total
	In-patient	Day surgery	In-patient	Day surgery	In-patient	Day surgery	
Number of cases (%)	5744 (71.8%)	2252 (28.2%)	9050 (52.4%)	8217 (47.6%)	248 (5.9%)	3982 (94.1%)	29493
Number of PCR	84	29	100	94	6	33	346
Incidence of PCR	1.46%	1.29%	1.10%	1.14%	2.42%	0.83%	1.17%

Table 2
The incidence of PCR and all intraoperative complications in surgery

Variables		PCR		All intraoperative complications	
		N	Percent (%)	N	Percent (%)
Surgery type	Inpatient surgery	190	1.26	231	1.54
	Day surgery	156	1.08	167	1.16
Gender	Male	158	1.31	178	1.47
	Female	188	1.08	220	1.26
Age group	31–40	1	0.65	1	0.65
	41–50	8	0.88	9	0.99
	51–60	43	1.05	50	1.22
	61–70	104	1.04	118	1.18
	71–80	130	1.28	145	1.43
	≥ 81	60	1.44	75	1.79
Surgery performed in the month of Chinese New Year	No	331	1.16	381	1.34
	Yes	15	1.42	17	1.60
Surgery performed in the first month the residents' rotation	No	317	1.19	362	1.36
	Yes	29	1.04	36	1.29
Surgery performed in the month of National day	No	300	1.15	345	1.33
	Yes	46	1.32	53	1.52
Increase of surgical volume compared to the previous month	Less than 30% of increase (including decrease of surgical volume)	241	1.14	278	1.31
	The increase was equal or more than 30% but less than 50% compared to the previous month	45	1.22	50	1.35
	The increase was equal or more than 50% but less than 100% compared to the previous month	6	1.08	9	1.62
	The increase was equal or more than 100%	54	1.33	61	1.50
Stage of the day surgery transition	Stage 1	113	1.14	136	1.70

Variables		PCR		All intraoperative complications	
		N	Percent (%)	N	Percent (%)
	Stage 2	194	1.12	221	1.28
	Stage 3	39	0.92	41	0.97
Day surgery quality and safety meeting	Before the meeting	195	1.49	238	1.82
	After the meeting	151	0.92	160	0.97

Table 3
Logistic regression of PCR according to the variables

	β	p	β_a	ORa(95%CI)	p < 0.001
Surgery type (in-patient vs. day surgery)	-0.16	0.14			
Gender	-0.19	0.08	-0.22	0.81(0.65–0.99)	0.046
Age	0.13	0.013	0.13	1.14(1.03–1.27)	0.013
Surgery performed in the month of Chinese New Year	0.20	0.46			
Surgery performed in the first month the residents' rotation	-0.13	0.49			
Surgery performed in the first month the residents' rotation	0.14	0.39			
Increase of surgical volume compared to the previous month	0.05	0.31			
Surgery performed in the month of National day	-0.02	0.01			
Before or after the day surgery quality and safety meeting	-0.49	≤0.001	-0.49	0.61(0.49–0.76)	≤0.001
Note: β_a : adjusted β ; ORa: adjusted OR					

Table 4
Logistic regression of all complications

	β	p	β_a	ORa(95%CI)	p
Intercept			-4.64		0.001
Surgery type	-0.29	0.005			
Gender	-0.15	0.131			
Age	0.15	0.002	0.14	1.15(1.05–1.28)	0.004
Chinese New Year	0.18	0.465			
Cycle	-0.05	0.78			
National day	0.14	0.35			
Increase of surgical volume compared to the previous month	0.05	0.29			
Stage of the day surgery transition	-0.28	0.0004			
Before or after the day surgery quality and safety meeting	-0.64	0.001	-0.63	0.53(0.44–0.65)	0.001
Note: β_a : adjusted β ; ORa: adjusted OR					

Discussion

With the rapid economic development in China, a significant rise in cataract surgeries has been recognized due to the expansion of the ophthalmological services, outreach program and increased public awareness and acceptance of phacoemulsification. Despite the effectiveness of Phaco surgery, the visual threatening complications are still one of the concerns since the training and experience of the surgeons and medical teams, the medical supplies and the general socio-economical states of the cataract patients vary substantially. The attention has been brought to the concern of the “quantity” gradually shifted to the concern of “quality”. Among the various methods that could be implemented to improve the quality of medical care and safety, clinical audit has been widely accepted as a prominent approach could be applied in daily practice with significant benefit.[10]

Our results in terms of complication rate, the increased risk of PCR related to the age are consistent with the aforementioned reports. [11, 12] However, the studies from Sweden did not find significant association with PCR, even the cutoff of these studies was higher (88 and 90 years old)[13, 14]. Theodoropoulou et al reported an increased PCR rate of 2.7% for patients over 90 years old while the PCR rate for patients over 90 years old was 3.3% (5/151) in the current study [15].

The second significant risk factor for PCR in our study is gender. Male patients showed a higher risk for PCR compared to the female (1.31% vs 1.08%), which was in line with the other authors' findings. Segerstad reported that male sex is significantly associated with intraoperative complications, along with age more than 90 years old and preoperative vision less than 1.0 LogMAR.[16] Ergon et al reported that the increased PCR risks could be due to the finding that the male has a higher chance for intraoperative floppy-iris syndrome. [17]

The overall incidence of PCR decreased significantly after the implementation of safety recommendation based on clinical audit results. The benefit of clinical audit is consistent with the reports from Europe, US and Austria which concluded that the surgical audit is one of the most important measure to improve performance and reduce clinical risks.[18–20] The safety recommendations were made according to various previous research concerning the medical safety and quality. First, the familiarity of the surgical team could impact the rate of surgical complications. According to the residency training program of our hospital, the rotation of the residents takes place on 1st of March and 1st of September every year. It would take some time for the residents to be familiar with the routine of the consultants and the nurses in terms of preoperative evaluations, surgical techniques, and patients' consultation. The lack of familiarity could have an impact on the teamwork during the perioperative care, which results in insufficient and inadequate communication. Kurmann et al evaluated the impact of familiarity among the members of the surgical team on morbidity in patients undergoing elective open abdominal surgery. Their study found that the surgical complications rate was significantly higher in the first month of the fellowship program than that in the last month of the program indicating team familiarity improves team performance and reduces the chance of surgical complications.[21] Grade et al found that the familiarity with the surgeon and his/her surgical style, personality and preferences could fill the gaps in the procedural focused communication for the supporting medical team members. They stated that the regular procedure-focused communication is one of the important key factors for the improvement of safety in operation room.[22] Previous reports also demonstrated that the common experience in collaborating allows teams to perform better under pressure, which enabling the team to better react to the unexpected surgical problems. The second possible contributing factor is the so-called "July effect" or cohort turnover, which means the surgical performance of the team could be affected by the new residents' arrival at the end of the academic year. However, the July effect remains to be one of the controversial subjects.[23, 24] Zeitoun et al reported the cohort changeover could negatively impact the efficiency in the teaching hospital although the mortality and readmission rate were not significantly increased by the cohort changeover of the residents and fellows.[25] The similar methodological limitations with the these studies prevent us to draw a firm conclusion. However, it is a valid point to draw the attention of the administration of the academic teaching hospital during the initial period of the residency training for maintaining the quality of eye care. The third influential factor is the depreciation of human capital of the surgical team after the holidays. The months of Chinese New Year and October are the time that many staff come back from a relatively long vacation for holidays. The research on the fluctuations of human capital demonstrated that the productivity could be compromised when the temporal distance between tasks increases. In medicine, studies showed that the surgeon's additional day off from the operation

room had a negative impact on their proficiency.[26, 27] However, when we tested these factors individually against the incidence of PCR, none of them showed a significant impact.

During the study period, the proportion of ambulatory day surgery for cataract increased gradually with a sudden increase during stage 3, which is the beginning of the 2020. The steady increase of surgical volume of day surgery could be due to the implementation of the regulation that the day surgery is covered by national social medical insurance. In the initial stage the patients and the surgeon were not adapted to the transition. While with covid-19 pandemic outburst since the beginning of 2020, the public awareness and acceptance for day surgery increase. The benefit of shorter stay in the hospital and flexible time schedule for surgery the day surgery of cataract become the preferred choice for most of the patients.

In conclusion, ambulatory day surgery for cataract patients could provide safe, efficient, and quality services. During the transitional period from in-patient to day surgery, careful planning and organization with dynamic clinical audit surveillance can further reduce the incidence of intraoperative complications, especially intraoperative PCR.

Declarations

Ethics approval and consent to participate

Ethical approval was obtained from the Medical Research and Ethic Committee of Tianjin Medical University Eye hospital. The collection of data in the current study followed the guidelines of the Declaration of Helsinki. All the patients gave their informed consent after being fully explained about the procedure while the personal data remains anonymous.

Authors' contributions

Dr. Bu Shaochong - Data analysis and manuscript writing

Prof. Li Xiaorong - Study design and manuscript revision

Prof. Zhao Shaozhen - Result interpretation and analysis

Dr. Tian Fang - Data collection and interpretation of the results

Mr. Li Mengran - Data collection

Ms. Feng Qin - Data entry and analysis

Dr. Yang Ruibo - Study design and result analysis

Consent for publication

All the participants in the study were given informed consent for the study and agree to share the information anonymously.

Competing interest

All the authors have neither competing nor financial interests to declare.

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Data sharing statement

The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

Patient and public involvement

No patient involved. The data of the current study was collected from the clinical audit reports. The audit results have been reported in the staff meeting of the hospital every month since the establishment of the clinical audit department. The PCR rate are presented on the official website of our hospital.

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Figures

Figure 1

The incidence of PCR during the studied period

Supplementary Files

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