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CLINICAL INVESTIGATION

Current status of late and recurrent intraocular lens dislocation: analysis of real-world data in Japan

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Abstract

Purpose To describe relevant patient demographic characteristics and investigate the influence of known risk factors for late intraocular lens (IOL) dislocation. To explore the associations between these risk factors and the incidence of recurrent IOL dislocation.

Study design Retrospective cohort study.

Methods This study was performed using Nationwide Diagnostic Procedure Combination data in Japan from April 1, 2008 through July 31, 2016. Descriptive statistics for late and recurrent IOL dislocation, incidence rates, and risk factors for recurrent IOL dislocation were analyzed using a Cox proportional hazard model.

Results We identified 678 patients with late IOL dislocation. Most were men (72%, 488/678), and the men were younger than their women counterparts (mean age 65.2 years vs. 74.5 years). The incidence rate of recurrent IOL dislocation was 5.1 per 100 person-years. All 20 cases of recurrent IOL dislocation were observed within the year following surgery. There were no significant associations between potential risk factors and recurrent IOL dislocation (adjusted hazard ratio [HR] 1.53, 95% confidence interval [CI] 0.55–4.26 for diabetes mellitus; adjusted HR 0.77, 95%CI 0.09–6.40 for atopic dermatitis); no recurrences occurred in patients with pseudoexfoliation syndrome, retinitis pigmentosa, or connective tissue disease.

Conclusions Late IOL dislocation occurs more frequently in men. We found that recurrent IOL dislocation was rare during long-term follow-up and there were no significant associations between the potential risk factors and recurrent IOL dislocation. Further studies are needed to clarify the sex-related differences involved in IOL dislocation.

Keywords Late IOL dislocation · Complications · Risk factors · Recurrent IOL dislocation · Epidemiology

Introduction

Cataract surgery is a successful technique for improving vision, and cataract surgical rate in Japan has risen to 8,091 per million people per year [1]. However, intraocular lens (IOL) dislocation is a serious complication of cataract surgery [2, 3]. Late IOL dislocation is a progressive condition caused by weakening of residual zonules after cataract surgery and is defined as developing three months postoperatively or later. The reported cumulative incidence is 0.1% to 1.0% in the 10 years after surgery [4, 5]. The longer the time that elapses following cataract surgery, the greater will be the risk of late IOL dislocation [4]. Recent reports suggest that late IOL dislocation is becoming more common because of the growing pseudophakic population [4] and the fact that more complicated cases are undergoing successful cataract surgery because of improved surgical techniques [6].

Risk factors for late IOL dislocation include zonular weakness and contraction of the capsule [3]. Diabetes mellitus (DM) [7], pseudoexfoliation syndrome (PEX) [8], atopic dermatitis (AD) [9, 10], retinitis pigmentosa (RP) [2], and connective tissue disease (CTD) [11] are possible risk factors that affect both eyes. PEX in particular is reported to

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be a leading cause of late IOL dislocation. One systematic review [8] calculated an odds ratio of 6.02 (95% confidence interval [CI] 3.67–10.17) for late IOL dislocation in patients with PEX. Other risk factors identified include high myopia [12], uveitis [13], trauma, previous vitrectomy [14], and a previous acute attack of glaucoma [15].

Several reports suggest that there could be a sex-related difference in late IOL dislocation [5, 12]. However, because late IOL dislocation is relatively rare, study samples are small, and the incidence rate and characteristics of recurrent IOL dislocation remain unclear.

The aims of this study were to describe the patient demographics, determine the influence of systemic risk factors such as sex, DM, PEX, AD, RP, and CTD on late IOL dislocation and explore the associations between those risk factors and the incidence of recurrent IOL dislocation. The study was performed using Diagnostic Procedure Combination (DPC) data and insurance claim data in Japan. The DPC is a case-mix classification system launched in 2002 by the Japanese Ministry of Health, Labor, and Welfare and designed for a lump-sum payment system [16, 17]. The DPC system was used in 1667 acute medical care hospitals in April 2016 [18].

Methods

Data source

We used a nationwide claims' database in Japan that included both in-and outpatient records. The data source was based on DPC data and insurance claims data compiled by Medical Data Vision Co., Ltd (MDV) [16]. In July 2016 the MDV database included 1.59 million patients from 275 acute medical care hospitals, including 217 acute ophthalmic care hospitals throughout Japan.

The DPC data contain the following: 1) anonymized inpatient demographics, including age and sex; 2) surgical information recorded by the Japanese procedural code (K-code) with the surgical side for eyes; and 3) diagnoses recorded by standardized diagnostic codes, linked to the International Classification of Disease, 10th Revision. Primary and secondary diagnoses and comorbidities on admission and complications after admission are also recorded. The MDV database also contains outpatient data in the majority of cases after the medical fee revision of 2012. These data enabled the researcher to trace insurance claims for as long as the patients visited the same hospital.

Study design

The study cohort consisted of patients with late IOL dislocation who underwent surgical intervention equivalent to IOL fixation between April 1, 2008 and July 31, 2016. To identify the study cohort, patients who met both of the following criteria were included: 1) a primary or secondary diagnosis on admission relevant to any type of IOL dislocation (dislocation, subluxation, or decentration) that had been diagnosed using the standardized diagnostic coding system, and 2) IOL fixation surgery performed during the same admission period and coded as K2821 (lens reconstruction with IOL implantation) or K2822 (lens reconstruction without IOL implantation). Thus, IOL fixation surgery for IOL dislocation was detected by a combination of diagnosis on admission and the K-code during the same admission period.

The exclusion criteria were: bilateral cataract surgery during one hospitalization period; diagnostic data and surgical information independent of each other in the DPC database; and lack of recording of the side of the IOL dislocation. When the side was not recorded, it could be identified from the operation notes for the cataract surgery; however, if bilateral cataract surgery was performed during the same hospitalization, the side could not be identified, so these eyes were excluded from the analysis. Moreover, we excluded early IOL dislocation, defined as occurring within three months following cataract surgery, which was identified by the entry of K2821 or K2822 within three months of the date of IOL fixation surgery. Furthermore, we excluded cases without outpatient insurance claims because of insufficient information. Follow-up visits were identified by the Japanese procedural code D257 (slit-lamp investigation with fundus examination) or D273 (slit-lamp investigation without fundus examination). Finally, we only included the earlier surgical side in the analysis and excluded the other side if surgery was performed on both eyes during separate hospitalization periods.

The study cohort was divided into two groups according to age (younger than 65 years vs. 65 years or older) for investigation of the presence of known systemic risk factors, including DM, PEX, AD, RP, and CTD, before the date of the first IOL fixation surgery for late IOL dislocation. Only confirmed diagnoses were analyzed. We also examined the incidence of recurrent IOL dislocation requiring second IOL fixation surgery during the study period, which was identified by a combination of diagnosis on admission and the K-code on the same side of the eyes. Finally, we explored the associations between these risk factors and recurrent IOL dislocation.

Statistical analysis

Patient characteristics at the baseline surgery date were summarized using descriptive statistics. Continuous variables are presented as the mean and standard deviation (SD) or median and interquartile range (IQR) where appropriate, and categorical variables as numbers and proportions. The

Kaplan-Meier method was applied for the above-mentioned two age groups, using the interval between the first and second IOL fixation dates. The intervals for patients who did not undergo a second surgery were censored during the study period at the last recorded date of D257 or D273. Survival estimates were compared using the log-rank test.

Predisposing factors for recurrent IOL dislocation were summarized using descriptive statistics. A person-years approach was applied to analyze incidence rates, and the exact Poisson distribution was used to calculate the 95% confidence intervals (CIs). Relative risks for the study variables were expressed as hazard ratios with 95% CIs and were calculated using the Cox proportional hazards model. In multivariable Cox proportional hazard models, hazard ratios for the study variables were adjusted for age as a continuous variable.

The threshold for statistical significance was set at $p<0.05$. All analyses were carried out using SAS version 9.4 software (SAS Institute Inc.).

Ethical considerations

This study was approved by the ethics committee of Kyoto University and performed in accordance with the tenets of the Declaration of Helsinki. The requirement for informed patient consent was waived because all information on individual patients was de-identified in the MDV database.

Results

The MDV database included 287,499 eyes (183,292 patients) that had been assigned cataract surgery procedural codes K2821 and K2822 during the study period; of these, 86.8% (n=159,089) filed outpatient insurance claims after discharge. Of the 822 eligible eyes (n=789) meeting the inclusion criteria, 128 were excluded because of bilateral cataract surgery (30 eyes, n=15), early IOL dislocation (19 eyes, n=19), or no outpatient visits (79 eyes, n=79) (Fig. 1). The final patient study cohort included 678 patients in 81 acute ophthalmic care hospitals.

The patient characteristics are summarized in Table 1. The mean age of the 678 patients was 67.8 years (SD, 14.3). The male patients were younger than their female counterparts (mean age 65.2 years [SD, 14.1] vs. 74.5 years [SD, 12.6], respectively). A majority of the patients were men (72.0%, 488/678). DM was the most common of the pre-specified risk factors in the study cohort (20.1%) followed by PEX (4.3%). When the patients were sub-grouped by age, DM, PEX, and RP were more frequently observed in those aged ≥65 years, and AD was more frequently observed in those aged <65 years (7.7% vs. 0.5%, respectively). CTD was only observed in patients aged ≥65 years.

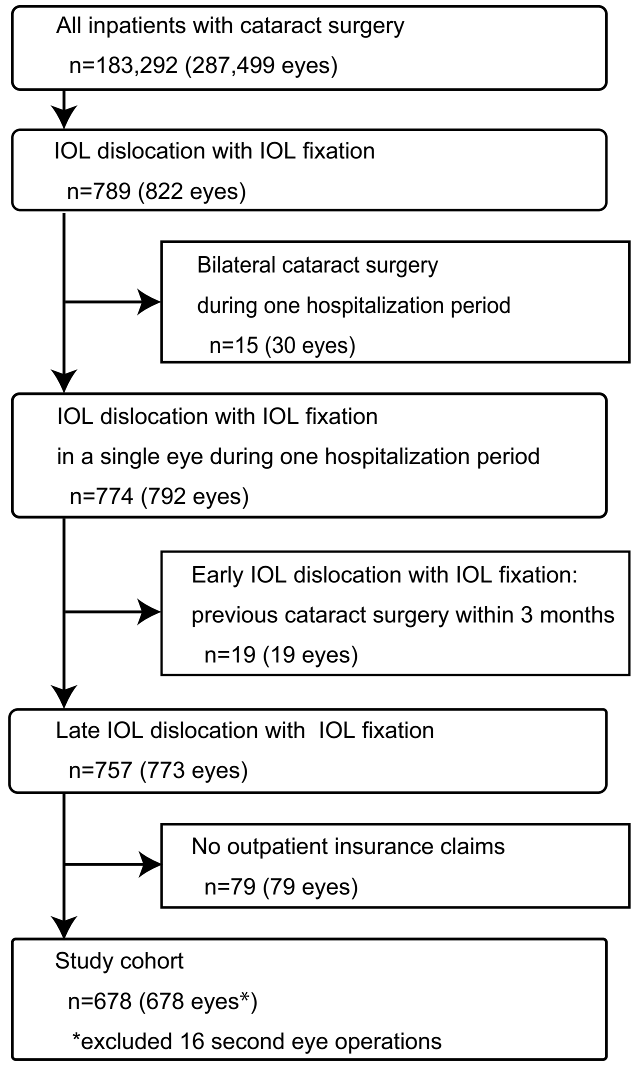

Fig. 1 Flow chart showing the number of patients (eyes) included in the analysis

Interestingly, the number of late IOL dislocations in men were preponderant in the <40-year age group; in contrast, in women, the number of these dislocations increased with age, although they decreased at ages ≥90 years (Fig. 2).

Kaplan-Meier survival curves for the incidence of recurrent IOL dislocation are plotted in Figure 3. The median observation period for the 678 patients was 132.5 days (IQR 36–356), and the median hospitalization period after IOL fixation surgery was five days (IQR 3–7). No statistically significant difference in incidence of recurrent IOL dislocation was found between the two age groups (p=0.49). All 20 cases of recurrent IOL dislocation were observed within the first postoperative year (median 49 days, IQR 11–113.5).

The incidence of recurrent IOL dislocation among the patients with late IOL dislocation is shown in Table 2 and Table 3. The overall incidence rate for recurrent IOL

Table 1 Demographic and clinical characteristics of patients with late intraocular lens dislocation

Characteristic	n (%)	Age, years Mean (SD)	<65 years n (%)	≥65 years n (%)
Total	678 (100.0)	67.8 (14.3)	246 (100.0)	432 (100.0)
Sex				
Male	488 (72.0)	65.2 (14.1)	210 (85.4)	278 (64.4)
Female	190 (28.0)	74.5 (12.6)	36 (14.6)	154 (35.6)
Risk factor				
DM	136 (20.1)	69.6 (11.5)	38 (15.4)	98 (22.7)
AD	21 (3.1)	45.5 (14.3)	19 (7.7)	2 (0.5)
PEX	29 (4.3)	81.9 (7.3)	1 (0.4)	28 (6.5)
RP	12 (1.8)	70.2 (7.6)	2 (0.8)	10 (2.3)
CTD	1 (0.1)	90 (NA)	0 (0.0)	1 (0.2)

AD, atopic dermatitis; CTD, connective tissue disease; DM, diabetes mellitus; IQR, interquartile range; NA, not available; PEX, pseudoexfoliation syndrome; RP, retinitis pigmentosa

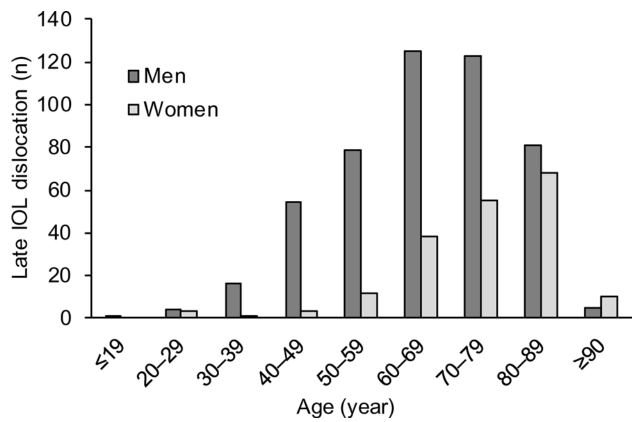

Fig. 2 Age distribution of patients with late intraocular lens dislocation at the surgery date

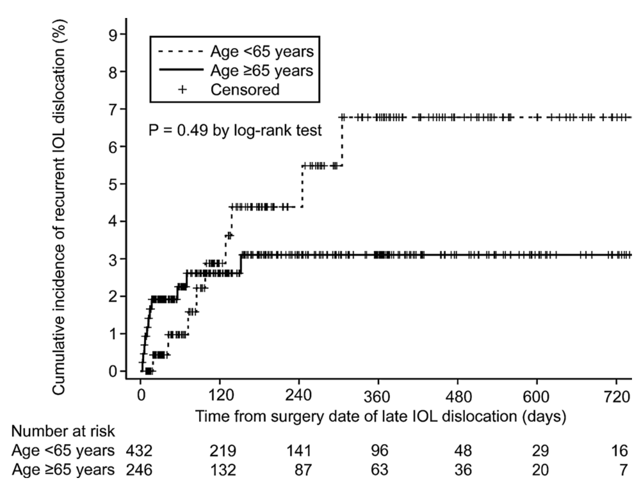

Fig. 3 Cumulative incidence of recurrent intraocular lens dislocation

Table 2 Descriptive statistics of recurrent dislocation in patients with late intraocular lens dislocation

Characteristic	Late IOL dislocation n	Recurrent IOL dislocations n (%)	<65 years (n=246) n (%)	≥65 years (n=432) n (%)
Total	678	20 (2.9)	9 (3.6)	11 (2.5)
Sex				
Male	488	15 (3.1)	8 (3.3)	7 (1.6)
Female	190	5 (2.6)	1 (0.4)	4 (0.9)
Risk factor				
DM	136	5 (3.7)	1 (0.4)	4 (0.9)
AD	21	1 (4.8)	1 (0.4)	0 (0)
PEX	29	0 (0)	0 (0)	0 (0)
RP	12	0 (0)	0 (0)	0 (0)
CTD	1	0 (0)	0 (0)	0 (0)

AD, atopic dermatitis; CTD, connective tissue disease; DM, diabetes mellitus; PEX, pseudoexfoliation syndrome; RP, retinitis pigmentosa

dislocation was 5.1 per 100 person-years and cumulative incidence was 2.9%. Recurrent IOL dislocation was observed in patients with DM and AD but not in those with PEX, RP, or CTD. Although no statistically significant difference in risk was found with regard to sex, age group, or known risk factors, recurrent IOL dislocation tended to be more common in patients aged <65 years than in those aged ≥65 years (crude hazard ratio, 0.73 [95% CI, 0.30–1.77]). In addition, unadjusted cox proportional hazards' analysis of age as a continuous number showed crude hazard ratio, 0.98 [95% CI, 0.95–1.01], (p=0.13).

Adjusted hazard ratio also revealed no significant differences in the above risk factors (adjusted hazard ratio 1.53, 95% CI 0.55–4.26 for diabetes mellitus; adjusted hazard ratio 0.77, 95% CI 0.09–6.40 for atopic dermatitis).

Discussion

The key findings of this study can be summarized as follows: (1) As the majority of cases occurred in men (72%) rather than in women (28%), there was a sex-related difference in the number of late IOL dislocations; (2) the incidence rate of recurrent IOL dislocation was 5.1 per 100 person-years, and all 20 events were observed within the first year after surgery, and, (3) recurrent IOL dislocation was most often observed in patients with DM and AD.

Late IOL dislocation occurred more frequently in men than in women (72.0%). This trend is also reported by others [5, 12]. Monestam suggests that men with PEX may have a weaker zonule, resulting in late IOL dislocation [5]. PEX has been associated with chronic damage to the zonules;

Table 3 Incidence rate and hazard ratio of recurrent dislocation in patients with late intraocular lens dislocation

Characteristic	Patients n	Person-years at risk	Recurrent IOL dislocations n	Incidence rate (per 100 person-years with 95% CI)	Unadjusted		Age-adjusted	
					Hazard ratio with 95% CI	*P*-values	Hazard ratio[a] with 95% CI	*P*-values
Total	678	389.6	20	5.1 (2.9–7.4)	NA	NA	NA	NA
Sex								
Male	488	273.7	15	5.5 (2.7–8.3)	1.19 (0.43–3.27)	0.74	0.96 (0.34–2.75)	0.94
Female	190	115.9	5	4.3 (0.5–8.1)	reference		reference	
Age								
<65 years	246	150.0	9	6.0 (2.1–9.9)	0.73 (0.30–1.77)	0.49	NA	NA
≥65 years	432	239.7	11	4.6 (1.9–7.3)	reference		NA	
Risk factors								
DM								
Yes	136	75.6	5	6.6 (0.8–12.4)	1.38 (0.50–3.80)	0.53	1.53 (0.55–4.26)	0.42
No	542	314.0	15	4.8 (2.4–7.2)	reference		reference	
AD								
Yes	21	18.6	1	5.4 (0.0–15.9)	1.29 (0.17–9.63)	0.81	0.77 (0.09–6.40)	0.81
No	657	371.0	19	5.1 (2.8–7.4)	reference		reference	
PEX								
Yes	29	17.1	0	0	NA	NA	NA	NA
No	649	372.5	20	5.4 (3.0–7.7)	NA		NA	
RP								
Yes	12	6.2	0	0	NA	NA	NA	NA
No	666	383.4	20	5.2 (2.9–7.5)	NA		NA	
CTD								
Yes	1	0.047	0	0	NA	NA	NA	NA
No	677	389.6	20	5.1 (2.9–7.4)	NA		NA	

AD, atopic dermatitis; CI, confidence interval; CTD, connective tissue disease; DM, diabetes mellitus; IOL, intraocular lens; NA, not available; PEX, pseudoexfoliation syndrome; RP, retinitis pigmentosa

[a]Adjusted for age as a continuous variable

moreover, it is reported in previous studies in Japan that the age of PEX onset is in the 40s and that its prevalence increases with age [19, 20]. Of note in our study was that late IOL dislocations in men were still preponderant in the <40-year age group, in which PEX is uncommon (Fig. 2).

Because previous studies have not found sex to be a significant risk factor for late IOL dislocation [6], the sex difference in the number of late IOL dislocations could reflect the different sex distribution according to age group in the pseudophakic population. Thus, men tend to undergo IOL implantation at a younger age than women for reasons other than age-related cataract, and a longer duration of pseudophakia could result in a sex difference in late IOL dislocation in each age group (Fig. 2). In this regard, one report [21] suggests that pediatric traumatic cataract cases were predominantly observed in men (79%, 84/106), which may support our findings.

In a previous retrospective study of the results of surgery for IOL dislocation by Kim et al., no distinction was made between early and late IOL dislocation [22]. In their report, recurrent IOL dislocation was observed in 10% (28/284) and IOL tilt or decentration in 4% (11/284) of cases during a median observation period of 163 days; however, the authors do not mention risk factors for recurrent IOL dislocation. Further, their results do not indicate a sex difference in cases of IOL dislocation (46% in men, 130/277). This discrepancy in the reported sex distribution could be attributable to differences between the inclusion criteria in our study and those used by Kim et al. Therefore, unlike late IOL dislocation, there may be no clear sex difference in early IOL dislocation.

Among the risk factors for late IOL dislocation, we observed AD more frequently in those aged <65 years (7.7%) than in ≥65 years (0.5%; Table 1). This result is in line with a previous report [23], where patients with AD who developed IOL dislocation (44.3±13.0 years) were younger than those without AD who developed IOL dislocation 6(6.3±13.0 years). This observation can be explained by the fact that AD is generally more common in younger individuals [24], and a difference in prevalence of AD may have contributed to the difference in incidence of late IOL dislocation across generations. AD has been associated with late IOL dislocation and retinal detachment in previous reports, and some researchers suggest a traumatic trigger from excessive eye rubbing or scratching [9, 10, 25]. This mechanism could be a possible cause of recurrent IOL dislocation. In our study, recurrent IOL dislocation was observed in only one patient with AD; however, patients with AD may need to be monitored closely for the development of this condition.

In contrast with AD, we observed DM more frequently in patients aged ≥65 years (22.7%) than in younger ones (15.4%). DM is reported to be associated with contraction of the capsule, a known mechanism for late IOL dislocation [26]. Further, Koike et al. report that peripheral vitreous removal with scleral depression for proliferative diabetic retinopathy was associated with late IOL dislocation during long-term follow-up (6.2±3.3 years) [27]. In our study, detailed information on factors such as clinical stage of diabetic retinopathy and previous vitrectomy was not recorded, and these could be confounders for late IOL dislocation.

In our study, the incidence rate of recurrent IOL dislocation was 5.1 per 100 person-years, and all cases were observed within the year following surgery. In a previous report, Vote et al. [28] investigated patients who underwent scleral IOL fixation with at least 12 months of follow-up and found that recurrent IOL dislocation caused by suture breakage was the most common complication (27.9%, 17/61). In contrast, Bading et al. report finding few cases of recurrent IOL dislocation (6.3%, 4/63) and among these suture breakage occurred in only two cases [29]. In our study, none of the 159 patients at risk in the 360 days following surgery (Fig. 3) actually experienced recurrent IOL dislocation. This finding suggests that recurrent IOL dislocation may be rare beyond the first postoperative year.

Although this fact was not a statistically significant finding in our study, it is noteworthy that patients aged <65 years had a higher incidence rate of recurrent IOL dislocation than did those aged ≥65 years (Table 3). The subgroup analysis reported by Vote et al. reveals the same tendency of a higher incidence of recurrent IOL dislocation in younger patients and suggests that this difference may be attributable to an "active lifestyle" [28]. However, in our study, the lower incidence rate of recurrent IOL dislocation in patients aged ≥65 years could simply reflect the greater number of patients in the elderly population who were not candidates for surgery because of poor general health. Further study is needed to elucidate the impact of an active lifestyle on recurrent IOL dislocation.

Limitations

To our knowledge, this study is the largest cohort of patients with late IOL dislocation reported to date based on a nationwide database for the Japanese population. Previous reports have been primarily based on limited numbers of cases from single centers [23, 30], and there have been no relevant epidemiologic studies conducted in Japan thus far. This study has enabled us to describe the characteristics of late and recurrent IOL dislocation more precisely by using a large database and to determine the incidence rate of recurrent IOL dislocation. However, our study has several limitations that should be borne in mind when interpreting its findings.

First, DPC data are not designed for research purposes but as part of a lump-sum payment system [16, 17], We excluded several cases with insufficient information in the process of this research, including patients without outpatient insurance claims and patients whose surgical side of the late IOL dislocation was unclear. These exclusions may have led to potential selection bias.

Second, because of the nature of DPC data, misclassifications could have occurred when diagnoses were not associated with payment. In our study, the proportion of patients who had PEX and experienced late IOL dislocation was lower than that in previous Japanese reports (3.5%–39.6%) [23, 30, 31]. This could reflect the fact that a diagnosis of PEX does not influence payment in DPC data. One validation study from Japan [32] reports that the diagnosis recorded in the DPC database had low sensitivity (0%–83.5%) and high specificity (96.7%–100%) for a number of diseases such as myocardial infarction and renal disease, commonly used to calculate the Charlson Comorbidity Index [33]. This, in turn, is used for risk adjustment in outcome assessment for use in administrative database research [34]. Although similar sensitivity/specificity for ophthalmic diseases has not been validated, if true, this could have resulted in the low detection of PEX in our study.

Third, there may be some confounding factors associated with eye conditions (e.g. uveitis or high myopia) or previous interventions, such as YAG capsulotomy [14] and vitrectomy that could influence the incidence of late IOL dislocation. However, the side on which these conditions were diagnosed and any procedures performed were not recorded in the DPC database. Therefore, in this study, we focused on risk factors that affect both eyes.

Fourth, details of the surgical techniques performed are not recorded in the DPC database. Several surgical techniques have been developed for IOL dislocation. Open-loop anterior chamber IOLs, scleral-sutured posterior chamber IOLs, and iris-sutured posterior chamber IOLs are reported to be comparatively safe with respect to complications [35]. In addition, sutureless intrascleral fixation has now been developed to avoid suture-related complications [36–38]. Thus, different surgical techniques could affect the incidence of recurrent IOL dislocation. In our research, insurance claims for vitrectomy were recorded in the surgical information; however, surgical techniques such as peripheral vitreous removal [27]—a reported risk factor for IOL dislocation—were not. Therefore, we did not take the surgery code for vitrectomy into consideration.

Fifth, we may have missed a subset of patients with early IOL dislocation, particularly those who had undergone cataract surgery at other institutions and were then referred for early IOL dislocation. In this study, we considered all cases of IOL dislocation to be late IOL dislocations if their records did not include cataract surgery (K2821 and K2822) within the previous three months. Similarly, the two types of late IOL dislocation, i.e. in-the-bag dislocation and out-of-the-bag dislocation, could not be differentiated, although out-of-the-bag dislocation is less commonly mentioned in previous reports [30, 39, 40].

We conclude that the association between recurrent IOL dislocation and potential risk factors such as DM, AD, PEX, RP, and CTD is insignificant; moreover, recurrent IOL dislocation is rare after the first year following corrective surgery. However, our present findings indicate that late IOL dislocation is more common in men—a difference that may be explained by the sex distribution in the pseudophakic population. Importantly, further studies are needed to clarify the observed sex-related difference in risk of IOL dislocation.

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