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STATIN USE AND INCIDENT CATARACT SURGERY: A CASE CONTROL STUDY

Jay C. Erie, MD¹, Matthew R. Pueringer, BS¹, Scott M. Brue, BS², Alanna M. Chamberlain, PhD³, and David O. Hodge, MS³

¹Department of Ophthalmology, Mayo Clinic, Rochester, Minnesota, USA

²Division of Biomedical Informatics Support System, Mayo Clinic, Rochester, Minnesota, USA

³Department of Health Sciences Research, Mayo Clinic, Rochester, Minnesota, USA

Abstract

Purpose—To determine the association between statin use and incident cataract surgery.

Methods—By using the resources of the Rochester Epidemiology Project, a retrospective population-based, case-control study was performed. Cases included 6,024 county residents aged 50 years and older who had first-eye cataract surgery between January 1, 2004 and December 31, 2011. Controls included residents who never had cataract surgery and who were matched to cases by age, sex, and index date within 1 month of surgery. Statin medications continuously prescribed for at least 1 year before the surgery date (cases) or index date (controls) were examined. Odds ratios (ORs) and corresponding confidence intervals (CIs) were estimated by using logistic regression models.

Results—There were 2,557 (42%) statin users among cases having cataract surgery compared to 2,038 (34%) statin users in controls never having cataract surgery ($P < 0.0001$). Incident cataract surgery was significantly associated with an increased odds of statin use (OR 1.29, 95% CI 1.19 to 1.55) after adjusting for age, sex, diabetes, cardiovascular disease, cerebrovascular disease, peripheral vascular disease, renal disease, oral and inhaled steroid use, and selective serotonin reuptake inhibitor use. The association persisted after adjustment for women (OR 1.34, 95% CI 1.22 to 1.49) and men (OR 1.17, 95% CI 1.05 to 1.30).

Conclusions—Incident cataract surgery is associated with an increased odds of statin use, and underscores the possibility that increasing statin use could be contributing to rising rates of cataract surgery.

Keywords

cataract surgery; epidemiology; population-based; Rochester Epidemiology Project; statins

INTRODUCTION

Statins are commonly used to treat hyperlipidemia to prevent cardiovascular disease.^{1,2} Lipid lowering agents, of which statins predominate, are the fourth most commonly prescribed drug group in the U.S, and the high rate of use is driven primarily by prescriptions to persons aged 50 years or older.³ Although statin therapy is widely prescribed for prevention of primary cardiovascular disease, investigators disagree about exposing a large healthy population to long-term statin therapy, considering possible untoward events and considerable costs.^{4,5}

Investigations into a possible association between statin use and cataract formation or cataract surgery has yielded conflicting results.⁶⁻¹⁹ Studies have reported no effect of statins on the lens,⁶⁻¹⁰ a protective effect,¹¹⁻¹³ and an increased risk of cataract and cataract surgery.¹⁴⁻¹⁸ Furthermore, some have suggested that the length of statin use may influence these outcomes; short-term statin use may increase the risk of cataract surgery and long-term statin use may be protective.¹⁹

Given that lipid lowering agents are used by up to 45% adults aged ≥ 60 years,²⁰ any unintended effect on cataract surgery rates would be useful information for patients and physicians. Therefore, by using the resources of the Rochester Epidemiology Project, we aimed to investigate the association between the use of statin medications and incident cataract surgery within a defined American population.

MATERIALS AND METHODS

Study Setting and Design

A population-based, case-control study was designed. This study was reviewed and approved by the Mayo Clinic and Olmsted Medical Center Institutional Review Boards and was performed according to the Declaration of Helsinki. All participants were identified by using the resources of the Rochester Epidemiology Project, a medical records linkage system that allows a user to search medical records, medical diagnoses, surgical interventions, and demographic information of virtually all persons residing in Olmsted County, Minnesota (2010 total county population = 144,248).²¹⁻²³ The characteristics of the Olmsted County population are similar to those of Minnesota and the Upper Midwest, although compared to the entire U.S., Olmsted County is less ethnically diverse, more educated, and wealthier.²¹ Nearly all health care to county residents is provided by Mayo Clinic and Olmsted Medical Center and their affiliated hospitals, and the Rochester Family Medicine Clinic. Only a small proportion of the population (approximately 2%) does not allow any of their medical records to be used for research.²¹

The Rochester Epidemiology Project enumerates the population by linking medical records across different health care providers to create a unique list of subjects with specified medical conditions and identification of residency status at each visit. This system serves as a data-retrieval system for a complete description of virtually all sources of medical and surgical care used by the Olmsted County population during a specified time.²¹⁻²³

Cases and Controls

Cases for this study were selected from Olmsted County residents aged 50 years and older who had first-eye cataract extraction between January 1, 2004 and December 31, 2011. By considering first-eye cataract surgery only, we excluded patients from the analysis of outcome when they had a diagnosis of the outcome at or before the baseline date. Additionally, first-eye cataract surgery is used to treat visually significant cataracts, and using first-eye surgery avoids occasional surgery for anisometropia or refractive symptoms that may occur in second-eye surgery. Cases were retrospectively identified by using the International Classification of Diseases, 9th Revision (ICD-9) procedure codes 13.1, 13.11, 13.2/9, 13.3, 13.41, 13.42, 13.43, 13.51, 13.59/9, 13.69/9, or 13.71, and *Current Procedural Terminology* (CPT) procedure codes 66982, 66983, or 66984 for cataract surgery. Included were first-eye cataract extraction by phacoemulsification or extracapsular cataract extraction as a primary procedure or as a combined procedure with penetrating keratoplasty or glaucoma shunt or incisional procedure. Cataract surgeries were excluded if they were combined with a vitreoretinal procedure to improve surgical visualization or in the surgical management of ocular trauma. A previous review of the codes used to identify cases verified that duplicate identification of cases was less than 1% when using the codes listed above.²⁴

Control participants were selected from county residents who never had cataract surgery and who were matched to the cases by sex, age (± 1 year), and index within ± 30 days of cataract surgery. Olmsted County residency at index date or surgery date was verified for all cases and controls by using validated procedures.²¹⁻²³

Statin Use

The Rochester Epidemiology Project prescription drugs database includes the drug issue date, drug name, strength, dosage form, quantity, and number of days supplied for all outpatient and inpatient drug prescriptions written at Mayo Clinic and Olmsted Medical Center for Olmsted county residents since January 1, 2003. Both institutions use proprietary electronic prescription systems in their office and hospital outpatient settings. Electronic prescriptions are retrieved from the proprietary systems and converted into RxNorm codes. Prescriptions are then grouped using the National Drug File – Reference Terminology (NDF-RT).²⁵ Statins included atorvastatin, lovastatin, pravastatin, simvastatin, and simvastatin/exetimibe.

A statin user was defined as a resident who was continuously prescribed a statin medication for at least 1 year before the surgery date (case) or index date (control). Residents who never received a statin at any time were defined as non-users. Residents who had used statins, but for less than 1 year, were categorized into the non-user group in the main analysis and were deleted from the sensitivity analyses.

In situations when the patient used sequential multiple statins, then all statins were included in the analysis. We chose not to categorize patients based on statin dose as previous studies have shown no statin dose-response effect for cataract formation.¹⁴

Statistical Analysis

SAS software (SAS Institute, Cary, North Carolina) version 9.3 was used for data analysis. Differences in statin use between the cataract surgery group and control group were examined by using logistic regression models. Relationships between cataract surgery and statin use were estimated by calculating odds ratios (ORs) and the associated 95% confidence interval (CI). In the multivariate analysis, we adjusted for age, gender, diabetes, cardiovascular disease, cerebrovascular disease, peripheral vascular disease, renal disease, oral and inhaled steroid use, and selective serotonin reuptake inhibitor use, which are recognized risk factors for development of cataracts and cataract surgery. We do not have county-specific data for smoking status or self-reported exposure to second hand smoke and the influence of these potential confounders could not be analyzed. Finally, we performed a sensitivity analysis to study what effect excluding residents who had used statins for less than a year would have on our results.

RESULTS

We identified 6,115 residents who had first-eye cataract surgery between January 1, 2004 and December 31, 2011. Excluded from the study were 91 residents who withdrew research authorization, leaving a cohort of 6,024 residents (2,401 [40%] men, 3624 [60%] women) with a mean age of 74 ± 9 years. We selected 6,024 controls who never had cataract surgery and who were matched by age, sex, and index date within 1 month of cataract surgery.

The baseline characteristics of cases and controls are shown in Table 1. Prolonged statin use of ≥ 4.5 years was similar between cases who had cataract surgery and controls who never had surgery (OR 1.01, CI 0.99 to 1.02). The cataract surgery group was more likely to use oral and inhaled steroids (OR 1.30, CI 1.20 to 1.41) and selective serotonin reuptake inhibitors (OR 1.36, CI 1.23 to 1.51), and more likely to have a medical diagnosis of cardiovascular disease (OR 1.33, CI 1.19 to 1.48), peripheral vascular disease (OR 1.45, CI 1.28 to 1.65), cerebrovascular disease (OR 1.49, CI 1.34 to 1.67), diabetes (OR 1.37, CI 1.25 to 1.50), or renal disease (OR 1.41, CI 1.26 to 1.58).

Table 2 shows the associations between statin use and incident cataract surgery. After adjusting for age, sex, cardiovascular disease, peripheral vascular disease, cerebrovascular disease, diabetes, renal disease, oral and inhaled steroid use, and selective serotonin reuptake inhibitor use, incident cataract surgery was significantly associated with any statin use (OR 1.44, CI 1.34 to 1.55), as well as the individual statins, simvastatin (OR 1.16, CI 1.07 to 1.27), atorvastatin (OR 1.16, CI 1.06 to 1.26), and lovastatin (OR 1.48, CI 1.25 to 1.76). Pravastatin was not associated with incident cataract surgery after adjustment for the above covariables. The association between statin use and cataract surgery persisted after adjustment for men (OR 1.34, CI 1.22 to 1.49) and women (OR 1.17, CI 1.05 to 1.30).

Statin use of less than 1 year occurred in 105 (4%) cases having cataract surgery and in 85 (4%) controls not having cataract surgery. A sensitivity analysis showed that the association between statin use and incident cataract surgery still persisted when these residents were excluded from analysis (OR 1.29, CI 1.19 to 1.39).

DISCUSSION

In our population based, case-control study with a large sample size of older Americans, incident cataract surgery in men and women was found to be associated with the use of statin medications after adjusting for age, gender, diabetes, cardiovascular disease, cerebrovascular disease, peripheral vascular disease, renal disease, oral and inhaled steroid use, and selective serotonin reuptake inhibitor use. Previous studies that evaluated associations between statin use and cataract formation or cataract surgery have provided conflicting results.⁶⁻¹⁹

Cataract surgery rates have more than doubled in the last two decades, and the rate of increase is faster than can be explained by aging demographics alone.^{26,27} Rising rates of second-eye cataract surgery²⁶ and changing vision criteria²⁸ contribute to the increasing surgery rates. Many prescription drugs, however, are known to be associated with cataract formation.^{19,29-31} Lipid lowering agents, of which statins predominate, are the fourth most commonly prescribed drug class in the U.S. and their use is increasing.² The changing prescription patterns for statins and their association with incident cataract surgery could be contributing to rising rates of cataract surgery. Understanding the relationship between statins and cataract surgery may be useful to physicians and patients when weighing the risks and benefits of initiating statin therapy.

A link between statin use and cataract formation is biologically plausible. Statins lower serum cholesterol. The human crystalline lens requires high cholesterol for proper membrane formation and to maintain transparency. Cataract formation accelerates in patients with hereditary cholesterol deficiency³² and in dogs that have been given high doses of statins.³³ Interestingly, the risk of cataract formation returns to normal within one year after stopping statin treatment.¹⁴

Two early population-based studies that were limited by small sample size, reported statin use to be protective for cataracts.^{11,12} By contrast, recent studies found that statin use was associated with an increased risk of cataract formation or cataract surgery.¹⁴⁻¹⁷ Weaknesses of these studies include limiting the study population to people over 65 years of age, which in our study population would have resulted in missing 19% of all cataract surgeries,¹⁷ defining statin users after only 90 days of use,¹⁶ and selection bias within a clinic population.¹⁵ Our findings, however, confirm these study results and provide additional evidence that the association is significant in both men and women.¹⁴

The association between cataract surgery and an increased odds of statin use extended across nearly all individual statins. This conclusion is similar to conclusions of others.¹⁴ Only pravastatin and ezetimibe/simvastatin were not significantly associated with cataract surgery.s.

Diabetes, older age, cardiovascular and cerebrovascular disease, steroid use, and selective serotonin reuptake inhibitor use have been associated with an increased likelihood of cataract surgery.^{29-31, 34} After adjusting for potential confounders, we found statin use to still be significantly associated with an increased risk of cataract surgery. This suggests that

statins may affect cataract surgery rates through mechanisms not influenced by these variables.

Strengths of the Rochester Epidemiology Project include the ability to perform population-based studies within a stable well-defined geographic area. Virtually all county residents receive their health care at sites that are included in our data capture, thus allowing for complete enumeration of cases.^{21,22} Greater than 90% of older adults are seen at least once per year at Rochester Epidemiology Project sites,²² which minimizes sample bias related to medical accessibility. Unlike Medicare beneficiary data, the Rochester Epidemiology Project includes residents aged younger than 65 years, and who are high users of statins.^{21,22} Finally, the Rochester Epidemiology Project avoids recall bias, and has a long record of more than 50 years of epidemiology studies with findings that are generally consistent with national data where available.^{21,23}

Some limitations should be noted. First, we examined statin use from written prescriptions, but we could not confirm if patients actually used the prescribed statins. This is a common limitation of studies that rely on prescription data. However, continuous statin prescriptions over prolonged periods (mean; 4.5 years) suggests compliance. Second, our study assessed cataract surgery rather than actual cataract formation. Cataract surgery criteria differ between practices, and the degrees of lens opacification considered necessary for surgical intervention in our county may differ from those in other regions. However, the use of cataract surgery as a criterion identifies patients with visually significant cataracts rather than mild lens opacities that are clinically unappreciated. Third, smoking is an important known risk factor for cataract formation. Exposure to secondhand smoke also has nearly the same negative systemic effects as active smoking.³⁵ These exposures to smoke could not be controlled in this study, and their effect on cataract surgery rates cannot be excluded. Fourth, indication bias is possible as statin users may have visited their doctors more frequently than non-users, providing them with more opportunity to be referred for cataract surgery. Finally, other unidentified confounders could have contributed to the relationship between cataract surgery and statin use.

In summary, our study clarifies previous conflicting reports and provides further evidence that incident cataract surgery is associated with statin use of a least 1 year in men and women aged 50 years or more. This association does not prove causation and should not be taken as reason to avoid or discontinue statin therapy. Statins are beneficial to a wide range of people at risk for cardiovascular disease, and their use has been increasing in the last 10 years. Changing prescription patterns for statins, however, may be increasing the need for cataract surgery. These findings provide additional information for clinicians and patients when weighing the potential risks and benefits of statin use.

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Table 1
Comparisons of Baseline Characteristics between Olmsted County Residents with & without Cataract Surgery (2004-2011)

Characteristic	<u>Cataract Surgery</u>		Odds Ratio (95% CI)	P Value
	Yes n=6024	No n=6024		
Mean Age, years [SD]	74 [9]	74 [8]	NA	NA
Male, n (%)	1462 (57)	1115 (55)	NA	NA
Female, n (%)	1095 (43)	923 (45)	NA	NA
Statin use in years, mean [SD]	4.6 [3.4]	4.5 [3.5]	1.01 (0.99 to 1.02)	0.58
Medication use, n (%)				
Steroid (oral and inhaler)	1724 (29)	1422 (24)	1.30 (1.20 to 1.41)	<0.0001
Selective Serotonin Reuptake Inhibitor	1024 (17)	788 (13)	1.36 (1.23 to 1.51)	<0.001
Medical Diagnosis, n (%)				
Diabetes Mellitus	1309 (22)	1018 (17)	1.37 (1.25 to 1.50)	<0.001
Cardiovascular Disease	1006 (14)	765 (11)	1.37 (1.19 to 1.48)	<0.001
Cerebrovascular Disease	836 (14)	586 (10)	1.50 (1.34 to 1.67)	<0.001
Renal Disease	775 (13)	570 (9)	1.41 (1.36 to 1.58)	<0.001
Peripheral Vascular Disease	622 (10)	442 (7%)	1.45 (1.28 to 1.65)	<0.001

Comparisons adjusted for age and gender.

SD=standard deviation; CI=confidence interval; NA=not applicable

Table 2
Associations found between use of Statin Medications and Incident Cataract Surgery

Cataract Surgery					
Characteristic	Yes	No	Unadjusted Odds Ratio (95% CI)	P Value	Multivariate-Adjusted* Odds Ratio (95% CI)
Any statin use, n (%)	2557 (42)	2038 (34)	1.44 (1.34 to 1.55)	<0.0001	1.28 (1.18 to 1.38)
Individual statin use, n (%) [‡]					
Simvastatin	1530 (60)	1245 (61)	1.31 (1.20 to 1.42)	<0.0001	1.16 (1.07 to 1.27)
Atorvastatin	1147 (45)	916 (45)	1.31 (1.19 to 1.44)	<0.0001	1.16 (1.06 to 1.28)
Lovastatin	348 (10)	223 (11)	1.60 (1.34 to 1.89)	<0.0001	1.48 (1.25 to 1.76)
Pravastatin	176 (7)	122 (6)	1.46 (1.15 to 1.84)	0.002	1.26 (1.00 to 1.60)
Ezetimibe/Simvastatin	79 (3)	68 (3)	1.16 (0.84 to 1.62)	0.36	1.01 (0.73 to 1.40)

CI=confidence interval

* Adjusted for age, gender, diabetes mellitus, cardiovascular disease, cerebrovascular disease, peripheral vascular disease, renal disease, steroid (oral and inhaled) use, and selective serotonin reuptake inhibitor use.

[‡] The sum of percent of sample that used each statin is more than 100% because of sequential multiple statin prescriptions in 25% of residents who had cataract surgery and 24% who never had cataract surgery.