Adverse Intraoperative Medical Events and Their Association with Anesthesia Management Strategies in Cataract Surgery

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Objective: To compare adverse medical events by different anesthesia strategies for cataract surgery.

Design: Prospective cohort study.

Participants: Patients 50 years of age and older undergoing 19,250 cataract surgeries at nine centers in the United States and Canada between June 1995 and June 1997.

Intervention: Local anesthesia applied topically or by injection, with or without oral and intravenous sedatives, opioid analgesia, hypnotics, and diphenhydramine (Benadryl).

Main Outcome Measures: Intraoperative and postoperative adverse medical events.

Results: Twenty-six percent of surgeries were performed with topical anesthesia and the remainder with injection anesthesia. There was no increase in deaths and hospitalizations associated with any specific anesthesia strategy. No statistically significant difference was observed in the prevalence of intraoperative events between topical and injection anesthesia without intravenous sedatives (0.13% and 0.78%, respectively). The use of intravenous sedatives was associated with a significant increase in adverse events for topical (1.20%) and injection anesthesia (1.18%), relative to topical anesthesia without intravenous sedation. The use of short-acting hypnotic agents with injection anesthesia was also associated with a significant increase in adverse events when used alone (1.40%) or in combination with opiates (1.75%), sedatives (2.65%), and with the combination of opiates and sedatives (4.04%). These differences remained after adjusting for age, gender, duration of surgery, and American Society of Anesthesiologists risk class.

Conclusions: Adjuvant intravenous anesthetic agents used to decrease pain and alleviate anxiety are associated with increases in medical events. However, cataract surgery is a safe procedure with a low absolute risk of medical complications with either topical or injection anesthesia. Clinicians should weigh the risks and benefits of their use for individual patients. *Ophthalmology 2001;108:1721–1726 © 2001 by the American Academy of Ophthalmology.*

In 1996, approximately 1.5 million cataract surgeries were performed on the Medicare population,[1] and for the past 15 years, this surgery has been almost exclusively done on an outpatient basis using a variety of local anesthesia techniques. Local anesthesia can be administered by injection (retrobulbar, peribulbar, subconjunctival, lid, or facial block) or topically. Retrobulbar injection became widely used in the 1940s,[2] and peribulbar injection was introduced in the 1960s with the hope of reducing rare but significant complications from retrobulbar anesthesia, such as globe perforation, orbital hemorrhage, and brain stem anesthesia.[3,4] More recently, topical anesthesia was introduced as a strategy to further reduce complications from injection anesthesia and provide more rapid visual recovery,[5,6] but some studies reported more pain during surgery with topical rather than injection anesthesia.[7,8]

There is currently wide variation in approaches to anesthesia for cataract surgery that seems to be determined

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mostly by surgeon preference and practice setting.[9] A survey of surgeons done in 1996 found 80% reporting the use of retrobulbar or peribulbar anesthesia, 12% using topical anesthesia, and 8% using other methods.[10] Further variation is introduced by the selection of sedating agents to reduce anxiety and decrease pain during administration of injection anesthesia and during surgery, and this variation seems to be influenced more by anesthesiologist and patient preferences.

Because the average age of patients undergoing cataract surgery is 72 years and many in this population have several comorbidities such as heart disease and diabetes, there may be medical consequences to providing intravenous sedation to such patients. In addition, these interventions may require monitoring of vital signs by trained personnel, usually an anesthesiologist or nurse anesthetist. The question addressed in this study is whether the rate of adverse medical events during cataract surgery is greater for certain anesthetic strategies than for others. We used observational data from a large randomized trial of the impact of preoperative medical testing for cataract surgery on adverse medical events, which involved 19,250 cataract surgeries performed in the United States and Canada from June 1995 through June 1997.[11–13]

Material and Methods

The study methods have been previously described.[11–13] All patients undergoing cataract surgery at nine centers in the United States and Canada were eligible for enrollment in the randomized trial. The centers included a mix of academic medical centers, community hospitals, and free-standing surgi centers. The only exclusion criteria were age less than 50 years, a history of a myocardial infarction within the past 3 months, surgeries with planned general anesthesia, surgeries on a second eye scheduled within 28 days of surgery on an enrolled first eye, patients who could not provide informed consent, and those who could not speak either English or Spanish. Combined procedures such as glaucoma and cataract surgery and surgeries that were converted to general anesthesia part way through surgery were included. Anesthetic agents and management were chosen by the medical team and were not controlled by the study protocol.

Patients who were scheduled for surgery were approached by study staff and, if found to be eligible, asked if they were willing to participate. Written informed consent was obtained from each patient. The Joint Committee on Clinical Investigations of the Johns Hopkins School of Medicine and institutional review boards at each clinical site approved the study. Patients then completed a demographic and morbidity history questionnaire. On completion of surgery, the type of anesthesia administered, the duration of surgery, and whether any medical events had occurred intraoperatively were recorded by the anesthesiologist or nurse anesthetist. At the time of discharge, any reason for a delay of discharge was recorded by the nursing staff on standardized forms. Seven days after surgery, patients were telephoned by study staff, and deaths, hospitalizations, or unplanned visits to a health care provider were noted. If a medical event was noted at any of these times, all medical records were reviewed by a study internist and anesthesiologist to determine whether a medical event that met the study definition had occurred. Intraoperative events were those that occurred during surgery or before discharge, and all other events within 7 days of surgery were considered postoperative. Events included deaths from any causes, myocardial infarction, myocardial ischemia, congestive heart failure, arrhythmia (new or worsened and requiring new or changed treatment), hypertensive and/or hypotensive events requiring treatment, stroke, transient ischemic attack, respiratory failure, bronchospasm, new or worsened oxygen saturation requiring supplemental oxygen, hypoglycemic event, or another new or worsened medical problem requiring medication or a medical procedure.

Local anesthesia was divided into topical anesthesia only and injection anesthesia (retrobulbar, peribulbar, facial nerve, or lid block) with or without topical anesthesia. Within these two categories, agents providing local anesthesia were divided into four groups: sedatives (diazepam, midazolam, or lorazepam) separated into two subgroups according to whether they were given orally or intravenously, opioid analgesics (alfentanil, fentanyl, meperidine, remifentanil, sufentanil), hypnotics (propofol, methohexital, pentothal, etomidate, ketamine), and diphenhydramine (Benadryl).

The analysis presented here uses observational data from a randomized trial. Because there was no impact of preoperative medical testing on adverse events (the primary outcome of the trial), the analysis is done by combining the two treatment groups from the randomized trial. To examine whether different anesthesia strategies were associated with varying rates of adverse medical events, two logistic regressions were fit. In the first, the outcome was all intraoperative events, and these were modeled as a function of anesthesia strategy, adjusted for age, gender, duration of surgery, and American Society of Anesthesiologists (ASA) physical status class. In the second regression, the outcome was all intraoperative and postoperative hospitalizations and deaths (a proxy for more serious medical outcomes), modeled as a function of anesthesia strategies adjusted for the same factors listed previously. In each regression, the reference anesthesia category was topical anesthesia alone or with oral sedatives only. Only anesthesia strategies used in at least 200 surgeries were included in the models.

Results

A total of 19,354 patients undergoing 20,775 surgeries were approached to participate in the study. Agreement to participate was obtained for 19,557 surgeries, of which 307 were canceled and not rescheduled during the study period; hence, 19,250 eligible surgeries took place. Of these, anesthesia data on 94 (0.5%) were missing, leaving 19,156 surgeries for analysis.

Twenty-six percent of surgeries in the study were performed using topical anesthesia (Table 1). Among those administered topical anesthesia, 35% used no other anesthetic agents, 12% used oral sedatives only, 32% used intravenous sedatives, and 21% used opioids and sedatives (oral or intravenous). Among those administered injection anesthesia, 32% were administered intravenous sedatives alone, 25% opioids and sedatives (oral or intravenous), and 16% received opioids, sedatives, and hypnotics. Of those administered sedatives intravenously, 99% were given midazolam. Smaller fractions of the surgeries were performed with other combinations of agents.

The percent of adverse medical events was 1.95% and 1.23% intraoperatively and postoperatively, respectively (Table 2). Only a small fraction of these were deaths or hospitalizations. There were 506 intraoperative and 111 postoperative cardiovascular events (myocardial infarction, ischemia, congestive heart failure, arrhythmias, hypertension, and hypotension). A large proportion of these were arrhythmias and hypertensive events (68% intraoperatively, and 47% postoperatively). The number of other events was

Table 1. Type of Anesthesia and Sedation

Agents Used	Topical Anesthesia		Injection Anesthesia*	
	n	%	*n*	%
None	1735	34.7	142	1.0
Opioids alone	5	0.1	36	0.3
Oral sedatives alone	608	12.2	114	0.8
Intravenous sedatives alone	1584	31.7	4583	32.4
Hypnotics alone	6	0.1	928	6.6
Diphenhydramine	0	0.0	1	0.0
Opioids and sedatives	1032	20.7	3511	24.8
Opioids and hypnotics	2	0.0	743	5.2
Sedatives and hypnotics	6	0.1	339	2.4
Sedatives and diphenhydramine	1	0.0	1382	9.8
Opioids, sedatives, and hypnotics	16	0.3	2303	16.3
Sedatives, hypnotics, and diphenhydramine	0	0.0	5	0.0
Opioids, sedatives, and diphenhydramine	1	0.0	70	0.5
Opioids, sedatives, hypnotics, diphenhydramine	0	0.0	6	0.0
Total	4996	100.0	14,163	100.0

*Any combination of peribulbar block, retrobulbar block, facial, or lid block, with or without topical anesthesia.

relatively small. The number of diagnoses is larger than the number of events because an event could be associated with more than one diagnosis.

The mean age at time of surgery varied from 71.8 years among those administered injection anesthesia with sedatives, opioids, and hypnotics to 77.5 years among those administered injection anesthesia with sedatives and diphenhydramine (Table 3). The mean duration of surgery was shortest for those administered injection anesthesia with intravenous sedation (16 minutes) and longest for those given injection anesthesia with opioids and sedatives (43.8 minutes). There was some variation in gender of patients by type of anesthesia, but the variation in ASA risk class was greater. The percent of patients with ASA risk class higher than II was 17.6 for those given injection anesthesia with opioids and hypnotics but 42.4 for those given injection anesthesia with sedatives, opioids, and hypnotics.

There was a strong association between the use of any intravenous agents and intraoperative medical events after adjusting for age in years, gender, duration of surgery in minutes, and ASA risk class (Table 4). Although the odds ratio for injection anesthesia alone or with oral sedatives was 5.6 (95% confidence interval [CI], 0.92, 33.5), this was not statistically significant because of the small number of events in this category of anesthesia. The use of injection anesthesia did not seem to be associated with an increased risk of adverse events per se, but the use of intravenous agents given with either topical or injection anesthesia was associated with increased risk of an adverse event. The use of more than one agent also was associated with increased risk of an adverse event. The odds ratios for one agent ranged from 9.8 to 12.3, but from 16.6 to 30.2 for two agents, and was 30.7 (95% CI, 9.7, 97.4) for injection anesthesia with sedatives, opioids, and hypnotics. A similar magnitude of association was seen for intraoperative cardiovascular events, most of which were arrhythmias (25%) and hypertensive events (43%) (data not shown).

There were no intraoperative deaths, and only three deaths within 7 days of surgery. There was no statistically significant association between type of anesthesia and all deaths and hospitalizations (Table 5). The exception was a lower percentage of adverse events among those administered injection anesthesia with sedatives and diphenhydramine, although there was only one event in this group. The percent of these outcomes was low for all anesthesia strategies (less than 1%).

Table 2. Types of Adverse Events

	Intraoperative		Postoperative	
	n	%	*n*	%
Type of event				
Deaths/hospitalization	8	0.04	58	0.30
Other medical	367	1.91	179	0.93
Total	375	1.95	237	1.23
Diagnoses				
Cardiovascular	506	2.63	111	0.58
Cerebrovascular	0	0.00	7	0.04
Pulmonary	15	0.08	9	0.05
Upper respiratory	1	0.01	33	0.17

Table 3. The Association Between Type of Anesthesia and Age, Gender, Duration of Surgery, and American Society of Anesthesiologists Risk Class

Type of Anesthesia	Mean Age	Mean Duration	Gender % Female	ASA % > II
Topical ± oral sedatives	73.8	33.3	54.9	35.3
Topical, IV sedatives	72.4	33.1	66.6	36.5
Topical, IV sedatives, opioids	72.1	26.2	62.1	75.2
Injection ± oral sedatives	73.8	38.8	54.7	39.5
Injection, IV sedatives	73.8	16.0	59.7	25.2
Injection, hypnotics	74.0	33.0	62.5	28.8
Injection, opioids, any sedatives	72.8	43.8	62.5	26.2
Injection, opioids, hypnotics	74.0	27.8	61.1	17.6
Injection, any sedatives, hypnotics	72.9	30.8	64.6	30.7
Injection, any sedatives, diphenhydramine	77.5	20.3	65.6	63.2
Injection, any sedatives, opioids, hypnotics	71.8	39.7	59.0	42.4

ASA = American Society of Anesthesiologists; IV = intravenous.

Table 4. Odds Ratios for the Association Between Type of Anesthesia and All Intraoperative Medical Events

Type of Anesthesia	N	n	%	Odds Ratio*	95% Confidence Interval
Topical ± oral sedatives	2343	3	0.13	1.00	
Topical, IV sedatives	1584	19	1.20	9.8	2.9, 33.3
Topical, IV sedatives, opioids	1032	44	4.26	30.2	9.3, 97.9
Injection ± oral sedatives	256	2	0.78	5.6	0.9, 33.5
Injection, IV sedatives	4583	54	1.18	12.3	3.8, 39.5
Injection, hypnotics	928	13	1.40	12.0	3.4, 42.1
Injection, opioids, any sedatives	3511	82	2.34	18.9	6.0, 59.9
Injection, opioids, hypnotics	743	13	1.75	18.0	5.1, 63.5
Injection, any sedatives, hypnotics	339	9	2.65	23.6	1.7, 87.9
Injection, any sedatives, diphenhydramine	1382	32	2.32	16.6	5.0, 54.5
Injection, any sedatives, opioids, hypnotics	2303	93	4.04	30.7	9.7, 97.4

*Adjusted for age, gender, duration of surgery, and American Society of Anesthesiologists class.
IV = Intravenous.

Discussion

Few data address the question of whether specific sedation strategies increase the risk of adverse events among patients undergoing cataract surgery. One trial in which patients were randomly assigned to receive patient-controlled midazolam or propofol versus no analgesia found no difference in blood pressure between the groups.[14] A study comparing intramuscular analgesia to placebo in 90 subjects found that intramuscular analgesia or sedation was associated with increased bradycardia compared with no intramuscular agents but was not associated with any other medical complications.[15] A study comparing intramuscular analgesics to placebos found an increased need for supplemental oxygen.[16] Two studies observed no adverse medical events such as arrhythmias associated with oral sedation,[17,18] and propofol and analgesics were not associated with events such as arrhythmias, congestive heart failure, stroke, myocardial infarction, respiratory failure, and hospitalizations.[19,20] Barbiturates and other intravenous agents were not associated with any hemodynamic complications.[21,22] Although many of these studies were randomized and placebo-controlled, the sample sizes were generally small, and the likelihood of observing any adverse medical events and detecting any differences between groups was very low.

The prevalence of deaths and hospitalization was very low in our study, and there did not seem to be an increased risk of these events with the administration of intravenous agents or the use of injection rather than topical local anesthesia. However, the administration of intravenous agents was associated with a statistically significant increase in intraoperative medical events, and the more types of agents administered, the higher the prevalence of adverse events. Most of these events were treatment for bradyarrhythmias and hypertension. The use of topical rather than injection anesthesia seemed to have very little relation to the risk of an adverse medical event. An intriguing, but unexplained, result is the statistically significant 78% reduction in hospitalizations and deaths among those receiving injection anesthesia with sedatives and diphenhydramine compared with topical anesthesia alone or with oral sedatives only. However, it should be noted that this strategy was administered at only one center, which applied this strategy to 98% of their cases, and this result might therefore reflect

Table 5. Odds Ratios for the Association Between Type of Anesthesia and Intraoperative and Postoperative Hospitalizations and Deaths

Type of Anesthesia	N	n	%	Odds Ratio*	95% Confidence Interval
Topical ± oral sedatives	2343	11	0.47	1.00	
Topical, IV sedatives	1584	2	0.13	0.30	0.07, 1.35
Topical, IV sedatives, opioids	1033	4	0.39	0.70	0.22, 2.26
Injection ± oral sedation	256	0	0.00	—†	
Injection, IV sedatives	4583	19	0.41	0.99	0.46, 2.15
Injection, hypnotics	928	4	0.43	1.06	0.33, 3.35
Injection, opioids, any sedatives	3511	8	0.23	0.56	0.23, 1.46
Injection, opioids, hypnotics	743	5	0.67	1.89	0.65, 5.51
Injection, any sedatives, hypnotics	339	2	0.59	1.47	0.32, 6.68
Injection, any sedatives, diphenhydramine	1382	1	0.07	0.12	0.01, 0.92
Injection, any sedatives, opioids, hypnotics	2303	10	0.43	0.96	0.40, 2.29

*Adjusted for age, gender, duration of surgery and American Society of Anesthesiologists class.
†For regression, injection +/− oral sedatives and injection with IV sedatives were combined. IV = intravenous.

other center-specific risks rather than the anesthesia strategy.

One advantage of our study was the large sample size, enabling us to examine several different anesthesia strategies and have sufficient numbers of medical events to obtain statistically and clinically significant results. The range of practice settings and limited exclusion criteria should make these results reasonably generalizable. One limitation of our study is that it was not randomized, and there are likely to be selection biases in the types of anesthesia administered to patients. In many of our centers, only one or two different anesthesia strategies were used, and there was substantial variation in event rates between centers, which is likely a function of the patient mix and threshold for intervention during surgery at these centers. Anesthesiologists who prefer to use pharmacologic treatment for the management of pain and anxiety may also prefer to use pharmacologic treatment for moderate acute hypertension and bradycardia. Another potential confounder is that certain patient characteristics that predispose them to receive more sedation (such as anxiety) would also make it more likely that they would receive antihypertensive treatment. Although the association of interest was adjusted for age, gender, duration of surgery, and ASA risk class, there may be some remaining confounding of the association between anesthesia strategy and medical events by center, patient, or anesthesiologist. Although there are no statistically significant effect modifiers, there was some indication that the variation in medical events by anesthesia strategy was more pronounced among patients 70 years and older and among those at lower risk of medical events on the basis of ASA risk class of I or II. Although our data are suggestive of an association between anesthesia strategy and adverse medical events, a randomized trial would be needed to provide stronger evidence for a causal link.

In a previous analysis of these data, there were significant differences between patient perceptions of pain during surgery and reporting of side effects within 24 hours of surgery by anesthesia strategy.[13] Sedatives and hypnotics were associated with increased postoperative side effects but not a reduction in pain during surgery. Increasing numbers of agents increased the reporting of side effects, and hypnotics were associated with increased reports of pain during surgery. The current analysis also indicates that patients administered many intravenous agents have a higher risk of an adverse medical event during surgery. The group administered injection anesthesia with sedatives and diphenhydramine reported less pain and comparable side effects compared with those administered topical anesthesia alone. This is the same group with the lowest reporting of hospitalizations and deaths. In general, it seems that intravenous agents are associated with increased side effects and medical events, whereas analgesia reduced pain during surgery but was always given with sedatives that were associated with reporting of more side effects and increased medical events. There did not seem to be any difference in the rate of medical events between topical and injection anesthesia, but the previous study did find that topical anesthesia without opioids was associated with increased pain during surgery.[13] The choice of anesthesia strategy is complex and should include a careful weighing of patient preferences and clinician assessment of the medical risks associated with different strategies to achieve optimal results. Data from our study suggest that the current common practice of administering multiple intravenous agents for cataract surgery may not be optimal.

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