Safety of cataract surgery under topical anesthesia with oral sedation without anesthetic monitoring

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ABSTRACT • RÉSUMÉ

Purpose: The current study was conducted to determine whether topical anesthesia with oral sedation and without an anesthetist present in the operating room is a safe and cost-effective strategy for low-risk patients undergoing cataract surgery.

Methods: This retrospective interventional case series included cases conducted between 2001 and 2003 at the Brandon Regional Health Centre in Brandon, Manitoba. Patients with visually significant cataracts were screened for study inclusion by using the following criteria: good general health, good dilation, moderate cataracts, cooperation with in-office tests and procedures, and understanding of cataract surgery. Oral sedation was provided by lorazepam, and an anesthetist was available to manage any medical adverse events. Topical anesthesia was achieved by means of tetracaine drops, lidocaine hydrochloride jelly, and intracameral lidocaine hydrochloride, as necessary. Main outcome measures were heart rate, systolic and diastolic blood pressure, oxygen saturation, intraoperative complications, and medical adverse events necessitating anesthetist intervention.

Results: A total of 538 eyes of 373 patients were included in the cataract surgery case series. No medical adverse events were reported in 454 cases (84.4%); 84 patients (15.6%) experienced adverse events, classified as mild in 13.5%, moderate in 1.1%, and severe in 0.9% (5 cases). The most common adverse event was mild pain, experienced in 69 procedures (12.8%). Moderate pain, necessitating use of intracameral 1% lidocaine, occurred in 3 procedures (0.6%).

Interpretation: Topical anesthesia appears to be a safe alternative to injection anesthesia without many of the disadvantages of the latter and may be preferable in carefully selected patients.

Contexte : Cette étude avait pour objet d'établir si l'anesthésie topique avec sédation par voie orale sans la présence d'un anesthésiste dans la salle d'opération était une stratégie sûre et rentable pour les patients à faible risque subissant une chirurgie de la cataracte.

Méthodes : On a passé en revue une série d'interventions qui avaient été effectuées entre 2001 et 2003 au Brandon Regional Health Centre, à Brandon (Manitoba). L'inclusion dans l'étude des patients ayant d'importantes cataractes été faite selon les critères suivants : bon état de santé en général, bonne dilatation, cataractes modérées, coopération avec le bureau pour les tests et procédures ainsi que connaissance de la chirurgie de la cataracte. On a utilisé du lorazépam pour la sédation par voie orale et un anesthésiste était disponible pour gérer tout événement médical indésirable. L'anesthésie topique a été effectuée par des gouttes de tétracaïne, de la gelée de chlorhydrate de lidocaïne avec ajout, au besoin, de chlorhydrate de lidocaïne intracamérulaire. La mesure des principaux résultats a porté sur la fréquence cardiaque, la tension artérielle systolique et diastolique, la saturation en oxygène, les complications peropératoires et les événements indésirables nécessitant l'intervention de l'anesthésiste.

Résultats : En tout, 538 yeux de 373 patients ont été inclus dans la série de cas de chirurgie de la cataracte. Aucun événement indésirable n'a été signalé dans 454 cas (84,4 %); 84 patients (15,6 %) ont eu des événements indésirables répartis entre légers (13,5 %), modérés (1,1 %) et sévères (0,9 %) (5 cas). L'événement indésirable le plus commun a été une légère douleur survenue dans 69 opérations (12,8 %). La

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douleur modérée, nécessitant l'injection intracamérulaire de lidocaïne 1 %, est survenue dans 3 opérations (0,6 %).

Interprétation : L'anesthésie topique semble être une alternative sûre à l'anesthésie par injection sans les nombreux inconvénients de celle-ci et est peut-être préférable pour les patients sélectionnés avec soin.

Today, cataract surgery is normally performed by using some form of local anesthesia plus conscious sedation, an anesthetic management approach that has allowed cataract surgery to evolve into a routine outpatient procedure.[1] Current anesthetic options typically include injection techniques, such as retrobulbar and peribulbar blocks and sub-Tenon injection, and topical anesthesia, possibly supplemented with intracameral lidocaine. Intravenous or oral agents may be used to achieve conscious sedation. Consensus does not yet exist on whether regional or topical anesthesia is the superior option, although topical anesthesia is becoming more commonly used.[2–4]

Relevant considerations include surgical outcomes, anesthetic complications and the need for anesthetic monitoring, patient comfort, and cost. Regional blocks have been associated with both local complications, such as retrobulbar hemorrhage, extraocular muscle damage with subsequent diplopia, blindness and increased intraoperative posterior vitreous pressure, and systemic complications, including the risk of brainstem anesthesia, a life-threatening condition.[2,5] Regional blocks also require increased intravenous sedation and the presence of an anesthetist, factors tending to increase the cost of surgery.[1] Furthermore, an analysis of patient report data on 19 250 surgeries determined that intravenous sedation was associated with increased postoperative drowsiness and nausea.[1]

Topical anesthetic strategies may overcome some of the disadvantages of regional blocks plus intravenous sedation. Modern topical anesthesia for cataract surgery had its origins in the 1990s with the development of small-incision self-sealing surgical techniques.[4,6–8] Topical techniques, with or without intravenous sedation, avoided the complications associated with regional blocks, while providing effective intraoperative anesthesia and faster recovery with no need for patching the eye. Furthermore, discontinuation of anticoagulant or antithrombotic therapy was not required.[9] These advantages, coupled with a reduced total procedural time, spurred rapid growth in the use of topical anesthesia. Surveys by the American Society of Cataract and Refractive Surgery found that 56% of surgeons used topical anesthesia during cataract surgery in 2001, compared with 30% in 1997 and only 8% in 1995.[10]

Topical anesthesia is, however, associated with its own problems, including a reported increase in intraoperative pain compared with retrobulbar anesthesia.[1] The addition of intracameral lidocaine to topical anesthesia has been shown to reduce intraocular sensation during phacoemulsification safely and effectively, thus addressing an important perceived disadvantage of the topical anesthetic option.[11–13] Concerns raised about the potential endothelial toxicity of intracameral anesthesia appear to be largely unfounded, although long-term data are lacking. Other potential problems associated with topical anesthesia include increased patient anxiety, squeezing during surgery, and stress for the surgeon who must talk the patient through the procedure.[14] As a result, candidates for cataract surgery under topical anesthesia must be carefully selected and screened.

Although an anesthetist is usually present during cataract surgery to administer intravenous sedation, recent data indicate that registered respiratory care practitioners (RRCPs) can provide monitored anesthesia safely and cost effectively.[3] Intravenous sedation, a standard approach to conscious sedation for cataract surgery, is also associated with adverse effects. One study of intravenous sedation found an increased incidence of medical adverse events, especially hypertension, whether topical or retrobulbar anesthesia was used.[15] Rosenfeld et al. found an anesthetist intervention rate of 37% when cataract surgery was completed using peribulbar anesthesia and intravenous sedation.[16] The authors were unable to identify risk factors predicting the need for anesthetist intervention. The increased risk of adverse events and prolonged recovery associated with intravenous sedation and the cost associated with the presence of an anesthetist throughout surgery raise questions about the necessity or even desirability of intravenous sedation in cooperative patients.

The current study was conducted to determine if topical anesthesia with oral sedation and without an anesthetist present in the operating room is a safe and cost-effective strategy for low-risk patients undergoing cataract surgery. This study was performed in the setting of minimal preoperative physical workup to explore the safety of a less invasive and less costly method of providing conscious sedation to low-risk patients.

METHODS

This retrospective interventional case series included cases conducted between May 17, 2001, and May 1, 2003. All surgeries employed topical anesthesia and oral sedation;

no anesthetist was present in the operating room. In addition, all cases were conducted in the Brandon Regional Health Centre in Brandon, Manitoba, and performed by a single surgeon (Dr. Rocha).

Patients with visually significant cataracts were screened for study inclusion. Inclusion criteria included good general health (American Society of Anesthesia class I [healthy] or class II [mild systemic disease]), good dilation, moderate cataracts, cooperation with in-office tests and procedures, and understanding of cataract surgery. A routine physical examination within the past year was necessary, but no preoperative examination or blood work was required. Only willing patients with minimal anxiety were considered for participation in this study. All procedures were conducted in accordance with the stipulations of the Declaration of Helsinki. Ethics approval for the study was obtained from the ethics committee, Brandon Regional Health Centre, Brandon, Manitoba. As cataract surgery is not an experimental procedure, standard hospital surgical consent forms were also utilized. All monitoring procedures were those routinely utilized for local anesthesia in the hospital setting.

Systemic exclusion criteria included age less than 35 years or greater than 95 years, any history of heart disease or cardiac surgery, respiratory problems, dementia, debility, deafness and inability to provide informed consent.[17] In addition, systolic blood pressure higher than 160 mm Hg, diastolic blood pressure higher than 90 mm Hg and heart rate greater than 90 beats per minute, measured in the office, excluded patients from the study. Exclusion criteria related to ocular status included reduced ocular fissure, extreme hyperopia, corneal scarring associated with diminished visibility, small pupil, dense cataract, and macular degeneration with poor fixation.

Oral sedation was accomplished with 1 mg lorazepam, administered 45 to 60 minutes before surgery. An anesthetist was available in the hospital to manage any medical adverse events. Routine preoperative ocular preparation included topical application of 2.5% phenylephrine (Chauvin Pharmaceuticals Ltd, France), 1% tropicamide (Chauvin Pharmaceuticals Ltd, France), 2% homatropine (Chauvin Pharmaceuticals Ltd, France), 0.03% flurbiprofen sodium (Ocufen; Allergan Inc, Markham, Ont.), 3.5 mg/mL ciprofloxacin solution (Ciloxan; Alcon Canada Inc, Mississauga, Ont.), and 5% povidone iodine solution.

In the operating room, oxygen was delivered via nasal cannula at 2–3 L/min. Anesthesia was achieved by instillation of a drop of 0.5% tetracaine (Chauvin Pharmaceuticals, Ltd, France) in the operative and contralateral eyes and by application of 2% lidocaine hydrochloride jelly (Astra-Zeneca Canada Inc, Mississauga, Ont.) for 5 minutes. Intracameral injection of preservative-free 1% lidocaine hydrochloride (Astra-Zeneca Canada Inc, Mississauga, Ont.) provided additional anesthesia for patients who experienced significant discomfort during the early phases of the procedure.

Operating microscope illumination was maintained at minimal levels until completion of the capsulorrhexis to allow light adaptation. Phacoemulsification was performed using a chopping technique with the Millennium system (Bausch & Lomb Canada Inc, Markham, Ont.). Polymethylmethacrylate intraocular lenses (IOLs) were inserted through a sutureless superior 5.0 mm scleral tunnel incision, and foldable IOLs were introduced through a 3.0 mm temporal clear corneal incision. After completion of the procedure, 2% pilocarpine gel (Pilopine gel 2%, Alcon Canada Inc, Mississauga, Ont.) and 3.5 mg/g ciprofloxacin ointment (Ciloxan; Alcon Canada Inc, Mississauga, Ont.) were applied, and a clear shield was used. Postoperative treatment with ciprofloxacin ophthalmic solution four times a day (Ciloxan; Alcon Canada Inc, Mississauga, Ont.) and 0.1% dexamethasone four times a day (Maxidex; Alcon Canada Inc, Mississauga, Ont.) was begun 6 hours after surgery and continued for 1 and 3 weeks, respectively.

The main outcomes measures were heart rate, systolic and diastolic blood pressure, oxygen saturation, intraoperative complications and medical adverse events necessitating anesthetist intervention. Heart rate, systolic and diastolic blood pressure, and oxygen saturation were recorded 1 hour preoperatively, monitored intraoperatively, and recorded immediately postoperatively, using a Datex-Ohmeda S/5 anesthetic monitoring machine (Beaverton, Ore.). The highest and lowest values for intraoperative heart rate, blood pressure and oxygen saturation were compared with the preoperative and the postoperative values. Pain was recorded and assessed on the basis of nursing notes and use of intracameral 1% lidocaine, which was used only for patients experiencing significant pain. Intraoperative complications and the need for anesthetist intervention were recorded.

Data were collected in an Excel file (Microsoft) and analyzed using Statview (SAS Institute). Data with normal distribution were analyzed with Student *t* tests, and paired data were analyzed using paired, 2-tailed tests. Results were considered statistically significant for p values <0.05.

Results

A total of 538 eyes of 373 patients were included in the cataract surgery case series; complete perioperative data

pertaining to heart rate, blood pressure, and oxygen saturation were available for 469 cases (87.2%). Medical adverse event and complication data were available for all cases. Demographic information is summarized in Table 1.

No medical adverse events were reported in 454 cases (84.4%), which were classified as completely successful. Eighty-four patients (15.6%) experienced adverse events, which were mild in 13.5%, moderate in 1.1%, and severe, necessitating the intervention of an anesthetist, in 5 cases (0.9%) (Table 2). The 5 severe adverse events all involved large changes in blood pressure (hypertension or hypotension), and all were managed successfully by the anesthetist. The most common adverse event was mild pain, experienced in 69 procedures (12.8%). Moderate pain, necessitating use of 1% intracameral lidocaine, occurred in 3 procedures (0.6%).

For systolic blood pressure, a statistically significant difference was seen between the preoperative levels and the highest and lowest levels recorded during surgery. No significant difference was noted between preoperative and postoperative values (Table 3). Similarly, a statistically significant difference was seen between the preoperative and the highest and lowest diastolic blood pressures levels. No significant difference was noted between preoperative and postoperative values (Table 3).

Table 1—Demographic data

Parameter	No.
Operative eyes	538
Right eye	269
Left eye	269
Patients	373
Male	115
Female	258
Age, mean (range), years	74.2 (38–91)

Data are No. unless otherwise specified.

Table 2—Adverse events in 538 cataract surgery procedures conducted under topical anesthesia and oral sedation

Adverse event	No. (%)
Mild adverse events	73 (13.5)
Mild pain	69
Itchy eye	2
Mild burning sensation	2
Moderate adverse events	6 (1.1)
Moderate pain	3
Nausea or dizziness	2
Oxygen required	1
Serious adverse events	5 (0.9)
Hypertension or hypotension (anesthetist intervention required)	5
Intensive care unit admission	0
Fatality	0
Intraocular complications	0

Changes in mean blood pressure values were skewed by large blood pressure changes (systolic >160 mm Hg and (or) diastolic >90 mm Hg) in 5 patients, which were classified as severe adverse events and necessitated the intervention of an anesthetist.

The mean heart rate tended to decrease throughout the procedure, showing statistically significant differences between the preoperative and the highest and lowest intraoperative levels recorded. A significant difference was also noted between preoperative and postoperative values (Table 3). The highest value for mean heart rate during the procedure was significantly lower than the immediate preoperative values (Table 3). Although both were elevated compared with postoperative values, all values remained within the normal range and did not require anesthetist intervention.

Mean oxygen saturation levels tended to increase during the latter part of the procedure. A statistically significant difference was seen between the preoperative and the highest and lowest levels oxygen saturation levels recorded. A significant difference was also noted between preoperative and postoperative values (Table 3). The postoperative increase in oxygen saturation may have been due in part to the administration of oxygen via nasal cannula during the procedure and to the relatively enclosed environment under the surgical drape.

No intraoperative complications, such as posterior capsule rupture, occurred in any case, no admissions to the intensive care unit were required, and no fatalities occurred. Recovery was uneventful after all 538 procedures.

Interpretation

Alternatives now exist to traditional regional anesthesia with intravenous sedation and full-time monitoring by an anesthetist. A recent study by Zakrzewski et al evaluated the safety and feasibility of having RRCPs provide anesthetic monitoring during routine cataract surgery with the support of an anesthetist who was available for consultation or intervention.[3] Their prospective series, which involved 1957 consecutive cases, found that RRCPs monitored 96% of cases without anesthetist intervention. More than 98% of cases in the series received intravenous sedation. These results demonstrate that RRCPs trained as anesthesia assistants can provide monitored anesthesia care safely and cost effectively. More widespread implementation of such a strategy has the potential benefit of decreasing both costs and demand for anesthesiology services.

For low-risk cataract surgery, topical anesthesia with oral sedation also appears to be a valid alternative to tra-

ditional retrobulbar anesthesia with intravenous sedation, even when no anesthetist is present and no preoperative physical examination or blood work is performed. Performing cataract surgery without continuous anesthetic monitoring is a relatively unfamiliar concept in North America. In Denmark, however, almost all cataract surgeries have been performed without anesthetic monitoring and without either intravenous or oral sedation since at least 1997.[18]

The current series of 538 cases found a low incidence of primarily mild adverse events, and 84.4% of cases were completed successfully without any adverse events. It is important to emphasize that although the cases reported in this series were performed without an anesthetist, all cases were conduced in a facility where an anesthetist was present, so that an anesthetist was available to manage any serious adverse events that did occur. The rapid availability of an anesthetist is a necessary precaution, as complications are possible during even the simplest procedures. In this study, intervention by an anesthetist was required in 5 (0.9%) procedures during which serious adverse events occurred. Statistically significant intraoperative changes in heart rate and blood pressure seen in this study most likely indicated patient stress. Whether this stress would have been eliminated with retrobulbar anesthesia and intravenous sedation is open to speculation.

A similar study by Katz et al reported no difference in the rate of medical events between topical and retrobulbar anesthesia.[15] Sherman et al also found that nonfatal complications of all types of anesthesia used in cataract surgery were rare enough to have a negligible effect on determining the best anesthetic approach.[19] Spiritus et al concluded that, for experienced surgeons, topical anesthesia was a safe and effective anesthetic approach for cataract surgery.[20] These studies support our conclusion that, from the perspective of safety, topical anesthesia is a valid alternative to injection anesthesia.

No intraocular complications or deaths occurred and no admissions to the intensive care unit were required. Occurrence of a complication may require conversion to block anesthesia with intravenous sedation or general anesthesia to complete the procedure.[21] The absence of complications in this series underscores the importance of appropriate patient selection and supports the validity of topical anesthesia with oral sedation as a safe alternative to retrobulbar local anesthesia.

A meta-analysis of previous studies determined that pain control with topical anesthesia was inferior to that achieved with regional blocks.[1] In contrast, the current case series found a low incidence and degree of pain both during and after the procedure, with moderate pain occurring in only 3 procedures (0.6%), mild pain in only 69 (12.8%), and no pain in the majority of procedures. These data suggest that in many cataract surgery patients, pain is relatively uncommon with the use of topical anesthesia and that the degree of pain is mild enough that it rarely caused significant distress. Appropriate patient selection may also have an important impact on the incidence or perception of pain. Patients were carefully screened before entry in the study and most participants felt comfortable with the surgical and anesthetic approach. As a result, a low incidence of patient anxiety and squeezing was recorded. Furthermore, the surgeon had substantial experience with cataract surgery and felt comfortable completing the cases under topical anesthesia. Mathew et al has reported that patients tended to report less pain with an experienced surgeon, compared with a less experienced surgeon, although the difference is not statistically significant.[22]

Table 3—Changes in heart rate, blood pressure, and oxygen saturation for cataract surgery procedures performed under topical anesthesia with oral sedation

	Mean (range), *n* = 469				
		Intraoperative			
Parameter	Preoperative	Maximum	Minimum	Postoperative	*p* value
Heart rate, beats/min	76.5 (49–115)	72.6 (44–124)	64.8 (40–116)	67.8 (43–118)	<0.001* <0.001†
Systolic blood pressure, mm Hg	144.7 (96–237)	155.6 (95–241)	137.4 (65–206)	145.0 (68–217)	<0.001* 0.68†
Diastolic blood pressure, mm Hg	79.6 (40–111)	86.0 (51–130)	75.6 (25–116)	80.6 (43–127)	<0.001* 0.08†
Oxygen saturation, %	97.6 (80–100)	99.1 (92–100)	97.1 (80–100)	98.8 (88–100)	<0.001* <0.001†

*Intraoperative maximum vs. preoperative, and intraoperative minimum vs. preoperative.

†Postoperative vs. preoperative.

Note: complete perioperative data pertaining to heart rate, blood pressure, and oxygen saturation were available for 469 of 538 (87.2%) procedures.

Our experience with performing cataract surgery with topical anesthesia plus oral sedation has been positive, and since the case series described in this paper, such an approach has become routinely used for appropriate patients.

Topical anesthesia with oral sedation with no anesthetist present is not only safe but also an effective use of resources, as it does not require preoperative physical examination or blood work. Schein et al investigated the value of routine preoperative medical testing before cataract surgery and concluded that testing increased Medicare costs without measurably increasing the safety of the surgery.[19] More than 10 years ago, an assessment of data from the American Medicare system found cataract surgery to be the most common surgical procedure and to account for more than $3.4 billion dollars annually.[23] More recently, Reeves et al found the expected cost per patient for intravenous sedation and block anesthesia with an anesthetist to be $US324.42, compared with $US6.77 for oral sedation and topical anesthesia, a 40-fold difference.[21] With the aging population, expenditures for cataract surgery are only likely to increase in the future.

Comparable Canadian data derived from reimbursement rates in Manitoba provide a per-procedure cost for preoperative testing and anesthetist fees of approximately $575 (Table 4).[24] Cataract surgery remains a common procedure in Canada today, and data gathered by the Institute for Clinical and Evaluative Sciences (ICES) provide an annual cataract surgery rate of 1174 procedures per 100 000 population in Ontario.[25] Applying that rate to the Canadian population produces an annual cataract surgery volume of 377 400 procedures.[26] If all cataract surgery procedures are assumed to have associated costs for preoperative testing and anesthetist fees, the total cost associated with preoperative testing and anesthetist fees would amount to more than $217 million annually. Admittedly, these calculations provide only crude estimates of potential cost savings, but more frequent use of topical anesthesia and oral sedation could substantially reduce the cost of cataract surgery in Canada, allowing scarce medical resources to be allocated to areas of greater need. In addition, as topical anesthesia shortens operative and recovery time, increased use of topical anesthesia could be expected to free operating and recovery room time and space and provide patient quality-of-life benefits.[6–8]

Table 4—Potential cost savings for cataract surgery without preoperative testing and examination and without an anesthetist present in operating room[24–26]

Expense type	Cost saving, Cdn$
Preoperative testing[24]	339.77
Preoperative physical examination[24]	102.50
Anesthetist[24]	128.12
Intraoperative sedation[24]	5.00
Subtotal	575.39
Cataract surgery rate per 100 000 [25]*	1 174
Canadian population[26] †	32 146 547
Annual procedures in Canada*	377 400
Total cost saving	217 152 186

*Estimate per 100 000 in 2003–2004 for Ontario, used to calculate annual number of procedures in Canada.

†Estimate April 2005.

Weaknesses of the current study include the retrospective nature of the data collection, the lack of a control group, and the lack of a formal patient questionnaire regarding overall satisfaction with the procedure and the degree of pain perceived. The outcomes of the current study, however, suggest that it may be possible to implement less invasive anesthesia, a less intensive approach to anesthetic monitoring, and a less costly approach to cataract surgery without sacrificing patient safety or excellent outcomes.

In conclusion, topical anesthesia appears to be a safe alternative to injection anesthesia without many of the disadvantages of the latter. Topical anesthesia may, in fact, be preferable to more invasive approaches for carefully selected patients treated by an experienced surgeon who is comfortable with topical anesthesia.

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