


# A prospective observational cohort study to evaluate patients' experience during sequential cataract surgery under monitored anesthesia care and topical anesthesia

Jarrett A. Heard, MD<sup>a,\*</sup>, Alicia A. Gonzalez Zacarias, MD<sup>a</sup> , Alec T. Lawrence, MD<sup>a</sup>, Nicoleta Stoicea, MD, PhD<sup>a</sup>, Marilly Palettas, MPH<sup>b</sup>, Juan Fiorda-Diaz, MD<sup>a</sup>, Michael G. Guertin, MD, MBA<sup>a</sup>, Amit Tandon, MD<sup>c</sup>, Deborah S. Lowery, MD<sup>a</sup>

## Abstract

Cataract surgery is the most common ambulatory surgery at our outpatient surgery center. Several studies have shown that patients with bilateral cataracts may experience different levels of anxiety, pain, and awareness during the first and second cataract extraction.

A prospective observational cohort study was conducted at The Ohio State University Wexner Medical Center Eye and Ear Institute in order to compare anxiety, general comfort, awareness, and pain levels in patients undergoing sequential cataract surgeries. Likert and numerical rating scale were used to assess the outcomes. Patients receiving monitored anesthesia care and topical anesthesia were included.

A total of 198 patients were enrolled in this study, 116 patients (59%) were female and 157 patients (78%) were Caucasians with a median age of 67 years among participants. Patients with rating “no anxiety” or feeling “somewhat anxious” were significantly higher during surgery 2 ( $P = < .001$ ). Most of the patients felt “extremely comfortable” during surgery 1 when compared to surgery 2 (54% vs 42.9%;  $P = .08$ ). No significant differences were found between surgeries regarding intraoperative awareness ( $P = .16$ ). Overall, patients experienced mild pain during both procedures (92.4% in surgery 1 compared to 90.4% in surgery 2;  $P = .55$ ). During the postoperative visit, 54% of the patients associated surgery 2 with less anxiety levels, 53% with no differences in general comfort, 60% felt more aware, and 59% had no differences in pain levels.

Previous exposure to surgery could have been associated with a significant reduction in anxiety levels reported during surgery 2. Non-pharmacological strategies aiming to reduce perioperative anxiety may be considered an alternative or additional approach to premedication in patients undergoing consecutive cataract surgeries.

**Abbreviations:** IV = intravenous, MAC = monitored anesthesia care, NRS = numerical rating scale, PACU = post-anesthesia care unit.

**Keywords:** anxiety, cataract surgery, phacoemulsification, postoperative pain, topical anesthesia

Editor: Somchai Amornymotin.

The authors have no funding and conflicts of interest to disclose.

Supplemental Digital Content is available for this article.

All data generated or analyzed during this study are included in this published article [and its supplementary information files].

<sup>a</sup> Department of Anesthesiology, <sup>b</sup> Department of Biomedical Informatics, Center for Biostatistics, <sup>c</sup> Department of Ophthalmology, The Ohio State University Wexner Medical Center, Columbus, OH.

\* Correspondence: Jarrett A. Heard, Department of Anesthesiology, The Ohio State University Wexner Medical Center, 520 Doan Hall, 410 West 10th Avenue, Columbus, OH 43210 (e-mail: Jarrett.Heard@osumc.edu).

Copyright © 2020 the Author(s). Published by Wolters Kluwer Health, Inc. This is an open access article distributed under the terms of the Creative Commons Attribution-Non Commercial License 4.0 (CCBY-NC), where it is permissible to download, share, remix, transform, and buildup the work provided it is properly cited. The work cannot be used commercially without permission from the journal.

How to cite this article: Heard JA, Zacarias AA, Lawrence AT, Stoicea N, Palettas M, Fiorda-Diaz J, Guertin MG, Tandon A, Lowery DS. A prospective observational cohort study to evaluate patients' experience during sequential cataract surgery under monitored anesthesia care and topical anesthesia. *Medicine* 2020;99:47(e21834).

Received: 10 September 2019 / Received in final form: 16 June 2020 / Accepted: 15 July 2020

<http://dx.doi.org/10.1097/MD.0000000000021834>

## 1. Introduction

Cataract surgery is the most common ambulatory surgery performed in ophthalmology.<sup>[1,2]</sup> The definitive treatment for senile cataract is surgical removal through phacoemulsification and insertion of an intraocular lens. This procedure has been associated with shorter operative times, smaller incisions, faster visual recovery, and lower risk of postoperative complications.<sup>[1–4]</sup>

Intraconal and extraconal injections were previously used for anesthesia management in patients undergoing cataract extraction. Ecchymosis, retrobulbar hemorrhage, extraocular muscle damage, ptosis, risk of globe perforation, optic nerve injury, and optic atrophy were some of the complications associated with this technique.<sup>[4,5]</sup> With the advances in surgical approaches, topical anesthesia has become the preferred anesthesia technique for cataract phacoemulsification procedures.<sup>[5,6]</sup> Even though reduced pain levels have been linked with the use of topical anesthesia, significant intraoperative pain, and anxiety continues to be frequently reported among patients.<sup>[5]</sup>

Cataract phacoemulsification is usually performed in the eye with greater visual deficit and complex condition first, followed by the less affected eye.<sup>[1]</sup> Recent studies have shown that patients

with bilateral cataract may experience different levels of anxiety, pain, and awareness during the first and second cataract extraction.<sup>[1,2]</sup> Increased discomfort and awareness have been reported during surgery 2 when compared to the first procedure.<sup>[1,6]</sup>

Monitored anesthesia care (MAC) consists of conscious sedation through the intravenous (IV) administration of propofol, benzodiazepines, and/or opioids. MAC combined with topical anesthesia has been associated with improved patients' satisfaction, and reduced pain levels and anxiety.<sup>[7,8]</sup> IV midazolam is widely used for premedication in surgical patients. However, Habib et al described that IV midazolam may be only necessary in patients with high preoperative anxiety scores.<sup>[7]</sup>

The Likert scale is widely used in clinical practice to assess several symptoms such as anxiety and discomfort. It consists in a agree-disagree scale for a series of statements where 1 means strongly disagree, 2 means disagree, 3 means undecided, 4 means agree, and 5 means strongly agree.<sup>[9]</sup> Likewise, the numerical rating scale (NRS) is a validated tool used to evaluate the pain level from 0 to 10, being 0 no pain at all and 10 the worst imaginable pain.<sup>[10]</sup>

### 1.1. Objective

To compare intraoperative anxiety, general comfort, awareness, and pain levels in patients undergoing consecutive cataract phacoemulsification under MAC and topical anesthesia.

## 2. Materials and methods

### 2.1. Study design

We conducted a prospective observational cohort study at The Ohio State University Wexner Medical Center, Eye and Ear Institute, in patients undergoing consecutive cataract phacoemulsification under MAC and topical anesthesia from January 2017 to March 2018. The study was approved by the Institutional Review Board of The Ohio State University and registered at ClinicalTrials.gov (NCT03002688; principal investigator D.L.; December 26, 2016). We followed the Strengthening of Reporting of Observational Studies in Epidemiology guidelines to report this study.

Adult patients scheduled to undergo sequential cataract surgeries within a 6 week time period performed by the same ophthalmologist were enrolled in this study. Subjects with cognitive impairment, language barrier, and not able to consent were excluded. Written informed consent was obtained from all the patients included in this study.

### 2.2. Perioperative management and data collection

Demographic variables including age, gender, race, height, weight, body mass index, and American Society of Anesthesiologists physical status were collected the day of the surgery. Subsequently, standard topical anesthesia including bupivacaine PF 0.75% 1 mL and cataract compounded gel (lidocaine 2%, cyclopentolate 1%, moxifloxacin 0.5%, phenylephrine 10% tropicamide 1%, flurbiprofen 0.03%) was applied 15 to 30 minutes before surgery. In addition, supplemental topical anesthesia (lidocaine PF 1.0% 0.5 mL intracameral or topical and bupivacaine PF 0.75% PRN) was administered by the surgeon in the operating room. IV midazolam (0.01–0.03 mg/kg) was used as premedication in all patients in both surgeries,

standard of care at our institution, with dosing and timing at the discretion of the anesthesiologist and in-room provider based on patients' comfort and awareness. "Premedication time" was defined as the time from midazolam administration to the incision time.

A questionnaire was verbally completed in the post-anesthesia care unit (PACU) after each surgery. The responses of this questionnaire were not available to the anesthesia provider during the second encounter. Anxiety, awareness, and general comfort were assessed based on Likert Scale. For the purpose of this study, patients were trained to report awareness based on Likert Scale, being level 1 "not aware" (do not recall any events during the surgery) and level 5 "extremely aware" (recall detailed events during the surgery). Likewise, NRS (0–10) was used to evaluate pain level (0–3: mild pain; 4–7: moderate pain; 8–10: severe pain). Lastly, a postoperative visit survey was completed 1 day after surgery 2 in order to compare the aforementioned variables between surgeries.

### 2.3. Statistical analysis

Demographic characteristics were summarized using descriptive statistics. Survey responses for reported anxiety, general comfort, awareness, and pain levels were summarized using counts for an individual's paired responses for both surgeries. The Sign Test was used to assess change from surgery 1 to surgery 2 of reported anxiety, general comfort, awareness, and pain level. Direct assessment of differences reported for these variables between the 2 surgeries were also categorized and compared as "Less" (any change less than 0 from surgery 2 compared to surgery 1), "No difference" (a difference of 0 from surgery 2 compared to surgery 1), or "More" (any change greater than 0 from surgery 2 compared to surgery 1). The postoperative survey completed 1 day after surgery 2 summarized the perceived differences between surgeries using the same categories. These direct and perceived differences reported between surgeries were summarized using descriptive statistics.

## 3. Results

A total of 198 patients (n = 198) were enrolled in this study out of which 116 patients (59%) were female and 157 patients (78%) were Caucasians. The median age was 67 years among participants (Table S1, <http://links.lww.com/MD/F57>). No significant differences were found in length of surgery, preoperative midazolam dose administered, and premedication time (Table S2, <http://links.lww.com/MD/F58>). In addition, no perioperative complications were reported in our patient setting.

### 3.1. Anxiety

The number of patients with "no anxiety" or feeling "somewhat anxious" was significantly higher during surgery 2 when compared to surgery 1. Hence, 64.7% of the patients who were "very anxious" and 66.6% of those who were "extremely anxious" during surgery 1, reported lower levels of anxiety during surgery 2 ( $P < .0001$ ; Table S3, <http://links.lww.com/MD/F59>).

### 3.2. General comfort

Most of the patients felt "extremely comfortable" during surgery 1 when compared to surgery 2 (54% vs 42.9%). In addition, only 4 patients in surgery 1 and 8 patients in surgery 2 reported feeling

either “not comfortable” or “somewhat comfortable” ( $P = .08$ ; Table S4, <http://links.lww.com/MD/F60>).

### 3.3. Awareness

No significant differences were found between surgeries regarding intraoperative awareness ( $P = .16$ ). The number of patients reporting to be either “extremely aware” or “very aware” in surgery 1 compared to surgery 2 was similar (74.2% and 69.1%, respectively). Likewise, the number of patients who were “not aware” or “somewhat aware” was comparable between surgeries (15.7% and 13.1% in surgery 1 and 2, respectively) (Table S5, <http://links.lww.com/MD/F61>).

### 3.4. Pain

Most of the patients reported mild pain during both procedures (92.4% in surgery 1 compared to 90.4% in surgery 2). Only 1 patient (0.5%) experienced severe pain during both surgeries ( $P = .55$ ; Table S6, <http://links.lww.com/MD/F62>).

### 3.5. Differences in Likert scale and NRS values between surgeries

Most of the patients experienced lower levels of anxiety and awareness during surgery 2 in comparison with surgery 1 (52% and 37% of the respondents, respectively). No differences of these variables were found in one-third of patients surveyed. Additionally, 34% of the patients had more discomfort during surgery 2 versus 41% that reported no difference in comfort between procedures. No differences in pain levels were found in 172 patients (86.6%) and only 7.5% of them experienced more pain during surgery 2 (Table S7, <http://links.lww.com/MD/F63>).

### 3.6. Qualitative patients’ perception between surgeries

During the postoperative visit (day 1 after surgery 2), 54% of the patients reported less anxiety during surgery 2, 53% reported no differences in comfort, 60% felt more aware during surgery 2, and 59% had no differences in pain levels (Table S7, <http://links.lww.com/MD/F63>).

## 4. Discussion

Recently, consecutive phacoemulsification cataract surgeries have been increasing worldwide.<sup>[3]</sup> Pain is the most common symptom assessed when considering patients’ satisfaction during and after cataract surgery, being topical anesthesia combined with MAC widely accepted for this type of procedure.<sup>[1,11]</sup> However, other determinant variables such as anxiety, awareness, and general comfort are frequently overlooked.

Sharma et al reported no significant differences in anxiety levels with the use of topical anesthesia during surgery 1 when compared to surgery 2 even after the administration of a single dose of midazolam.<sup>[7,12]</sup> In contrast, Khezri et al evaluated the effects of melatonin on anxiety in patients undergoing phacoemulsification surgery. The authors reported a significant reduction of anxiety scores during and after the procedure with the use of 3 mg of melatonin 60 minutes before surgery.<sup>[8]</sup> Likewise, Ursea et al found that patients experienced less anxiety during surgery 2 compared to surgery 1 when combining MAC and topical anesthesia.<sup>[11]</sup>

Major variations in pain levels have been reported in patients undergoing consecutive cataract surgeries.<sup>[3,13,14]</sup> These variations have been associated with the patients’ ability to recall their intraoperative overall experience and the level of sedation.<sup>[1–3,11]</sup> Moreover, the level of pain experienced may have a significant impact on patients’ cooperation during surgery.<sup>[3,4]</sup>

In our study, anxiety levels were significantly reduced during surgery 2 with most of the patients reporting mild pain levels and high levels of awareness in both surgeries. Therefore, the fact that patients were aware during the entire procedure was not correlated with the level of pain nor the level of anxiety experienced. Considering that the preoperative administration of midazolam and premedication times were comparable among surgeries, our findings may result from non-pharmacologic interventions instead (ie, increased patients’ counseling, reinforcing surgeon-patient relationship, and the fact that patients knew the most affected eye was previously treated).

Even though some reports showed more discomfort during surgery 2, the independent evaluation of this variable could be challenging.<sup>[1,3,11]</sup> Level of comfort, awareness, and patients’ cooperation with the surgical procedure are significantly affected by intraoperative pain.<sup>[3]</sup> Although higher comfort levels were experienced during surgery 1 in our patient setting, these results were not statistically significant and were not correlated with significant changes in pain levels between procedures.

Additionally, we identified some discrepancies when comparing direct and perceived perioperative variable assessments between surgeries (ie, PACU and postoperative day 1 visit respectively). Even though similar preoperative midazolam doses were administered and most of the patients were actually less aware with no differences in pain levels among procedures, patients perceived being more aware and experiencing more pain during surgery 2 when compared to surgery 1. Time frame between surgeries and setting (outpatient clinic) during the postoperative visit, could explain the aforementioned differences between the direct (ie, PACU) and the perceived (ie, postoperative visit 1) assessments. On the other hand, perceived anxiety and comfort levels were similar when compared to direct assessments (Table S7, <http://links.lww.com/MD/F63>).

## 5. Limitations

Relevant limitations concerning the observational nature of this study such as the absence of a baseline questionnaire and delivered verbal comfort during the surgery were identified. In order to overcome the latter limitation, we only included in our data analysis patients receiving care from the 3 main anesthesia providers based on the numbers of cases per physician. Moreover, we only analyzed data from patients who had sequential cataract surgeries within a 6-week time period.

## 6. Conclusion

We compared anxiety, awareness, general comfort, and pain levels in patients undergoing consecutive cataract surgeries under a standardized anesthesia management. Previous exposure to surgery could have been associated with a significant reduction in anxiety levels reported in surgery 2. MAC combined with topical anesthesia may be an effective anesthetic approach in patients undergoing consecutive cataract surgery. Our findings suggest that reduced awareness and deep sedation techniques may not be required for cataract surgery since they did not correlate with

significant improvement on pain levels. Physicians should consider new non-pharmacological strategies aiming to reduce perioperative anxiety such as familiarizing patients with the perioperative process, operating room environment, and anesthetic burden before surgery 1.

### Author contributions

**Conceptualization:** Jarrett A Heard, Alec T Lawrence, Nicoleta Stoicea, Michael G Guertin, Amit Tandon, Deborah S Lowery.

**Data curation:** Jarrett A Heard, Alicia A Gonzalez Zacarias, Alec T Lawrence, Marilly Palettas, Juan Fiorda-Diaz, Michael G Guertin, Amit Tandon, Deborah S Lowery.

**Formal analysis:** Jarrett A Heard, Alicia A Gonzalez Zacarias, Alec T Lawrence, Nicoleta Stoicea, Marilly Palettas, Juan Fiorda-Diaz, Michael G Guertin, Amit Tandon, Deborah S Lowery.

**Funding acquisition:** Deborah S Lowery.

**Investigation:** Jarrett A Heard, Alec T Lawrence, Nicoleta Stoicea, Michael G Guertin, Amit Tandon, Deborah S Lowery.

**Methodology:** Jarrett A Heard, Alec T Lawrence, Nicoleta Stoicea, Marilly Palettas, Michael G Guertin, Amit Tandon, Deborah S Lowery.

**Project administration:** Jarrett A Heard, Alec T Lawrence, Nicoleta Stoicea, Michael G Guertin, Deborah S Lowery.

**Resources:** Jarrett A Heard, Alec T Lawrence, Michael G Guertin, Deborah S Lowery.

**Software:** Deborah S Lowery.

**Supervision:** Jarrett A Heard, Alec T Lawrence, Michael G Guertin, Amit Tandon, Deborah S Lowery.

**Validation:** Jarrett A Heard, Alicia A Gonzalez Zacarias, Alec T Lawrence, Marilly Palettas, Juan Fiorda-Diaz, Michael G Guertin, Amit Tandon, Deborah S Lowery.

**Visualization:** Alicia A Gonzalez Zacarias, Michael G Guertin, Deborah S Lowery.

**Writing – original draft:** Jarrett A Heard, Alicia A Gonzalez Zacarias, Alec T Lawrence, Marilly Palettas, Juan Fiorda-Diaz, Deborah S Lowery.

**Writing – review & editing:** Jarrett A Heard, Alicia A Gonzalez Zacarias, Alec T Lawrence, Marilly Palettas, Juan Fiorda-Diaz, Michael G Guertin, Amit Tandon, Deborah S Lowery.

### References

- [1] Adatia FA, Munro M, Jivraj I, et al. Documenting the subjective patient experience of first versus second cataract surgery. *J Cataract Refract Surg* 2015;41:116–21.
- [2] Yu JG, Ye T, Huang Q, et al. Comparison between subjective sensations during first and second phacoemulsification eye surgeries in patients with bilateral cataract. *J Ophthalmol* 2016;2016:6521567.
- [3] Akkaya S, Ozkurt YB, Aksoy S, et al. Differences in pain experience and cooperation between consecutive surgeries in patients undergoing phacoemulsification. *Int Ophthalmol* 2017;37:545–52.
- [4] Aslankurt M, Aslan L, Baskan AM, et al. Pain and cooperation in patients having dominant-side or nondominant-side phacoemulsification. *J Cataract Refract Surg* 2014;40:199–202.
- [5] Dadaci Z, Borazan M, Oncel Acir N. Pain perception in phacoemulsification with topical anesthesia and evaluation of factors related with pain. *Turk J Ophthalmol* 2016;46:151–5.
- [6] Bardocci A, Ciucci F, Lofoco G, et al. Pain during second eye cataract surgery under topical anesthesia: an intraindividual study. *Graefes Arch Clin Exp Ophthalmol* 2011;249:1511–4.
- [7] Habib NE, Mandour NM, Balmer HG. Effect of midazolam on anxiety level and pain perception in cataract surgery with topical anesthesia. *J Cataract Refract Surg* 2004;30:437–43.
- [8] Khezri MB, Merate H. The effects of melatonin on anxiety and pain scores of patients, intraocular pressure, and operating conditions during cataract surgery under topical anesthesia. *Indian J Ophthalmol* 2013;61:319–24.
- [9] Likert R. A technique for the measurement of attitudes. *Arch Psychol* 1932.
- [10] Ferreira-Valente MA, Pais-Ribeiro JL, Jensen MP. Validity of four pain intensity rating scales. *Pain* 2011;152:2399–404.
- [11] Ursea R, Feng MT, Zhou M, et al. Pain perception in sequential cataract surgery: comparison of first and second procedures. *J Cataract Refract Surg* 2011;37:1009–14.
- [12] Sharma NS, Ooi JL, Figueira EC, et al. Patient perceptions of second eye clear corneal cataract surgery using assisted topical anaesthesia. *Eye (Lond)* 2008;22:547–50.
- [13] Kashyap A, Varshney R, Titiyal GS, et al. Comparison between ropivacaine and bupivacaine in deep topical fornix nerve block anesthesia in patients undergoing cataract surgery by phacoemulsification. *Indian J Ophthalmol* 2018;66:1268–71.
- [14] Lindley-Jones MF. Topical anaesthesia for phacoemulsification surgery. *Clin Exp Ophthalmol* 2000;28:287–9.