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ORIGINAL RESEARCH

Long-Term Satisfaction of Oral Sedation versus Standard-of-Care Intravenous Sedation for Ocular Surgery

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Purpose: Long-term patient satisfaction may influence patients' perspectives of the quality of care and their relationship with their providers. This is a follow up to a comparative effectiveness study investigating oral to intravenous sedation (OIV study). The OIV study found that oral sedation was noninferior in patient satisfaction to standard intravenous (IV) sedation for anterior segment and vitreoretinal surgeries. This study aims to determine if patient satisfaction with oral sedation remained noninferior long term.

Patients and Methods: Patients were re-interviewed using the same satisfaction survey given during the OIV study. Statistical analysis involved t-tests for noninferiority of the long-term mean satisfaction score of oral and IV sedation. We also compared the original mean satisfaction score and the follow-up mean satisfaction score for each type of sedation and for both groups combined.

Results: Participants were interviewed at a median of 1225.5 days (range 754–1675 days) from their surgery. The original mean satisfaction score was 5.26 ± 0.79 for the oral treatment group (n = 52) and 5.27 ± 0.64 for the intravenous treatment group (n = 46), demonstrating noninferiority with a difference in mean satisfaction score of 0.015 ($p < 0.0001$). The follow-up mean satisfaction score was 5.23 ± 0.90 for oral sedation and 5.60 ± 0.61 for IV sedation, with a difference in the mean satisfaction score of 0.371 ($p = 0.2071$). Satisfaction scores did not differ between the original mean satisfaction score and the follow-up mean satisfaction score for the oral treatment group alone ($p = 0.8367$), but scores in the intravenous treatment group increased longitudinally ($p = 0.0004$).

Conclusion: In this study, long-term patient satisfaction with oral sedation was not noninferior to satisfaction with IV sedation, unlike our findings with short-term patient satisfaction in our original study. Patient satisfaction also remained unchanged over time for the oral treatment group, but patients in the intravenous treatment group reported higher long-term satisfaction with their anesthesia experience compared to the immediate post-operative period.

Keywords: longitudinal, ocular surgery, anesthesia, oral triazolam, intravenous midazolam, noninferiority

Introduction

Over the past few years, research groups have investigated the feasibility of office-based ocular procedures after the Centers for Medicare & Medicaid Services released a statement advocating for in-office cataract surgeries to limit healthcare expenditures.[1] This transition involves the consideration of anesthesia services. Cataract surgeries are primarily conducted with a topical anesthetic combined with a systemic sedative agent administered intravenously,[2] while general anesthesia is reserved for complex cases.[3] The use of oral sedation, as opposed to intravenous sedation, may be a cost- and space-saving measure facilitating the transition to office-based ocular procedures, but there remains a paucity of literature examining patient satisfaction with sedation in ocular procedures.

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Patient satisfaction is a proxy for patient experience, and from a patient's perspective, it is often a reflection of the quality of their healthcare.[4–6] Patient satisfaction has been found to be associated with higher treatment adherence, higher patient retention, and lower rates of medical litigation.[4,7–9] Companies such as Press Ganey measure this metric in over 41,000 healthcare facilities using standardized and validated patient experience questionnaires.[5,10,11] The Centers for Medicare & Medicaid Services and private insurance payors use patient satisfaction scores to determine compensation and reimbursement for hospitals and physicians.[5,12] In the field of ophthalmology, patient satisfaction surveys have been used to assess various aspects of ocular care, including video conferences for visits during the COVID-19 pandemic, provision of wait times, and group appointments for glaucoma management.[13–15]

There have been few studies regarding patient satisfaction with sedation administered during ocular surgeries. Our group conducted the oral versus intravenous sedation (OIV) study at Boston Medical Center, in which we randomized nearly 300 patients undergoing anterior segment, vitreoretinal, and glaucoma surgeries to either oral or intravenous (IV) sedation and investigated patient satisfaction during the post-operative period. Our published results in Peeler et al (2019), Siegel et al (2022), and Lee et al (2022) established noninferiority of oral sedation to IV sedation in cataract, retina, and non-cataract anterior segment surgeries, respectively.[16–18]

The safety of oral sedation in cataract surgery has been well established.[19–22] In 2016, the Kaiser Permanente Colorado group studied 21,501 cataract surgeries performed under oral sedation without an anesthesiologist in minor procedure rooms from 2011 to 2015 and found similar rates of adverse events compared to surgeries performed in ambulatory and hospital outpatient departments.[21] However, patient satisfaction was not measured in the Kaiser study.

The objective of this follow-up prospective study was to determine whether patient satisfaction with oral sedation remained noninferior to IV sedation in the long term. Determining if patient satisfaction remains consistent longitudinally is useful for capturing patients' perspectives on their own quality of care and, reportedly, their relationship with their providers.[23] We hypothesized that long-term patient satisfaction with oral sedation is noninferior to IV sedation and, regardless of sedation type, should not be significantly altered longitudinally.

Materials and Methods

Overview

This was a prospective, double-masked, single-center longitudinal study conducted at Boston Medical Center, an urban teaching hospital, and approved by the Institutional Review Board of Boston Medical Center and Boston University Medical Campus (H-41307). Our study adhered to the tenets of the Declaration of Helsinki. Informed consent was obtained for all participants. The patients eligible for, and included, in this study were the same subjects who completed the original OIV study,[16–18] which involved 1:1 randomization to either oral triazolam or IV midazolam for a cataract, cornea, glaucoma, or retina surgery. Patients with a body mass index (BMI) of less than 35 kg/m^2 were randomized to receive either 0.125 mg oral triazolam with IV saline placebo or 1.0 mg IV midazolam with oral microcrystalline cellulose placebo. Patients with a BMI of at least 35 kg/m^2 were randomized to receive either 0.25 mg oral triazolam with IV saline placebo or 2.0 mg IV midazolam with oral microcrystalline cellulose placebo. Since this was a double-masked study design, all patients, including those randomized to oral triazolam, were intravenously cannulated during the procedure. Patients in the original study were asked to complete validated satisfaction surveys during their first post-operative visit. In the current study, subjects were called again and asked to participate in the follow-up study by completing the same satisfaction survey, and they were given the choice to have the survey administered either over the phone or during a standard-of-care appointment. Patients were additionally asked to confirm demographic variables such as age, ethnicity, sex, race, and preferred primary language. The research assistants conducting the interviews and the patients were both masked with respect to the type of anesthesia administered during the surgery.

Satisfaction Survey

The satisfaction survey (Supplementary Material 1) was based on the Iowa Satisfaction with Anesthesia Scale, a validated survey for assessing patient satisfaction with cataract surgeries.[24] The 12 items on this satisfaction survey

were the same questions administered during the original OIV study, scored on a scale of 1 to 6, and used to measure patient satisfaction. A score of 1 indicated the lowest level of satisfaction, and a score of 6 indicated the highest level of satisfaction.

Primary Outcome

The primary outcome was the mean satisfaction score for each type of sedation, including oral and IV.

Statistical Analysis

Statistical Analysis Software (SAS v. 9.4) was used to conduct the analyses, which were performed in collaboration with a biostatistician (HJC). Patients were stratified into either the oral treatment group or the IV treatment group based on their randomization during the original OIV study. Categorical patient demographics, including the distributions of race, sex, ethnicity, spoken language, and type of surgery, were compared using chi-square tests and Fisher's Exact tests, while continuous patient demographics, including age and follow-up time, were compared with independent samples t-tests between the study groups.

In order to determine noninferiority between the two types of sedation for the satisfaction score in the follow-up study, a two-sample *t*-test for noninferiority was conducted between the follow-up mean satisfaction score of IV and oral treatment groups. Similar to the original study's noninferiority test,[16–18] we chose a noninferiority margin of 0.5, based on pilot survey results demonstrating that any differences within this margin would not be considered clinically relevant. Given that this is a secondary analysis with a limited pool of patients to survey from the original OIV studies, we applied the power calculation used in the original OIV studies[16–18] to determine the minimum sample size of this follow-up study. The sample size capable of detecting a significant difference between the two anesthetic groups with a power of 90% and a 1:1 randomization to an anesthetic group was 80 participants (40 in each group). We conducted a one-tailed *t*-test for noninferiority between the mean satisfaction score of the IV and oral treatment groups, and reported a 95% confidence interval (CI) similar to the hypothesis testing performed in the original study.[16–18]

In addition, longitudinal change in patient satisfaction was assessed for oral and IV sedation separately using paired samples t-tests between the mean satisfaction score from the original OIV interview and the follow-up interview. The original mean satisfaction score reported in this work was calculated using only those patients who responded to the follow-up survey in order to compare paired means.

In order to determine the presence of any confounding effect from any additional intervening surgery occurring after their eye surgery, we used an independent samples *t*-test comparing the follow-up mean satisfaction score between patients who underwent subsequent surgeries (ocular or non-ocular) and patients who did not have any subsequent surgeries.

P-values less than 0.05 were considered statistically significant for all analyses.

Results

Ninety-eight of the 283 patients in the original OIV study completed the follow-up survey—52 from the oral triazolam group, and 46 from the IV midazolam group. Patients who participated in the follow-up study (n = 98) are hereafter referred to as "included" patients. Patients who were not included in the follow-up study (n = 185), due to withdrawal of consent, lack of patient response, or incorrect contact information on file, are hereafter referred to as "excluded" patients. Included and excluded patient groups differed significantly with respect to gender, ethnicity, race, and primary spoken language distributions (Table 1). Given these demographic differences between included and excluded patient groups, we evaluated the association between these demographic variables and mean satisfaction scores from the original OIV survey using linear regression analysis. The mean satisfaction score was not significantly associated with gender (p = 0.4802), ethnicity (p = 0.3835), race (p = 0.1748), or primary spoken language (p = 0.0628) among all patients. The mean satisfaction score was also not significantly associated with gender (p = 0.5450), ethnicity (p = 0.2874), race (p = 0.8089), or primary spoken language (p = 0.1681) among the excluded patient group. Included patients were interviewed at a median elapsed time of 1225.5 days (range 754–1675 days) from their date of surgery. Patients in the two anesthetic groups, the oral and intravenous groups (among the included patients only), were similar with respect to age, follow-up time, and distribution of sex, ethnicity, race, and type of surgery (Table 2).

Oral sedation was noninferior to IV sedation among all patients in the original OIV study. In the current follow-up study, the mean satisfaction score was 5.23 ± 0.90 for the oral treatment group and 5.60 ± 0.62 for the IV treatment

Table 1 Comparison of Patient Demographics Between Included and Excluded Patients

Parameter	Included		Excluded		P-value
	N	%	N	%	
Overall (n=283)	98	34.63	185	65.37	
Age (years), mean ± SD	60.20±14.32		60.72±13.29		0.7607
Type of Sedation					0.4800
Oral	52	53.06	90	49.50	
Intravenous	46	46.94	95	50.50	
Sex					0.0456
Female	35	35.71	89	48.11	
Male	63	64.29	96	51.89	
Ethnicity					0.0391
Hispanic/Latino	43	43.88	62	33.51	
Non-Hispanic/Latino	55	56.12	115	62.16	
Declined	0	0	8	3.96	
Race					<0.0001
Black or African American	40	40.82	71	38.38	
White	20	20.41	40	21.62	
Native Hawaiian or Other Pacific Islander	2	2.04	1	0.54	
Asian	0	0	2	1.08	
American Indian and Alaska Native	0	0	1	0.54	
Other	24	24.49	6	3.24	
Declined	12	12.24	64	34.59	
Language					0.0081
English	40	40.82	110	59.46	
Spanish	42	42.86	57	30.81	
Haitian-Creole	14	14.29	18	9.73	
Portuguese	2	2.04	0	0	
Type of Surgery					0.3969
Cataract	27	27.55	58	31.35	
Retina	28	28.57	56	30.27	
Cornea	30	30.61	40	21.62	
Glaucoma	13	13.27	31	16.76	

Abbreviation: SD, standard deviation.

Table 2 Comparison of Included Patient Demographics by Sedation Type

Parameter	Oral Triazolam		IV Midazolam		P-value
	N	%	N	%	
Overall (n=98)	52	51.85	46	48.15	
Age (years), mean ± SD	60.75±15.90		60.65±11.62		0.9726
Follow-Up Time (days), mean ± SD	1218±217		1263±193		0.2840
Sex					0.3049
Female	21	40.38	14	30.43	
Male	31	59.62	32	69.57	
Ethnicity					0.9603
Hispanic/Latino	24	46.15	21	45.65	
Non-Hispanic/Latino	28	53.85	25	54.35	
Declined	0	0	0	0	
Race					0.9068
Black or African American	22	42.31	18	39.13	
White	12	23.08	10	21.74	
Native Hawaiian or Other Pacific Islander	1	1.92	1	2.17	
Asian	0	0	0	0	
American Indian and Alaska Native	0	0	0	0	
Other	15	28.85	15	32.61	
Declined	2	3.85	1	2.17	
Language					0.6616
English	23	44.23	16	34.78	
Spanish	22	42.31	20	43.48	
Haitian-Creole	6	11.54	9	19.57	
Portuguese	1	1.92	1	2.17	
Type of Surgery					0.9195
Cataract	14	26.92	13	28.26	
Retina	14	26.92	14	30.43	
Cornea	16	30.77	14	30.43	
Glaucoma	8	15.38	5	10.87	

Abbreviation: SD, standard deviation.

group. Noninferiority of the oral to the IV group in the follow-up study was not demonstrated, with a difference in mean satisfaction score of 0.37 (p = 0.2071, CI: -infinity to 0.6322).

Given the noninferiority results, we completed analyses to assess the change in patient satisfaction by the type of anesthesia over time (Table 3). In the oral treatment group alone (n = 52), there was no significant difference in the

Table 3 Longitudinal Patient Satisfaction (Paired Samples *T*-Test Results)

	Original MSS, Mean±SD (Range)	Follow-Up MSS, Mean±SD (Range)	Change in MSS Mean±SD (Range)	P-value
Oral Triazolam	5.25±0.80 (2.58–6.00)	5.23±0.90 (2.67–6.00)	−0.03±0.87 ((−2.17)-2.33)	0.8367
IV Midazolam	5.27±0.64 (3.42–6.00)	5.60±0.61 (3.83–6.00)	0.33±0.79 ((−1.75)-2.16)	0.0074

Abbreviations: MSS, mean satisfaction score; SD, standard deviation.

original and follow-up mean satisfaction score (p = 0.8367). However, in the IV treatment group (n = 46), a significant change was found between the original and follow-up mean satisfaction score (p = 0.0074). Among the IV treatment group, a one-sample *t*-test at a 95% confidence level showed that the follow-up mean satisfaction score was significantly higher than the original mean satisfaction score (p = 0.0004).

We also investigated the presence of any confounding effect from intervening surgeries occurring after their eye surgery. There was no significant difference in the follow-up mean satisfaction score between patients who underwent subsequent eye surgeries after original OIV surgery (n = 34, 5.28 ± 0.96), and patients who did not have successive eye surgeries (n = 64, 5.47 ± 0.69; p = 0.2786), or between patients who did (n = 22, 5.55 ± 0.66) and did not (n = 76, 5.36 ± 0.83) undergo a subsequent non-ophthalmological surgery (p = 0.3136).

Discussion

Our study group previously established the noninferiority of oral sedation to intravenous sedation in the post-operative period among patients undergoing cataract, cornea, glaucoma, and retina surgeries.[16–18] The results of this current study comparing long-term patient satisfaction did not find oral sedation to be noninferior to IV sedation, and it showed that patient satisfaction with IV sedation was improved with a longer recall period, while remaining unchanged for oral sedation.

To our knowledge, no previous study has investigated long-term patient satisfaction with sedation during ocular surgery. Our results refute our working hypothesis that oral sedation would remain noninferior to IV sedation longitudinally. One plausible explanation for this difference may be explained by differences in the amnestic properties of IV and oral benzodiazepines. Intravenous diazepam induces anterograde amnesia, unlike oral diazepam, which has been demonstrated in periodontal surgeries.[25] Moreover, IV midazolam, used in this study, has been found to have a greater amnestic effect than other benzodiazepines and sedatives such as dexmedetomidine.[26,27]

Patients' perception of pain is directly associated with overall satisfaction with care.[28,29] A cross-sectional study conducted at the surgical unit of Johns Hopkins University from 2008 to 2009 found that this was particularly true if patients perceived that the staff gave their maximum effort to relieving pain.[29] It has also been established that long-term patient retention in care is dependent on patient satisfaction.[30] Although long-term satisfaction for a one-time procedure is subject to many biases, the results of this study are clinically significant because a single negative event may motivate patients to transfer their care elsewhere.

The difference in short- and long-term outcomes in this study highlights the need to balance the advantages of oral sedation, such as a non-invasive approach, easy method of delivery,[31] significant cost savings, reduced need for intravenous medication, and obviating the need for fasting prior to surgery, with the goal of maximizing patient-centered outcomes. Oral sedation permits greater flexibility in transitioning ocular procedures from the operating room to the office where studies have demonstrated the safety of oral sedation without the presence of an anesthesia provider or intravenous lines.[19,21] Furthermore, Chen et al (2015) conducted a cost comparison between IV and oral midazolam and reported that a 5 mg dose of IV midazolam costs 100 times more than a comparable dose of oral midazolam.[22] The reduced need for anesthesia staff and lower medication costs associated with oral sedation decrease the overall costs of eye surgery for both the patient and the facility.

The strength of our study lies in its double-masked study design. Patients were evenly distributed across sedation and surgery type and our study demographics included a diverse range of races, ethnicities, and ages, making the results of this study more generalizable. Our study also has limitations. First, the Iowa Satisfaction with Anesthesia Scale is validated for assessing patient

satisfaction after cataract surgeries but not for other types of eye surgeries, such as retina, cornea, and glaucoma surgeries. Furthermore, of the 283 patients completing the original study, 98 (35%) patients elected to participate in this follow-up study. However, our response rate met the minimal sample size needed and is consistent with the response rates in follow up of previous longitudinal studies regarding patient satisfaction.[32,33] Patients included and excluded in this study differed with respect to sex, primary language, racial, and ethnic distributions (Table 1), and it is unclear what impact this may have had on the results. However, we found that these demographic factors were not significantly associated with the mean satisfaction score from the original OIV survey among all patients and among the excluded patients, indicating the loss of excluded patients from the follow-up study likely did not bias the follow-up mean satisfaction score analysis. Additionally, of the 98 patients interviewed, 34 patients had additional eye surgery, and 22 patients had a non-ocular surgical procedure between the date of their original surgery and the date that they were interviewed for this follow-up study. Their interview answers may be subject to recall bias on the surgery in question for the study versus their subsequent surgical experiences. Recall bias may also have been due to a long median follow-up period of 1225.5 days. However, we attempted to minimize recall bias by clarifying the date of the surgery, type of eye surgery, and the name of the surgeon operating during the original OIV surgery. Furthermore, there was no significant difference in the follow-up mean satisfaction score between patients who underwent subsequent surgeries (35% underwent a non-ophthalmological surgery and 22% underwent an eye surgery) after the original eye surgery and those who did not, indicating that undergoing subsequent surgeries did not confound patients' satisfaction ratings of the original OIV surgeries.

Conclusion

We found that patient satisfaction with oral sedation did not maintain its noninferiority to IV sedation in the long term, with long-term patient satisfaction higher in the IV sedation group. While our results may be limited by a small sample size, our results may have implications for patients' overall perception of their surgical experience. While these results do not promote the use of oral sedation, they should be balanced with the advantages that oral sedation in eye surgery can offer in terms of patient safety, convenience, and cost. Future investigations should examine long-term patient satisfaction with ocular anesthesia among larger samples of subjects.

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Disclosure

The authors report no conflicts of interest in this work.

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