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Intraoperative Awareness in a Regional Medical System

A Review of 3 Years' Data

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Background: **Intraoperative awareness in patients undergoing general anesthesia is an infrequent but well-described adverse outcome. The reported incidence of this phenomenon is between 0.1% and 0.9%.**

Methods: **With institutional review board approval, the authors reviewed continuous quality improvement data from 3 yr (2002–2004) at the locations where the physician group provided anesthesia. Board-certified anesthesiologists supervising certified registered nurse anesthetists in the anesthesia care team model of practice delivered all anesthetics. Brain function monitors were not used in the operating room setting. Patients were interviewed twice during a 48-h postoperative period and, as part of that process, underwent a modified Brice interview to determine intraoperative awareness. All cases that met the criteria for awareness were examined by the continuous quality improvement committee to modify anesthetic practice and were included in this study.**

Results: **Data from 211,842 patients undergoing anesthesia were considered. Of these, the continuous quality improvement process followed up 177,468 (83.1%). Cases were not included in the study if the patient was younger than 18 yr, did not have a general anesthetic, or had a terminal event during the hospital course. By these criteria, a total of 87,361 patients followed by the continuous quality improvement process were at risk for awareness. Six patients reported instances of recall.**

Conclusion: **The incidence of intraoperative awareness in this large sample of patients from a regional medical center undergoing general anesthesia was 0.0068%, or 1 per 14,560 patients, substantially less than that reported in the recent literature.**

THE incidence of intraoperative awareness is reported to occur in between 0.1% and 0.9% of cases.[1–5] This incidence has not been prospectively confirmed in a large community-based US population of patients undergoing general anesthesia. Most of the reported studies have been performed outside the United States, and all have been performed in academic centers. We report here the results of a study performed at a major regional healthcare system looking at data collected over a 3-yr period in a wide variety of patient populations.

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The data were collected by the continuous quality improvement (CQI) department of a physician group that provides anesthesiology services to eight locations within a large metropolitan area in the Southeastern United States. These facilities consist of an 861-bed academic medical center, six community hospitals, and one surgery center (table 1). The physician group uses a CQI system to monitor and improve the performance and outcomes of all anesthetics performed by the group. The authors started this study with two hypotheses: first, that the academic center would have a similar incidence of awareness to that of other academic centers reported in the literature, and second, that there would be a statistically significant increase in the incidence at the academic center from that of the community hospitals.

Materials and Methods

After institutional review board approval (Carolinas Medical Center, Charlotte, North Carolina), we examined CQI data from January 2002 to December 2004 collected at eight of the locations where the physician group provides the anesthesia services. All anesthetics were provided by board-certified anesthesiologists supervising certified registered nurse anesthetists in the anesthesia care team model of practice. Brain function monitors are not used in the operating room setting. Our group gives anesthetics that are based on protocols for specific surgeries. These are balanced anesthetics that use halogenated anesthetic compounds combined with intravenous narcotics. This approach can be modified based on the patient's physical status and surgical needs. Intravenous agents as the sole anesthetic are rarely used. The use of specific agents, such as benzodiazepines, is not required and is left to the individual practitioners' discretion.

The quality assurance (QA) process collects information on all surgical patients at a number of times during the hospital stay. This data tool represents more than 50 quality indicators and covers the patient's entire anesthetic experience. Recovery room nurses initially questioned the patients about the possibility of recall in the postanesthesia care unit. The CQI team then interviewed patients within 1–2 days after their anesthetic. As per standing policy, during each interview, the patient was questioned about the anesthesia experience and the possibility of awareness. The questions about recall took the form of a modified Brice interview (appendix).[6] Patient satisfaction surveys were also mailed to all patients after

Table 1. Participating Institution Data

Facility	Beds*	Obstetric Cases/yr†	ED Visits/yr*	Operating Rooms*	Surgeries/yr†
1	861	7,433	109,776	42	40,791
2	130	2,626	53,027	9	9,287
3	97	2,737	No data	8	7,942
4	208	0	1,984	12	7,555
5	75	270	25,173	4	2430
6	137	341	26,999	5	4,503
7	72	NA	10,203	2	1,176
8	NA	NA	NA	4	1,834
Total	1,580	13,407	227,162	86	75,516

* Data from Metzer,[9] pp 221–34. † Data from Southeast Anesthesiology Consultants, Continuous Quality Improvement.
ED = emergency department; NA = not applicable.

their discharge requesting feedback on all aspects of their anesthetic care. Inclusion criteria for this study were all patients older than 18 yr who underwent a general anesthetic during the study period. Patients were excluded if they did not survive the surgery and immediate postoperative period or were unable to be followed up by the CQI team.

Results

From the 211,842 anesthetics delivered during the study period, 177,468 (83.12%) were followed by the CQI process. A total of 87,361 patients were identified as being at risk for awareness by meeting the study criteria of having been older than 18 yr, undergoing a general anesthetic, and surviving the immediate postoperative period. This study found 6 cases where patients reported events that could be reasonably classified as "awareness" or "recall," for an incidence of 0.0068% (table 2). Four cases were found in patients undergoing cardiac surgery. The incidence of awareness in cardiac cases was 0.12% (4 in 3,208 cases).

The patients with recall or possible recall were found to be older (55.5 *vs.* 46 yr), of higher American Society of Anesthesiologists physical status (3.67 *vs.* 2.37), and involved in longer anesthetics (340.7 *vs.* 126 min) than the general population (table 3). All of the instances of awareness occurred in cases where neuromuscular blocking agents were used. The anesthetic management also included the use of endotracheal tubes and end-tidal anesthetic gas monitoring. One case (20%) did not use benzodiazepines as a premedicant. There was no use of nitrous oxide in any case of recall in this study (table 4).

There was an apparent difference in the incidence of recall between the academic medical center (Institute 1 in table 1) and the other anesthetizing locations. The patients at this location were slightly older (47 *vs.* 46 yr), were of higher American Society of Anesthesiologists physical status (2.45 *vs.* 2.37), and had longer cases (153 *vs.* 126 min) than the population at the community hospitals (table 3). This level I trauma and teaching hospital had 5 cases of recall out of 52,751 cases, for an incidence of 0.0095%. The other institutions had a combined incidence of 0.003%, or 1 case of recall in 34,610 cases. However, this difference was not statistically significant (Fisher exact test, P value = 0.413).

Discussion

In 2003, Sebel *et al.*[1] examined the incidence of awareness in anesthesia. This was the first such study performed in the United States. Data from seven academic anesthesiology programs were used, and an incidence of recall of 0.13% was found, with a rate of 1–2 cases per

Table 2. Study Enrollment and Response Rates

Facility	Total Cases 2002–2004	CQI Data 2002–2004	Percent CQI Coverage	Excluded Cases*	Total Cases in Study	Recall Cases
1	119,470	108,437	90.76	55,686	52,751	5
2	28,008	16,965	60.75	8,229	8,736	0
3	22,272	17,339	77.85	11,116	6,223	1
4	21,329	19,817	92.9	6,934	12,883	0
5	8,141	6,192	76.06	2,762	3,430	0
6	3,381	2,606	77.08	1,124	1,482	0
7	4,503	3,406	75.64	2,281	1,125	0
8	4,738	2,706	57.11	1,975	731	0
Total	211,842	177,468	83.12	90,107	87,361	6

* Patients were excluded from the study if they were younger than 18 yr, did not undergo a general anesthetic, or did not survive the immediate postoperative period.
CQI = continuous quality improvement.

Table 3. Demographic Data for Participating Institutions

Demography	Total (n = 87,361)	Institute 1 (n = 52,751)	Patients with Awareness (n = 6)
Age, yr	46 (16.1)	47 (16.28)	55.5 (12.5)
ASA physical status	2.37	2.45	3.67
Male/female	37,175/50,186	23,926/28,825	4/2
ED visits/yr*	227,162	120,000	
Trauma cases†	—	10,728	0
Obstetric cases/yr‡	13,407	7,433	0
Cardiac cases	3,208	2,816	4
Surgery			
Duration of anesthesia, min	126 (171.4)	153 (194.8)	340.7 (57.4)
Elective/acute and emergency surgery	79,670/7,691	§	3/3

Data are mean (SD) or number.

* Data from Metzer.[9] † Trauma cases are those at Institute 1 in the 3-yr period of the study. Some of these patients were excluded from the study because they did not meet the guidelines for inclusion. ‡ Data from Southeast Anesthesiology Consultants, Continuous Quality Improvement. § Database did not separate elective/emergency cases at Institute 1 (academic center) from total cases.

ASA = American Society of Anesthesiologists; ED = emergency department.

1,000 patients at each site. This study corroborates information from other countries, and these data seem to have remained consistent.

There is a large discrepancy between the observed and expected rates of awareness under anesthesia in our study. If the published incidence of recall (0.1–0.9%) is accepted, we should have found between 87 and 786 cases in our study. However, we found only 6 cases, giving an incidence of 0.0068%, or 1 in 14,560 cases. Potential sources of these differences could include the method of data collection, the frequency of patient interviews, and the patient population in our study.

Our CQI process prospectively collects information on all surgical patients at a number of times during the hospital stay. This data tool represents more than 50 quality indicators and covers the patient's entire anesthetic experience. Patients are interviewed on the possibility of recall in the immediate postoperative period by the postanesthesia care unit nurses. We then use QA registered nurses to complete a full bedside interview with the patient between 1 and 2 days after his or her emergence from anesthesia. These corporate employees have been specially educated in anesthetic procedures and complications and in strategic interview techniques. One of the first sets of questions asked of the patient is the possibility of the occurrence of recall using questions based on the modified Brice protocol (appendix). In those cases where the patient underwent surgery on an outpatient basis, this second interview could be conducted by telephone. Patient satisfaction surveys are mailed to all patients after their discharge, requesting feedback on all aspects of their anesthetic care, and the results are closely scrutinized. The CQI group then analyzed data and further investigated cases of untoward events. In a situation where awareness during anesthesia was suspected, the full CQI committee analyzed each case and ascribed it to either a definite or a possible recall group. For the purpose of this study, all cases of possible recall have been included.

Table 2 shows the coverage of cases by the CQI service. At the academic center, 90.76% of the patients are followed up throughout their hospital course. This rate decreases to 83.12% overall when the community hospital data are added. The high percentage of QA follow-up decreases the likelihood that cases of recall were missed by the study. The CQI data are regularly audited retrospectively, using a statistically significant sample size to ensure the accuracy of collected data. The number of charts is chosen to ensure a 95% confidence level and a 3.6 confidence interval. The analysis uses 6 charts per physician per quarter chosen randomly. In 2004, the CQI team reviewed 732 charts out of 76,000 cases. The statistical method for ensuring a valid sampling of charts was chosen by the statistician of the surveyed healthcare system.

If a case of recall is suspected, several processes are initiated. The physician responsible for the anesthetic care of the patient does a personal interview with the patient. During this visit, the anesthesiologist ensures that the patient's concerns are treated in a timely manner. A consultation with a mental health professional is pursued if either party believes there is a need.

In 2000, Sandin *et al.*[7] reported a prospective study of awareness in 11,785 patients. This article interviewed patients in the postanesthesia care unit and the repeated the interview 1–3 days and 7–14 days after anesthesia. This study found that 27.8% (5 of 18) of their cases of awareness were found only at the third interview. Sebel *et al.*[1] used a different investigative technique where they interviewed the patients once in the postanesthesia care unit, and then a follow-up interview was attempted at least 1 week after anesthesia. In this study, approximately one third of the cases of awareness were detected in the later interview. Although at this time there is no conclusive evidence that either the number or the timing of data collection provides the actual incidence of anesthetic recall, the authors believe that the use of two separate interviews, along with the patient survey that is

Table 4. Details of Demographic and Case Data from Patients Who Experienced Awareness or Possible Awareness during Surgery

Patient Demography							
Cases of Recall	Sex	Age, yr	Weight, kg	Height, cm	ASA Physical Status	Emergency	Surgery
1	M	54	85	177.8	IVE	Yes	Heart transplantation
2	F	63	115	170.2	IV	No	CABG
3	M	53	88.6	175.26	IVE	No	CABG
4	M	46	99	183	IVE	Yes	Heart transplantation
5	M	76	76	175	III	No	R CEA
6	F	41	110	160	III	No	Gastric bypass

mailed after discharge, is a valid method of detecting recall in patients. It is of note that the authors have not learned of any other instances of recall by either formal (legal) or informal complaints from any of the tens of thousands of patients interviewed and cared for.

The postanesthesia care unit and QA nurses use a modified version of the Brice questionnaire as a screening tool for awareness (table 2).[6] The author's group elected to substitute two of the original questions, "What was the worst thing about your operation?" and "What was the next worst," with the more process-oriented "Were you put to sleep gently?" and "Did you have any problems going to sleep?" If the patient seemed to have memory, further questions would be used to obtain as detailed an account of the experience as possible. This open-ended questioning technique has been previously described by Fleisher *et al.*[8] and is designed to elicit information in a nonalarming way. This modification of the Brice questionnaire differs from that used by Sandin *et al.*[7] and Sebel *et al.*[1]; however, there is no evidence that the use of specific questions is the only viable way of discovering recall. Although it is possible that this modification of the questionnaire might have caused an underestimation of the incidence of recall, the primary questions that Brice used to elicit recall are unchanged. The authors do not believe that the substitution of two nonrecall related questions in this series would cause a greater than 10-fold decrease in the incidence of awareness.

The authors started this study with two hypotheses. First, the incidence of awareness at the academic center would have a similar incidence of awareness to that of other academic centers reported in the literature. Second, there would be a significant difference between the academic center and the community hospitals. The reasoning behind the first hypothesis is that Institute 1 is a tertiary care, level I trauma center and teaching hospital. This hospital has academic departments in all major specialties, with the exception of anesthesiology. The institution has more than 100,000 annual emergency room visits and more than 7,000 deliveries per year, while serving a metropolitan area of more than 1 million (tables 1 and 2). This is double the volume of any of the other academic centers in North Carolina.[9] The payor mix for these patients includes 39% Medicare/Medicaid reimbursement and 7% self-pay. The authors believe that this provides a well-matched patient population to other academic medical centers. However, the incidence of awareness at this institution is markedly different from that reported in the literature.

The second hypothesis that the authors started with is that there would be a statistically significant increase in the incidence of recall between the major medical center and the community hospitals. This would be expected because of the increase in patient acuity, as well as the larger number of patients at increased risk for awareness due to high-risk cases in the teaching hospital. However, as shown in the results section, the difference between the two groups is not statistically significant.

The authors believe that their data are valid, but some subtle cases of awareness or dreaming may have been missed by this approach. However, it still does not explain the large difference between the incidence of verifiable awareness in this study *versus* that in previously published reports. Possible considerations could be the anesthesia providers involved, the types of anesthetics chosen, and/or investigational bias.

Clinical anesthesiologists supervising certified registered nurse anesthetists in the anesthesia care team model of practice delivered all anesthetics in this study. Our group gives anesthetics that are based on protocols for specific surgeries. These are balanced anesthesia protocols that rely heavily on the use of halogenated anesthetic compounds combined with intravenous narcotics. This approach can be modified based on the patient's physical status and surgical needs. The use of intravenous agents as the sole anesthetic is rarely used. The mandatory use of specific agents, such as benzodiazepines, is not required and is left to the individual practitioners' discretion. The results of QA investigations lead to changes in process and protocols for anesthetic management. This process also includes regular lectures on QA topics, which further sensitizes anesthesia providers to issues of recall. The authors believe that this combined approach minimizes the risk of intraoperative awareness.

Table 4. Continued

Anesthesia									
Duration of Anesthesia, min	Premedication	Coinduction	Induction	Maintenance	Post Pump Maintenance	N_2O	ETAGC Monitoring	NMB	Airway
369	Benzodiazepine	Opioid	Thiopental	Isoflurane	Precedex	No	Yes	Yes	ETT
410	Benzodiazepine	Opioid	Etomidate	Isoflurane	Precedex	No	Yes	Yes	ETT
255	Benzodiazepine	Opioid	Thiopental	Isoflurane	Isoflurane and Precedex	No	Yes	Yes	ETT
370	Benzodiazepine	Opioid	Etomidate	Isoflurane	Isoflurane	No	Yes	Yes	ETT
390	None	Opioid	Thiopental	Isoflurane	NA	No	Yes	Yes	ETT
350	Versed	Opioid	Diprivan	Desflurane	NA	No	Yes	Yes	ETT

ASA = American Society of Anesthesiologists; CABG = coronary artery bypass graft; CEA = carotid endarterectomy; ETAGC = end-tidal anesthetic gas concentration; ETT = endotracheal tube; N_2O = nitrous oxide; NA = not applicable; NMB = neuromuscular blocking agent.

There are three possible causes for awareness: light anesthesia, increased anesthetic requirement, and anesthesia machine malfunction or misuse.[10] All confirmed cases of recall in this study were due to light anesthesia. These cases were found in one of the groups generally considered to be at high risk for awareness, *i.e.*, patients undergoing cardiac, trauma, or obstetric procedures.[10,11] However, it is interesting to note that no cases of recall were found in either trauma or obstetric patients in this study. The two other cases of recall were in patients undergoing a carotid endarterectomy and a gastric bypass.

Patients 1 and 2 in our study (tables 4 and 5) both underwent cardiac surgical procedures using cardiopulmonary bypass. Our practice had been to use a propofol infusion starting with rewarming to facilitate early extubation. At the request of one of our surgeons, we had begun to use dexmedetomidine infusion in lieu of propofol. These patients were not given additional narcotics or benzodiazepines, nor did halogenated compounds supplement the anesthetic at the conclusion of the case. By this substitution, the anesthesia team had inadvertently given an anesthetic that was lacking in amnestic qualities. Both patients recalled the end of their procedure and the start of their intensive care stay. An analysis of the anesthetic records did not reveal any hemodynamic cues that would have indicated awareness to the anesthesia care team.

Patients 3 and 4 also reflected the use of a "light" anesthetic. In both of these cases, the patient was given only a subtherapeutic dose (0.25 minimum alveolar concentration) of halogenated anesthetic compound at the commencement of the case. This may have been because of depressed cardiac function in these patients. On incision, the anesthetic record clearly demonstrated an increase in blood pressure and heart rate in both patients, which was treated by the use of additional anesthetic agents. The description of recall in both cases clearly indicates that the patients were aware at the time of initial incision.

Patients 5 and 6 were determined to have been cases of possible recall that have been included in the study for completeness. The first patient (patient 5) underwent two anesthetics, the first for the repair of a right carotid lesion. When the patient awoke, there was evidence of a left hemiparesis. The surgeon was reconsulted, and after the patient was evaluated, anesthesia was induced a second time for exploration of the right neck incision. The patient had no specific recollections of the surgeries but recalled sensations and emotions

Table 5. Patient's Experiences of Awareness during Surgery (QA Consensus)

Patient	Experience
1	Patient recalls being awake in ICU. Remembers vague feeling of motion in chest. That may be from the operating room. Does not report any pain or feelings of concern. (Recall)
2	Patient recalls pulling on chest and stapling. Expresses feeling of being unable to do anything: "I knew no one could hear me." Also reported extreme pain: "When they were pulling on my chest it hurt so bad." (Recall)
3	Patient felt a little pain in groin. This passed quickly and patient does not remember anything else. Patient was not worried or concerned about feelings. (Recall)
4	Patient felt initial chest incision. Did report hearing some vague buzzing, but no report of pain on any interview. Patient was not overly concerned by occurrence. (Recall)
5	Patient evidenced some apprehension about anesthetic on interview. No evidence of pain or direct memory of any portion of procedure. (Possible recall)
6	Patients comments, "I remember my muscles coming back," "I remember the breathing tube coming out," and "I was hurting until I got to recovery." No obvious intraoperative recall. Remembers the period at end of case where patient was still intubated. Patient expressed no concern or anxiety over occurrence. (Possible recall)

Items in parentheses reflect decision of Continuous Quality Improvement Committee.

ICU = intensive care unit.

that could be from the examination period between the two anesthetics. Patient 6 was undergoing a bariatric procedure and remembered the muscle relaxation wearing off at the end of the case, and the process of extubation.

In this study, two thirds of the cases (four of six cases) of intraoperative awareness were directly attributable to light anesthesia. The CQI process enabled the department of anesthesia to make specific recommendations based on each of the categories of recall that were obtained. In the cases where the use of the agent dexmedetomidine contributed to the possibility of recall, protocols were put in place to ensure that patients coming off bypass would have sufficient amnestic anesthetic maintenance until the end of the case. In the cases where a light anesthetic was given at the start of the case due to cardiac dysfunction, the CQI process encouraged the use of amnesia-inducing anesthetic agents that had a minimal depressant effect on the cardiovascular system. These protocol changes were implemented in a timely fashion after review *via* the QA process.

In summary, only 6 patients out of 87,621 patients undergoing general anesthesia (0.0068%) responded to prospective surveys by describing events or memories suggestive of intraoperative awareness. The authors believe that the use of an outcome-driven CQI processes can provide mechanisms by which the incidence of recall during anesthesia can be lowered compared with what has been previously reported.

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Appendix: CQI Structured Interview Questions to Elicit Incidence of Recall

1. What was the last thing you remember before surgery?
2. What is the first thing you remember once you woke up?
3. Did you have any dreams while you were asleep for surgery?
4. Were you put to sleep gently?
5. Did you have any problems going to sleep?

Modified from Brice *et al.*[6]; used with permission.

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