Airway Management for Deep Sedation: Current Practice, Limitations, and Needs as Identified by Clinical Observation and Survey Results

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Using deep sedation, adjunct airway devices such as oral or nasal airways are frequently required to maintain airway patency. Traditional oral airways (TOAs, made of rigid plastic) or nasal airways (made of pliable materials) can be associated with adverse effects, contributing to a trend of anesthesia providers placing nasal airways orally. A clinical observational study and an electronic provider survey were conducted to examine this emerging practice. The observation study objective was to investigate reported postoperative sore throat occurrence associated with use of either a nontraditional airway (nasal airway used orally) or TOA in deep sedation procedures (N = 243). Patients receiving nontraditional airways reported significantly less postoperative sore throat than those receiving TOAs (17% vs 40%, respectively; P < .001). These results prompted a broader exploration into airway practices of anesthesia providers via an electronic survey. Most respondents (n = 293) reported adverse effects, including gagging/coughing on insertion, oral cavity injury, and bleeding with TOAs. More than half (52.8%) reported using nasal airways orally. These results suggest a clinical void in current airway management options for deep sedation. Providers indicated the need for airway devices that provide a patent airway while mitigating adverse effects associated with commonly used airways.

Keywords: Airway complications, deep monitored anesthesia care (MAC), deep sedation, oral and nasal airways, postoperative sore throat.

The settings in which anesthesia is being delivered are increasingly moving outside traditional hospital operating rooms and into procedure rooms in office-based and ambulatory surgery facilities. Regardless of setting, effective airway management of patients undergoing procedures requiring anesthesia and sedation is critically important to the clinical care team. If a patient is not receiving adequate oxygenation, hypoxia or brain injury can occur within minutes.[1] In 2010, more than 47% of ambulatory procedures were performed at ambulatory surgery centers vs hospitals.[2] Additionally, in 10% to 30% of ambulatory surgery procedures, monitored anesthesia care (MAC) was chosen as the anesthesia service because of the benefits of preserving spontaneous breathing and airway reflexes while the patient is under sedation.[3] Deep sedation, also referred to as deep MAC, consists of a sedation depth at which the patient can only be awakened by pain. Use of deep sedation is increasing because of rapid patient recovery, less physiologic disruption, and positive and timely procedure completion.[3-5] Additionally, with the rise of the global opioid epidemic, there is a strong movement to manage pain through nonopioid medications and modalities. One of the benefits of performing operations using deep sedation is the ability to employ nonopioid medications with infiltration of local or regional anesthesia for pain control.[3]

Although deep sedation is increasingly used in surgical procedures, it poses some risks. According to the American Society of Anesthesiologists (ASA) closed claims database, the most common sedation (MAC) malpractice claim is inadequate oxygenation/ventilation, with more than 80% of claims of this nature resulting in brain damage or death.[6] Investigators with the American Association of Nurse Anesthetists (AANA) Foundation closed claims database also report that respiratory events are the greatest cause of adverse outcomes, with MAC and regional anesthesia identified as a contributing factor to those claims.[7] As the US population continues to grow older and obesity becomes more prevalent, the risk for upper airway complications during anesthesia in these patient groups increases as well.[8] With sedation, an anticipated appropriate intervention is necessary if upper airway obstruction occurs to prevent further morbidity or mortality.[5] Cautery fires are the most common equipment-related malpractice claim with MAC procedures, and oxygen is identified as the oxidizer in 95% of the cases.[6,9] Furthermore, MAC procedures accounted

for more than two-thirds of total operating room fire-related claims from 1985 to 2013 and were 5 times more frequent from 2000 to 2009 than before 1990.[9] This trend corresponds with the increase in MAC procedures performed year to year and also with the rise of facial plastic surgery procedures.[9]

Given the shift in performing more procedures under deep sedation/deep MAC, the anesthesia tools and practices originally designed for acute settings have not necessarily evolved commensurately. Two types of airway devices routinely used in sedation operations are oral and nasal airways. The core function of these devices is to maintain a patent upper airway and decrease complications of upper airway collapse during the induction of anesthesia, after extubation, and during sedation.[10,11] They alleviate airway obstruction by creating a passageway between the tongue and the posterior pharynx, providing a route through which ventilation can be managed. Oral and nasal airways provide the same clinical function, although their placement and physical characteristics differ. Traditional oral airways (TOAs) are commonly curved, made from rigid plastic, and fill about one-third to one-half of a patient's oral cavity. Nasal airways are smaller in diameter and are made from soft, flexible plastic, thermoplastic elastomer compound, or rubber.[11]

Both oral and nasal airways are associated with adverse effects ranging in severity. Oral airways can stimulate coughing, gagging, bleeding, or swelling; cause damage to teeth, oral mucosa, and the uvula; and can induce postoperative sore throat (POST).[12,13] A common complaint affecting patient satisfaction, POST is frequently listed as an undesirable outcome during the postoperative or postprocedure period.[14-16] Also, TOAs can inadvertently displace the tongue into the back of the mouth, causing airway obstruction.[12,13] Furthermore, oral airways may require additional patient positioning using the chin/jaw lift maneuver. Nasal airway placement can increase cardiovascular responses, cause nasal pressure sores, and provoke epistaxis.[17] Nasal airways can be difficult to place in patients with nasal structural abnormalities or defects and should not be used in patients with severe coagulopathy or suspected basal skull or nasal fractures.[13,17,18]

As a result of the adverse effects associated with traditional oral airway devices, the authors have identified an emerging trend in clinical practice to place nasal airways orally, particularly for deep sedation cases. Early experiences and feedback from anesthesia providers indicate that nasal airways inserted through the mouth are easier to position than TOAs and decrease the need for patient positioning using the chin/jaw lift maneuver. Additionally, nasal airways used orally may reduce patient discomfort, specifically with regard to POST. Although there are perceived benefits to using nasal airways orally, they are not designed to be placed orally and can pose safety risks to the patient, including the risk of occlusion if the airway becomes depressed (eg, the patient bites the airway), the risk of device breakage due to patient biting, and the risk of dislodgement into the oropharynx and further migration into the larynx or esophagus. Use of the nasal airway orally or a manner inconsistent with the intended purpose may also pose liability issues for the anesthesia provider and facility. To date, the use of nasal airways orally has not been recorded in the literature, which could be due to liability concerns related to use other than that for which it has been officially approved.[19]

The aim of the investigation consisted of 2 objectives: (1) to compare whether different airway approaches, a TOA or a nasal airway being used orally, affected the incidence of POST in an outpatient surgery patient population; and (2) to better understand anesthesia providers' current airway practices, the utility of current airway devices, and corresponding patient outcomes associated with certain types of airways. Although POST has been studied extensively in general anesthesia procedures, little to no information exists on POST incidence rates after deep sedation. Although the primary objective of the clinical observation study was to examine differences in POST incidence rates between airways (oral airways and nasal airways used orally), the study also provides a baseline incidence rate for this classification of sedative procedures. Based on the results of the clinical observation study, a national electronic survey of a large, diverse population of anesthesia providers further examined current airway practices and outcomes associated with distinct airways. The intent of the survey was to identify potential needs in airway management relative to current practice.

Methods

• ***Clinical Observational Study.*** A study was conducted to examine POST in patients receiving deep sedation using a traditional or nontraditional oral airway.

• *Study Design and Inclusion/Exclusion Criteria.* The prospective observational study was performed at an 8-operating room outpatient surgery center affiliated with a Level I pediatric and trauma center. Full approval was obtained from the institutional review boards (IRBs) at the study sites. Patients were recruited by participating Certified Registered Nurse Anesthetists (CRNAs) as encountered according to the surgery schedule. Inclusion criteria included age 18 years or older, English speaking, undergoing a surgical procedure in the supine or lithotomy position, receiving deep sedation, and requiring an oral airway placed to provide a patent airway. Exclusion criteria included American Society of Anesthesiologist (ASA) physical status classification greater than 4, surgery that involved the head or neck, and/or uncontrolled gastroesophageal reflux disease (GERD).

• *Patient Sample Size, Enrollment, and Data Collection.*

Patient characteristics and study factors	No POST (n = 183)	POST (n = 60)	Total (N = 243)	*P* value[a]
Mean age (SD), y	50.4 (14.4)	45.4 (14.2)	49.2 ± 14.5	.41
Gender, F/M, No.	138/45	43/17	181/62	.34
ASA classification, I/II/III, No.	53/122/8	14/41/5	67/163/13	.35
Mean BMI (SD), kg/m^2	27.8 (5.8)	28.2 (5.8)	27.9 (5.8)	.27
History of GERD, Yes/No, No.	19/164	11/49	30/213	.08
Glycopyrrolate use, Yes/No, No.	86/97	41/19	127/116	.004
Airway, TOA/Nontraditional, No.	48/135	33/27	81/162	< .001

Table 1. Significance of POST Occurrence Versus Patient Characteristics and Airway Device
Abbreviations: BMI, body mass index; GERD, gastroesophageal reflux disease; POST, postoperative sore throat; TOA, traditional oral airway.
[a]Analyzed with χ^2 test.

Enrollment of 243 patients was targeted for study completion based on a sample size calculation for the incidence of POST using an estimated population proportion calculation with a 5% margin of error, a confidence level of 90%, an expected sample proportion of 33%, and a 2% increase to allow for potential subject attrition due to incomplete form completion.[20] Over 5 months, 12 CRNAs collected data from 243 patients who met the inclusion/exclusion criteria. Informed consent was obtained from all participating subjects. Anesthesia providers administered care according to their standard practices. At his or her discretion, the CRNA could choose to place either a currently available TOA or a nasal airway used orally (nontraditional oral airway). Intraoperatively, the CRNA recorded demographic data (age, gender, ASA physical status, body mass index [BMI], controlled GERD), glycopyrrolate use, and airway use on a study form. Because glycopyrrolate is an antisialagogue, patients who receive glycopyrrolate may have increased dryness of the mucosa in the upper airway, thus resulting in a greater occurrence of POST. Occurrence of POST was captured after the awake patient was transferred to the recovery unit; the patient was asked "Do you have throat discomfort?" and the response was recorded on the study form. Postoperative sore throat was considered present if the patient verbally acknowledged discomfort, irritation, pain, hoarseness, difficulty swallowing, and/or scratchy or dry mouth/throat. The incidence of POST was categorized using a binary scale and recorded as present or absent.

• *Statistical Analysis.* Analyses of patient-reported POST occurrence data were performed using a χ^2 test, descriptive analysis, and linear regression using IBM SPSS Statistics for Windows, Version 21.0 (IBM Corp). Data were analyzed to determine the incidence of POST, the relationship to the type of airway used, and whether other descriptive variables collected affected POST occurrence. The following descriptive variables were considered: age, gender, ASA physical status, BMI, history of controlled GERD, and glycopyrrolate use. Categorical variables were selected based on risk factors associated with POST.

• *Clinician Airway Use Survey:* A survey was conducted of clinicians to evaluate current airway practices, associated outcomes, limitations, and needs.

• *Survey Design and Statistical Analysis.* An electronically distributed national survey was developed to capture information and outcomes regarding oral and nasal airways from anesthesia providers. This survey was disseminated via a closed-group Facebook site with more than 18,000 CRNAs and student registered nurse anesthetist (SRNA) members. The survey consisted of 19 questions, including demographic queries, oral and nasal airway use and outcome events, patient positioning with airway use, and assessment and experience of using a nasal airway in the oral cavity. Respondents completing the electronic survey were automatically entered into a drawing for a gift card as a way to incentivize responses.

For the survey, IRB approval was requested from the University of Minnesota, and the project was granted exemption from IRB review based on survey content. No funding was necessary for the implementation of the project. Descriptive and inferential statistics, including confidence intervals, were used to analyze the survey data.

Results

• *Clinical Observational Study.* Demographic characteristics and outcomes of the 243 patients are presented in Table 1. Of 243 patients, 81 subjects received a TOA, and 162 were treated with a nontraditional airway (nasal airway used orally). No significant differences in demographic variables (mean age, gender, ASA physical status, mean BMI, and GERD history) vs POST occurrence were observed ($P > .05$). Out of 243 patients, 60 (25%) suffered from POST. A statistically significant difference (χ^2 test) in POST incidence was found depending on the type of airway used ($P < .001$); 40% of patients who received a TOA reported POST, compared with 17% of patients who received the nontraditional airway.

This study also revealed a positive correlation (χ^2 test) between POST and glycopyrrolate use ($P = .004$); 32% of patients who received glycopyrrolate experienced POST,

compared with 16% of patients who did not receive the medication. However, there was no statistical correlation between glycopyrrolate use and type of airway employed ($P = 0.36$, χ^2 test). Glycopyrrolate use was recorded in 48% of subjects receiving a TOA and 54% of subjects receiving a nontraditional airway device.

• ***Clinician Airway Use Survey.*** Two hundred ninety-three respondents completed the electronic survey on airway use. Respondents consisted of CRNAs (58.7%), retired CRNAs (1%), and SRNAs (40.3%). Adverse effects and stimulation resulting in negative patient outcomes were reported by respondents for both traditional oral and nasal airways (Table 2). Ninety-eight percent of respondents indicated that they used the chin/jaw lift maneuver in place of an airway because of the patient's condition or the clinical scenario, and 88.9% reported using the maneuver with TOAs. Nasal airways used via oral insertion were reported by 52.8% of respondents. The top 3 reasons provided by the respondents were to improve airway patency, to reduce chin lift, and did not want to risk a nosebleed with nasal airway placement; the full list of reasons is summarized in Table 3. The largest proportion of the respondents who reported using nasal airways orally indicated they used them sometimes (72.4%), followed by rarely or once (13.5%), half the time (8.3%), most of the time (3.8%), and always (1.9%). Respondents were asked how long they had been using nasal airways orally. Most respondents reported using this practice for less than 1 year (58.5%), followed by 1 to 5 years (26.8%), 5 to 10 years (9.3%), greater than 15 years (3.3%), and 10 to 15 years (2.2%). Additionally, 36% of respondents reported experiencing adverse effects with oral use of a nasal airway, including coughing/gagging on insertion (75.9%), air passage occlusion/patient biting the airway (24.1%), and patient biting and severing the airway (1.9%).

Respondents who have not used a nasal airway orally and chose to provide a reason (39% of total respondents; n = 114) noted the following motives for their decision: current airway devices are sufficient (35.7%), unaware of oral use (34.5%), oral use is not listed as an approved indication for use (11.3%), have heard of adverse outcomes from the oral use (8.9%), and other (9.5%). Respondents were permitted to select more than 1 reason. Finally, 98.2% of respondents selected that they would be interested in trying a novel airway device that was similar in structure to a nasal airway but was designed for use in the mouth.

Adverse outcome	Number (%)[a]
Oral airway	
Coughing or gagging on insertion	180 (61.4)
Damage to lips	173 (59.0)
Damage to oral mucosa	106 (36.2)
Damage to teeth	21 (7.2)
Cardiac stimulation (hypertension, arrhythmias, tachycardia)	33 (11.3)
Emesis	15 (5.1)
Other	8 (2.7)
Nasal airway	
Bleeding	
Scant to slight	203 (69.3)
Moderate	101 (34.5)
Heavy	36 (12.3)
Cardiac stimulation (hypertension, arrhythmias, tachycardia)	31 (10.6)
Dislodgement of nasal airway further into patient	3 (1.0)
Refractory bleeding requiring surgical intervention	1 (0.3)
Nasal airway entrance into cranial vault	0 (0)
Other	7 (2.4)

Table 2. Adverse Outcomes Associated with Oral and Nasal Airway Use (N = 293)
[a]Respondents were allowed to select more than 1 adverse outcome associated with oral or nasal airway use.

Discussion

• ***Clinical Observational Study.*** Given the rise of ambulatory surgery cases, including deep sedation procedures, as well as the observed emerging trend in clinical practice to place nasal airways orally to alleviate redundant pharyngeal tissue obstructing the upper airway and reduce associated adverse effects, the current clinical observational investigation was performed.[2-4] The investigation, which evaluated patients receiving deep sedation in outpatient procedures, showed that 25% of the participants experienced POST. The type of airway used was a statistically significant variable affecting POST occurrence, with 40% of patients who received TOAs experiencing POST and 17% of patients who received nasal airways used orally experiencing POST. Higher POST rates with TOAs may be due to the physical structure of these devices, which may have caused irritation and injury to the oral mucosa, palate, and or/tongue. Glycopyrrolate use was also found to be a significant factor affecting POST, but there was no significant correlation found between glycopyrrolate use and the type of airway device used.

Although a controlled clinical study would have been preferred to examine differences in POST incidence rates between studied airway devices, thus reducing potential confounding factors, the authors were not able to undertake this level of investigation because of the use of a nasal airway in a manner inconsistent with its intended purpose. Limitations with the observational study included anesthesia providers being allowed to use their airway device of choice/standard of care. Consequently,

Reasons for using nasal airway in oral cavity	Online survey responses (n = 159), No. (%)[a]
Improve airway patency during sedation/MAC	135 (84.9)
To reduce chin lift during sedation/MAC	78 (49.1)
Did not want to risk a nose bleed with nasal airway placement	77 (48.4)
The patient was not sedated enough to place a standard oral airway	76 (47.8)
To reduce jaw thrust during sedation/MAC	66 (41.5)
Other: less stimulating, less risk of damage to oral cavity, easier to place, frees up provider from patient positioning	15 (9.4)

Table 3. Reasons for Using a Nasal Airway Orally
Abbreviation: MAC, monitored anesthesia care.
[a]Respondents were allowed to select more than 1 reason for using a nasal airway orally.

twice as many subjects were enrolled in the nontraditional airway group vs the TOA group. As a result, POST outcomes could have been affected by the provider's skill, selected TOA, size of the nasal airway used, whether lubrication was applied, environmental factors, and medication influences such as varying amounts of narcotics used. Additional limitations include the range of procedure times and lack of standardization of oxygen flow, which may influence the incidence of sore throat by drying out the mucosal membranes. Finally, a sore throat measurement was not performed preoperatively; to adequately measure the incidence of POST, a baseline measurement should be performed to rule out confounding factors such as a cold or other respiratory tract illness.

• ***Clinician Airway Use Survey.*** The electronic survey provided high-level insight into outcomes experienced by anesthesia providers with oral and nasal airways. Most providers reported witnessing adverse outcomes with using an oral airway device, including coughing/gagging on insertion (61%) and injury to some part of the oral cavity (7.2%-59%), as shown in Table 2. Respondents also indicated adverse outcomes with nasal airways used nasally, including some level of bleeding (35%-69%) and cardiac stimulation (11%; Table 2). More than half of respondents (52.8%) indicated they had used a nasal airway orally. The largest segment of this group (58.5%) reported that they had experience using nasal airways orally over a span of less than 1 year, which may correspond with the quantity of SRNAs (40.3%) who completed the survey. Finally, almost all respondents (98.2%) expressed interest in airway device alternatives designed to reduce adverse effects experienced with TOAs.

There were limitations with the survey employed in the investigation. Surveys were completed by providers at their will, and therefore they may not provide an accurate assessment of the overall population of anesthesia providers' opinions and experiences with oral and nasal airways. Additionally, some of the surveys were filled out incompletely or in a contradictory manner. For example, some respondents answered that they had used the nasal airway orally but later responded to a question asking why they had not used the nasal airway orally. These inconsistencies were adjusted or deleted, potentially affecting the results.

• ***Need for Improved Oral Airway Options for Deep Sedation Procedures.*** With the increasing number of operations being performed out of the operating room at outpatient and ambulatory facilities, and with the most common malpractice claim with sedation being respiratory events resulting from inadequate oxygenation/ventilation, it is critically important to have an airway device that provides a patent airway.[3,6] Additionally, comorbidities that can exacerbate airway obstruction such as increasing age, sleep apnea, and obesity are rising in the US population, furthering the need for airway devices and techniques that can maintain airway patency in variable settings.[9,21] Given these considerations, it is imperative that any new airway device is easy to place and use and that it results in limited adverse effects so that providers will be willing to employ the device during practice.

The second most common malpractice claim associated with sedation procedures is caused by equipment failures/malfunctions resulting in fires.[6] Currently, traditional oral and nasal airway devices are not actively involved in the breathing circuit when supplemental oxygen is supplied to a patient undergoing sedation for a procedure. However, given the incidence rates of fires resulting from these procedures, it may be beneficial to supply oxygen through the airway device rather than through a nasal cannula or face mask, thereby maintaining an adequate oxygen saturation level while reducing combustible gas in the operating field. The current guidelines for reducing fires with the use of sedation in the operating room advise maintaining fraction of inspired oxygen (FIO_2) below 30% or removing the supply of oxygen for at least 1 minute before using a source of ignition such as cautery, lasers, or other items that generate heat.[22] This requires active vigilance and communication by the clinical team and is at times overlooked, resulting in dangerous and potentially life-threatening outcomes for the patient.[23,24]

The results of the clinical observational study and anesthesia provider survey evaluated in this investiga-

tion demonstrate a need for airway devices that provide a patent airway by creating an airway passage by displacing the redundant pharyngeal soft tissue while mitigating adverse patient effects. In response to these investigations, the following airway attributes were identified that may be useful in addressing current airway needs in deep sedation:

- Softer material and smaller diameter compared with traditional oral airways, for easier placement and less patient stimulation
- Ability for the distal end of the airway to sit lower in the pharynx than currently available oral airways, potentially reducing the need to use the chin/jaw lift maneuver and the commonly associated jaw pain that patients experience
- Integrated bite blocks designed to prohibit the patient from biting down and compressing or severing the airway if softer tubing is used
- Flanges that decrease the risk of the airway becoming dislodged
- Ability for the airway to connect directly to the anesthesia circuit or manual resuscitator, helping increase oxygen delivery to the patient and potentially improving operating room safety while following safety guidelines by removing oxygen from the surgical field

Conclusion

The current investigation was undertaken in response to an identified emerging trend of anesthesia providers placing nasal airways orally to alleviate airway obstruction by displacing the redundant pharyngeal soft tissue and to reduce adverse effects with TOAs. Patients undergoing sedation experienced significantly less POST ($P < .001$) with a nontraditional airway (nasal airway used orally, 17%) than with a TOA (40%). Most surveyed anesthesia providers observed some type of adverse effect with traditional oral and nasal airways, which led to a noteworthy subgroup of respondents (52.8%) reporting the use of nasal airways orally. The study outcomes suggest a clinical void in current airway management options for deep sedation, and providers indicated the need for improved airway devices that provide a patent airway while mitigating adverse effects.

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DISCLOSURES

Roxanne McMurray is the inventor of the McMurray Enhanced Airway and is vice president of clinical management at McMurray Medical, Minneapolis, Minnesota. Megan McMurray is the daughter of Roxanne McMurray but has no financial ties to McMurray Medical. The other authors have no financial relationships with any commercial interest related to the content of the article. The authors did discuss off-label use within the article.

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