Nasal Ventilation Mask for Prevention of Upper Airway Obstruction in Patients With Obesity or Obstructive Sleep Apnea

Connor E. Willard, DNP, CRNA
Andi N. Rice, DNP, CRNA
Marion E. Broome, PhD, RN, FAAN
Susan G. Silva, PhD
Virginia C. Muckler, DNP, CRNA, CHSE

This project aimed to develop and implement a nasal ventilation mask (NVM) guideline to reduce the incidence of airway obstruction in outpatients undergoing endoscopy procedures. An observational design was used to evaluate implementation of an NVM guideline as the oxygen delivery method for this patient population. An evidence-based guideline for NVM use was developed for patients with obstructive sleep apnea (OSA) and/or an elevated body mass index (BMI) above 35 kg/m² undergoing esophagogastroduodenoscopy and/or colonoscopy procedures at an outpatient endoscopy clinic. Patients receiving moderate or deep sedation for esophagogastroduodenoscopy, colonoscopy, or both procedures who had a BMI of at least 35 kg/m² and/or an OSA diagnosis were observed for oxygen desaturation, airway maneuvers, and use of airway adjuncts. Intraoperatively, the group of patients who wore an NVM compared with the group that did not wear an NVM had 3 times greater chance of having at least one occurrence of an oxygen saturation less than or equal to 90% and almost 4 times greater chance of having an oxygen desaturation 5% or greater of baseline oxygen saturation. The NVM offers supportive ventilation and the ability to provide positive pressure assistive breaths, both of which are beneficial to the increasingly obese population.

Keywords: Airway management, nasal ventilation mask, obesity, outpatient sedation.

The prevalence of obesity in the United States has steadily increased over the last 50 years. Data from the 1960 to 1962 National Health and Nutrition Examination Survey (NHANES) showed an incidence of body mass index (BMI) equal to or greater than 30 kg/m^2 and equal to or greater than 40 kg/m^2 to be 13.4% and 0.9%, respectively, in adults aged 20 to 74 years.[1] Comparatively, NHANES data from 2013 to 2014 demonstrated that the incidence of adult BMI equal to or greater than 30 kg/m^2 increased to 38.2% and a BMI of equal to or greater than 40 kg/m^2 reached 8.1%.[1] As the nationwide trend of obesity climbs, it is expected that sleep-disordered breathing will also increase because a marked relationship has been identified between the two.[2]

Obstructive sleep apnea (OSA), a form of sleep-disordered breathing, is defined as the intermittent collapse of upper airway tissues during sleep, resulting in repeated episodes of hypopnea or apnea from airway obstruction.[3] While a person is awake, upper airway muscle tone keeps the airway patent. The loss of this muscle tone during sleep, anesthetic sedation, or general anesthesia, predisposes a patient to airway obstruction.[4] Individuals with morbid obesity are at increased risk of airway obstruction, because their anatomy often combines a large neck circumference with excess lateral pharyngeal adipose tissue resulting in a narrowed airway.[5] This is further supported by results of computed tomography and magnetic resonance imaging, which have demonstrated that pharyngeal airways are narrower for patients with OSA than for patients without OSA.[6,7] Currently, standard practice for procedures that require moderate to deep anesthetic sedation involves the use of passive oxygenating devices, including nasal cannulas and face masks. Although these devices are effective for oxygenation, they are ineffective in the presence of airway obstruction.[5]

Patients of all weight ranges who have a diagnosis of OSA are at increased risk of loss of the airway during procedures that require anesthetic sedation. During such procedures, airway obstruction and subsequent hypoxia may require procedure interruption for the anesthesia provider to correct the obstruction with an airway maneuver. Examples of maneuvers include chin lift, jaw thrust, or insertion of an airway adjunct, such as an oropharyngeal airway or nasopharyngeal airway. With airway obstruction, not only do patients experience harmful apneic or hypopneic events, but also interrupted procedures can result in longer procedure times and the

administration of increased amounts of anesthetic sedation. Increased anesthetic sedation may lead to a greater risk of obstructive events, which can occur as late as after the procedure in the postoperative anesthesia care unit (PACU).[8] In addition to the increased prevalence of obesity and OSA, the number of endoscopic procedures performed outside the operating room is rising. A patient with obesity and OSA who has an endoscopic procedure is at increased risk of upper airway obstruction.[9]

Obesity has been shown as a strong causal factor for OSA, although a definitive diagnosis of OSA can be made only with polysomnography.[10,11] Polysomnography, however, is time-consuming, expensive, and inconvenient. As a result, OSA remains undiagnosed in up to 90% of those with the condition.[12] Peppard and colleagues[10] updated OSA prevalence rates by using older, outdated sleep studies as models, which they then applied to current US demographics. They estimated that the prevalence of moderate to severe OSA was approximately 20% in adults between 30 and 70 years of age and 33% in adults between 50 and 70 years of age. Patients with OSA experience apneic and hypopneic events that can lead to harmful health consequences, such as hypoxia; disjointed sleep; and amplified variations in heart rhythm, blood pressure, and intrathoracic pressure. When these events persist, more long-term repercussions such as hypertension, cardiovascular morbidities, and declining cognitive function can manifest.[10]

Continuous positive airway pressure (CPAP) is considered the quintessential treatment of OSA.[3] Not only is CPAP ventilation effective in treating OSA, it also reduces the incidence of the aforementioned adverse effects, including sympathovagal activation and recurrence of atrial fibrillation.[13] Furthermore, CPAP has been shown to improve blood pressure in patients with diagnoses of hypertension and OSA.[3] The standard CPAP machine involves the use of an oronasal face mask, which covers the nose and mouth while resting on the chin and nasal bridge and delivers a selected continuous positive pressure.[14]

The effectiveness of an oronasal face mask has been questioned for patients with OSA compared with the newly developed nasal ventilation mask (NVM), which covers the nose only. The Starling resistor concept explains why a full face mask is less advantageous than an NVM. A Starling resistor is a tube passing through a sealed box and is commonly used to represent the human pharyngeal airway.[15] An NVM enhances the Starling resistor model by increasing the pressure inside the pharynx (tube) above the pharyngeal critical closing pressure, thereby keeping the pharynx open.[16] The oronasal mask, by comparison, disrupts this model by administering pressure simultaneously through the nose and mouth, which may collapse the pharynx.[17] A randomized controlled trial by Oto et al[18] was conducted to determine whether CPAP via an NVM was more effective at maintaining airway patency than an oronasal mask in 73 patients with OSA during induction of general anesthesia for elective surgery. The study found that the rate of effective tidal volume was significantly higher ($P < .01$) and the median expired tidal volume was significantly larger with NVMs than with oronasal masks ($P < .01$).[18] Andrade et al[17] observed 18 patients with a range of OSA severity who were treated with nasal, oronasal, and oral CPAP masks during sleep. They concluded that NVMs were able to stabilize breathing in all patients, whereas 66.7% of patients receiving CPAP via oronasal mask and 87.5% via oral routes experienced obstructive events.[17]

Because oronasal CPAP masks are not appropriate for procedures that require access to the mouth such as esophagogastroduodenoscopy (EGD), high-flow nasal cannulas are routinely used. Apneic episodes often result if upper airway obstruction occurs as previously described. In comparison, NVMs allow continuous oxygen flow and positive airway pressure near 20 cm H_2O pressure or higher to push oxygen into the airway, while actively inflating the lungs, allowing for carbon dioxide removal, and relieving upper airway obstruction.[19] A 2017 case report of a pulmonary compromised patient who required cerebral clot evacuation described how nasal positive airway pressure offered a noninvasive means to supplemental oxygen during deep sedation, particularly if patients have compromised pulmonary function or are at risk of upper airway collapse.[20] Furthermore, an observational study of 30 adult patients, 18 of whom had a BMI more than 30 mg/kg^2, undergoing general anesthesia for elective surgery demonstrated that the NVM facilitates noninvasive positive pressure ventilation, while allowing adequate oxygenation and ventilation for a variety of patients, including those who were edentulous, had a Mallampati score of 3, and a BMI above 30 kg/m^2.[19] Last, using a hyperinflation bag attached to the NVM allows for continued positive pressure support and/or rescue ventilation during patient transport and recovery in the PACU.[5,21] The evidence provided identifies why an NVM can enhance the quality of care in many patient populations.

The purpose of this quality improvement (QI) project was to develop and implement an NVM guideline to reduce the incidence of airway obstruction and subsequent hypoxia in patients undergoing EGD and/or colonoscopy procedures at an outpatient endoscopy clinic who either had an OSA diagnosis, a BMI of at least 35 kg/m^2, or both. The implemented practice change was designed to increase patient safety by decreasing the incidence of airway obstruction and subsequent hypoxia in patients at increased risk of airway obstruction while receiving monitored anesthesia care (MAC) during EGD or colonoscopy procedures.

The specific aims of this project were to (1) develop and implement an NVM guideline for patients at risk of

airway obstruction undergoing EGD and/or colonoscopy procedures, (2) describe and compare patient characteristics among patients at risk of airway obstruction for whom the NVM was applied as the oxygen delivery method during these procedures and for those who did not have the NVM applied, and (3) identify barriers to the implementation of the NVM guideline.

Methods

• ***Design, Setting, and Sample.*** Following submission to the institutional review board and determination of exempt status, this project was implemented at an outpatient endoscopy clinic composed of 6 procedure rooms in a large academic health system in the Southeastern United States. The clinic performs approximately 800 procedures each month, on average 75% of which are EGD or colonoscopy procedures. The clinic is staffed by 10 Certified Registered Nurse Anesthetists (CRNA) working in an anesthesia care team model with anesthesiologists who rotate through the clinic.

A 2-group or comparative observational design was used to evaluate the implementation of an NVM guideline for the oxygen delivery method in this patient population and to compare the incidence of airway obstruction and subsequent hypoxia during the intraprocedural period. The 2 groups were the NVM group and the No NVM group. Patients included were 18 years of age or older who received MAC for an EGD, colonoscopy, or both procedures who had an OSA diagnosis or a BMI of at least 35 kg/m^2, or both, either of which places patients at increased risk of airway obstruction. Patients excluded were those who presented to the clinic intubated, required intubation at any time during or after the procedure, had an active bowel obstruction, and those at increased risk of aspiration, as indicated by the American Society of Anesthesiologists nil per os guidelines.

A convenience sample of 100 adults was observed during EGD, colonoscopy, or a combination of both procedures, to achieve 80% statistical power. Observations were continued until each group reached 50 patients during the procedural period. The first group included patients for whom the anesthesia provider selected the NVM method to apply during the intraprocedural period (NVM, n = 50). The second group included patients for whom the anesthesia provider selected the current practice of an end-tidal carbon dioxide ($ETCO_2$) monitoring nasal cannula as the oxygen delivery method during the intraprocedural period (No NVM, n = 50). Patients who met inclusion criteria were observed during the intraprocedural periods for hypoxia and airway interventions as previously described.

• ***Innovation and Implementation.*** Before this QI project, there were no clinic guidelines to assist providers in deciding which patients could benefit from an NVM. Existing evidence from the literature was used to develop a guideline for the use of NVMs for patients at risk of airway obstruction while undergoing EGD and/or colonoscopy procedures. The guideline flowchart was created to guide providers through a series of steps to determine if the patient was an appropriate candidate for NVM and aligned with inclusion and exclusion criteria. The guideline was developed and approved by a multidisciplinary committee consisting of proceduralists, anesthesiologists, CRNAs, and nursing staff. Buy-in was achieved, and all agreed that the decision of whether to apply the NVM would remain that of the individual provider who would consider the appropriateness and necessity of the NVM for each patient on an individual basis.

For this project, the clinic was testing in clinical trials the SuperNO_2VA device. This NVM is designed to support ventilation in patients who are sedated with anesthesia by providing variable positive airway pressure,[20] particularly those at greater risk of upper airway obstruction who may or may not also have an elevated BMI.[21] The device was approved by the US Food and Drug Administration in October 2017. Education regarding the guideline was provided over a 2-week period to clinic staff, including all staff nurses, CRNAs, anesthesiologists, and gastroenterologists, regarding proper use of the NVM and the intended population of patients at increased risk of airway obstruction. An in-service was presented by a device cocreator and device representatives during a staff meeting. Those not in attendance were later educated one-on-one by the device representatives.

Following the educational period, the procedure schedule was reviewed daily to identify patients who met the inclusion criteria for the convenience sample. Patients identified as having met inclusion criteria were observed for the duration of their procedure. When a patient met inclusion criteria but the NVM was not applied, the anesthesia provider was asked the rationale for not applying the NVM in an attempt to gain insight into the barriers to implementation of the guideline.

• ***Data Collection.*** Patient demographic and clinical characteristics for the 100 patients were collected from the electronic health record (EHR) and confirmed during the patient interview. Characteristics included (1) ASA classification, (2) gender, (3) age, (4) BMI category, (5) dentition status, (6) Mallampati classification, (7) comorbidities, (8) whether an OSA diagnosis (*International Classification of Diseases, Ninth Revision*) was present, and (9) procedure type. Patients with an OSA diagnosis were asked to confirm or deny regular, nightly use of the CPAP machine. Other information collected from the EHR included anesthesia time and intraprocedural time. For this project, intraprocedural time was measured from the time the scope was placed until the time it was withdrawn, and anesthesia time was measured as the time the anesthesia provider began contact with the patient until the patient's care was transferred to the PACU nurse.

The primary patient outcome of interest was whether an airway obstruction occurred during the endoscopy procedure. For each patient, specific indicators of airway obstruction during the procedure were collected via direct observations. These indicators included the following: (1) number of oxygen saturations less than or equal to 90%[22]; (2) number of oxygen desaturations greater than or equal to 5% of baseline oxygen saturation, (3) number of procedure pauses of any duration secondary to hypoxia; (4) number of airway maneuvers performed; and (5) whether an airway adjunct was inserted. Oxygen flow meters were set for 3 to 4 L/min for cases using an $ETCO_2$ monitoring nasal cannula and 10 L/min for cases using the NVM according to the device manufacturers' recommendations.[20] For the outcome analysis, each indicator of airway obstruction was dichotomized into a binary outcome, coded as no occurrence (0) or at least one occurrence (1).

• ***Data Analysis.*** Descriptive statistics were used to report patient characteristics and airway obstruction outcomes collected for the total sample and by group (NVM vs No NVM). Nondirectional statistical tests were conducted with the level of significance set a priori at .05. Chi-square tests (alternatively, Fisher exact) and independent *t* tests were used to evaluate group differences in patient characteristics and identify potential covariates for the outcome analyses. For each binary outcome, a test for group differences in proportions was conducted using a χ^2 or Fisher exact test, and a Cohen *d* equivalent value and its 95% CI was calculated as an estimate of effect size. Logistic regression and odds ratios were planned if there was a need to control for potential covariates. Barriers to implementation of the NVM method and reasons providers did not use the NVM method when patients met criteria were summarized for consistent themes.

A sample size calculation was conducted during the project planning stages to determine the sample size per group required to achieve 80% statistical power, assuming the following: (1) a χ^2 test or logistic regression method without covariates would be applied to test for group difference in the indicators of airway obstruction outcomes; (2) 2-tailed tests with significance set at .05 for each test; and (3) medium effect sizes (Cohen *w* = 0.30; Cohen *d* equivalent of 0.50). The required sample size for 80% power was 200 (100 per group). Given the exploratory nature of this initial QI project, a sample size of 50 per group was obtained because of the limited availability of the NVMs. Because the project was underpowered for expected small to medium effects, the project focused on describing effect sizes and their 95% CI. Effect sizes and barriers to implementation will then be used to inform future initiatives.

Results

The comparison of demographic characteristics for the NVM and No NVM groups indicated no significant differences, except for BMI category (Table 1). A significantly greater percentage of patients in the NVM group had morbid/super (severe) obesity with a BMI of at least 40 kg/m^2 or greater compared with the No NVM group. For comorbidities, the NVM group had a significantly higher rate of hypertension, diabetes, and total comorbidities compared with the no NVM group. In contrast, the NVM group had a significantly lower percentage of patients with chronic pain relative to the No NVM group (Table 2). Thus, BMI category, diabetes, chronic pain, and total comorbidities were identified as potential covariates for the outcome analyses.

Table 3 summarizes the results for the 5 indicators of airway obstruction during the endoscopy procedure as well as postprocedure oxygen saturations less than or equal to 90%; all were coded as no occurrence (0) and at least one occurrence (1) for the outcome analysis. Four of the 5 intraprocedural outcomes had a low observed frequency ($n \leq 5$) in the NVM group for the outcome event, defined as at least one occurrence of the event. Logistic regression models with covariates included were not conducted because (1) bivariate analyses indicated no statistically significant association between each potential covariate and each outcome along with small effect sizes and (2) issues with heterogeneity of outcome variance in the NVM group affected model fitting for 4 of the 5 measures. Therefore, χ^2 or Fisher exact tests were used to test for an association between group and outcomes. The NVM group compared with the No NVM group had a significantly lower percentage of patients with intraprocedure airway obstruction as indicated by oxygen saturation less than or equal to 90% ($P = .377$) and oxygen saturation of 5% or greater of the baseline oxygen saturation ($P = .029$). Both effect sizes were in the medium range, as indicated by a Cohen *d* equivalent of 0.50 to 0.79. The groups, however, did not differ in the percentage of patients with intraprocedural airway maneuvers performed. Bivariate analyses were not performed on the 3 outcomes with a low frequency for the event in both groups.

Discussion

The primary purpose of this QI project was to develop and implement an NVM guideline to reduce the incidence of airway obstruction and subsequent hypoxia in patients undergoing EGD and/or colonoscopy procedures who had an OSA diagnosis, a BMI of at least 35 kg/m^2, or both. Among the indicators of airway obstruction, there was a significant decrease in the incidence of oxygen saturation less than or equal to 90% and oxygen desaturations at or above 5% of baseline oxygen saturation when the NVM guideline was implemented, but no reduction in airway maneuvers performed. The incidence of airway adjunct insertions and hypoxia as measured

Characteristic	Total (N = 100)	No NVM (n = 50)	NVM (n = 50)	*P* value
Age, mean (SD), y	58.6 (12.7)	58.8 (14.1)	58.5 (11.2)	.913
Male gender, No. (%)	43 (43)	18 (36)	25 (50)	.157
ASA class				.118[a]
2	18 (18)	12 (24)	6 (12)	
3	81 (81)	38 (76)	43 (86)	
4	1 (1)	0 (0)	1 (2)	
Procedure type, No. (%)				.904
EGD	30 (30)	14 (28)	16 (32)	
Colonoscopy	58 (58)	30 (60)	28 (56)	
EGD and colonoscopy	12 (12)	6 (12)	6 (12)	
Mallampati score, No. (%)				.211[b]
1	15 (15)	6 (12)	9 (18)	
2	49 (49)	29 (58)	20 (40)	
3	31 (31)	13 (26)	18 (36)	
4	5 (5)	2 (4)	3 (6)	
BMI,[c] No. (%)				.007
Underweight/normal	15 (15)	11 (22)	4 (8)	
Overweight/obesity	51 (51)	29 (58)	22 (44)	
Morbid/super obesity	34 (34)	10 (20)	24 (48)	
OSA diagnosis, No. (%)	68 (68)	30 (60)	38 (76)	.086
CPAP mask use, No. (%)	46 (46)	20 (40)	26 (52)	.229
Facial hair: mustache, No. (%)	24 (24)	11 (22)	13 (26)	.640
Dentition, No. (%)				.834
Missing teeth	9 (9)	4 (8)	5 (10)	
Edentulous	5 (5)	2 (4)	3 (6)	
Baseline oxygen saturation, mean (SD), %	97.1 (2.0)	97.1 (2.0)	97.0 (2.0)	.756

Table 1. Patient Demographic and Clinical Characteristics

Abbreviations: BMI, body mass index; CPAP, continuous positive airway pressure; EGD, esophagogastroduodenoscopy; NVM, nasal ventilation mask; OSA, obstructive sleep apnea.

[a]Chi-square test with ASA class was collapsed into class 1/2 or class 3/4 categories,

[b]Chi-square test with Mallampati score was collapsed into 1/2 or 3/4.

[c]BMI was collapsed into underweight/normal (< 18.5-29.9 kg/m^2), overweight/obesity (30-39.9 kg/m^2), or morbid/super obesity (≥ 40 kg/m^2).

by procedure pauses was low regardless of whether the NVM guideline was applied. Of note, the extent of airway maneuvers varied among providers; therefore, each was counted as a single maneuver regardless of duration. For example, if the anesthesia provider performed a chin lift for 10 seconds, released 30 seconds, and later repeated a chin lift; this counted as 2 maneuvers.

Sample characteristics also warrant consideration. With the average duration of an EGD and colonoscopy as 10 and 30 minutes, respectively, it is assumed that longer procedure times would lead to more frequent procedure pauses and a greater number of airway adjunct insertions.

It is also important to note the differences in clinical characteristics between the 2 groups. The NVM group had a significantly higher rate of hypertension, diabetes, and total number of comorbidities, which one can infer is attributed to the greater percentage of patients with morbid obesity. A significantly greater percentage of patients had morbid obesity in the NVM group, which, when combined with the knowledge of increased risk of airway obstruction associated with obesity, may explain why anesthesia providers were more likely to use the NVM on patients with higher BMIs.

The equal distribution of oxygen saturations at 90% or lower and oxygen desaturations of 5% or more of their baseline oxygen saturation in patients with an OSA diagnosis vs those without an OSA diagnosis can most likely be attributed to the high rate of undiagnosed OSA secondary to lack of appropriate screening. According to the American Academy of Sleep Medicine, approximately 12% of the American population has OSA, and undiagnosed OSA costs nearly $150 billion annually because

Comorbidity	Total (N = 100)	No NVM (n = 50)	NVM (n = 50)	*P* value
Hypertension	69 (69)	27 (54)	42 (84)	.001
Coronary artery disease	12 (12)	5 (10)	7 (14)	.538
Arrhythmia	21 (21)	13 (26)	8 (16)	.220
Hyperlipidemia	46 (46)	19 (38)	27 (54)	.108
Peripheral vascular disease	11 (11)	4 (8)	7 (14)	.338
Asthma	23 (23)	13 (26)	10 (20)	.476
Chronic obstructive pulmonary disease	16 (16)	8 (16)	8 (16)	> .999
Dyspnea on exertion	7 (7)	2 (4)	5 (10)	.436
Current tobacco use	10 (10)	3 (6)	7 (14)	.182
Cerebrovascular accident	5 (5)	1 (2)	4 (8)	.362
Headaches/migraines	13 (13)	6 (12)	7 (14)	.766
Neuropathy	23 (23)	9 (18)	14 (28)	.235
Anxiety	22 (22)	10 (20)	12 (24)	.629
Depression	33 (33)	14 (28)	19 (38)	.288
Psychological disorder[b]	9 (9)	2 (4)	7 (14)	.160
Thyroid disease[c]	16 (16)	5 (10)	11 (22)	.102
Diabetes	43 (43)	14 (28)	29 (58)	.002
Gastroesophageal reflux disease	61 (61)	30 (60)	31 (62)	.838
Irritable bowel syndrome[d]	12 (12)	9 (18)	3 (6)	.065
Anemia	17 (17)	5 (10)	12 (24)	.062
Chronic renal failure	11 (11)	3 (6)	8 (16)	.110
Nonalcoholic steatohepatitis	10 (10)	3 (6)	7 (14)	.182
Osteoarthritis	40 (40)	22 (44)	18 (36)	.414
Chronic pain	21 (21)	15 (30)	6 (12)	.027
Cancer	22 (22)	12 (24)	10 (20)	.629
Total comorbidities, mean (SD)	6.60 (3.20)	5.90 (2.96)	7.30 (3.31)	.028

Table 2. Patient Comorbidities[a]

[a]Data are No. (%) except for total comorbidities. For each comorbidity, a 2 × 2 χ^2 test or Fisher exact test was performed. Independent *t* test was used to test for group differences in mean total comorbidities.
[b]Schizophrenia, obsessive compulsive disorder, bipolar disorder, and/or posttraumatic stress disorder.
[c]Hyperthyroidism or hypothyroidism.
[d]Ulcerative colitis or terminal ileitis.

of lost productivity, motor vehicle accidents, workplace accidents, and increased healthcare costs.[23] These statistics emphasize that the absence of an OSA diagnosis does not indicate the absence of the sleep disorder and that providers must continue to diligently monitor patients receiving MAC for snoring, gasping, or choking during sedation—signs of OSA.

• ***Barriers to Implementation of Nasal Ventilation Mask.*** Although the NVM guideline was encouraged in this project, ultimately the decision to apply the NVM was that of the individual provider, who considered the appropriateness and necessity of the NVM for each patient on an individual basis. The staff CRNAs at the clinic work solely in this environment. They regularly manage and treat patients undergoing these procedures, and it is understandable that practice change can be difficult. The most common barrier to implementation reported by the anesthesia providers was that a patient's body habitus did not warrant use of the NVM. On further inquiry, providers reported that if the patient did not have a large neck circumference or was deemed to have an adequate thyromental distance, the device was not necessary to use since they believed it was more expensive and required longer setup time than for a nasal cannula. However, it is important to note that even though it seemed the device took longer to place on the patient than a nasal cannula, this represents an expected learning curve with a new device. The extended device application time may have discouraged anesthesia providers from using the device because it may have been perceived to slow down their turnover times and decrease their efficiency. Proper and repeated training opportunities are essential with the implementa-

Binary Outcome	No NVM (n = 50), No. (%)	NVM (n = 50), No. (%)	*P* value[a]	Cohen *d*[b]	Cohen *d* 95% CI
Intraprocedure outcomes					
Oxygen saturation ≤ 90%			.037	0.63	0.02 to 1.25
No occurrence	37 (74)	45 (90)			
≥ 1 occurrence	13 (26)	5 (10)			
Oxygen desaturation ≥ 5% of baseline oxygen saturation				.029	0.71
0.04 to 1.38					
No occurrence	38 (76)	46 (92)			
≥ 1 occurrence	12 (24)	4 (8)			
Pauses secondary to hypoxia			—[c]	—	—
No occurrence	49 (98)	50 (100)			
≥ 1 occurrence	1 (2)	0 (0)			
Airway maneuvers performed			.230	−0.27	−0.70 to +0.17
No occurrence	27 (54)	21 (42)			
≥ 1 occurrence	23 (46)	29 (58)			
Airway adjunct insertion			—	—	—
No occurrence	48 (96)	50 (100)			
≥ 1 occurrence	2 (4)	0 (0)			
Postprocedure outcome					
Oxygen saturation < 90%			—	—	—
No occurrence	49 (98)	47 (94)			
≥ 1 occurrence	1 (2)	3 (6)			

Table 3. Outcomes: Indicators of Airway Obstruction

Abbreviation: NVM, nasal ventilation mask.

[a]A 2 × 2 χ^2 test or Fisher exact test.

[b]Cohen *d* equivalent effect sizes: small effect = 0.20, medium = 0.50, and large = 0.80.

[c]Dash indicates no bivariate analysis was conducted because of very low frequency of outcome, defined as 1 or more occurrences, in both groups.

tion of any new device in attempts to facilitate acceptance and offset barriers to implementation.

• ***Study Limitations.*** A potential limitation of this QI project was that the individual provider made the ultimate decision to apply the NVM. The decision to use the device was partially based on an objective assessment (measurement of neck circumference and thyromental distance) that was conducted in a subjective fashion (visual inspection). Although this may be common practice in anesthesia, the absence of actual measurement removes the objectivity of the assessment. Hence, providers were not compliant with the objective guideline criteria that consisted of an OSA diagnosis, a BMI of at least 35 kg/m^2, or both. Additionally, the site chose to use BMI of 35 kg/m^2 or greater rather than 30 kg/m^2 or greater, which is the BMI parameter used by the Centers for Disease Control and Prevention to define obesity.[24]

Another limitation was a slight inconsistency in data collection. Although 90% of the data were collected by a primary observer, there were occasions when cases observed for this project were being performed simultaneously. In these situations, the data were reported by the anesthesia provider assigned to the case. The primary observer provided anesthesia providers with verbal instruction and a data collection demonstration using the data collection sheet.

Furthermore, individual providers were aware of the cases being evaluated, which may have influenced the degree to which airway interventions were carried out and whether the NVM was applied. Providers may have been concerned that colleagues would perceive that NVM application was the result of poor anesthetic management. Conversely, some providers may have been early adopters and frequently opted to place the NVM to test the new device.

Last, this initial QI assessment was limited by the sample size of 50 patients per group. A priori power calculation indicated a sample of size of 100 per group would be needed to achieve 80% power to test for group differences in the airway obstruction outcomes assuming a Cohen *d* medium effect size of 0.50. Although the effect size for intraprocedure oxygen saturation of 90%

or less and oxygen desaturation of 5% or more exceeded 0.50, low statistical power along with low event rates for several airway obstruction outcomes were major concerns. Thus, direction and magnitude of effect was the focus of this project.

• ***Compliance and Sustainability.*** The potential for sustainability of this QI project at the clinic is promising because of the nature of the device to provide noninvasive positive pressure pulmonary support during procedures. During the 4-week data collection period, 480 procedures were performed at the clinic, with 164 cases eligible for the NVM device. Because the decision of whether to apply the NVM was that of the individual provider, compliance during the project was 30.5%. Initially, the device negatively affected workflow, and barriers to implementation were noted after some anesthesia providers and gastroenterologists expressed concerns regarding prolonged turnover time. However, after repetitive use of the device, it was anecdotally reported that implementation became faster, and the value and benefits of the device were realized by all parties involved. As application time continues to decrease, NVM use may increase, leading to fewer oxygen desaturations, which could lead to fewer procedural interruptions and increased overall efficiency of the clinic.

• ***Cost Considerations.*** Although cost analysis was not an aim of the project, its consideration is noteworthy. The cost of an NVM is design dependent, ranging from $25 to $40, which exceeds the cost of a standard $ETCO_2$ nasal cannula, which can average $5.75.[25-28] However, as the findings of this study demonstrate, the airway adjunct needs of a patient at risk of airway obstruction often exceed that of an $ETCO_2$ nasal cannula, and use of an NVM in patients who warrant one can save the additional costs associated with respiratory compromise. A $0.79[29-31] to $3.69[32-34] oropharyngeal or nasopharyngeal airway, depending on the procedure, is frequently required to maintain airway patency. A face mask, averaging $1,[35-37] may often be used for transport and recovery in the postprocedural area, and in some situations, a $15.50[38-40] resuscitation bag may be necessary for intervention. Respiratory failure requiring ventilation had an estimated cost of $27,134 per incident,[41] demonstrating that the cost of respiratory compromise is exponential in comparison to that of a single NVM.

• ***Areas for Further Research.*** Evaluating the effectiveness of the NVM compared with the patient's OSA risk score and/or neck circumference may be beneficial to determine more objectively which patients would benefit from an NVM during a procedure requiring anesthetic sedation. Another area for further research is to measure and compare the amount of time patients spend in the postprocedural area between the 2 groups. If the NVM prevents periods of apnea and therefore prevents the patient from becoming increasingly hypercapnic while receiving sedation, one may infer that patients should recover more quickly from sedation when they wear an NVM. The NVM may also conserve facility resources when used for patients who fail to bring their CPAP or bilevel positive airway pressure device on the scheduled procedure day. A decrease in recovery times would, in turn, improve cost effectiveness and efficiency for the clinic.

Conclusion

Patients with obesity and OSA often require resources that offer safety features targeting the issues these patient populations face when a secured airway is unwarranted. Nasal ventilation masks are relatively novel, with a paucity of literature to demonstrate their effectiveness, yet their use shows promise for patients with obesity, an increasing population. This project demonstrates that the NVM offers not only supportive ventilation in sedated patients but also the ability to provide positive pressure assistive breaths.

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AUTHORS

Connor E. Willard, DNP, CRNA, was a student at Duke University School of Nursing, Durham, North Carolina, at the time of the writing of this article. Email: cewillard28@gmail.com.

Andi N. Rice, DNP, CRNA, is a consulting associate of the Nurse Anesthesia Program at Duke University School of Nursing. Email: andirice@gmail.com.

Marion E. Broome, PhD, RN, FAAN, is dean of the Duke University School of Nursing. Email: marion.broome@duke.edu.

Susan G. Silva, PhD, is an associate research professor in the Duke University School of Nursing. Email: susan.silva@duke.edu.

Virginia C. Muckler, DNP, CRNA, CHSE, is an associate clinical professor of nurse anesthesia at Duke University School of Nursing and a National League for Nursing simulation leader. Email: chris.muckler@duke.edu.

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