A Prospective, Randomized Trial Comparing the Use of High Flow Nasal Cannula, Standard Face Mask and Standard Nasal Cannula in Morbidly Obese Patients with High Risk of Obstructive Sleep Apnea Undergoing Colonoscopy

NCT03479905

Research Protocol

Document Date 10-12-2020

A Prospective, Randomized Trial Comparing the Use of High Flow Nasal Cannula, Standard Face Mask and Standard Nasal Cannula in Morbidly Obese Patients with High Risk of Obstructive Sleep Apnea Undergoing Colonoscopy

Institution/Funding Source: University of Texas Southwestern, Dallas, TX;
Departments of Anesthesiology and Pain Management

Principal Investigator: Christina Riccio, M.D.

1. Introduction and Purpose:

It is standard practice in the United States and many parts of world to perform Gastrointestinal (GI) endoscopy with the patient under deep intravenous sedation (1). Obesity is accepted as a patient specific risk factor for hypoxic events during procedural sedation for GI endoscopic procedures. The obese population has a higher prevalence of obstructive sleep apnea (OSA), which is characterized by repeated obstruction of the upper airway, and leads to apnea and desaturation. This prospective, randomized study was designed to compare the effectiveness of the high flow nasal cannula, standard nasal cannula and standard face mask in morbidly obese patients with a high risk of sleep apnea, (BMI ≥ 40, STOPBANG ≥5) receiving deep intravenous sedation during colonoscopies. This study will assess which method leads to a lower incidence of intraoperative desaturation events compared to the current standard of care.

Hypothesis 1- The High Flow Nasal Cannula (HFNC) group will have a significantly lower incidence of desaturation episodes (SpO2 <90) than both the standard nasal cannula group and face mask group during procedural sedation for colonoscopies.

Primary objective: To compare the rates of incidence and frequency of desaturation episodes during procedural sedation in *morbidly obese subjects with high likelihood of OSA* undergoing colonoscopies.

Hypothesis 2- The HFNC group will have a significantly lower frequency of desaturation episodes (SpO2 <90) than both the face mask and standard nasal cannula groups during procedural sedation for colonoscopies.

Secondary objective 1: To compare the number of interventions made by the anesthesia providers required to treat desaturation events during procedural sedation in *morbidly obese subjects with a high likelihood of OSA* undergoing colonoscopies.

Hypothesis 3- The HFNC group will require fewer interventions to treat hypoxic events than the standard nasal cannula and face mask groups during procedural sedation for colonoscopies.

Secondary objective 2: To determine the frequency of desaturation episodes and sedation-related adverse events during procedural sedation in *morbidly obese subjects with high likelihood of OSA*.

Hypothesis 4- Use of HFNC would decrease sedation-related adverse events in *morbidly obese subjects with a high likelihood of OSA*.

2. Background:

The prevalence of morbid obesity is increasing worldwide. As the severity of obesity increases, the incidence of diagnosed obstructive sleep apnea also rises. Studies have shown an incidence of sleep apnea as high as 64% in patients with a body mass index (BMI) over 40 and 100% in patients with a BMI greater than 60 (2). Patients with OSA have been shown to have significant desaturations under intravenous sedation due to airway narrowing and obstruction. Several studies have also shown that morbidly obese subjects, independent of a diagnosis of OSA, run a higher perioperative risk of adverse airway events, including hypoxia. Quadeer et al found a 51% overall incidence of desaturation below 90% in a prospective observational study with 79 patients undergoing endoscopy under "conscious sedation." They also found a significant difference in the frequency of desaturation events between obese (BMI > 30) and non-obese patients (3). Many morbidly obese subjects present to our institution for GI procedures under deep sedation. Data collected from our institution over the last six months revealed a 50% incidence of desaturation below 90% during colonoscopies under deep IV sedation in both the standard nasal cannula and HFNC at 40% FiO2 groups. Providing anesthesia for this patient population is challenging and requires careful titration of drugs and superb airway management skills.

The current standard of care for oxygen delivery in this setting is a Salter nasal cannula. Patel et al have been working with a transnasal high flow device (THRIVE) and have shown it to increase apnea times in patients with difficult airways post induction of general anesthesia (4). These patients received neuromuscular blockade and made no respiratory effort, however, the patency of their airway was maintained with a manual jaw thrust by anesthesia providers. They concluded that the device combines the benefits of apneic oxygenation with continuous positive airway pressure and gaseous exchange occurs through flow-dependent dead space flushing (5).

Humidified high flow nasal cannula (HFNC) oxygen therapy utilizes an air oxygen blend allowing from 21% to 100% FiO2 delivery and generates up to 60 L/min flow rates (6,7). The gas is heated (35 to 40 degree Celsius) and humidified through an active heated humidifier and delivered via a single limb heated inspiratory circuit (to avoid heat loss and condensation) to the subject through a large diameter nasal cannula (8, 9). Theoretically, HFNC offers significant advantages in oxygenation and ventilation over conventional methods (9). Constant high flow oxygen delivery provides steady inspired oxygen fraction (FiO2) and decreases oxygen dilution (10). It also washes out physiologic dead space and generates positive end expiration pressure (PEEP) that augments ventilation (10, 11). In the current narrative review, Sotello et al. summarized factors explained the improvement in respiratory parameters by using HFNC (12). (1) Washout of the nasopharyngeal dead space; (2) reduction in inspiratory resistance associated with gas flow through the nasopharynx; (3) improvement in respiratory mechanical parameters associated with gas temperature and state of humidification; (4) reduction in metabolic work associated with gas conditioning; (5) provision of mild distending pressure.

Some studies have demonstrated a positive effect of HFNC on the apnea-hypopnea index (AHI) showing that use of HFNC could decrease hypoxic episodes in subjects with repetitive upper airway obstruction such as obstructive sleep apnea. The STOP-BANG questionnaire (SB) has been used successfully to screen patients undergoing therapeutic endoscopic procedures at higher risk for sedation-related adverse events (13). Mehta et al (14) evaluated the prevalence of

undiagnosed OSA at their endoscopy center and the relationship between a positive SB result and sedation-related adverse events. They found that 48.5% (118/243) of patients were SB+ and exhibited a higher level of potentially adverse medical conditions, with 66.3% (161/243) being classified with an SB score of 3.

We are hypothesizing that the HFNC at a FiO2 of 100% at 60 L/min will help maintain a patent airway and improve gaseous exchange in morbidly obese (BMI ≥40) patients with SB scores ≥5 undergoing deep sedation for colonoscopies and will result in a significant decrease in intraoperative desaturation events, thus improving morbidity and overall safety for this population.

3. Concise Summary of Project:
The study population for this randomized prospective clinical trial will consist of male and female subjects, between the ages of 18-80, with a BMI of 40 or greater and a STOPBANG score ≥5 undergoing colonoscopies. Consent will be obtained by anesthesia providers involved in the study. OSA screening questionnaire (STOPBANG) will be completed during review of the patient's history and physical exam. Subjects will then be randomized in a stratified fashion to either the HFNC (Comfort Flo System) group, standard face mask group or the Salter cannula group. Then subjects will be brought into the procedure room and placed on all standard ASA monitors (BP cuff, EKG, pulse oximetry). Oxygen saturation will be measured at baseline (prior to the administration of any propofol or supplemental oxygen) and then continuously during procedural sedation.

HFNC group: A high flow nasal cannula will be placed on the patient at a setting of FiO2 100% and titrated up to 60L/min depending on patient tolerance. 60 L/min is the max flow rate and will be used as tolerated for maximum benefit.

Research intervention: The Comfort Flo system (Teleflex Medical, Research Triangle Park, NC, USA) will be used for high flow nasal cannula during colonoscopy. The Comfort Flo System has an air-O_2 blender setting and a FiO2 analyzer to confirm FiO2 delivered to the patient.

Control groups:
A Salter nasal cannula will be used at 4L/ minute during the colonoscopy. The FiO2 delivered to the patient at this rate has been shown to be equal to 36% (15).

Face mask group: A standard face mask will be used at 8L/minute during the colonoscopy. The FiO2 delivered to the patient at this rate has been shown to be equal to 60% (16).

The cannulas will be placed on the patients 5 minutes prior to the start of the anesthetic. All patients will receive a similar intravenous anesthetic with a propofol infusion titrated to a Richmond Agitation-Sedation Scale (RASS) score of 3-4. A lidocaine bolus of up to 100 mg can be used prior to the start of the propofol infusion for initial tolerance of the drug.

Patient saturation is recorded every minute during the anesthetic on the electronic medical record and is available for review. The frequency of all measurements at or below 90% will be recorded by the Electronic Medical Record (EMR). The anesthesia providers intervene when the patient's saturation falls below 90%, by either manually performing a jaw thrust, placing a nasal or oral

airway, bag mask ventilation, increasing the patients FiO2 or decreasing the rate/ pausing the propofol infusion or endotracheal intubation. They will be instructed to write a quick note at the time of intervention in the EMR reporting the lowest saturation witnessed and describing their maneuver. Duration of the study will be the length of the procedure through discharge from the Postoperative Anesthesia Care Unit (PACU).

Outcome Measures:

- Lowest recorded oxygen saturation
- The frequency of desaturation episodes (SpO2 <90%)
- Total dose of propofol for sedation during colonoscopy
- Anesthesiologist intervention (intubation, airway repositioning, chin lift)
- Type of airway used (oral airway, nasal airway, bag mask ventilation, suctioning)
- Premature termination of procedure
- Unplanned hospital admission

4. Study Procedures:

- OSA screening with the SB questionnaire: SB is made up of 8 yes or no questions (14). High risk of obstructive sleep apnea if yes to ≥5 questions; low risk of obstructive sleep apnea: yes to <5 questions.
- Randomizations to the high flow nasal cannula group, the face mask group or the Salter cannula group. Subjects will be randomized in a 1:1:1 ratio according to a computer generated randomization list provided by the study statistician.
- All standard monitoring (BP, EKG, and pulse oximeter) will be placed on all patients in the procedure room. Supplemental oxygen will be placed on the patients 5 minutes prior to the start of the anesthetic and set to rate of 4L/min for standard nasal cannula, 8L/min for the face mask group and 100% FiO2 up to 60 L/min for the HFNC group.
- Anesthesia achieved with a propofol infusion titrated to a RAS score of 3-4.
- All desaturation points at or below 90% recorded via intraoperative electronic charting (Epic).
- Frequency and method of intervention aimed at increasing the patient's saturation by the provider will be recorded on the EMR at the time of intervention with a quick note.

5. Sub-Study Procedures:

N/A

6. Criteria for Inclusion of Subjects:

- Age between 18-80
- Subjects undergoing colonoscopies
- Morbidly obese BMI ≥ 40
- STOPBANG score ≥5

7. Criteria for Exclusion of Subjects:

- Subjects deemed hemodynamically unstable by the anesthesia team
- Subjects who are an aspiration risk and will require endotracheal intubation.
- Pregnancy
- Subjects with an allergy to propofol
- Patients who are unable to tolerate the high flow nasal cannula secondary to discomfort

- Subjects unwilling to sign consent
- Patients that received medications other than lidocaine and propofol

8. Sources of Research Material:

- Subjects undergoing colonoscopy
- Electronic Medical Record
- Anesthesia Reports
- PHI including name, medical record number, contact information including demographic information including age, gender, race, birth date, weight, height, BMI and medical and surgical history, medication list, ASA classification.
- **Procedural sedation-related variables**: propofol dose, propofol infusion time, opioid use, any other combination agent for the procedural sedation during colonoscopy, Procedure time, premature termination of procedure.
- **Respiratory event-related variables**; Anesthesiologist intervention (intubation, airway repositioning, Chin lift); Type of airway used (oral airway, nasal airway, bag mask ventilation, suctioning), Laryngospasm or any other airway obstruction; pulse oximetry reading, the number and duration of apnea/hypoxia episodes.
- **Hemodynamic variables** such as baseline blood pressure
- **Postoperative Recovery:** Aldrete score in recovery, the time spend in PACU
- Unplanned hospital admission
- Stop Bang questionnaire for OSA screening

9. Recruitment Methods and Consenting Process:

All patient recruitment will take place in the GI endoscopy suite. Subject will be identified by reviewing daily endoscopy schedule. A designated team of anesthesiologists and nurse anesthetists involved in the study will be responsible for screening, consenting and enrolling potential subjects. The patient's chart will be reviewed to determine eligibility with the use of a HIPAA waiver form. Information about the study will be given in a pressure-free, confidential private area in a face-to-face meeting and the voluntary nature of the research will be emphasized to the subjects.

The purpose of the study and risks and potential complications of the study will be explained. Adequate time will be given to read consent form to consider whether or not participate in the study. All questions will be answered before the patient is asked to sign the consent form. If the patient agrees to participate, then he or she will sign the consent form and HIPAA Authorization Form prior to any study procedures.

10. Potential Risks:

This study has minimal risk. The anesthetic management in each group will not differ from the current standard of care.

Risk for HFNC*:*

HFNC systems deliver heated, humidified gas which may protect airway mucosa.

HFNC may produce distending pressure in the lung, similar to CPAP pressures. There may be potentially unpredictable pressures generated by HFNC which may be significant in pediatric but

not the adult obese population. Mild distending pressure may provide better patent airway in obese subjects. Flow rate of HFNC will be adjusted for maximum benefit to the subject (40-60 L/minutes). The unpredictable distending pressure may cause opening of the narrowed airway or cause raptures of small airways.

Psychological Stress: Some of the questions related to the study may make the subject feel uncomfortable. Subjects may refuse to answer any of the questions, or take a break or stop participation in the study at any time.

Loss of Confidentiality: Any time information is collected; there is a potential risk of loss of confidentiality. Every effort will be made to keep your information confidential.

11. Subject Safety and Data Monitoring:
Investigators will ensure patient safety throughout the procedure. This will include following all standards of care with regard to conducting a safe anesthetic in the endoscopy suite. All standard ASA monitors will be used, adequate O2 delivery will be ensured and the proper interventions by the providers will be carried out during significant desaturation episodes. Subjects will recover from the anesthetic in the endoscopy suite recovery room. All data will be collected by the EMR as per usual (EPIC).

The study PI is responsible for the subject`s safety and data integrity.

12. Procedures to Maintain Confidentiality:
All participants will be given an identification number such that identifiable, personal information will not be used. Every effort will be made to keep all data collection sheets confidential and any electronic data sets will be password protected and secure. Electronic documents will be de-identified according to information security policies. Paper documents will be shredded.

13. Potential Benefits:
There is no benefit to subjects. Use of the Comfort Flo high flow nasal cannula may lead to a significant decrease in hypoxic events in morbidly obese, likely sleep apneic, patients undergoing deep sedation for colonoscopies. Also, use of a face mask with higher flow rates than the standard of care may also lead to a significant decrease in hypoxic events in this population. Information gained from this study will increase patient safety and decrease the morbidity and possibly, mortality, in this challenging patient population.

14. Biostatistics:
Data collected from our institution over the last six months revealed a 50% incidence of desaturation below 90% during colonoscopies under deep IV sedation in both the standard nasal cannula group. The study is powered to detect a 50% reduction in the frequency of desaturation episodes in patients with FM and a 60% reduction in patients with HFNC compared to patients using a standard nasal cannula. The study would require a sample of 68 subjects per group to detect a difference between 25% desaturation rate in the FM group and 50% desaturation rate in the standard nasal cannula group with 80% power and a type 1 error rate of 0.025 using a chi-square test with unpooled variance. With n = 68/group, the study would have 94% power to detect a difference of 30% (20% desaturation rate in HFNC versus 50% desaturation rate in standard nasal

cannula group, type 1 error rate = 0.025). Assuming a 5% non-completion for various reasons, the study will enroll 72 subjects per group resulting in total enrollment of 216 subjects.

Continuous data will be summarized using means and standard deviations and categorical data will be summarized using frequencies and percentages. The two co-primary comparisons of proportions of desaturation episodes below 90% in subjects in the face mask and in the HFNC groups with that for subjects in the standard nasal cannula group will be done using Z tests with unpooled variance. Each of the two primary comparisons will be done with a type 1 error rate of 0.025 to maintain the study-wise error rate at 0.05. A two-sided interim analysis comparing desaturation rates in the HFNC and standard nasal cannula groups for futility or early stopping of enrollment will be done after 50% enrollment using O'Brien-Fleming method for Lan and Demet's alpha-spending function.

Mean numbers of desaturation episodes and interventions needed to treat hypoxic events will be compared using Student's t-tests or Wilcoxon-Mann-Whitney tests. Frequencies of sedation-related adverse events will be compared using chi-square tests or Fisher's exact tests. Normality of the sample data will be assed using normal quantile plots. Level of significance will be set at 0.05 and Bonferroni corrections will be made for all primary hypotheses tests.

15. References:

1- Cong Y & Sun X: Mask adaptor—a novel method of positive pressure ventilation during propofol deep sedation for upper GI endoscopy. Gastrointestinal Endoscopy, 68(1), 2008, 127-131.
2. Goudra BG, Singh PM, Penugonda LC, et al. Significantly reduced hypoxemic events in morbidly obese patients undergoing gastrointestinal endoscopy: Predictors and practice effect. J Anaesthesiol Clin Pharmacol. 2014; 30(1): 71–77. doi: 10.4103/0970-9185.125707
3. Qadeer MA, Rocio Lopez A, Dumot JA, Vargo JJ. Risk factors for hypoxemia during ambulatory gastrointestinal endoscopy in ASA I-II patients. Dig Dis Sci. 2009; 54: 1035–40.
4- Patel A, Nouraei S.A. Nasal Ventilation: Oxygenation, No DESAT, and THRIVE. Review Article. Aug 8, 2016. Anesthesiology News.
5. Patel A. Transnasal Humidified Rapid-Insufflation Ventilatory Exchange (THRIVE): a physiological method of increasing apnea time in patients with difficult airways. Anesthesia. 2015; 70(3): 323-329.
6. Gotera C, et al. "Clinical evidence on high flow oxygen therapy and active humidification in adults." Rev. Port. Pneumol., 19 (5) (2013), pp. 217–227
7. Spoletini G, et al. Heated humidified high-flow nasal oxygen in adults: mechanisms of action and clinical implications CHEST J., 148 (1) (2015), pp. 253–261
8. Ricard J.D. High flow nasal oxygen in acute respiratory failure. Minerva Anestesiol., 78 (7) 2012, 836–841
9. Lee CC, Mankodi D, Shaharyar S et al. High flow nasal cannula versus conventional oxygen therapy and non-invasive ventilation in adults with acute hypoxemic respiratory failure: A systematic review Respiratory Medicine, Volume 121, 2016, 100-108
10. Ritchie JE et al. Evaluation of a humidified nasal high-flow oxygen system, using oxygraphy, capnography and measurement of upper airway pressures. Anaesth. Intensive Care, 39 (6) (2011), p. 1103

11. Groves N, Tobin A. High flow nasal oxygen generates positive airway pressure in adult volunteers. Aust. Crit. Care, 20 (4) (2007), pp. 126–131
12. Sotello D, Rivas M, Mulkey Z, Nugent K. High-Flow Nasal Cannula Oxygen in Adult Patients: A Narrative Review. Review Article. The American Journal of the Medical Sciences, 349(2), 2015, 179-*185*
13. Chung F, Elsaid H: Screening for obstructive sleep apnea before surgery: why is it important? Current Opinion in Anesthesiology: 2009; 22(3): 405–411.
14. Mehta PP, Kochhar G, Kalra S et al. Can a validated sleep apnea scoring system predict cardiopulmonary events using propofol sedation for routine EGD or colonoscopy? A prospective cohort study. Gastrointestinal Endoscopy, 2014; 79(3): 436-444.
15. Manley BJ, Owen LS, Doyle LW, Andersen CC et al. High-Flow Nasal Cannulae in Very Preterm Infants after Extubation. N Engl J Med 2013; 369:1425-1433.
16. John F Nunn. Applied Respiratory Physiology. 3rd edition. Butterworths, 1987.

A Prospective, Randomized Trial Comparing the Use of High Flow Nasal Cannula, Standard Face Mask and Standard Nasal Cannula in Morbidly Obese Patients with High Risk of Obstructive Sleep Apnea Undergoing Colonoscopy

NCT03479905

Informed Consent Form (English)

Document Date 3/12/2018

The University of Texas Southwestern Medical Center
Parkland Health & Hospital System
Children's Medical Center
Retina Foundation of the Southwest
Texas Scottish Rite Hospital for Children
Texas Health Presbyterian Hospital Dallas

CONSENT TO PARTICIPATE IN RESEARCH

Title of Research: **A Prospective, Randomized Trial Comparing the Use of High Flow Nasal Cannula, Standard Face Mask and Standard Nasal Cannula in Morbidly Obese Patients with High Risk of Obstructive Sleep Apnea Undergoing Colonoscopy**

Funding Agency/Sponsor: Department of Anesthesiology and Pain Management, UT Southwestern Medical Center

Study Principle Investigator: Christina Riccio, MD.

You may call these study doctors or research personnel during regular office hours at [469-419-8446]. At other times, you may call them at any time at 214-786-3541.

Instructions:
Please read this consent form carefully and take your time making a decision about whether to participate. Taking part is voluntary. As the researchers discuss this consent form with you, please ask him/her to explain any words or information that you do not clearly understand. The purpose of the study, risks, inconveniences, discomforts, and other important information about the study are listed below. If you chose to take part in this study, you will sign this consent form. You will be given a copy to keep for your records.

Why is this study being done?
Obesity may cause a decrease in blood oxygen levels due to narrowing or closure of the airway during sleep (Obstructive Sleep apnea). This study is being done to find out whether the High Flow Nasal Cannula (Comfort Flo) can provide better oxygen supply to you compared to a standard face mask and a standard Salter nasal cannula during sleep (anesthesia sedation) for a colonoscopy.

The following definitions may help you understand this study:
- Randomization means you will be placed by chance (like drawing straws) into one of the three study groups, Salter nasal cannula, standard face mask or the High Flow Nasal Cannula (Comfort Flo).
- Researchers means the study doctor and research personnel at the University of

Texas Southwestern Medical Center at Dallas and its affiliated hospitals.

- Standard medical care means the regular care you would receive from your personal doctor if you choose not to participate in this research.
- Body mass index (BMI) is a measure of body fat based on your weight in relation to your height. BMI of 40 and above is accepted as extremely high.

Why am I being asked to take part in this research study?

You are being asked to take part in this study because you have a high risk of obstructive sleep apnea due to your high BMI and you will receive deep intravenous (via your vein) sedation for your colonoscopy.

Do I have to take part in this research study?

No. You have the right to choose whether you want to take part in this research study. If you decide to participate and later change your mind, you are free to stop participation at any time. If you decide not to take part in this research study it will not change your legal rights or the quality of health care that you receive at this center.

How many people will take part in this study?

About 216 people will take part in this study at Parkland Health Hospital System.

What is involved in the study?

If you agree to be in this study, you will be asked to sign this consent form. Once the researchers determine you can take part in this study, the following procedures will be take place:

<u>Procedures and Evaluations during the Research</u>:

- You will be randomly assigned to the High Flow Nasal cannula (The Comfort Flo nasal cannula), standard face mask or standard Salter Cannula group.

- You will fill out a short questionnaire (STOPBANG questionnaire) with 8 'Yes' or 'No' questions to evaluate your risk for narrowing or closure of your airway during sleep (obstructive sleep apnea) which is common in obesity. This will take approximately 3 minutes. The STOPBANG questionnaire will be used to determine your eligibility to participate in this study. If you are not eligible, you will be treated with nasal cannula or face mask as standard of care.

- A nasal cannula will be placed in your nostrils. The standard Salter nasal cannula is smaller than the Comfort Flo nasal cannula. It will deliver oxygen to you at a rate of 4 liter in a minute. It is not humidified and it will feel dry and cold.

  The Comfort Flo nasal cannula is slightly larger than the standard cannula and is placed in your nose the same way. It will deliver oxygen to you at 40-60 liters per minute and it can feel much stronger than the standard cannula. It is humidified, however, and it will feel warm and wet.
- If you are assigned to the standard face mask group, a standard plastic face

mask will be used to deliver oxygen to you during your colonoscopy. The face mask will deliver oxygen to you at a rate of 8 liters per minute. It is not humidified and it will feel dry and cold.

- The investigator will collect information regarding your health status, agents used for sedation (sleep), colonoscopy duration, type of airway used, and any airway difficulties during your colonoscopy, blood oxygen levels, recovery condition, and time spent in the recovery unit after your colonoscopy. This information will be collected by reviewing your medical record.

How long can I expect to be in this study?
You will be in this study during your colonoscopy and recovery after your procedure in the Postoperative Anesthesia Care Unit. You can choose to stop participating in this study for any reason at any time. However, if you decide to stop participating in the study, we encourage you to tell the researchers.

What are the risks of the study?
There is minimal risk to subjects by participating in this study. Regardless of participating in this research, you will receive oxygen via a nasal cannula. The anesthetic management in either group will not differ from the current standard of care. You will still receive a general anesthetic medication in your vein for your colonoscopy as is done in most endoscopy centers.

Risk for High Flow Nasal Cannula:
There may be minimal risk for injury in the surface lining of the airways (mucosa) . This risk is not higher than the standard nasal cannula because the Comfort Flo nasal cannula delivers heated, humidified gas.

The Comfort Flo nasal cannula may produce distending pressure in the lung, similar to continuous positive airway pressure which is known as CPAP. There may be potentially unpredictable pressures generated by the Comfort Flo nasal cannula which may be significant in children but not adults. The unpredictable distending pressure may cause opening of the narrowed airway or cause raptures of small airways. The flow rate of Comfort Flo nasal cannula will be adjusted for your maximum benefit.

Loss of Confidentiality
Any time information is collected; there is a potential risk of loss of confidentiality. Every effort will be made to keep your information confidential; however, this cannot be guaranteed.

Psychological Stress
Some of the questions related to the study may make the subject feel uncomfortable. You may refuse to answer any of the questions, or take a break or stop participation in the study at any time.

Other Risks
There may possibly be other side effects that are unknown at this time. If you are concerned about other, unknown side effects, please discuss this with the researchers.

How will risks be minimized or prevented?
Your blood pressure, heart rate, oxygen levels and level of sedation will be continuously monitored during the colonoscopy by an experienced anesthesia provider. Potential risks and discomforts will be minimized to the greatest extent possible and on any evidence of an adverse event, the study protocol will be aborted and you will be withdrawn from the study.

What are the possible benefits of this study?
If you agree to take part in this study, there will not be direct benefits to you. This study is intended to evaluate if the Comfort Flo nasal cannula system provides better oxygen supply to you during your colonoscopy.

What options are available if I decide not to take part in this research study?
You do not have to participate in this research to receive care for your medical problem. Instead of being in this study, you have the following options:

- Oxygen can be delivered during your colonoscopy with a Salter nasal cannula or standard face mask.

Please talk to the researchers or your personal doctor about these options.

Will I be paid if I take part in this research study?
No. You will not be paid to take part in this research study. There are no funds available to pay for parking expenses, transportation to and from the research center, lost time away from work and other activities, lost wages, or child care expenses.

Will my insurance provider or I be charged for the costs of any part of this research study?
No. Neither you, nor your insurance provider, will be charged for anything done only for this research study (i.e., the Screening Procedures, Experimental Procedures, or Monitoring/Follow-up Procedures described above).

However, the standard medical care for your condition (care you would have received whether or not you were in this study) is your responsibility (or the responsibility of your insurance provider or governmental program). You will be charged, in the standard manner, for any procedures performed for your standard medical care.

What will happen if I am harmed as a result of taking part in this study?
It is important that you report any illness or injury to the research team listed at the top of this form immediately. Compensation for an injury resulting from your participation in this research is not available from the University of Texas Southwestern Medical Center

at Dallas or Parkland Health and Hospital System. You retain your legal rights during your participation in this research.

Can I stop taking part in this research study?
Yes. If you decide to participate and later change your mind, you are free to stop taking part in the research study at any time.
If you decide to stop taking part in this research study, it will not affect your relationship with the UT Southwestern staff or doctors. Whether you participate or not will have no effect on your legal rights or the quality of your health care.

If you are a medical student, fellow, faculty, or staff at the Medical Center, your status will not be affected in any way. Your doctor is a research investigator in this study. S/he is interested in both your medical care and the conduct of this research study. At any time, you may discuss your care with another doctor who is not part of this research study. You do not have to take part in any research study offered by your doctor.

Will my information be kept confidential?
Medical information collected during this study and the results of any test or procedure that may affect your medical care may be included in your medical record. The information included in your medical record will be available to health care providers and authorized persons including your insurance company.

You should know that certain organizations that may look at and/or copy your medical records for research, quality assurance, and data analysis include:

- Representatives of government agencies, like the Food and Drug Administration (FDA), involved in keeping research safe for people, and
- The UT Southwestern Institutional Review Board.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

In addition to this consent form, you will be asked to sign an "Authorization for Use and Disclosure of Protected Health Information." This authorization will give more details about how your information will be used for this research study, and who may see and/or get copies of your information.

Whom do I call if I have questions or problems?
For questions about the study, contact **Dr. Christina Riccio** at 469-419-8446 during regular business hours and at any time at 214-786-3541.

For questions about your rights as a research participant, contact the UT Southwestern Institutional Review Board (IRB) Office at 214-648-3060.

SIGNATURES:

YOU WILL BE GIVEN A COPY OF THIS CONSENT FORM TO KEEP.

Your signature below certifies the following:

- You have read (or been read) the information provided above.
- You have received answers to all of your questions and have been told who to call if you have any more questions.
- You have freely decided to participate in this research.
- You understand that you are not giving up any of your legal rights.
- You understand that a copy of this signed consent document, information about this study, and the results of any test or procedure that may affect your medical care, may be included in your medical record. The information included in your medical record will be available to your health care providers and other authorized persons including your insurance company.

_____

Name of Participant (Printed)

_____ _____ _____ AM / PM

Signature of Participant Date Time

_____

Name of Person Obtaining Consent (Printed)

_____ _____ _____ AM / PM

Signature of Person Obtaining Consent Date Time

A Prospective, Randomized Trial Comparing the Use of High Flow Nasal Cannula, Standard Face Mask and Standard Nasal Cannula in Morbidly Obese Patients with High Risk of Obstructive Sleep Apnea Undergoing Colonoscopy

NCT03479905

Informed Consent Form (Spanish)

Date 3/12/2018

The University of Texas Southwestern Medical Center
Parkland Health & Hospital System
Children's Medical Center
Retina Foundation of the Southwest
Texas Scottish Rite Hospital for Children
Texas Health Presbyterian Hospital Dallas

DECLARACIÓN DE CONSENTIMIENTO INFORMADO PARA PARTICIPACIÓN EN UNA INVESTIGACIÓN MÉDICA

Título de la Investigación:	**Ensayo futuro, aleatorio, que compara el uso de cánulas nasales de alto flujo, mascarillas estándares y cánulas nasales estándares en pacientes con obesidad mórbida en alto riesgo de apnea obstructiva del sueño durante una colonoscopía**
Agencia Patrocinadora:	Departamento de Anestesiología y Manejo del Dolor, UT Southwestern Medical Center
Médicos Encargados del Estudio:	Christina Riccio MD.

Usted puede comunicarse con los médicos o personal encargado de la investigación, llamando durante horas regulares de oficina al [469-419-8446]. Fuera de las horas regulares de oficina, puede comunicarse con ellos al [214-786-3541].

Instrucciones:
Por favor lea cuidadosamente este formulario de consentimiento y tome su tiempo para decidir si desea participar en el estudio. Cuando los investigadores conversen con usted sobre este formulario, pídales que le expliquen cualquier palabra o información que no comprenda con claridad. A continuación encontrará el propósito, riesgos, inconvenientes, molestias y demás información importante relacionada con el estudio. Si decide participar, le proporcionaremos una copia de este formulario para sus archivos.

¿Por qué están realizando este estudio?

La obesidad puede provocar una disminución de los niveles de oxígeno en la sangre debido al estrechamiento o cierre de las vías respiratorias durante el sueño (apnea obstructiva del sueño). Estamos realizando este estudio para determinar si la cánula nasal de alto flujo (Comfort Flo) puede mejorar el suministro de oxígeno en comparación con una mascarilla estándar y una cánula nasal Salter estándar durante el sueño (sedación por anestesia) para la colonoscopía.

Las siguientes definiciones pueden ayudarlo a comprender mejor este estudio:

- Aleatoriedad significa que se asignará al participante indistintamente (al azar, como si se lanzara una moneda al aire) a cualquiera de los grupos de estudio: con la cánula nasal Salter o con la cánula nasal de alto flujo (Comfort Flo).

- Investigadores se refiere a los médicos encargados del estudio y el personal en University of Texas Southwestern Medical Center en Dallas y sus hospitals afiliados.
- Asistencia médica regular se refiere al cuidado que recibiría usted normalmente a través de su médico de cabecera si decidiera no participar en esta investigación.
- El índice de masa corporal (BMI, por sus siglas en inglés) es una medición de la grasa corporal que se basa en el peso con relación a la estatura. Un BMI de 40 o superior se considera sumamente alto.

¿Por qué me han pedido que participe en esta investigación?
Se le ha pedido que participe en este estudio porque tiene un alto riesgo de apnea obstructiva del sueño debido a su alto índice de masa corporal, y recibirá sedación profunda por vía intravenosa (a través de una vena) para la colonoscopía.

¿Tengo que participar en este estudio de investigación?
No, usted tiene derecho a decidir si desea o no participar en este estudio de investigación. Si decide hacerlo y posteriormente cambia de opinión, estará en libertad de suspender su participación en cualquier momento que desee. Si por el contrario decide no participar en este estudio de investigación, sepa que su decisión no cambiará sus derechos legales ni la calidad de asistencia médica que reciba en este centro.

¿Cuántas personas participarán en este estudio?
Participarán aproximadamente unas 216 personas en este estudio que se realizara en Parkland Health & Hospital System.

¿Qué pasos involucra este estudio?
Si acepta participar en este estudio, se le pedirá que firme este formulario de consentimiento. Una vez que los investigadores determinen que puede usted participar en este estudio, se levarán a cabo los siguientes procedimientos:

Procedimientos y evaluaciones durante la investigación:

- Se le asignará al azar al grupo de cánula nasal de alto flujo (la cánula nasal Comfort Flo), al grupo de mascarilla estándar o al grupo de cánula Salter estándar.

- Debe completar un breve cuestionario (cuestionario STOPBANG) de 8 preguntas con “Sí” o “No” para evaluar su riesgo de un estrechamiento o cierre de las vías respiratorias durante el sueño (apnea obstructiva del sueño), que es frecuente en pacientes con obesidad. Esto tomará aproximadamente 3 minutos. El cuestionario STOPBANG se utilizará a fin de determinar su elegibilidad para participar en este estudio. Si usted no es elegible, se le dará tratamiento con una cánula nasal o una mascarilla de acuerdo con las normas estándar de atención.

- Se le colocará una cánula nasal en las fosas nasales. La cánula nasal Salter estándar es más pequeña que la cánula nasal Comfort Flo. Le suministrará oxígeno a razón de 4 litros por minuto. No está humidificada y sentirá frío y resequedad.

La cánula nasal Comfort Flo es ligeramente más grande que la cánula nasal estándar, y se coloca en la nariz de la misma manera. Le suministrará oxígeno a razón de 40 a 60 litros por

minuto, y sentirá una presión de aire mucho más intensa que con la cánula estándar. Sin embargo, está humidificada, y sentirá humedad y calor.

- Si se le asigna al grupo de la mascarilla estándar, se utilizará una mascarilla de plástico estándar para suministrarle oxígeno durante la colonoscopía. Esta mascarilla le suministrará oxígeno a razón de 8 litros por minuto. No está humidificada y usted la sentirá seca y fría.

- El investigador recopilará información acerca de su estado de salud, sustancias utilizadas para sedación (sueño), duración de la colonoscopia, tipo de vía respiratoria que se utiliza, dificultades respiratorias (si las hubiera) durante la colonoscopia, presión arterial, nivel de oxígeno en sangre, estado de recuperación y tiempo en la sala de recuperación después de la colonoscopia. Esta información se recopilará mediante la revisión de su expediente médico.

¿Cuánto durará mi participación en este estudio?
Participará en este estudio durante la colonoscopia y la recuperación de la colonoscopia en la Unidad de Atención Posoperatoria con Anestesia. Usted puede elegir dejar de participar en este estudio por cualquier motivo y en cualquier momento. Sin embargo, si decide dejar de participar en el estudio, le recomendamos que se lo informe a los investigadores.

¿Cuáles son los riesgos involucrados en este estudio?
Hay un riesgo mínimo para los sujetos que participan en este estudio. Independientemente de que participe o no en el estudio, recibirá oxígeno a través de una cánula nasal. La administración de anestesia en ambos grupos será igual a la atención estándar actual.
Recibirá medicamento de anestesia por vía intravenosa para la colonoscopia, como suele hacerse en casi todos los centros de endoscopia.

<u>Riesgo para la cánula nasal de alto flujo</u>
Existe un riesgo mínimo de sufrir lesiones en el revestimiento externo de las vías respiratorias (mucosa). Este riesgo no es mayor que el de la cánula nasal estándar porque la cánula nasal Comfort Flo administra gas calentado y humidificado.

La cánula nasal Comfort Flo puede producir presión de distensión en los pulmones, similar a la presión positiva continua de las vías respiratorias (CPAP, por sus siglas en inglés). Podría haber presiones potencialmente impredecibles generadas por la cánula nasal Comfort Flo, que pueden ser considerables en niños, pero no en adultos. La impredecible presión de distensión podría causar la apertura de la vía respiratoria estrechada u ocasionar rupturas en las vías respiratorias pequeñas. La velocidad de flujo de la cánula nasal Comfort Flo se ajustará para brindarle el máximo beneficio.

<u>Pérdida de Confidencialidad</u>
En cualquier momento se recopila información; Existe un riesgo potencial de pérdida de confidencialidad. Se hará todo lo posible para mantener su información confidencial; Sin embargo, esto no puede ser garantizado.

<u>Estrés Psicológico</u>
Algunas de las preguntas relacionadas con el estudio pueden hacer que el sujeto se sienta incómodo. Usted puede negarse a contestar cualquiera de las preguntas, o hacer una pausa o

dejar de participar en el estudio en cualquier momento.

Otros Riesgos
Puede haber otros efectos secundarios que se desconocen en este momento. Si le preocupan otros efectos secundarios desconocidos, por favor hable con los investigadores.

¿Cómo se minimizan o evitan riesgos?
Durante la colonoscopía, un anestesista experimentado estará monitorizando constantemente su presión arterial, frecuencia cardíaca, niveles de oxígeno y nivel de sedación. Los riesgos y molestias potenciales se minimizarán en la mayor medida posible y, si hay evidencia de un suceso adverso, se cancelará el protocolo del estudio y se le retirará a usted del estudio.

¿Cuáles son los posibles beneficios de este estudio?
Si acepta participar en este estudio, no habrá beneficios directos para usted. Este estudio tiene el propósito de evaluar si el sistema de la cánula nasal Comfort Flo le proporciona mejor suministro de oxígeno a usted durante la colonoscopia.

¿Cuáles son mis opciones si decido no participar en este estudio de investigación?
Usted no tiene que participar en esta investigación para recibir atención médica para su problema. En lugar de estar en este estudio, tiene las siguientes opciones:

- Durante la colonoscopía, se le puede suministrar oxígeno por medio de una cánula nasal Salter o una mascarilla estándar.

  Hable con los investigadores o con su médico personal sobre estas opciones.

¿Me pagarán si participo en este estudio de investigación?
No hay fondos disponibles para cubrir gastos de estacionamiento, traslado de ida y vuelta al centro de investigaciones ni para cubrir horas de trabajo u otras actividades perdidas así como salarios no recibidos o gastos por el cuidado de niños.

¿Le cobrarán a mi compañía de seguros o a mí por alguna parte de este estudio de investigación?
No. Ni usted, ni su proveedor de seguros, se le cobrará por cualquier cosa hecha sólo para este estudio de investigación (es decir, los procedimientos de detección, Procedimientos experimentales, o un control / seguimiento de los procedimientos descritos anteriormente).

Sin embargo, la atención médica estándar para su condición (sin importar que hubiera recibido está o no estuviera en este estudio) es su responsabilidad (o la responsabilidad de su proveedor de seguros o programa gubernamental). Se le cobrará, de la manera estándar, por cualquier procedimiento realizado por su atención médica estándar.

¿Qué sucede si me lesiono al participar en este estudio?
Es importante que informe de cualquier enfermedad o lesión al equipo de investigación que aparece en la parte superior de este formulario inmediatamente. No habrá compensación disponible para lesiones sufridas al participar en esta investigación, por parte de The University of Texas Southwestern Medical Center at Dallas ni Parkland Health & Hospital System.

Usted conserva sus derechos legales durante su participación en esta investigación.

Puedo dejar de ser parte de este estudio de investigación?
Sí. Si decide participar y luego cambia de opinión, usted es libre de dejar de participar en el estudio de investigación en cualquier momento.

Si decide dejar de tomar parte en este estudio de investigación, no afectará a su relación con el personal de UT Southwestern o médicos. Ya sea que participe o no tendrá ningún efecto sobre sus derechos legales o la calidad de su atención médica.

Si usted es un estudiante de medicina, compañeros, profesores o personal del Centro Médico, su estado no se verá afectado de ninguna manera.

Su médico es un investigador de la investigación en este estudio. Ei/ella está interesado tanto en su atención médica y la realización de este estudio de investigación. En cualquier momento, usted puede discutir su tratamiento con otro médico que no es parte de este estudio de investigación. Usted no tiene que participar en cualquier estudio de investigación ofrecida por su médico.

¿Se resguardará la confidencialidad de mi información?
Podríamos incluir, en su registro médico, la información recaudada durante este estudio así como los resultados de cualquier examen o procedimiento realizado, lo cual pueda afectar la asistencia médica que usted reciba. La información incluida quedará a disposición de los proveedores médicos y personal autorizado, incluyendo a su compañía de seguro.

Como sabrá, entre las organizaciones que pueden mirar o fotocopiar su historial médico para propósitos de investigación, control de calidad y análisis de datos se incluyen:

- Representantes de agencias gubernamentales como the US Food and Drug Administration o FDA, interesadas en mantener la seguridad de la investigación médica para los participantes, y
- UT Southwestern Institutional Review Board (Junta de Revisión Institucional)

Según lo requerido por la ley, habrá una descripción de esta investigación en la Internet, en el http://www.ClinicalTrials.gov. Esta página web no incluye, sin embargo, información que pueda identificar a los participantes. A lo sumo, incluye un resumen de los resultados obtenidos. Usted puede visitar esta página web en cualquier momento que desee.

Además de este formulario, se le pedirá que firme la “Autorización para el Uso y Divulgación de Información Médica Protegida” o "Authorization for Use and Disclosure of Protected Health Information", como se le conoce en inglés. Esta autorización le proporcionará más detalles sobre cómo se utilizará su información para este estudio y quiénes pueden mirar o fotocopiar la misma.

¿A quién debo llamar si tengo dudas, preguntas o algún problema?
Si usted tiene dudas o preguntas sobre el estudio, comuníquese con la Dra. Christina Riccio al 469-419-8446 durante horas regulares de oficina y al 214-786-3541 después de horas de

oficina, durante los fines de semana y días festivos.

Para preguntas sobre sus derechos como participante en esta investigación, comuníquese con la oficina de The UT Southwestern Institutional Review Board (IRB) al 214-648-3060

FIRMAS:

LE ENTREGAREMOS UNA COPIA DE ESTE FORMULARIO DE CONSENTIMIENTO PARA SUS ARCHIVOS.

Su firma a continuación certifica lo siguiente:

- Ha leído (o le han leído) la información suministrada arriba.
- Ha recibido las respuestas a todas sus preguntas y le han dicho a quién llamar en caso de que tenga alguna pregunta más.
- Ha decidido de su propia voluntad participar en esta investigación.
- Entiende que no está renunciando a ninguno de sus derechos legales.
- Usted entiende que existe la posibilidad de que en su historial médico se incluyan una copia firmada de este consentimiento, información sobre este estudio y los resultados de cualquier prueba o procedimiento realizado, lo cual podría afectar su asistencia médica. La información incluida en su historial médico estará a la disposición de los proveedores de atención médica y a las personas autorizadas, incluso a su compañía de seguro médico.

_____

Nombre del Participante
(escrito en letra de molde)

_____	_____	_____AM/PM
Firma del Participante	Fecha	Hora

_____

Nombre de la Persona que Obtuvo el Consentimiento
(escrito en letra de molde)

_____	_____	_____AM/PM
Firma de la Persona que Obtuvo el Consentimiento	Fecha	Hora