Protocol

Evaluating the efficiency and tolerability of the Oxygenating Bite Block

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Cedars-Sinai

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Collaborating Institutions and Researchers	Not applicable

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1.0 Protocol Summary

Study Purpose	• *It* is to evaluate the tolerability and efficacy of the Oxygenating Bite Block (OBB).
Research Procedures	• Utilize the Oxygenating Bite Block during endoscopy procedure, • Questionnaire for the patient, • Questionnaire for anesthesiologist, and • Questionnaire for gastroenterologist.
Subject Population	Ten obese patients scheduled to undergo: • upper endoscopy, • esophageal-gastro duodenoscopy (EGD), • endoscopic ultrasound (EUS), or • endoscopic retrograde cholangiopancreatography (ERCP).
Duration of Subject's Participation	• One visit/One day

2.0 Background, Rationale

Hypoxemia due to respiratory depression or airway obstruction is a known risk associated with endoscopic procedures, with studies showing that hypoxemia occurs in 11–50% of cases [1].

The current standard for oxygenating and monitoring a sedated patient for endoscopy has not evolved since the advent of capnography over 30 years ago. The procedure for sedation for upper endoscopy, ERCP and Transesophageal Echocardiography from an anesthetist's standpoint is as follows: A bite block is placed to protect the teeth and maintain oral latency for scope placement. A choice is then made to use either a face mask with a hole cut to pass the endoscope through, or to use a nasal cannula to oxygenate and monitor respirations. The face mask can easily be pushed into the patients' eyes inadvertently by the endoscopist creating a safety hazard, or the nasal cannula can be used which provides a lower fractional oxygen concentration.

This Oxygenating Bite Block (OBB) overcomes both problems and additionally it improves on both monitoring and oxygenating. The oxygen is delivered at the distal portion of the scope guide which reduces the anatomic dead space that the oxygen is required to overcome before reaching the lungs. Sedated patients loose muscle tone and have a reduced ability to ventilate their lungs with fresh air. The endoscopists often use CO_2 to insufflate while they are examining the patient and the CO_2 is 20x as diffusible as oxygen - requiring the O_2 being delivered to overcome the diffusion gradient of CO_2 coming from the esophagus. This reduction in dead space and improved oxygenation should make sedation safer. An additional improved safety aspect of this device is the integrated $ETCO_2$ monitor which can be attached to a

capnography machine and monitor to ensure the sedated patient is breathing well. The ETCO2 is sampled from inside the mouth which is a more accurate sampling location. Additionally, sedation for endoscopies with propofol is increasingly being done by non-anesthetists. Propofol is a significant respiratory depressant, and the incidence of complications and hypoxemia is higher when the endoscopist uses propofol without and anesthetist present [2]. The oxygenating bite block is designed to improve oxygenation and monitoring in these situations.

Differences between the OBB and the Oral Airway
The conventionally used Anesthesia and sedation support device is known as an 'Oral Airway'. Our study device is called the OBB. Both the OBB and the Oral Airway are small disposable devices that go in the mouth with the same basic form and size. The OBB is an oral airway that delivers oxygen, ***thus eliminating the need for a separate oxygen delivery product*** like a nasal cannula or face mask. The OBB delivers oxygen closer to the glottic opening in the retro pharynx, thus eliminating 'dead space'. Dead space is a space where Oxygen/CO2 exchange does not occur.

Additionally, the OBB has an OS (or 'mouth' of the devise) where an endoscope can be placed and the ETCO2 sampling occurs via tubing attached to the device. This allows ETCO2 sampling to improve safety for sedated patients. By oxygenating and monitoring ETCO2, the OBB is just an advanced and safer oral airway. This novel device is not sufficiently different in dimensions or use than currently existing technology.

The OBB has a slightly thinner flange than the Oral Airway and a larger opening at the mouth which is identical to the existing bite blocks currently in use. This larger opening will allow the OBB to be used during endoscopy sedation. The commonly used 'Oral Airway' cannot be used during endoscopy sedation due to the thickness of the flange and the limited space between the teeth, which prevents passage of an endoscope.

The Oxygenating Bite Block (OBB) we are using for this study does not hold FDA 510k clearance, therefore this device would be categorized as an investigational, non-significant risk device due to the following reasons:

- Is NOT intended as an implant and does NOT present a potential for serious risk to the health, safety, or welfare of a subject.
- Is NOT purported or represented to be for use supporting or sustaining human life and does NOT present a potential for serious risk to the health, safety, or welfare of a subject;
- Is NOT for a use of substantial importance in diagnosing, curing, mitigating, or treating disease, or otherwise preventing impairment of human health and does NOT present a potential for serious risk to the health, safety, or welfare of a subject; or
- Does NOT otherwise present a potential for serious risk to the health, safety, or welfare of a subject.

- Does NOT meet device exemption criteria.

3.0 Study Purpose and Objectives
The primary objectives of this study are:

1) To evaluate the tolerability and efficacy of the Oxygenating Bite Block during sedation for endoscopic procedures.
2) To evaluate the Oxygenating Bite Block from the endoscopist and anesthesiologist perspective. These professionals will be part of the study team.

The secondary objectives of this study are:

1) To collect preliminary answers regarding the physician and patient tolerability and feasibility of the OBB through questionnaires.

4.0 Study Population

4.1 Inclusion Criteria

Subjects may be included in the study only if they meet ALL of the following criteria:

- Obese patients scheduled to undergo upper endoscopy,
- Willingness and ability to sign an informed consent document,
- ASA class I – III obese adults,
- Subjects will be of diverse racial and ethnic backgrounds.

4.2 Exclusion Criteria

Subjects will be excluded from the study for ANY of the following reasons:

- Patients deemed to be at significant airway risk,
- Under 18 years of age since there is no justification to include them,
- Missing or loose incisor or canine teeth
- Temporomandibular joint disease
- Maxillofacial abnormalities (deformities of the jaw, lips, and tongue)
- Pregnant women since there is no justification to include them,
- Emergency surgeries,
- Any other conditions which may interfere with the conduct of the study.

4.3 Subject Identification, Recruitment, and Consent

Subjects will be initially identified in the following ways:

- The PI will contact and present the study protocol to endoscopists, and anesthesiologists who are responsible for patients undergoing upper endoscopy, esophageal-gastro duodenoscopy (EGD), endoscopic ultrasound (EUS), or endoscopic retrograde cholangiopancreatography (ERCP) procedures. The day of the procedure the endoscopist or anesthesiologist will hand out the invitation/introductory letter to the patient and explain the study in the preoperative holding area.

If the subject is interested in participating, the endoscopist or anesthesiologist will contact the investigators who will perform the inform consent process. The population will be obese patients at Cedars-Sinai Medical Center. Subjects will be recruited in-person the day of their scheduled endoscopy procedure.

- Recruitment documents will be used: an invitation letter.

4.3.1 Consent Description

Informed consent will take place in the preoperative holding area the day of the scheduled procedure. The investigator will perform the informed consent process by re-explaining the study in detail, providing the ICF/HIPAA, and obtaining the subject's signature.

5.0 Study Design and Procedures

5.1 Schedule of Events

Not applicable.

Legend

- **R** = Research item/procedure done only for research purposes and their costs are covered by the study. You are not responsible for the costs of these procedures.
- **S** = Standard of care item/procedure that is part of regular care and billed to the patient/insurance. You and your insurance company will be responsible for these costs.
- **RB** = Research item/procedure that is related to use of the study device or administration and monitoring of study drug but billed to the patient/insurance. You and your insurance company will be responsible for these costs.
- **SS** = Standard of care item/procedure that is part of regular care but their costs are covered by the study. You are not responsible for the costs of these procedures.

Procedures	Visit #1
Demographic Information	S
Endoscopy	S
Informed Consent	R
Oxygenating Bite Block	R
Questionnaire	R

5.2 Study Design and Duration

This a prospective, observational pilot study that aims to evaluate an Oxygenating Bite Block prototype in obese patients undergoing endoscopy. The endoscopy procedure nor the anesthesia management will change from current practices. The investigators will

hand out a short questionnaire to the patient, anesthesiologist, and endoscopist following the procedure regarding tolerability and/or feasibility of the device.

The duration of the study is about one day.
The study will be conducted on-site at Cedars-Sinai.

5.3 Description of Study Procedures

The study involves participation at a single timepoint only. The study procedures to be done are listed below.
The only data to be collected are three questionnaires. Following the procedure, the patient, anesthesiologist, and gastroenterologist will be given a short questionnaire administered in-person regarding the tolerability and feasibility of the OBB.

The following will be collected and analyzed from the patient questionnaire:
1) Satisfaction of sedation level during the procedure
2) Tolerability of the OBB
3) Presence of a sore throat

The following will be collected and analyzed from the anesthesiologist questionnaire:
1) Ease of use of the OBB
2) Adequacy of teeth protection
3) Efficacy of oxygenation of the OBB
4) Efficacy of oxygenation in comparison with currently available alternatives for MAC
5) Efficacy of ETCO2 monitoring
6) Potential future use of the OBB
7) Desaturation of patient
8) Professional opinion of the OBB

The following will be collected and analyzed from the gastroenterologist questionnaire:
1) Patient tolerability of the OBB
2) Potential future use of the OBB
3) Interference of the OBB with endoscopy performance
4) Professional opinion of the OBB

6.0 Data Collection and Management

6.1 Data Procurement

- **Identification/Access/Abstraction**

☐ Members of the study team will require access to the clinical data source (e.g., electronic medical record) to identify eligible data/specimens and to conduct data abstraction or gain access to specimens.[1]

☐ Separate registry or repository will identify, abstract, and/or provide specimens and/or data to the study team.

☒ Other:

Data will be collected directly from the patient, anesthesiologist and endoscopist using a questionnaire and no identification will be included.

- **Source(s) of Data/Specimens**:
  No medical record data will be accessed as part of this research.
  All data is collected from the questionnaire for the patient, questionnaire for the anesthesiologist, and questionnaire for the gastroenterologist.

6.2 Time Period of Data under Review

- Data will be collected from/at the following timepoints: Same day of the scheduled procedure.
- Information will be stored in a locked office of the investigators and maintained for a minimum of two years after the completion of the study.

6.3 Data Elements

The following data points will be collected:

- Diagnosis
- Date of treatment
- Questionaries responses.

The information to be accessed and reviewed is that which is minimally necessary to achieve the goals of this research.

HIPAA Identifiers
☐ Diagnosis
☐ Date of treatment

6.4 Confidentiality and Security of Data

- **Retention/Destruction of Study Materials:** Study data- questionnaires will be kept and/or destroyed according to applicable policy.
- **Limited Access:** No private identifiable information will be collected.

[1] Clinical records can only be accessed by study team members who are listed on the CS-IRB application and are IRB Certified.

- **Storage of Physical Records:** Physical records will be maintained for this study at a secure location where access is limited to approved personnel. The records will not be removed from Cedars-Sinai premises.

7.0 Data and Safety Monitoring

7.1 Data and Safety Monitoring Plan

The study will be monitored by the PI to ensure appropriate study conduct, including obtaining proper access to data/specimens, compliance with the HIPAA Privacy Rule, compliance with Cedars-Sinai policy, and adhering to the plans outlined in the protocol for all study procedures, abstracting and recording data, data and/or specimen security and maintenance, and data accuracy and integrity. Any adverse events, deviations, protocol exception requests, potential unanticipated problems involving risks to subjects or others, or other events will be submitted to the IRB in accordance with IRB reporting policy. All study procedures will be conducted in accordance with standard clinical practice.

8.0 Sample Size and Statistical Considerations

8.1 Sample Size

This is a single on-site study at Cedars-Sinai. The sample size of the study is 10 subjects.

8.2 Statistical Sample Size Justification

A statistical sample size is not required because this study involves:

- A pilot study with at most 20 subjects

8.3 Statistical Analysis Methodologies

This pilot study will obtain *response rates*. The questionnaire for the patient, questionnaire for the anesthesiologist, and questionnaire for the gastroenterologist for this research study, will be collated and reviewed by the investigator to provide the outcome data. We will use *frequencies and percentages and the similar responses will be compared across the 3 questionnaires applied.*

No statistical methods description is required given that the study does not require a sample size justification.

9.0 References

1. 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 May;54(5):1035-40. doi: 10.1007/s10620-008-0452-2.

2. de Paulo GA, Martins FP, Macedo EP, Gonçalves ME, Mourão CA, Ferrari AP. Sedation in gastrointestinal endoscopy: a prospective study comparing nonanesthesiologist-administered propofol and monitored anesthesia care. Endosc Int Open. 2015 Feb;3(1):E7-E13. doi: 10.1055/s-0034-1377835.