A Novel Device to Monitor Breathing and Deliver Oxygen During Monitored Anesthesia Care (MAC)

Presenting Author: Tariq Chaudhry, MD, Visiting Associate Professor, Department of Anesthesia, Tufts Medical Center, Boston.

Background: Nasal Cannulas are typically used during an estimated 50-70 million MAC procedures in the US every year. Dislodgement of nasal prongs, limited oxygen flow, oral-breathing and jaw-clenching in hypoxic patients are some of the limitations seen with the nasal cannulas.

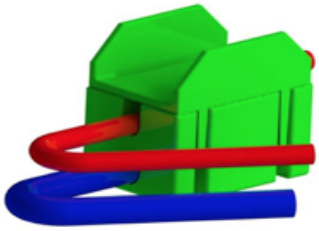
Technological advancements in recent years have resulted in tremendous growth of Non-Operating Room Anesthesia (NORA) procedures.[1, 2] Aging patient population with increasing comorbidities, novel procedures requiring deeper levels of sedation and anesthesia techniques that ensure same-day discharge are important considerations. NORA procedures, compared to those performed in the OR have a higher frequency of severe injury and death.[3,4,5] Per ASA Closed Claims Data, MAC was the most common anesthetic technique in remote location claims (50% of claims) than the 6% OR claims.[6] Over-sedation leading to respiratory depression and hypoxemia resulted in a third of all claims.[7,8]

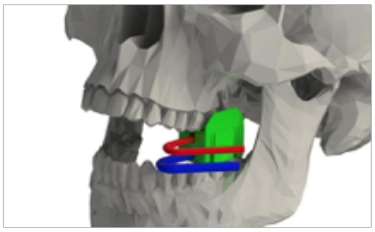
Materials and Methods: Anesthesia Intra-oral Monitor (AIM) is a novel device, approximately 1x1 inch in size with a high-flow oxygen port for oro-pharyngeal oxygen delivery and a second port for oral-capnography. It can be placed on either side of a patient's mouth, between the molars leaving the oral cavity partially open. Oro-pharyngeal oxygen delivery increases the size of oxygen reservoir while oxygen source closer to trachea causes less dilution with air resulting in FiO_2 as high as 80% compared to the 50% FiO_2 with a nasal cannula.[9]

Sedated patients mostly breathe orally during upper GI endoscopies and oral capnography captured sufficient data in 100% of the patients.[10] AIM is compatible with oral breathing and could eliminate the need for bite-blocks, mouth guards, oxygen masks or retro-fitting oxygen and CO_2 tubing into the patient's mouth during upper endoscopies, bronchoscopies or awake fiber-optic intubations. The AIM's access to a patient's oral cavity could facilitate the placement of airway-resuscitation devices in hypoxic patients.

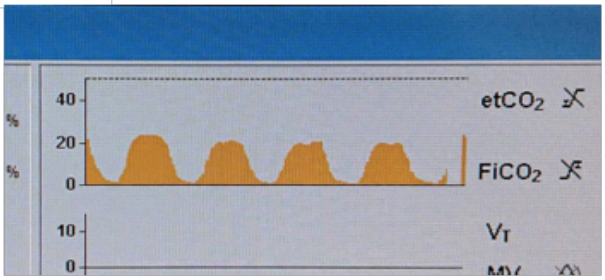
AIM is in the initial development phase with a recently issued patent by the US Patent Office. A prototype has been developed and tested on a limited scale. Initial results have been encouraging, oral capnography waveform was successfully captured with oxygen flow as high as 18 lit/min.

Conclusion: With the rapid development of novel interventional techniques in cardiology, radiology, G.I and pulmonary medicine, NORA cases are expected to constitute over 50% of the anesthesia cases during the next decade.[11] As productivity pressures rise with coverage of multiple locations and some in remote areas of the hospital, general anesthesia is often chosen over MAC citing patient safety. Compared to general anesthesia, sedation is associated with lower mortality, fewer hospital days and a 28% decrease in direct hospital costs during Transcatheter Aortic Valve Replacement (TAVR).[12] As the healthcare environment looks to improve value by decreasing costs, an emphasis on quality measurement and metrics reporting, a safer, inexpensive device that minimizes patient injuries during MAC is highly desirable.





AIM with oxygen delivery and oral capnography ports.



AIM-provided oral access and oral capnography waveform capture using the AIM prototype.

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