What Makes the Panoramic Oxygen Mask™ (POM) Different and Why It Should Become the Standard of Care.

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Patients undergoing upper endoscopy procedures with or without conscious sedation run the risk of reduced oxygen levels (hypoxia) and reduced respiratory rates (hypoventilation). Both of these conditions are not uncommon and can lead to heart attacks, strokes or even death. Professional societies and national expert peer groups have issued practice guidelines for sedation and analgesia that call for continuous monitoring of the patient's basic vitals; breathing status and level of consciousness. Direct observation is facilitated by electronic devices (pulse oximetry, capnography), directly indicating the patient's breathing status and the depth of sedation. In fact, a recommendation from the American Society of Anesthesiologists suggest that monitoring for apnea, (not breathing), using capnography is a useful adjunct in the assessment of the respiratory status of patients undergoing sedation and analgesia. In addition, The Joint Commission on the Accreditation of Healthcare Organizations (JCAHO) recommends ventilation monitoring during procedural sedation for gastrointestinal endoscopy.

So, to meet the above mentioned guidelines and recommendations, what are doctors currently using?

There are several options:

1. Homemade devices – Attaching oxygen supply tubing to a nasopharyngeal airway. However, the FiO₂ is low and a capnography cannula is still required. Some routinely add a mask on top of the cannula to increase the FiO₂; unfortunately, when the mask is removed to perform the procedure the patient’s oxygen level falls (desaturation) and it has lots of parts, almost always a negative.

A second homemade option is to put a plastic bag over the patient’s head. Even though it would increase the FiO₂, I think rebreathing their CO₂ would create bigger problems. Not to mention the suffocation problem, if the gas flow is lost.
2. There are a number of commercial devices that combine a nasal cannula that can provide oxygen, monitor CO₂ and a bite block for the procedure. A standard cannula has a maximum FiO₂ of 44% and is often less if the patient is breathing deep or is a mouth breather. Some devices that provide oxygen and measure CO₂ only use one side of the cannula for oxygen reducing the flow rate and FiO₂ to the patient. Other devices have attempted to overcome the FiO₂ issue by having a dual cannula set-up (one for oxygen and one for CO₂), however the device is still limited to 44% oxygen.

| DualGuard - Flexicare® $22 ea. | Smart Capnoline - Guardian™ |
| Max FiO₂ - 44% | Covidien - $21 - $44 |
| on 6 LPM | Max FiO₂ 44% on 6 LPM |

So, the obvious problems with the dual type devices is low oxygen administration and cost.

Here’s where the POM mask comes into play. The POM is a modified non-rebreather or simple mask (according to which adapter is used) with a maximum delivery of 80% – 90% FiO₂.

High concentration up to 90% FiO₂ has a reservoir bag

Medium concentration up to 60% FiO₂ does not have a reservoir bag

The POM mask has a luer connection on the front of the mask (comes with a CO₂ sampling line).

**IMPORTANT POINT:** Most masks on the market that utilize a CO₂ connector on the mask produce a very poor capnography wave and capnometry number due to the flow of oxygen washing out the CO₂. The POM mask overcomes this problem with the high concentration connector only. The high concentration connector has a valve that closes when the patient exhales preventing the oxygen from flowing into the mask and washing out the CO₂. However, the medium concentration connector is a straight port with a continuous flow of gas into the mask.
The POM is the only mask available with two anatomically placed entry points or membranes that allows access to the patient’s nose or mouth. These two modifiable membranes allow for many different size scopes, tubes, or probes making it is extremely versatile for many types of procedures. The mask does not have to be removed to perform a procedure, reducing the chance of low oxygen levels and provides a connection for capnography monitoring for increased patient safety, a significant issue in the healthcare industry.

POM - Cost under $8 (includes sampling line, oxygen supply tubing and both a high and medium connector).

The other devices do incorporate a bite block that helps guide the scope. Bite blocks are currently available for an average price of $2 - $5.50. Even with the price of the bite block, the POM mask is around half the price, if not less, than the other devices currently being used.

Two Independent Studies completed by Dave Piper, PE Piper Medical Products.

End Tidal CO₂ Testing Panoramic Oxygen Mask At 3% ETCO₂ .

“The POM is more sensitive or ‘accurate’ in allowing the capture of ETCO₂ than nasal cannula.”

Oxygen Delivery Testing Panoramic Oxygen Mask Simulated Patient Conditions -

“With The POM's ability to provide ultimate ‘panoramic access’ to the patient’s nose or mouth while monitoring end-tidal CO₂, and also providing these high FiO₂ percentages, it can be easily concluded that the Panoramic Oxygen Mask will become the standard of care for all upper endoscopy procedures under conscious sedation.”

Summary:

Benefits of the POM . . .

1. High FiO₂ Capabilities
2. Accurate wave form capnography
3. Dual oral and nasal entry points
4. Cost-effective (Reduced cost)
5. Does not change current practice
6. Safer for the patient
Clinical Support:

“The nasal cannula often becomes an ineffective tool for providing supplemental oxygen when the patient’s mouth is open and the endoscopy probe is in place.”

James Tse, M.D, Ph.D.; Shaul Cohen, M.D.; Paul Stricker, M.D. “A Simple and Effective Technique to Increase Oxygenation for Patients with Nasal Cannula during Upper Endoscopy Anesthesiology 2 2005, Vol.102, 484. doi:

“Oxygen should be given to all sedated patients and selected unsedated patients throughout the procedure and recovery period.”

Sedation Guidelines for Gastro Intestinal Endoscopy MJAFI 2009; 65 : 161-165
(Medical Journal Armed Forces India)

“Automated graphic assessment of respiratory activity is superior to pulse oximetry and visual assessment for the detection of early respiratory depression during therapeutic upper endoscopy.”

Gastrointestinal Endoscopy Volume 55, Issue 7, June 2002, Pages 826–831

“Potentially important abnormalities in respiratory activity are undetected with pulse oximetry and visual assessment.”

(Gastrointestinal Endoscopy Journal)

Capnographic monitoring of respiratory activity improves patient safety during procedural sedation for elective ERCP/EUS by reducing the frequency of hypoxemia, severe hypoxemia, and apnea.”

Capnographic Monitoring of Respiratory Activity Improves Safety of Sedation for Endoscopic Cholangiopancreatography and Ultrasonography.


“When using nasal cannula, there is little control over the inspired concentration, which can vary from 25 to 40% with flow rates of 2 ± 4 LPM, depending upon the pattern and volume of breathing.”