Myths, fallacies and practical pearls in GI lab

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Abstract

Many prevalent practices and guidelines related to Gastrointestinal endoscopy and procedural sedation are at odds with the widely available scientific-physiological and clinical outcome data. In many institutions, strict policy of pre-procedural extended fasting is still rigorously enforced, despite no evidence of increased incidence of aspiration after recent oral intake prior to sedation. Supplemental oxygen administration in the setting of GI procedural sedation has been increasingly adopted as reported in the medical journals, despite clear evidence that supplemental oxygen blunts the usefulness of pulse oximetry in timely detection of sedation induced hypoventilation, leading to increased number of adverse cardiopulmonary outcomes. Use of Propofol by Gastroenterologist-Nurse team is erroneously considered dangerous and often prohibited in various institutions, at the same time worldwide reports of remarkable safety and patient satisfaction continue to be published, dating back more than a decade. Of patient monitoring practices that have been advocated to be standard, many merely add cost, not value. Advances in the technology often are not incorporated in a timely manner in guidelines or clinical practices, e.g., Capsule endoscopy or electrocautery during GI procedures do not interfere with proper functioning of the current pacemakers or defibrillators. Orthopedic surgeons have continued to recommend prophylactic antibiotics for joint replacement patients prior to GI procedures, without any evidence of need. These myths are explored for a succinct review to prompt a change in clinical practices and institutional policies.

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Core tip: Many prevalent endoscopic procedural practices and policies are not only unsupported by clinical and scientific evidence, but are counterproductive. Rather than enhancing patient safety and comfort, these increase risk and expense, introduce unnecessary delays. Evidence to reach proper decisions about these topics has been available for a while, but is not appropriately acknowledged and implemented. Avoiding these pitfalls can have a significant positive impact because these policies cover routine events, actions and decisions, including: required prolonged pre-procedural fasting, routine supplemental oxygen during sedation, prohibition of Propofol use by non-anesthesia personnel, multiple monitoring practices and prophylactic recommendations.

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MYTH

“The great enemy of the truth is very often not the lie-deliberate, contrived, and dishonest - but the myth - persistent, persuasive and unrealistic.” - John F Kennedy.

A fallacy is a mistaken belief, based on flawed or incomplete data or an unsound argument. A fallacy,
once discredited, loses its force of persuasion, e.g., the earth is flat. Without careful review of the key evidence contradicting a simplistic impression, someone new to a topic can easily come to an erroneous conclusion.

A Myth, on the other hand, is complex and tenacious. Despite conclusive refuting data and reasoning, myths can persist for an impressive period of time. In fact, some myths have resurgences and succeed in replacing established sound practices with erroneous ones.

History is replete with myths propounded by giants of their times.

Aristotle thought that while the heart was the seat of intelligence, the brain cooled the blood. He reasoned that humans are more rational than the beasts because, among other reasons, they have a larger brain to cool their hot-bloodedness!

Galen (second century), was one of the foremost physicians of his time. He deliberately engaged others in debate to prove them wrong. It is ironic that he made the practice of bloodletting a standard treatment that continued for more than a thousand years! That myth was responsible for more deaths from intervention than perhaps any other single medical procedure. On December 12, 1799, President George Washington developed a sore throat. As treatment, about three liters of his blood were removed from his body by venesection during a 10-16 h period (with his consent and at his request). He consequently died.

Modern medicine aspires to be evidence based, but there is a strong undercurrent of tradition and reverence for experts. Many of the clinical practices start as empirical attempts but then gain mythological flavor. Many guidelines are nothing more than intuitive opinions but are often rigidly enforced despite evidence indicative of lack of effectiveness or harm.

“Whatever is almost true is quite false, and among the most dangerous of errors, because being so near truth, it is more likely to lead astray.” - Henry Ward Beecher.

In many GI labs around the world, the following myths and fallacies are currently believed and practiced, as reflected in the published articles, institutional policies and personal practice patterns. Their persistence serves as testament to the mythical and entrenched nature of these beliefs.

**MYTH: PRIOR TO MODERATE SEDATION, OVERNIGHT FASTING IS EFFECTIVE AND ESSENTIAL FOR PREVENTION OF ASPIRATION**

Prolonged pre-procedure fasting requirement, (regardless of the time of day when the procedure gets done) is a rigidly enforced “rule” in many institutions. Extensive review of literature has failed to show any statistical evidence of increased risk of aspiration despite recent oral intake, in relation to endoscopic and other moderate procedural sedation\(^1,2\). The myth of Nothing orally after midnight has persisted in many institutions. Some others have adopted an arbitrary 4-h fasting requirement. This frequently leads to delay and often inconveniences the patient. No research data has shown the value of even 2-h intake restriction\(^1,2\).

The rationale provided is: (1) Oral intake leads to increased gastric content; (2) Gastric content is vomited during the sedation; and (3) Vomit is aspirated in the respiratory tract, creating a complication.

The clinically-observed facts are: Gastric content is not well correlated with recent intake\(^3\), and may be low despite the intake or may be high despite fasting for extended duration, due to gastric retention. Endogenous gastric secretion and saliva add to it in variable amounts.

In the setting of GI bleeding, the stomach is often filled with blood and blood clots. People coming in with food bolus impactions and with a considerable amount of food in their stomachs have undergone emergency endoscopy without a high incidence of aspiration.

Vomiting and regurgitations are extremely rare during the endoscopic procedures under current procedural sedation and endoscopic techniques, when the significant gastric contents are present.

In the rare event of vomiting, aspiration is uncommon, partly because patients for endoscopic procedures are generally not in supine position, and many have some protective reflexes.

Stated differently: (1) Gastric contents: not well correlated with liquid intake after an hour or more; (2) Gastric contents: very low risk of vomiting; and (3) Vomiting: very low risk of aspiration.

Prohibition on chewing gum or similar extremely restrictive measures have no data or basis to support them.

A case can be made for usefulness of liberal clear liquid intake more than a couple of hours before the procedure: Proper hydration improves the patient’s general well-being, helps avoid dehydration, and may make intravenous access easier.

The American Society of Emergency Physicians panel reviewed the scientific data and evidence related to pre-procedural sedation oral intake and made a policy change in 2005 to remove the requirement of fasting from moderate sedation, leaving the decision to the discretion of the treating physician\(^3\).

Since then and until now, no increased incidence of aspiration-related complications has been observed or reported since then. After the more-recent follow-up review, the clinical policy was reaffirmed and kept unchanged\(^3\).

**Pearl**

For diagnostic GI endoscopic procedures, it makes intuitive sense to instruct patients not to take solids immediately prior to Gastroscopy, as it will impair visualization. If for some reason this is not the case, then recent oral intake should not be considered an absolute contraindication. The oral intake status of

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all patients should be reviewed and discussed with the patient, including the potential risk of aspiration even if the patient has been fasting. If, in the judgment of the treating physician, the benefits of the procedure far outweigh the potential risk of aspiration, and the patient consents and assumes the risk, then proceeding with the sedation and the procedure should be individualized and outcomes should be reviewed on an ongoing basis.

**MYTH: PROCEDURAL SEDATION SHOULD INCLUDE ROUTINE ADMINISTRATION OF SUPPLEMENTAL OXYGEN TO INCREASE PATIENT SAFETY**

Supplemental oxygen use is frequently (erroneously) advocated for procedural sedation in the GI lab. Oftentimes, its use is mandated by the institutional policy and is enforced for all patients.

However, those advocating this practice do not dispute the following: (1) When hemoglobin is near 100% saturated, additional fractional increase in the inspired oxygen cannot further increase oxygen content of the blood; (2) Pulse oximetry does not measure ventilation. It estimates oxygen saturation of hemoglobin. Alveolar ventilation serves the function of more than just oxygenation of the blood. CO2 clearance from the lungs is the other major process; (3) There is a lag between onset of hypoventilation and development of hypoxemia as reflected by oxygen desaturation; and (4) The reason for the desaturation in this setting is not reduction in oxygen in the ambient environment, but due to the patient’s hypoventilation induced by the sedative agents.

Oxygen supplementation is appropriate in the setting of low ambient oxygen: (1) Lack of oxygen in the ambient air; (2) Lower oxygen saturation; (3) oxygen supplementation; and (4) Improved oxygen saturation in the blood. High altitude physiological observations and studies have demonstrated that humans tolerate isolated very low oxygen saturation levels for short periods of time very well.

The myth of appropriateness of oxygen supplementation to treat hypoventilation-related desaturation is a fallacy because it does not take into account the etiology and pathophysiology of desaturation.

Pulse oximetry value is a proxy and an indirect indicator of alveolar ventilation, just as urine output is an indirect indicator of renal function. Instances of reduced urine output should not all be treated in the same way. Giving a diuretic to a dehydrated patient may temporarily increase the urine output, but it would be precisely the wrong thing to do.

Similarly, if supplemental oxygen is given, various ventilatory parameters worsen more than when compared to room air sedation. Niesters et al. demonstrated that while the deterioration in the ventilatory function was quite pronounced, the pulse oximetry continued to show normal readings.

In addition, it is insufficient to simply observe the patient’s appearance and vitals to promptly and reliably detect the onset and extent of hypoventilation. Fortunately, room air Pulse oximetry is quite sensitive in the detection of the onset of sedation-associated hypoventilation. It is a myth that capnometry offers any advantage over room air Pulse oximetry. Supplemental oxygen prevents or delays oxygen desaturation resulting from hypoventilation induced by sedation. For similar reduction in pulse oximeter reading, hypercapnia is more pronounced in the setting of supplemental oxygen because of the longer duration of hypoventilation.

A supplemental oxygen-induced normal pulse oximetry reading creates a false sense of security for the person monitoring the patient and sets him or her up for a delay in the intervention directed towards improving ventilation in these early stages. Desaturation is an effect: not to be “window dressed” without addressing the underlying process.

Due to hypoventilation, impaired clearance leads to increased partial pressure of CO2 in the alveoli. Consequently, it becomes harder for the inspired oxygen to reach the alveoli, which may create a vicious cycle.

Inspired oxygen also reduces the hypoxic ventilatory drive, compounding the problem. Extreme elevation of CO2 could produce CO2 narcosis. Acute respiratory acidosis may develop with persistent hypoventilation.

It is a myth that short periods of hypoxemia, if detected and treated, improve clinical outcome. Review of available data of Pulse oximetry for perioperative monitoring has shown that researchers have repeatedly looked for such evidence and have not found it.

Hypoxemia is the effect of the hypoventilation, not the cause; therefore the measures solely directed towards delaying hypoxemia without addressing the hypoventilation will end up with higher likelihood of oversedation. In case of medications such as Midazolam and Fentanyl, the patient may continue to appear awake but progressive hypoventilation occurs. With propofol, early detection of hypoventilation is crucial in avoiding further dosing to stay within the therapeutic window.

The patients are appropriately advised to not use thick nail polish because it would reduce the sensitivity of the pulse oximeter sensor. It is remarkable that those who advocate avoidance of thick nail polish do not recognize the similarity between this recommendation and the fact that supplemental oxygen also markedly reduces the sensitivity and value of pulse oximetry in the setting of sedation.

The rationale given for using supplemental oxygen is that oxygen is essential for life; therefore, preventing any drop in oxygen saturation is a “safety” measure. However, a national study of cardiopulmonary unplanned events after GI endoscopy found that upon CORI (Clinical Outcomes Research Initiative) database review, routine use of supplemental oxygen was associated with significantly more Cardiopulmonary Unplanned
Events\(^{[13]}\).

It is of concern that institutional policies and published studies have increasingly advocated and reported routine supplemental oxygen administration despite evidence that it is counterproductive has been available for more than a decade.

**Pearl**

Based on these facts and principles, the optimum approach may be to start sedation with the patient breathing room air (assuming no baseline hypoxemia on room air). The patient should be encouraged to take intermittent deep breaths to maintain ventilation. Airway management should be done as soon as the saturation drops by 4-6 points (from 100 to 96), as this is definitive evidence of hypoventilation and, therefore, the sedative effect. Avoidance or reduction of further sedative agent doses from this point onwards is prudent. If desaturation worsens, then ventilatory assistance along with supplemental oxygen is indicated. Oxygen alone, if ventilation is absent, does not correct the situation.

**MYTH: SEDATION FOR GI PROCEDURES IN SLEEP APNEA PATIENTS IS VERY RISKY AND IS ASSOCIATED WITH A HIGHER INCIDENCE OF BAD OUTCOMES WITH STANDARD MONITORING**

Indeed, patients with sleep apnea have added risk factors, but once known and incorporated in the management plan, current monitoring and care has produced equally good outcomes in this subset of the patients compared to non-sleep apnea patients\(^{[13-15]}\).

**Pearl**

Patients with sleep apnea can safely receive procedural sedation, but they should be very closely watched as the risk of hypoventilation with sedation is higher and airway obstruction more likely. Room air pulse oximetry, small titrated doses, meticulous airway management and prompt use of reversal agents should be part of the plan.

**MYTH: USE OF REVERSAL AGENTS DURING OR AFTER THE ENDOSCOPIC PROCEDURE IS A COMPLICATION, AND THE PATIENT MUST BE OBSERVED FOR LONGER PERIODS IN THE RECOVERY AREA DUE TO THE SIGNIFICANT RISK OF CLINICALLY DANGEROUS “REBOUND SEDATION”**

Many institutions and regulatory agencies consider use of reversal agent such as Naloxone or Flumazenil to be “complications”, requiring an incidence report that may even need to be reported to State regulatory agencies.

This myth implies that clinically inappropriate and avoidable oversedation must have occurred, because the reversal agent was required.

These policies and regulations also require extended intensive monitoring of these patients after use of a reversal agent, more than for other sedated patients who were not reversed. This policy is instituted to look for the mythical and dangerous “rebound sedation”.

The following reasoning and data show that these are myths:

- Sensitivity to the sedative agents is known to have a wide range of variability. A relatively small dose may lead to unexpected profound respiratory depression. In this setting, reversal of this effect is a safety measure, not a complication, e.g., tapping on the brakes while driving through traffic is hardly proof of speeding.
- There are times during many procedures, particularly colonoscopies, where increasing doses of Fentanyl or Midazolam are needed to counter the discomfort related to the pressure of the scope through a tortuous segment of the colon. However, once the discomfort has abated due to straightening of the colonic segment or at the end of the procedure, the unopposed residual sedative effects of these medications manifest due to the duration of the action of the drug. A reversal agent would promptly mitigate the effects of the drug. Moreover, ongoing analgesia after completion of the procedure is not needed, in contrast to after traditional surgery.
- It is also a myth that these patients need to be routinely observed for extended periods (much longer than usual) after use of the reversal agent.
- Bad outcomes due to Rebound sedation after reversal agent use, even after a massive overdose in the setting of poisoning, accidental or otherwise, are extremely rare\(^{[16,17]}\).
- Because titrated doses of short-acting sedatives are used in the GI lab, clinical practice experiences and reported studies in the medical literature have shown this practice to be very safe. Studies reporting routine use of reversal agents showed no clinically significant rebound sedation\(^{[18,19]}\).
- Resedation was reported in one study\(^{[20]}\), but those patients remained clinically stable; return to the hospital and additional medical interventions were not required.

**Pearl**

The use of reversal agent is a safety measure. Despite the reversal agent having a shorter duration of action than the drug reversed, dangerous rebound sedation is not encountered in clinical setting due to continued metabolism and clearance of the sedative agent during this time.

Individualizing the observation based on clinically-unusual recovery is advisable over an indiscriminately prolonged observation policy after use of reversal agents.
MYTHS RELATED TO HOW MUCH MONITORING EQUIPMENT IS REQUIRED TO SAFELY PERFORM THE ENDOSCOPIC PROCEDURAL SEDATION

Current monitoring practices include Pulse oximetry, intermittent blood pressure recording, continuous electrocardiogram tracing, and, in some instances, Capnography and Bispectral Index.

In the United States Endoscopy labs, continuous cardiac monitoring is virtually universal. Around the world, this is not very common. The discrepancy has not been associated with any worsening of the outcome.

It is recommended that one nurse be dedicated exclusively to monitor the patient during sedation.

No studies have ever shown an outcome advantage from any of these recommendations of monitoring practices.

How much monitoring is sufficient to avoid sedation related serious complications? Külling et al.[21] provided data in the setting of Propofol-based sedation in the GI lab without presence of anesthesia personnel.

This large study showed that by monitoring the patients with a Pulse oximeter alone, (no cardiac or blood pressure monitoring), along with a single nurse monitoring the patient as well as assisting the endoscopist, more than 27000 procedures were performed under gastroenterologist-directed Propofol, without significant complications.

Room air pulse oximetry has been demonstrated to be clinically as effective as Capnometry[22] and Bispectral Index[23] in monitoring for hypoventilation in these patients.

Pearl

Monitoring should be optimized. Room air Pulse oximetry along with good airway management may be sufficient for the vast majority of patients. Artifacts and malfunctions of monitoring devices (electrocardiogram, etc.) should not be allowed to become a distraction during the monitoring of endoscopic procedures.

MYTH: IMPLANTED DEFIBRILLATORS AND PACEMAKERS NEED TO BE RESET IF ELECTRO-CAUTERY IS USED DURING THE ENDOSCOPIC PROCEDURES

Implanted Defibrillators are commonly turned off and presumed to be at risk for accidental activation by electrocautery in many GI labs. This is an example of not incorporating the advances in technology and accumulated evidence into the current guidelines. Guidelines have remained in place for a long time after the technological changes have made them obsolete and erroneous. Devices currently in use are shielded and do not sense the electrocautery as a dysrhythmia[23,24].

Pearl

Newer Defibrillators and pacemakers do not require any adjustment for GI procedures. It is a good practice to avoid placing cautery pads close to the defibrillator device.

Despite initial concerns, Capsule endoscopy also has not been found to interfere with these devices, nor does pacemaker affects imaging done with Capsule endoscopy[25,26].

Capsule endoscopy may be safely undertaken in patients with pacemakers and implanted defibrillators.

MYTH: PROPOFOL USE UNDER THE DIRECTION OF GASTROENTEROLOGISTS IS UNSAFE; ITS USE BY ANESTHESIA SPECIALISTS IS SAFER

This myth is quite prevalent in the United States and some other parts of the world, whereas in many other places, including Switzerland, increasing adoption of Propofol by the gastroenterologist has been reported[27].

On this issue, extensive data is available, spanning more than a decade. A team of a gastroenterologist and registered nurses has provided Propofol-based sedation with remarkable safety, excellent patient experience and without the additional cost of anesthesia personnel[28,29].

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On the other hand, Gangi et al.[30], in his study, found that Propofol given by anesthesia personnel was associated with a higher complication rate. This may be due to their practice of using larger doses (for induction of the General anesthesia that is followed by assisted ventilation), whereas the endoscopy patients are expected to breathe on their own[31].

The argument is commonly made that Propofol package insert restricts its administration solely to formally trained anesthesia personnel.

However, the actual phrase published by the manufacturer states:

“For general anesthesia or monitored anesthesia care (MAC) sedation, (emphasis added) DIPRIVAN Injectable Emulsion (Propofol) should be administered only by persons trained in the administration of general anesthesia and not involved in the conduct of the surgical/diagnostic procedure.” DIPRIVAN® (Propofol) INJECTABLE EMULSION, USP Fresenius Kabi USA, LLC Revised 5/14.

The gastroenterologists do not use Propofol for General anesthesia or MAC, and, therefore, the requirement of these abilities is not applicable in this setting[32-34].

For example, many primary physicians have acquired the skill to perform flexible sigmoidoscopy. Their use of a (longer) colonoscope in the GI lab would not be questioned or prohibited as long as the colonoscope is used to perform only flexible sigmoidoscopy.
**Pearl**

Propofol has been used by Gastroenterologists around the world for more than a decade with remarkable safety and patient satisfaction. It should be an option for interested and skilled physician and nurse teams. It should be undertaken after adequate training of the entire team. Patient safety should be the highest priority. This can be accomplished by learning the pharmacology of the drug and using small titrated doses (with or without combination with small doses of other agents that can be reversed) along with room air pulse oximetry to promptly detect hypoventilation.

**MYTH: PROPOFOL LEADS TO DEEP SEDATION, WHEREAS NARCOTICS AND BENZODIAZEPINES PROVIDE MODERATE SEDATION**

As reported by Patel et al, deep sedation frequently occurs in the GI lab with Narcotics and Benzodiazepines during sedation given by gastroenterologists and is routinely managed by them. On the other hand, Cohen et al and Sipe et al have reported that a moderate level of sedation is consistently achievable with low-dose Propofol-based sedation.

Many sedative agents, if given in large enough doses, lead to a state of general anesthesia. A general anesthetic, alcohol, has been available worldwide (over the counter) for centuries!

**Pearl**

Depth of sedation is age and dose dependent and exhibits a wide variability. The therapeutic effect and side effects are potentiated when these agents are combined. It is not the agent, but how and to what effect it is used that should be the focus.

**MYTH: ENDOTRACHEAL INTUBATION SKILL IS NECESSARY FOR GI SEDATION WITH PROPOFOL**

It is a myth because due to ultra short duration of action of the drug, and in the setting of smaller titrated doses, the transient respiratory depression from Propofol is likely to dissipate well before the intubation equipment can be assembled and used. If apnea does occur, then ambu bag ventilation is effective in assisting ventilation for a short duration.

**Pearl**

An ambu bag and oxygen should always be immediately available, and the team must practice regularly to stay skilled for its effective use. Early recognition of hypoventilation and proper airway management should further reduce the incidence of rare events when assisted ventilation is required.

**MYTH: FOR PATIENTS WITH PROSTHETIC JOINTS, ENDOSCOPY FREQUENTLY LEADS TO INFECTION AND PROPHYLACTIC ANTIBIOTICS ARE ESSENTIAL**

The Orthopedic Surgical Society has recommended giving antibiotics prior to endoscopic procedures. However, current Endoscopy society guidelines, after reviewing the available clinical data, recommends against it.

Despite the fact that endoscopies without prophylactic antibiotics have been routinely performed worldwide for last several decades, without adhering to the Orthopedic Surgical Society recommendations, only a couple of joint infections have been reported in this setting, that could be coincidental.

The real and frequent risks and other implications of unnecessary antibiotic use must be weighed against this rare event. Antibiotics should not be given solely for an unproven theoretical protective effect.

**Pearl**

This issue should be discussed with each patient and the risk of infection should be put in proper perspective. This should help in avoiding prophylactic antibiotics of questionable benefit in this setting.

**CONCLUSION**

Neither “expert recommended” nor “increasingly adopted” practices and policies are immune from being fallacies and myths. In the Endoscopy suite, arguably the most significant inappropriate practice is the routine use of Supplemental oxygen because it is a practice contrary to the physiologic and scientific data with demonstrated adverse effects. It puts ventilatory monitoring by Pulse oximetry at a disadvantage. All of us should review in depth research on these issues and develop a mindset of continually questioning and re-examining the policies and practices in light of scientific data as well as technological advancements, e.g., shielded implanted defibrillators related to electrocautery.

“The chief cause of poverty in science is imaginary wealth. The chief aim of science is not to open a door to infinite wisdom, but to set a limit to infinite error.” Bertolt Brecht: Life of Galileo.

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