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Lies, Damned Lies and Anesthesia Myths

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INTRODUCTION

Physicians, journalists and the lay public prefer a plausible narrative (particularly if it includes mechanistic details) to being forced to acknowledge that “I don’t know” or “the data are suggestive but inconclusive.” The inevitable result is that unproven hypotheses, repeated endlessly in lectures and textbooks and assumed to be facts, become part of the canon of the specialty. Whether these misapprehensions be “lies, damned lies, and statistics,” using a turn of phrase that Mark Twain attributed to Benjamin Disraeli (erroneously) in Twain’s Chapters from My Autobiography, or whether they be “anesthesia myths” I will leave to the reader/listener to decide.¹

We will consider a representative subset of unproven (and, in some cases, disproven) hypotheses during the course of this brief presentation. For convenience, I have divided the topics into three classes: those related to resuscitation, those related to general anesthesia and those related to regional anesthesia.

RESUSCITATION TOPICS

Normal saline is an appropriate maintenance fluid in surgical patients

Intravenous fluid therapy arose in the 1800s as a means of combating dehydration from cholera, then became part of routine care for surgical patients in the 1900s.² At present day, the IV fluids of choice for adults in most surgical suites are either 0.9% (Normal) saline or a “balanced” salt solution (Normosol, Plasma-lyte, or lactated Ringer’s (Hartmann’s) solution). The sad truth is that multiple lines of evidence demonstrate that use of 0.9% saline leads predictably to a greater incidence of hyperchloremia, a condition associated with worse outcomes (including longer lengths of stay and a greater likelihood of death).^{3,4} In the absence of hypochloremic metabolic alkalosis there are sparse indications for large volumes of 0.9% saline, and no good reasons to use 0.9% saline as a routine maintenance solution.⁵

Cricoid pressure improves patient safety

Cricoid pressure was introduced to anesthesia by Brian Sellick article in 1961.⁶ In 26 patients considered at risk for aspiration, no regurgitation occurred before or after application of cricoid pressure in 23. In 3 patients, regurgitation occurred after cricoid pressure was relieved following tracheal intubation. The assumption was that cricoid pressure prevented regurgitation from occurring prior to and during intubation in these 3 patients. But, Sellick did not provide details of induction drugs, ventilation, patient body habitus, or other relevant factors that might also explain differences between the two groups.⁷ Sellick assumed that the cricoid cartilage, esophagus, and anterior surface of the vertebral body would be in consistent anterior to posterior

alignment. He presumed that his maneuver would fully occlude the esophagus, would prevent gastric contents from refluxing past the cricoid, and thus would reduce the incidence of pulmonary aspiration associated with “full stomach” conditions. Finally, he assumed that cricoid pressure had no adverse consequences. Current data using CT and MR imaging techniques confirm that the cricoid, esophagus, and vertebral body are not in consistent alignment and cricoid pressure does not consistently occlude the esophagus. Small studies in animals and cadavers demonstrate that cricoid pressure prevents reflux of water injected at increased pressure into the esophagus, but there are no human studies on this phenomenon.⁷ There are no outcome studies showing a reduced incidence of aspiration with use of cricoid pressure, but such studies would not be feasible given rates of aspiration during emergency surgery of 1 per 1000 or less. As for adverse effects of cricoid pressure, multiple studies have shown that it can worsen the clinician’s view of the airway during direct laryngoscopy.⁹ If one were to grade the quality of the evidence supporting the use of cricoid pressure using standards of the Oxford Centre for Evidence Based Medicine, a grade no better than D could be assigned!⁷ Curiously, cricoid pressure is regarded as standard of care by many.

GENERAL ANESTHESIA

Invasive monitoring yields a more hemodynamically stable induction

Many books and many clinicians emphasize the importance of placing hemodynamic monitors before induction of general anesthesia. But is there any evidence that having information from a pulmonary artery catheter improves hemodynamic stability during induction? In a randomized comparison, inductions conducted without benefit of pulmonary artery catheter data required no more interventions to maintain stable hemodynamics than inductions “guided” by data from the pulmonary artery catheter.¹⁰ Moreover, placement of an introducer sheath and pulmonary artery catheter after induction of general anesthesia took less time than when performed before induction. Finally, there are no convincing data showing that pulmonary artery catheterization improves outcomes.¹¹

A slow, careful cardiac induction is preferable

Many clinicians recommend a “slow, careful induction” in cardiac and other sick patients. But, is there evidence that a slow induction results in fewer hemodynamic perturbations than a well-conducted rapid sequence induction? In patients scheduled for coronary artery surgery, rapid sequence induction with sufentanil and succinylcholine produced similar hemodynamics and necessitated no more interventions with vasoactive drugs or intravenous fluid

boluses than a slower (2 min) opioid-relaxant induction or a very slow, careful (5-10 min) opioid-relaxant induction.¹²⁻¹⁴

REGIONAL ANESTHESIA

Methemoglobinemia and prilocaine

Methemoglobinemia has long been linked to prilocaine, the only local anesthetic that is metabolized to *o*-toluidine. According to textbooks, prilocaine will reliably produce medically important degrees of methemoglobinemia when doses >600 mg are administered. Recent work by Vasters and colleagues suggests that serious degrees of methemoglobinemia can be associated with prilocaine doses as small as 400 mg in fit adult patients.¹⁵ Interestingly, in another recent study, the local anesthetic most commonly associated with serious degrees of methemoglobinemia was benzocaine.¹⁶

Interscalene blocks and general anesthesia

In 2000 a report appeared in *Anesthesiology* describing 4 patients who experienced disastrous neurological complications after undergoing interscalene blocks while anesthetized.¹⁷ The suggestion was made (and reinforced in an ASRA guideline) that “Interscalene blocks should not be performed in anesthetized or heavily sedated adult or pediatric patients.”^{18,19} But does the evidence show that anesthetized or heavily sedated patients are more likely to have neurologic damage? In fact, large series of interscalene blocks performed in patients receiving general anesthesia report an incidence of adverse neurologic events no different from that reported in large series of interscalene blocks performed without general anesthesia.^{21,21} A large study of interscalene blocks in anesthetized children found no evidence that general anesthesia contributes to patient injury.²² These authors and others²³ argue that it is not reasonable to publish a practice guideline that, in effect, labels the use of deep sedation or general anesthesia before interscalene block as a deviation from safe practice when the available literature disagrees with that conclusion.

CONCLUSIONS

There are a great many accepted practices and published statements in anesthesia that are not supported by strong data sets. In some cases, the available data contradict the prevailing opinion. Although there is little evidence that out and out lies are being promulgated knowingly, it is clear that myths and unproven hypotheses continue to masquerade as received knowledge in our specialty.

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Current Advances in Cardiac Anesthesia

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Learning Objectives:

The participants will be able to evaluate the concept of Health Technology Assessment (HTA) and Value-based practice in Cardiac Anesthesiology. Recent advance in a technology and a drug will be assessed to highlight the HTA concept:

1. Transcatheter Aortic Valve Replacement (TAVR): determine the outcomes of TAVR, Open AVR and Medical Management in patients with severe aortic disease;
2. Colloids: evaluate The Evidence For Fluid Replacement Therapies (Colloids Vs Crystalloids In Acute Care – ICU, Cardiac Surgery).

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Transcatheter aortic valve replacement (TAVR)- Latest RCT, SR-MA

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[CONCLUSIONS: In inoperable AS patients, TAVR substantially reduced the risk of cardiovascular death. In high-risk patients, TA-TAVR and AVR were associated with elevated peri-procedural risk more than with TF-TAVR, although cardiovascular death was higher after TF-TAVR. Therefore, TF-TAVR should be considered the standard of care for severely symptomatic inoperable patients or those at high risk of noncardiovascular mortality after conventional surgery. (THE PARTNER TRIAL: Placement of AoRTic TraNscatheter Valve Trial; NCT00530894).]

COLLOIDS: LATEST SR-MA

1. Bansal M, Farrugia A, Balboni S, Martin G. Relative survival benefit and morbidity with fluids in severe sepsis - a network meta-analysis of alternative therapies. *Curr.Drug Saf.* 2013 Sep;8(4):236-245. [A network meta-analysis compared trials for crystalloids, albumin and hydroxyethyl starch (HES). A literature search of human randomized clinical trials was conducted in databases, the bibliographies of other recent relevant systematic reviews and data reported at recent conferences. Mortality outcomes and RRT data with the longest follow up period were compared. A Bayesian network meta-analysis assessed the risk of mortality and a pair-wise meta-analysis assessed RRT using crystalloids as the reference treatment. RESULTS: 13 studies were identified. A fixed-effects meta-analysis of mortality data in the trials demonstrated an odds-ratio (OR) of 0.90 between crystalloids and albumin, 1.25 between crystalloids and HES and 1.40 between albumin and HES. The probability that albumin is associated with the highest survival was 96.4% followed by crystalloid at 3.6%, with a negligible probability for HES. Sub-group analyses demonstrated the robustness of this result to variations in fluid composition, study source and origin of septic shock. A random-effects pairwise comparison for the risk of RRT provided an OR of 1.52 favoring crystalloid over HES. CONCLUSION: Fluid therapy with albumin was associated with the highest survival benefit. The higher morbidity with HES may affect mortality and requires consideration by prescribers.]
2. Gillies MA, Habicher M, Jhanji S, Sander M, Mythen M, Hamilton M, et al. Incidence of postoperative death and acute kidney injury associated with i.v. 6% hydroxyethyl starch use: systematic review and meta-analysis. *Br.J.Anaesth.* 2014 Jan;112(1):25-34. [Systematic review and meta-analysis of trials in which patients were randomly allocated to 6% HES solutions or alternative i.v. fluids in patients undergoing surgery. RESULTS: Four hundred and fifty-six papers were identified; of which 19 met the inclusion criteria. In total, 1567 patients were included in the analysis. Dichotomous outcomes were expressed as a difference of proportions [risk difference (RD)]. There was no difference in hospital mortality [RD 0.00, 95% confidence interval (CI) -0.02, 0.02], requirement for RRT (RD -0.01, 95% CI -0.04, 0.02), or AKI (RD 0.02, 95% CI -0.02 to 0.06) between compared arms overall or in predefined subgroups. CONCLUSIONS: We did not identify any differences in the incidence of death or AKI in surgical patients receiving 6% HES. Included studies were small with low event rates and low risk of heterogeneity. Narrow CIs suggest that these findings are valid. Given the absence of demonstrable benefit, we are unable to recommend the use of 6% HES solution in surgical patients.]
3. Hartog CS, Welte T, Schlattmann P, Reinhart K. Fluid replacement with hydroxyethyl starch in critical care--a reassessment. *Dtsch.Arztzeitl.* 2013 Jun;110(26):443-450. [On the basis of a selective literature search focusing on reports of the use of HES 130/0.4 and HES 130/0.42 in sepsis, trauma, and intensive care medicine, data from randomized controlled trials (RCTs) are presented, and up-to-date meta-analyses and reviews are discussed. Moreover, the authors conducted an independent meta-analysis of HES 130 in comparison to crystalloids or albumin in intensive care medicine, sepsis, and trauma. RESULTS: Seven RCTs were evaluated, involving a total of 7838 patients treated for sepsis or trauma, or in intensive care. HES 130 was associated with a higher cumulative risk of death (relative risk [RR] 1.10, 95% confidence interval [CI] 1.01-1.20), more frequent need for a renal replacement procedure (RR 1.26, 95% CI 1.08-1.46), and more frequent need for blood transfusion (RR 1.22, 95% CI 1.08-1.37). There was no patient-relevant benefit. Four recent meta-analyses of data from a total of more than 10 000 patients confirmed these concerns about the safety of HES in general and, in particular, of low-molecular-weight HES 130 for patients in intensive care. The safety of 6% HES 130 in the immediate perioperative period has not been adequately demonstrated. DISCUSSION: Because of safety concerns, fluid replacement with HES in critically ill patients cannot be recommended. Evidence for its superior efficacy, safety and cost effectiveness in preoperative use is also lacking.]
4. Jacob M, Fellahi JL, Chappell D, Kurz A. The impact of hydroxyethyl starches in cardiac surgery inverted question mark a meta-analysis. *Crit.Care* 2014 Dec 4;18(6):656. [Databases PubMed, Embase and the Cochrane controlled trials register for randomised controlled trials (RCT) in English or German language comparing HES to any other colloid or crystalloid during open heart surgery. Blood loss and transfusion requirements were higher for older starches with mean molecular weights more than 200 kDa compared to other volume substitutes. In contrast, this effect was not observed with latest generation tetra starches (130/0.4), which even performed better when compared to albumin (blood loss of tetra starch versus albumin: standardised mean difference (SMD) -0.34; 95% CI -0.63, -0.05; $P = 0.02$; versus gelatin -0.06; 95% CI -0.20, 0.08; $P = 0.39$; versus crystalloids: -0.05; 95% CI -0.20, 0.10; $P = 0.54$). Similar results were found for transfusion needs. Length of stay in the intensive care unit or hospital were significantly shorter with tetra starches compared to gelatin (intensive care unit: SMD -0.10; 95% CI -0.15, -0.05; $P = 0.0002$) and crystalloids (Hospital: SMD -0.52; 95% CI -0.90, -0.14; $P = 0.007$). CONCLUSIONS: This meta-analysis of RCTs could not identify safety issues with tetra starches compared with other colloid or crystalloid solutions in terms of blood loss, transfusion requirements or hospital length of stay in cardiac surgery. The safety data on coagulation with older starches raises some issues that need to be addressed in future trials.]

5. Patel A, Laffan MA, Waheed U, Brett SJ. Randomised trials of human albumin for adults with sepsis: systematic review and meta-analysis with trial sequential analysis of all-cause mortality. *BMJ* 2014 Jul 22;349:g4561. [Eighteen articles reporting on 16 primary clinical trials that included 4190 adults in critical or intensive care with sepsis, severe sepsis, or septic shock. A median of 70.0 g daily of pooled human albumin was received over a median of 3 days by adults with a median age of 60.8 years as part of fluid volume expansion and resuscitation, with or without correction of hypoalbuminaemia. The relative risk of death was similar between albumin groups (that received a median of 175 g in total) and control fluid groups (relative risk 0.94; 95% confidence interval 0.87 to 1.01; $P=0.11$; $I(2)=0\%$). Trial sequential analysis corrected the 95% confidence interval for random error (0.85 to 1.02; $D(2)=0\%$). Eighty eight per cent of the required information size (meta-analysis sample size) of 4894 patients was achieved, and the cumulative effect size measure (z score) entered the futility area, supporting the notion of no relative benefit of albumin (GRADE quality of evidence was moderate). Evidence of no difference was also found when albumin was compared with crystalloid fluid (relative risk 0.93; 0.86 to 1.01; $P=0.07$; $I(2)=0\%$) in 3878 patients (GRADE quality of evidence was high; 79.9% of required information size) or colloid fluids in 299 patients (relative risk 1.04; 0.79 to 1.38; $P=0.76$; $I(2)=0\%$) (GRADE quality of evidence was very low; 5.8% of required information size). When studies at high risk of bias were excluded in a predefined subgroup analysis, the finding of no mortality benefit remained, and the cumulative z score was just outside the boundary of futility. Overall, the meta-analysis was robust to sensitivity, subgroup, meta-regression, and trial sequential analyses. CONCLUSIONS: In this analysis, human albumin solutions as part of fluid volume expansion and resuscitation for critically unwell adults with sepsis of any severity (with or without baseline hypoalbuminaemia) were not robustly effective at reducing all-cause mortality. Albumin seems to be safe in this setting, as a signal towards harm was not detected, but this analysis does not support a recommendation for use.]
6. Patel A, Waheed U, Brett SJ. Randomised trials of 6% tetrastarch (hydroxyethyl starch 130/0.4 or 0.42) for severe sepsis reporting mortality: systematic review and meta-analysis. *Intensive Care Med.* 2013 May;39(5):811-822. [A structured literature search was undertaken to identify prospective randomised controlled trials (RCTs) in adult patients with severe sepsis receiving 6% tetrastarch (of potato or waxy maize origin) as part of fluid resuscitation in comparison with other non-HES fluids after randomisation in the critical care setting. A systematic review and meta-analysis were performed. RESULTS: Six RCTs were included ($n = 3,033$); three from 2012 ($n = 2,913$) had low risk of bias. Median tetrastarch exposure was 37.4 ml/kg (range 30-43 ml/kg). Ninety-day mortality was associated with tetrastarch exposure [relative risk (RR) 1.13; 95% confidence interval (CI) 1.02-1.25; $p = 0.02$] compared with crystalloid. The number needed to harm (NNH) was 28.8 (95% CI 14.6-942.5). Publication bias and statistical heterogeneity ($I(2) = 0\%$) were not present. Tetrastarch exposure was also associated with renal replacement therapy ($p = 0.01$; NNH 15.7) and allogeneic transfusion support ($p = 0.001$; NNH 9.9). No difference between groups was observed for 28-day mortality, for comparison with colloid as control, or for waxy maize-derived tetrastarch, but power was lacking. Overall mortality was associated with tetrastarch exposure (RR 1.13; 95% CI 1.02-1.25; $p = 0.02$). CONCLUSIONS: In our analysis, 6% tetrastarch as part of initial fluid resuscitation for severe sepsis was associated with harm and, as alternatives exist, in our view should be avoided.]
7. Rochwerg B, Alhazzani W, Sindi A, Heels-Ansdell D, Thabane L, Fox-Robichaud A, et al. Fluid resuscitation in sepsis: a systematic review and network meta-analysis. *Ann.Intern.Med.* 2014 Sep 2;161(5):347-355. [14 studies (18916 patients) were included with 15 direct comparisons. Network meta-analysis at the 4-node level showed higher mortality with starches than with crystalloids (high confidence) and lower mortality with albumin than with crystalloids (moderate confidence) or starches (moderate confidence). Network meta-analysis at the 6-node level showed lower mortality with albumin than with saline (moderate confidence) and low-molecular-weight starch (low confidence) and with balanced crystalloids than with saline (low confidence) and low- and high-molecular-weight starches (moderate confidence). LIMITATIONS: These trials were heterogeneous in case mix, fluids evaluated, duration of fluid exposure, and risk of bias. Imprecise estimates for several comparisons in this network meta-analysis contribute to low confidence in most estimates of effect. CONCLUSION: Among patients with sepsis, resuscitation with balanced crystalloids or albumin compared wi

Airway Dilemmas—Are You Well Equipped?

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ABSTRACT

A dilemma occurs when an event forces us to make a decision. In a dilemma, there are by definition, two choices; in reality, this is relatively rare since there usually more than two options. (Dilemmas are probably easier to deal with when stressed, compared with a situation presenting a plethora or choices.) When anticipated, we have time to reflect or obtain assistance; when unanticipated difficulties occur, we may not have such a luxury. It is the latter that I will be primarily discussing. Such airway encounters may vary from an unexpectedly challenging laryngoscopy to the inability to oxygenate. Decisions range from the simple insertion of an oral airway or repositioning the head to performing an emergency surgical airway. When encountered, it is important to have a critical awareness of the effectiveness of our efforts, to avoid self-deception, refrain from fixation errors and repeating ineffective strategies. It is also important to anticipate our subsequent actions. Better outcomes result from familiarity with an appropriate algorithm, may be facilitated by cognitive aids, objective verification of the patient's status, immediately available basic and rescue equipment, sufficient prior experience with this equipment and the support of a team of operators.

INTRODUCTION

Over the past two decades, we have made significant advances in airway management. The publication in 1993 of the first ASA Task Report provided Guidelines to manage the difficult airway.¹ This has undergone subsequent revisions in 2003 and 2013.^{2,3} Several national and specialty societies have also published practice guidelines to deal with the anticipated and unexpected difficult airway.⁴⁻⁸ Increasing use of flexible bronchoscopic intubation, supraglottic airways, video laryngoscopy, near-universal use of capnography and oximetry have contributed to improved outcomes.⁹ But clearly there is room for further improvement.¹⁰

In 2005, 37-year-old Elaine Bromiley entered a well-equipped independent healthcare facility in the U.K. for nasal sinus surgery. A high regarded specialist anesthesiologist provided her care. A preoperative assessment indicated that she was in good general health, had undergone previous uneventful anesthetics and apart from slightly restricted neck movement, he identified no airway concerns. Unfortunately, airway management failed and the outcome was tragic. A video recreation of the events, created by Australian Dr. Nicholas Chrimes is profoundly moving and probably more impactful than the words on this page. Please take the time to view it: <http://simpact.net.au/bromiley.html>

Her husband, Martin Bromiley is an airline pilot with a background in human factors. He founded The Clinical Human Factors Group to help well-trained professionals behave

appropriately when confronted by stressful circumstances. In his Foreword to the 4th National Audit Project of the Royal College of Anaesthetists and the Difficult Airway Society (NAP4), stated that “life is a hard teacher, first comes the exam, then the lesson.”¹¹ This report looked at an estimated 2.9 million anesthetics provided in the U.K. during a 12-month period. They were interested in the frequency and causes of serious adverse outcomes related to airway management. These included brain injury, death, ICU admission as a result of an airway complication and an emergency surgical airway. They identified 133 such complications, and the quality of care was judged to be good in only 18%. Such events were not common but identification and correction of the root causes may reduce their occurrence.

We will look at airway dilemmas, what they are, how often they occur, practice guidelines, the mental barriers, equipment, simulation and teamwork.

AIRWAY DILEMMAS

The ASA Task Force identifies 5 elements of initial airway management, each of which might fail. (Other relevant considerations include extubation of the difficult airway and dissemination of the information to the patient and subsequent care providers.) The prevalence of failure will depend upon the case mix, but estimates provided by a recent review¹² are quite reasonable. The elements and their respective failure rates are:

- 1) Impossible facemask ventilation (FMV) . . . 0.1-0.2%
- 2) ventilation with a supraglottic airway (SGA) . . 1-2%
- 3) laryngoscopy (direct) 1-18%
- 4) intubation. 0.05-0.35%
- 5) surgical airway. 0.02-0.0024

These figures may be somewhat misleading. These don't take into consideration the provider, the case mix or the prediction of difficulties. Furthermore, failure of FMV is not really a problem if it is recognized and corrected by successful placement of a SGA or intubation. It's another thing entirely if neither of these can be accomplished. Failure of direct laryngoscopy (DL) is not a problem if a video laryngoscope is available and provides a laryngeal view or if blind intubation can be achieved using a tracheal introducer (aka bougie). The NAP4 Report found that a surgical airway was rarely required but almost always poorly performed, particularly in an operating room.

A meta-analysis looked at 35 studies involving 50,760 adults in whom predictors of difficult DL and the laryngeal view were documented. A Cormack-Lehane > 3 view (i.e. epiglottis only or not even the epiglottis) was seen in 5.8% of patients and the bedside predictors had poor to moderate sensitivity and moderate to fair specificity.¹³

Direct laryngoscopy failed in nearly 6% of patients felt to be candidates for this technique. A Danish study reviewed a national database involving 188,064 anesthetics wherein intubation was attempted.¹⁴ They found that 3383 patients were difficult to intubate, 3154 of whom were unanticipated (93%) despite a prior airway assessment. Difficult FM ventilation was seen in 857 patients and unanticipated in 808 (94%). The study dichotomized patients into easy/difficult; in truth, difficulty is more accurately assessed along a continuum of difficulty. Such studies have demonstrated that at least moderate difficulty with tracheal intubation is encountered in about 8% of patients in the operating room (and at twice that rate when encountered outside the operating room)^{15,16}

What are the lessons of these studies? Prior airway assessment is imperfect but significantly better than chance at identifying potential difficulties. When difficulties are anticipated they are more likely to be encountered than when they were not anticipated; a prior assessment provides us with a better opportunity to prepare for failure. Adverse outcomes without prior assessment may also result in unsuccessful lawsuits.

Of the many important findings of the NAP4 report, two themes stand out:

- repeated attempts with the same technique were seldom helpful and often escalated the problem
- serious airway misadventure was often the result of the *“failure to prepare for failure”*.¹¹

ALGORITHMS AND COGNITIVE AIDS

The algorithms mentioned above 3-5,7 and others, were an attempt at being evidenced-based. Unfortunately, the quality of the evidence is frequently marginal and thus most of the recommendations are a consensus of expert opinion. Though the evidence supporting the respective algorithms is largely the same, for various reasons the recommendations vary somewhat. For example, the ASA Difficult Airway Algorithm refers to “multiple attempts” whereas the Canadian guidelines recommends no more than 3 attempts in total and the DAS recommends no more than 4 attempts. There are many other differences between the various guidelines which make for interesting debates at conferences. What is truly important at the bedside is familiarity with an algorithm that is familiar to those with whom you work, so all participants are on the same page. It is essential to maintain situational awareness, avoid fixation errors, be open to suggestions from others and have the backup plan and familiar equipment immediately available.

Airway algorithms are by nature complex, despite the best efforts of their authors to achieve simplicity. “Ah, yes but what ifs...” result in additional pathways and footnotes. It is incumbent upon a prudent physician to be familiar with the national or local practice guidelines, however when faced with an unexpected dilemma, it is challenging to make rational decisions. Chrimes and Fritz have developed a cognitive aid, the Airway Vortex Approach, compatible with existing algorithms that helps focus the participants’ decision-making.¹⁷ http://vortexapproach.com/Vortex_Approach/Vortex.html The vortex metaphor, which resembles a funnel—think flushing toilet—places the emphasis on oxygenation rather than how this is achieved; it emphasizes

when rather than how. When oxygenation is being achieved, you and the patient are on the upper rim of the vortex (“green zone”) and the situation is stable. Multiple unsuccessful attempts result in centrifugal migration through the vortex to the “blue zone” where timing is more limited (choices: FM, SGA or intubation). They suggest a maximum of three tries within each category, optimizing patient positioning, device selection, adjuncts, muscle tone and operator. If these fail, the patient has entered the dark blue zone and further deterioration occurs very quickly with grave consequences. An emergency surgical airway (ESA) is required and since this takes time, even in practiced hands, we can’t afford to wait until we’ve exhausted our options.

We have discussed the cognitive components, both algorithms and aids that may facilitate mental access to the material we have stored. The next aspect of preparedness is familiarity with the devices.

EQUIPMENT

During the past 25 years, we have moved from having to choose between a curved or straight blade to a veritable airway supermarket. There are dozens of SGAs, video laryngoscopes and video/optical stylets from which to choose with products continually appearing, disappearing and morphing. Many of the studies evaluating these devices are of limited use. Be cautious of those involving manikins, untrained individuals, irrelevant outcomes or patients dissimilar from those we care for. It is important to avoid extrapolating outcomes obtained by experts to those who may be less familiar with a device. For example, expertise with direct laryngoscopy does not necessarily result in skill with a video laryngoscopy; thus studies performed by experienced anesthesiologists but unfamiliar with a device or technique may be more or less applicable than those performed by students well-trained on a particular tool. When the GlideScope was initially investigated, it was our expectation that laryngeal exposure was a relevant outcome yet half of our failed intubations occurred in patients with a good or excellent laryngeal view.¹⁸ Hand-eye coordination came naturally to some but remained awkward for others. The importance of familiarity was demonstrated in a database review involving 2,004 patients in whom the GlideScope was used either as a primary or rescue device. One site had much greater experience with the device and significantly better outcomes.¹⁹

It is not enough to have a device available. Reserving its use only for rescue purposes provides insufficient opportunity to acquire competence and it is less likely to be helpful. This can only be achieved by regular use in normal airways; with regular use, there will be a sufficient number of unanticipated challenges that competency will develop. The airway provider will come to appreciate the limits of the device in their own hands. It is not the device that successfully manages the airway but a skilled operator using a familiar tool.

It is not necessary to have all the available devices and indeed, this will reduce familiarity. Candidate products should be selected from each category and short-listed based upon trusted expert opinion, institutional needs and resources; they should be evaluated and practiced on manikins and trialed on patients with seemingly normal airways. Considerations include the required range of sizes, a preference for single or

reusable products, cost per use, relevant published evidence and product support. For video laryngoscopy, susceptibility to fogging, versatility, channeled vs. non-channeled, Macintosh-style vs. angulated blade design and the ability to record should also be considered.

The equipment selected must be both familiar and easily accessible. Its very presence may help reduce fixation errors (though offering too many choices may create additional problems). At the very least, the equipment on a difficult airway cart should include SGAs, adjuncts such as oral and nasal airways, stylets and tracheal introducers (or bougies), alternative laryngoscopes, both direct and indirect (video laryngoscopes), a flexible bronchoscope and tools for an emergency surgical airway. Since the timing of extubation is elective, airway exchange catheters may be stored elsewhere.

TRAINING

After selecting the devices, training should progress systematically from manikin, to routine and then increasingly challenging patients. Attendance at airway workshops prior to or after early exposure is likely to be helpful. A department might elect to identify “power users” who concentrate on developing expertise with a device or technique and serve as a local resource. Intuitively, this will result in more rapid skill acquisition and fewer failures or complications. With techniques such as video laryngoscopy and flexible bronchoscopic intubation, the author has found it very helpful to record and review each effort to identify opportunities for improvement.

It is unknown how many times a procedure should be performed to be judged competent.²⁰ Different individuals acquire skills at different rates and judge mastery by different standards. Consider our surgical colleagues performing laparoscopic or robotic surgery; we are no different! Malcolm Gladwell discussed the 10,000-hour rule providing countless examples of skills (musical, athletic, intellectual etc.) that required that kind of investment to achieve mastery.²¹ We shouldn't expect to achieve proficiency after “giving it a go.”

SIMULATION

High-fidelity simulation provides an opportunity to combine an individual's and group's cognitive and manual skills with their ability to react cooperatively in a seemingly high-stakes airway dilemma, without the risk of patient harm. Expert non-judgmental feedback from colleagues, facilitators and video recordings promote learning and can “close the gap between acquisition of skills and meaningful use of the acquired skills” particularly those that apply to infrequently encountered situations.²² Prior performance of uncommon procedures, such as an emergency surgical airway even if done on plastic, may increase adherence to guidelines, resulting in fewer delays, cognitive and technical errors.^{23,24}

CONCLUSIONS

Minor airway challenges occur frequently and fortunately and are usually resolved with few adverse outcomes. Major airway dilemmas occur infrequently and can be disastrous, causing significant morbidity, mortality and adverse closed claims decisions. Since some of these events are unanticipated, we must do our best to be prepared when these occur.

Preparation is cognitive (familiarity with practice guidelines and algorithms), mental (situational awareness including the avoidance of self-deception, fixation errors, egocentric decision-making), cooperative and technical. Algorithms are intended to limit the number of choices that have to be considered when faced with frustration. Turning a complex problem into a dilemma actually reduces the number of choices we have to make. Dilemmas are good! Cognitive aids may facilitate access to information that can be blocked in stressful circumstances. Basic and supplementary equipment must be immediately available and familiar. Selection should be expert or consensual but should cover the range of patients and possible encounters. Familiarity comes only with regular use, which should be preceded by manikin training, expert assistance followed by use on patients with easy airways. Clinical simulation may enhance group cooperation, familiarity with infrequently performed tasks and lower the barrier to more timely interventions.

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Quality and Economics in Anesthesia – Let’s Step Up to the Plate!

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INTRODUCTION

Anesthesiology might be the safest of all medical disciplines, with a ‘failure’ rate of fewer than 1 in 1,000 cases and a history of interest in patient outcomes that dates back more than a century. Landmarks include Rovenstine’s promulgation of collected anesthesia case records in the 1930s,¹ Beecher and Todd’s examination of perioperative mortality in the 1950s,² and creation of the Anesthesia Patient Safety Foundation, the Foundation for Anesthesia Education and Research and the Anesthesia Closed Claims Project in the 1980s. In 1999 the Institute of Medicine published *To Err is Human*, calling attention to preventable errors in healthcare and initiating a focused effort to improve the quality of medicine in America.³ Anesthesiology was singled out as the medical discipline which had done the most to improve patient safety. In 2009 the American Society of Anesthesiologists took another step forward by founding the Anesthesia Quality Institute (AQI). The AQI’s mission is to improve patient outcomes through development of a national anesthesia registry.⁴

The AQI created the National Anesthesia Clinical Outcomes Registry (NACOR) in 2010 to capture basic data on every case, every day from participating practices. A second registry, the Anesthesia Incident Reporting System (AIRS) was created in 2011 to capture detailed information from individual cases of interest. Data is collected from anesthesia practices of all types and sizes and aggregated to create benchmarks for clinical outcomes. The collected data encompass all aspects of anesthesia quality including operational efficiency, safety, and patient experience. Practices contributing to the AQI receive continuous online access to dozens of reports on their data. NACOR reports show trends over time and how the practice compares to the rest of NACOR. Electronic tools allow for most reports to be subdivided by facilities in the practice, individual providers, and specific surgical procedures. NACOR reports are designed to facilitate practice management, and to address burgeoning regulatory requirements from the federal government and the Joint Commission.

Aggregated information from NACOR and AIRS describe the practice of anesthesiology in the United States, and is distributed to ASA and subspecialty society leaders; Anesthesia in the US 2 is available to AQI participants for download from the website. AQI maintains “dashboards” of key indicators for ASA leaders, subspecialty societies such as the Society for Obstetrics and Perinatology, and select ASA Committees. This Refresher Course Lecture will provide a brief overview of the structure, mechanics and current status of the AQI, NACOR and AIRS, and will present some snapshots of aggregated national data.

DATA ACQUISITION

The AQI gathers information about the specialty of anesthesiology. This includes published reports in the scientific literature, business articles and reports, and internal ASA communications. The most important sources of data, however, are NACOR and AIRS. Participation in the AQI is open to every anesthesiology practice in the United States, and any provider in the world can submit case reports to AIRS. There is no requirement for a minimum level of technology or the use of software from any specific vendor. There is no charge to ASA members for participation in NACOR.

Practices wishing to join begin by signing a Business Associate agreement that outlines the extent of information to be shared and the rights and responsibilities of both parties. The AQI is accredited as a Patient Safety Organization by the Agency for Healthcare Research and Quality (AHRQ), and the confidentiality of data contributed to the AQI is protected by both federal law and the Illinois Medical Studies Act. The AQI collects all data in de-identified form, and is further bound by its practice agreements to preserve the confidentiality of all patients, facilities, providers and groups.

NACOR is designed to accumulate data through periodic electronic reporting. Participating practices complete an online demographic survey that describes their organization, the facilities they work in, and the members of the group. This provides context for subsequent case-specific data. AQI works with the practice to build links between their existing software (billing systems, hospital systems, QM programs) and NACOR. The goal is to collect whatever case-specific electronic data exists, without requiring new data entry by working anesthesiologists. Data contributed to the AQI is entirely de-identified. Patient names and numbers are removed, and facilities and providers are recorded by code numbers.

At present, every anesthesia practice uses electronic billing software, and the AQI works with vendors of these products to enable periodic reporting. A participating practice is NOT required to have an anesthesia information management system (AIMS). It is expected that electronic anesthesia records will advance over time, and AQI is aiming for a future state in which a large amount of case-specific data is available through such systems. In the meantime, the AQI is working with practices and vendors to design, improve and deploy electronic systems to facilitate the aggregation of clinical data. One function of AQI is to develop consensus-based standards for defining and reporting relevant outcomes in anesthesiology, and to share these with the healthcare information technology industry. A second important function is to advise anesthesia practices on which elements of patient care are most important to measure, and make them aware of technologies that may facilitate electronic data collection.

The AQI began recruiting participant practices in late 2009, and as of February 20, 2014 has signed agreements with 457 groups. These practices represent the breadth of anesthesiology in the United States, including a mix of academic and private groups, large and small practices and both single-center and multi-hospital corporations. These practices include more than 37,000 anesthesia practitioners working in more than 3500 surgical facilities.

NACOR began collecting case data on January 1, 2010, and currently includes records on more than 24 million cases. Information available from every case includes the date, location and duration of surgery; the specific surgical and anesthesia procedures performed; the patient's age, sex, zip code and primary diagnosis; the anesthesia coverage model; and the providers involved. Many AQI Participant Practices contribute further electronic information based on their local software systems. Additional data may include quality improvement forms (safety and complications), patient experience (nausea and vomiting, pain management, satisfaction), operational efficiency (length of stay, readmission or upgrades of care) and detailed information about the case itself (medications used, procedures performed, patient vital signs, fluid management). Departments of Anesthesiology that are contributing AIMS data to the Multicenter Perioperative Outcomes Group (MPOG; <http://mpog.med.umich.edu/>) can arrange to have this same data transmitted simultaneously to NACOR, thus reaping both research and quality management benefits from the same information.

REPORTING

AQI reports data to a variety of stakeholders (Figure 1). AQI participating practices receive quarterly online reports from NACOR which include their own submitted data (trended over time) and aggregated national benchmarks. Features of the reports allow the practice to 'slice and dice' their data to examine specific facilities, providers, cases or patient types. Reports can be constructed out of multiple variables, and displayed to the level of the individual practitioner. This allows the practice to use NACOR data for federal and hospital requirements (such as PQRS submission and for the Joint Commission), and allows individuals to use

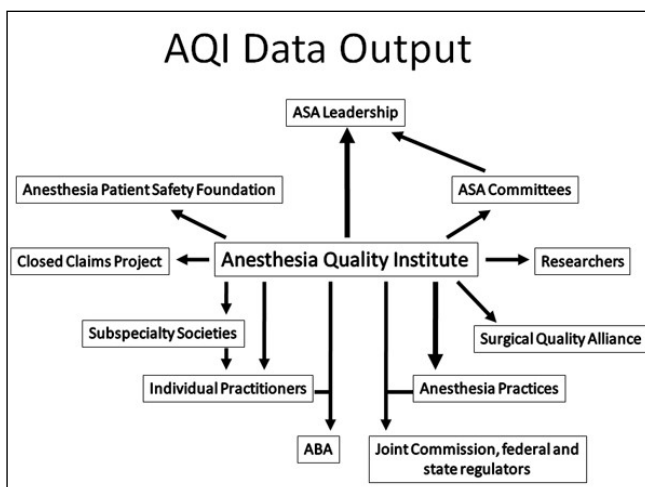


Figure 1. Outputs and stakeholders of Anesthesia Quality Institute data.

NACOR data for maintenance of certification and licensure. Outcome benchmarks can be created based on the peer groups of greatest relevance (for example: hospital-affiliated surgery centers in the Southeast US). Member practices can construct reports on their own, or can request specific reports and analysis from the AQI. In 2013 the AQI began publishing a "Participant User File" (PUF) as a tool for academic research by anesthesiologists in AQI-participant practices. The PUF includes cleaned, de-identified, case-level data from each full year of NACOR accumulation, as well as a data dictionary that describes the meaning and context of each field. Access to the PUF is available by completing an application on the AQI website.

AQI is working with ASA Committees and anesthesia subspecialty societies to provide custom aggregate data reports. Collaborations with AQI can take many forms, but one model is illustrated by the relationship between the AQI and the Society for Ambulatory Anesthesia (SAMBA). Anesthesia practices with a large proportion of ambulatory cases can contract with SAMBA to receive ambulatory-specific reports – based on data collected in NACOR – that offer greater granularity for this subspecialty area. SCOR is a software "front-end" offered by SAMBA that facilitates rapid collection of case data at the point of care and submission to NACOR. Groups participating with both AQI and SAMBA will gain added value in understanding the ambulatory component of their practice. More information is available at <http://www.sambahq.org/>.

LIMITATIONS OF NACOR

Automated harvest of electronic data obeys the prime rule of the information age: garbage in = garbage out. Data in NACOR is accumulated from hundreds of facilities, each with its own unique mix of patients, operations and providers. Data transmission is through dozens of different electronic systems, many of which use unique definitions for outcomes of interest. This makes aggregation challenging, but does not affect the greatest value of NACOR data for quality improvement: examination of outcomes over time within a single practice or facility. Development of benchmarks requires unification of disparate data without full knowledge of its heterogeneity, and interpretation of benchmark data should be undertaken with a grain of salt.⁵ This is why the demographic information collected from each practice is important: it allows an understanding of the context of data collection at individual sites. For some common elements NACOR data is highly reliable (e.g. surgical case times). For other elements, such as the occurrence of postoperative nausea and vomiting, there are no standard definitions to draw on and many different ways of collecting the data. Benchmarks in this area will be less solid, although trends over time within a single practice – sharing a common definition and level of risk – will remain useful.

Another concern is the potential bias among practices that are participating in NACOR. It is likely that early adopters are those groups which already put significant value on data collection and analysis, and are best able to apply the quality management lessons learned. Recent internal validation of NACOR data against the National Inpatient Sample suggests that NACOR is gathering 15-20% of any specific surgical case

nationally, with a bias towards larger hospitals and urban settings. This might bias NACOR towards better performing groups and lower aggregated rates of major complications.

ANESTHESIOLOGY AS A SPECIALTY

The American Medical Association reports 42,000 anesthesiologists in its records, but does not report how many of them are engaged in full-time clinical practice. ASA includes about 52,000 members, of which 33,000 or so are 'active' practitioners. The American Hospital Association lists 6,300 acute care hospitals in the US, while the Centers for Medicare and Medicaid Services (CMS) makes payments to more than 5,200 ambulatory surgery centers. Anesthesia services are also billed from specialty hospitals (e.g. orthopedic, neurosurgical, women's, children's, cardiac, and psychiatric hospitals), clinics and freestanding physicians' offices. The diffusion of anesthesia services – and the work of anesthesiologists – from traditional operating room suites to other environments is one of the major demographic trends in our specialty. Data from NACOR suggest a steady increase in the proportion of outpatient vs. inpatient surgeries (Figure 2), with the current figure at about 70% outpatients.

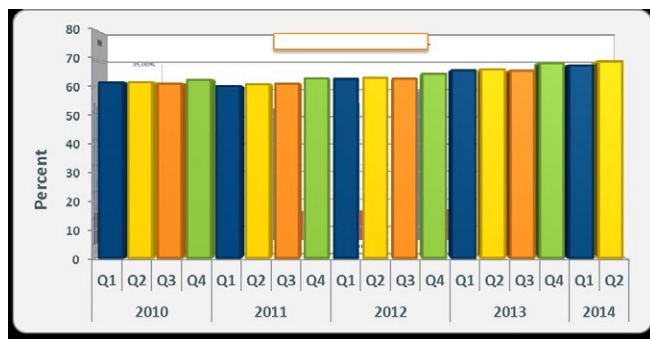


Figure 2. Percentage of outpatient surgical cases (home within 23 hours) in the National Anesthesia Clinical Outcomes Registry, by quarter.

The average practicing anesthesiologist in the US is 51 years old. 25% of the 18,000 anesthesiologists in NACOR are women, but this percentage increases in more recent graduating classes; 40% of PGY-1 residents are women. 73% of anesthesiologists in NACOR are certified by the American Board of Anesthesiology. 85% report working full-time, for an average of about 50 hours per week. Recent work force projections prepared by the RAND corporation for ASA suggest that the supply and demand of anesthesiologists are in approximate balance.⁶ Surgical volume has increased a steady 3-4% per year for the past two decades, and this is unlikely to change in the years ahead. The availability of anesthesiologists in a market may help to create demand, as it becomes possible to cover non-traditional services such as complex GI, cardiac electrophysiology, dentistry and interventional radiology. It appears there will be continued need for our services in the years ahead.

More than 5000 anesthesiology residents are currently in training at 130 accredited programs. More than 50% of graduates will continue into fellowships this year (a steadily increasing percentage), with the last available numbers showing 305 pain fellows, 165 cardiothoracic fellows, 185 pediatric anesthesia fellows, and 131 critical care fellows. Others are pursuing extra training in obstetrics, transplant,

trauma and other disciplines that are non-ACGME approved. It is not known how many are pursuing bench research or supplemental training in public policy, statistics, business or epidemiology.

DEMOGRAPHICS OF ANESTHESIA PRACTICE

Participating practices in the AQI range from one person private practices up to groups which include more than 600 physician anesthesiologists and a like number of nurse anesthetists. While 11% of practices in NACOR include a university hospital, approximately 50% of participating anesthesiologists report some time spent teaching residents, student nurses, or anesthesiologist assistants.

60% of providers in NACOR are physician anesthesiologists and 40% are nurse anesthetists. This represents a bias in NACOR relative to the approximately 50:50 nationwide ratio of the professions. 65% of the practices in NACOR work with NAs and 10% with AAs; the remainder are physician-only groups. The care team model of one physician medically directing some number of residents, AAs or NAs is dominant in NACOR, representing more than 75% of all cases.

On average, practices in NACOR report deriving 16% of their income from direct contracts with a hospital (an increase from last year), 5% from "self-pay" patients, and 37% from Medicare or Medicaid. There is substantial variability in these numbers from group to group. Further shifting of these demographics is likely as the effects of the Affordable Care Act ripple through medicine and the trend towards larger anesthesia group practices continues.

Thirty-two percent of NACOR facilities are medium-sized community hospitals (100-500 beds), accounting for almost 40% of all the cases reported (Figure 3). 24% of facilities are freestanding ambulatory surgery centers and another 9% are hospital associated outpatient surgery facilities; these two groups account for 30% of all cases. Large community and university hospitals represent only 10% of all NACOR facilities, but perform 24% of all cases.

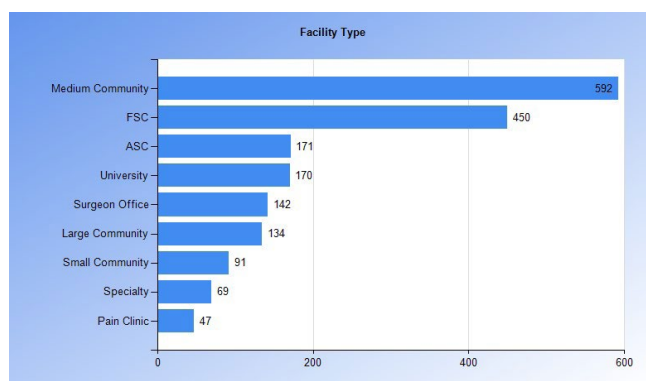


Figure 3. Types of surgical facilities reporting cases to the National Anesthesia Clinical Outcomes Registry.

DEMOGRAPHICS OF ANESTHESIA CASES

Approximately 10% of all patients in NACOR are 18 years or younger; 38% are aged 19-49; 26% are 50-64; 19% are 65-79; and 7% are 80 years or older. The average anesthesia practice will soon see far more geriatric than pediatric patients. Figure 4 shows the distribution of male and female patients by age in NACOR. ASA physical status increases with age. One third

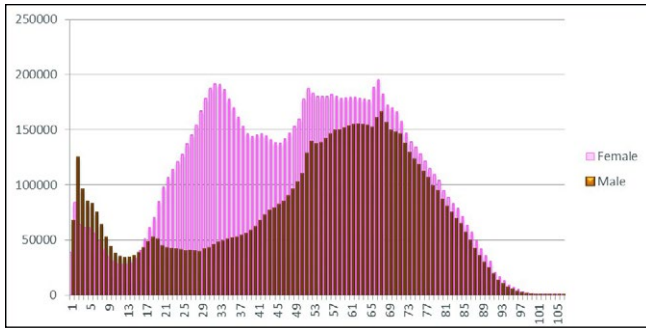


Figure 4. Patient age and sex in the National Anesthesia Clinical Outcomes Registry, all cases reported.

of 50 year old patients are ASA III or greater. This proportion rises to more than 60% by age 80.

Two thirds of the cases in NACOR were performed under general anesthesia, 18% as monitored anesthesia care, and 10% with spinal or epidural. Peripheral nerve block was the primary anesthetic in less than 5% of cases. It is possible that these numbers will shift as ultrasound-guided regional techniques become more popular.

The most common cases in American anesthesia practice are shown in Figure 5, sorted by patient age. For the most part

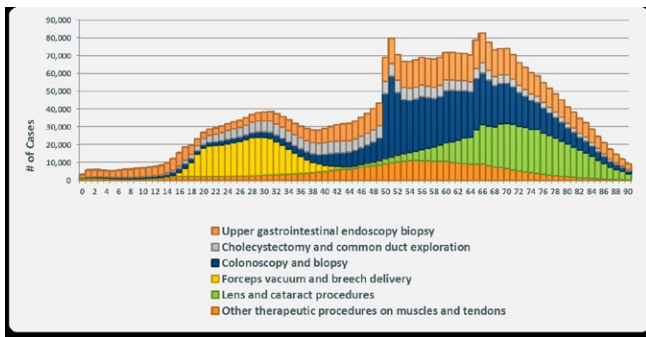


Figure 5. The most common cases reported to the National Anesthesia Clinical Outcomes Registry, by patient age.

these are short cases performed under sedation, often in non-operating room locations. Multiplying the number of cases done by the average duration of the anesthetic yields a different view of practice (Figure 6), better emphasizing how anesthesia practices assign their personnel. Understanding

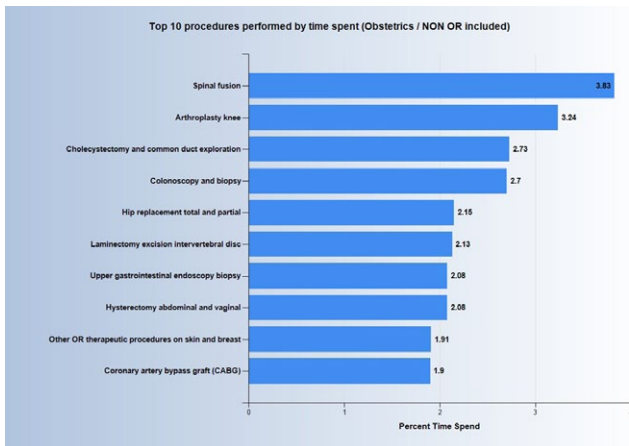


Figure 6. The most common cases reported to the National Anesthesia Clinical Outcomes Registry, by time spent per case.

case mix is critical to understanding how to manage an anesthesia business, one important piece of benchmarking

that NACOR participation can provide. Even more useful is an examination of variability in how different groups and facilities deliver similar anesthetics. Figure 7 shows the mean and standard deviation of case duration for >150 facilities

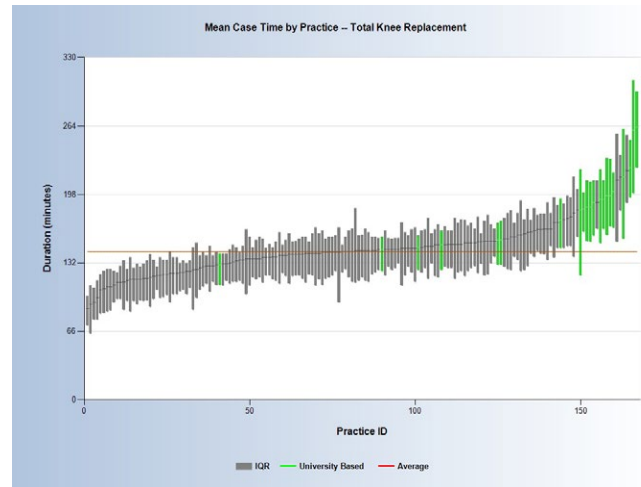


Figure 7. Mean and standard deviation of anesthetic time for total knee replacement in facilities reporting data to the National Anesthesia Clinical Outcomes Registry.

performing total knee replacement and reporting their data to NACOR. The degree of variation is remarkable, with average case time ranging from about 75 minutes to more than 4 hours. This represents an enormous in-efficiency in OR utilization, and has significant financial impact on hospitals and anesthesia departments. Using this kind of NACOR data to benchmark practice performance, and track improvement over time, can provide a competitive advantage.

CLINICAL OUTCOMES

One or more measures of clinical quality are reported by most NACOR participants, representing more than half of all cases. The most common outcome measures are the procedure codes for the PQRS measures: timely administration of antibiotics, observation of sterile precautions during central line placement, and maintenance of intraoperative normothermia. These measures— incentivized by the Center for Medicare and Medicaid Services—are reported by 55% of NACOR participants, with a generally high rate of successful compliance. About 30% of AQR practices collect and report more detailed clinical outcomes, using a variety of different information technology platforms and varying definitions for the measures themselves.

Serious adverse events, defined as those that cause patient harm or serious risk of harm, have been reported in about 0.8% of the approximate 3.5 million cases done by the groups that have electronic reporting of these occurrences. Definitions of these are relatively standardized, based on the recommendations of ASA's Committee on Performance and Outcome Measures. Serious adverse events range from dural puncture headache to peripheral nerve injury to hemodynamic instability to stroke and myocardial infarction. Perioperative death—the ultimate adverse event—is reported by these same groups, and provides a crude all-cause mortality of 0.05%, or about 1 in 10,000 anesthetics.

Working with a diverse group of stakeholders, AQR hosted the First Annual Conference on Standard Definitions

in Anesthesia (DefCon 1) in April, 2013. Participants included anesthesiologists with an interest in electronic data, patient safety, and anesthesia practice management, as well as representatives from anesthesia software vendors. Working together, a consensus document was developed that recommends a 'core set' of outcome measures to capture during the perioperative, recovery and post-recovery periods of any anesthetic. This document can be downloaded from the AQI site at http://www.aqihq.org/files/Outcomes_of_Anesthesia_Summer_2013.pdf and is available to any company developing software in this area, and to any anesthesia practice working to initiate a quality management program.

As yet the number of serious adverse events captured in NACOR is too small for statistical analysis, other than making the observation that anesthesia is generally very safe. Serious adverse events or mortality have occurred in fewer than 10 cases per 1,000 in NACOR, with the leading subcategories being the need for upgraded care (ICU admission or hospital admission of an outpatient) and the need for resuscitation (variable definitions apply). While committed to the long-term development of outcome benchmarks, the AQI intends to move cautiously in reporting them. Because the frequency is so low, and the consequences of disclosure are serious, any public reporting of major adverse events will require unified definitions, risk adjustment across reporting locations, and selected auditing of submitted data. For the time being, detailed reports about major adverse outcomes will be confined to the private quality management reports shared between the AQI and participating practices. Aggregate reports of outcomes with a common definition across practices will be published as the numbers allow; the first of these is a look at perioperative cardiac arrest published in the February 2015 Anesthesia & Analgesia.⁷

THE ANESTHESIA INCIDENT REPORTING SYSTEM

A nationwide benchmarking registry such as NACOR is the ultimate example of top-down quality management, but there is value in "bottom-up" reporting as well. Discussion of interesting cases is the cornerstone of the morbidity and mortality conference, and remains a powerful educational tool. This justifies AQI's creation of the Anesthesia Incident Reporting System (AIRS), as well as continuing support of the Anesthesia Closed Claims Project, the Postoperative Visual Loss Registry, and other such efforts. The goal is collection of detailed information ('stories') from unusual and educational cases. The mechanism is a simple online form that can be submitted confidentially from any internet-capable computer. Submission to AIRS is protected from legal discovery by AQI's status as a Patient Safety Organization, and all reports are stored in a de-identified format. Case submissions are periodically reviewed by a committee of experts. Cases with unique teaching potential are 'fictionalized' and presented monthly in the ASA NEWSLETTER. All cases are periodically analyzed for common features, and aggregated to identify trends in patient safety. AIRS currently includes "sub-modules" for reporting on a number of different sub-populations (pediatrics, obstetrics) and specific event categories (postoperative respiratory depression, errors

arising from medication shortages). AIRS can be accessed at: <https://www.aqiairs.org>.

More than 1500 case reports have been submitted through the online site or the mobile application released in October 2013. Case reports have come from at least 80 different institutions. Ten percent of cases involve harm to patients, while the remainder describe near misses (often due to the reactions of the anesthesia team) and unsafe conditions. About half of the cases are judged by the reporter to be preventable. Forty case discussions based on AIRS have appeared in the ASA Newsletter to date.

FUTURE INITIATIVES OF THE AQI

The primary mission of AQI will remain expansion of NACOR. This will occur through ongoing recruitment of new practices and increasing the quantity and depth of data collected from current participants. As technology advances, the NACOR model of continual passive collection of existing clinical data will become progressively more powerful. Efforts are underway now with the largest EHR companies to build outcome capture into their systems as a routine feature; both companies have developed templates for NACOR data reports that will greatly increase the granularity of clinical information in the registry. Other AIMS vendors are not far behind.

In early 2014 AQI became the technical vendor for a partnership between ASA and the American Congress of Obstetricians and Gynecologists (ACOG) to create a new kind of registry – the Maternal Quality Improvement Project (MQIP) – focused on team-based shared outcomes in labor and delivery. The methodology will involve creation and standardization of structured data fields within the existing electronic healthcare records of an institution to facilitate subsequent registry harvest of the data. The goal is to get the data efficiently, without imposing additional documentation burden on the clinicians themselves, while minimizing the need to employ clinical abstractors.

In 2014 NACOR was designated by CMS as a Qualified Clinical Data Registry (QCDR). This is a new mechanism for performance reporting for physicians and practices. In the process of establishing the QCDR, AQI and ASA had the opportunity to nominate our own, specialty-specific measures for reporting. This marks the first time in the history of federal healthcare quality incentive programs that our profession has had such direct and immediate control of the measures that will be used to judge us. Further growth in participation in NACOR will mirror the maturation of the QCDR. In time, participation in NACOR will help anesthesiologists meet their quality management, regulatory and maintenance-of-certification needs, while simultaneously generating data for comparative effectiveness research and other 'big-data' scientific projects.

SUMMARY

The AQI is an important resource for anesthesiologists and their practices. NACOR is the measuring stick that practices can use to benchmark their performance, both in terms of business efficiency and in clinical outcomes. Data from AQI help shape ASA committee work, educational products and advocacy efforts. The goal of NACOR and AIRS

is a complete picture of anesthesia practice in the United States, empowering anesthesiology as the leader in patient safety. More information on the AQI, including educational material on quality management and anesthesia information technology, can be found on our website at www.aqihq.org.

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New Anticoagulants and Regional Anesthesia

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Learning objectives:

1. Discuss the pharmacology of antithrombotic and antiplatelet medications.
2. Identify risk factors for regional anesthesia related bleeding.
3. Develop management strategies to improve neurologic outcome in patients undergoing regional anesthesia while receiving antithrombotic or antiplatelet therapy.

The actual incidence of neurologic dysfunction resulting from hemorrhagic complications associated with neuraxial blockade is unknown; however, recent epidemiologic studies suggest the incidence is increasing.¹ In a review of the literature between 1906 and 1994, Vandermeulen et al.² reported 61 cases of spinal hematoma associated with epidural or spinal anesthesia. In 87% of patients, a hemostatic abnormality or traumatic/difficult needle placement was present. More than one risk factor was present in 20 of 61 cases. Importantly, although only 38% of patients had partial or good neurologic recovery, spinal cord ischemia tended to be reversible in patients who underwent laminectomy within eight hours of onset of neurologic dysfunction.

It is impossible to conclusively determine risk factors for the development of spinal hematoma in patients undergoing neuraxial blockade solely through review of the case series, which represent only patients with the complication and do not define those who underwent uneventful neuraxial analgesia. However, large inclusive surveys that evaluate the frequencies of complications (including spinal hematoma), as well as identify subgroups of patients with higher or lower risk, enhance risk stratification. In the series by Moen et al.³ involving nearly 2 million neuraxial blocks, there were 33 spinal hematomas. The methodology allowed for calculation of frequency of spinal hematoma among patient populations. For example, the risk associated with epidural analgesia in women undergoing childbirth was significantly less (1 in 200,000) than that in elderly women undergoing knee arthroplasty (1 in 3600, $p < 0.0001$). Likewise, women undergoing hip fracture surgery under spinal anesthesia had an increased risk of spinal hematoma (1 in 22,000) compared to all patients undergoing spinal anesthesia (1 in 480,000).

Overall, these series suggest that the risk of clinically significant bleeding varies with age (and associated abnormalities of the spinal cord or vertebral column), the presence of an underlying coagulopathy, difficulty during needle placement, and an indwelling neuraxial catheter during sustained anticoagulation (particularly with standard heparin or LMWH). They also consistently demonstrate the need for prompt diagnosis and intervention. Practice guidelines or recommendations summarize evidence-based reviews.

However, the rarity of spinal hematoma defies a prospective-randomized study, and there is no current laboratory model. As a result, the consensus statements developed by the American Society of Regional Anesthesia and Pain Medicine represent the collective experience of recognized experts in the field of neuraxial anesthesia and anticoagulation.⁴ They are based on case reports, clinical series, pharmacology, hematology, and risk factors for surgical bleeding. An understanding of the complexity of this issue is essential to patient management.

ORAL ANTICOAGULANTS

Clinical experience with patients who, congenitally, are deficient in factors II, IX, or X suggests that a factor activity level of 40% for each factor is adequate for normal or near-normal hemostasis. Bleeding may occur if the level of any clotting factor is decreased to 20% to 40% of baseline. The PT is most sensitive to the activities of factors VII and X and is relatively insensitive to factor II. During the first few days of therapy, the PT reflects primarily a reduction of factor VII, the half-life of which is approximately 6 hrs. After a single dose, marked prolongation of the INR may occur, although adequate factor levels are still present. However, with additional doses, an INR greater than 1.4 is typically associated with factor VII activity less than 40% (and the potential for inadequate clotting).⁵

Few data exist regarding the risk of spinal hematoma in patients with indwelling epidural catheters who are anticoagulated with warfarin. The optimal duration of an indwelling catheter and the timing of its removal also remain controversial. Odoom and Sih⁶ performed 1000 continuous lumbar epidural anesthetics in vascular surgical patients who were receiving oral anticoagulants preoperatively. The thrombotest (a test measuring factor IX activity) was decreased (but not below 10% activity) in all patients prior to needle placement. Heparin was also administered intraoperatively. Epidural catheters remained in place for 48 hours postoperatively. There were no neurologic complications. While these results are reassuring, the obsolescence of the thrombotest as a measure of anticoagulation combined with the unknown coagulation status of the patients at the time of catheter removal limit the usefulness of these results. Therefore, except in extraordinary circumstances, spinal or epidural needle/catheter placement and removal should not be performed in fully anticoagulated patients.

There were no symptomatic spinal hematomas in two smaller series with a total of nearly 700 patients undergoing neuraxial block in combination with warfarin anticoagulation perioperatively.⁶⁻⁸ In both studies, epidural catheters were left indwelling approximately two days. The mean international normalized ratio (INR) at the time of catheter removal was 1.4, although in a small number of patients the INR was therapeutic (2.0-3.0). A large variability in patient response

to warfarin was also noted, demonstrating the need for close monitoring of the coagulation status. There were no spinal hematomas in a series of 11,235 patients receiving epidural analgesia after total knee replacement⁹. Patients received warfarin (5-10 mg) starting the night of surgery. Epidural catheters were removed within 48 hrs. The mean INR in a subset of 1030 patients at the time of catheter removal was 1.5 (range, 0.9-4.3); the INR was less than 1.5 in nearly 40% of patients. These series suggest that not only the INR but also the duration of warfarin therapy must be considered and that prolongation within the first 48 hrs may represent a significant increase in risk.

INTRAVENOUS AND SUBCUTANEOUS STANDARD HEPARIN

The safety of neuraxial techniques in combination with intraoperative heparinization is well documented, providing no other coagulopathy is present. In a study involving over 4000 patients, Rao and El-Etr¹⁰ demonstrated the safety of indwelling spinal and epidural catheters during systemic heparinization during vascular surgery. However, the heparin was administered at least 60 minutes after catheter placement, level of anticoagulation was closely monitored, and the indwelling catheters were removed at a time when circulating heparin levels were relatively low. A subsequent study in the neurologic literature by Ruff and Dougherty¹¹ reported spinal hematomas in 7 of 342 patients (2%) who underwent a diagnostic lumbar puncture and subsequent heparinization. Traumatic needle placement, initiation of anticoagulation within one hour of lumbar puncture and concomitant aspirin therapy were identified as risk factors in the development of spinal hematoma in anticoagulated patients. Subsequent studies using similar methodology have verified the safety of this practice, provided the monitoring of anticoagulant effect and the time intervals between heparinization and catheter placement/removal are maintained.

Low-dose subcutaneous standard (unfractionated) heparin is administered for thromboprophylaxis in patients undergoing major thoracoabdominal surgery and in patients at increased risk of hemorrhage with oral anticoagulant or low molecular weight heparin (LMWH) therapy. There are nine published series totaling over 9,000 patients who have received this therapy without complications,¹² as well as extensive experience in both Europe and United States without a significant frequency of complications. There are only five case reports of neuraxial hematomas, four epidural^{2,13} and one subarachnoid,¹⁴ during neuraxial block with the use of subcutaneous heparin.

The largest study of thrice daily unfractionated heparin involved 768 epidural catheter placements. Sixteen patients from this group had a positive match for hemorrhage codes on their discharge records, with none of the episodes being identified within a major hemorrhage category. Laboratory value analysis failed to reveal changes in the aPTT values of significance.⁴ The safety of neuraxial blockade in patients receiving doses greater than 10,000 U of UFH daily or more than twice-daily dosing of UFH has not been established. Although the use of thrice-daily UFH may lead to an increased risk of surgical-related bleeding, it is unclear whether

there is an increased risk of spinal hematoma. If thrice-daily unfractionated heparin is administered, techniques to facilitate detection of new/progressive neurodeficits (eg, enhanced neurologic monitoring occur and neuraxial solutions to minimize sensory and motor block) should be applied.

LOW MOLECULAR WEIGHT HEPARIN

Extensive clinical testing and utilization of LMWH in Europe over the last ten years suggested that there was not an increased risk of spinal hematoma in patients undergoing neuraxial anesthesia while receiving LMWH thromboprophylaxis perioperatively.^{2,15} However, in the five years since the release of LMWH for general use in the United States in May 1993, over 60 cases of spinal hematoma associated with neuraxial anesthesia administered in the presence of perioperative LMWH prophylaxis were reported to the manufacturer.^{16,17} Many of these events occurred when LMWH was administered intraoperatively or early postoperatively to patients undergoing continuous epidural anesthesia and analgesia. Concomitant antiplatelet therapy was present in several cases. The apparent difference in incidence in Europe compared to the United States may be a result of a difference in dose and dosage schedule. For example, in Europe the recommended dose of enoxaparin is 40 mg once daily (with LMWH therapy initiated 12 hours preoperatively), rather than 30 mg every twelve hours. However, timing of catheter removal may also have an impact. It is likely that the lack of a trough in anticoagulant activity associated with twice daily dosing resulted in catheter removal occurring during significant anticoagulant activity. Importantly, there are no data to suggest that the risk of spinal hematoma is increased with specific LMWH formulations.¹⁶ The incidence of spinal hematoma in patients undergoing neuraxial block in combination with LMWH has been estimated at 1 in 40,800 spinal anesthetics and 1 in 3100 continuous epidural anesthetics.¹⁸ It is interesting in that the frequency of spinal hematoma in this series is similar to that reported by Moen et al³ for women undergoing total knee replacement with epidural analgesia.

Indications for thromboprophylaxis as well as treatment of thromboembolism or MI have been introduced. These new applications and corresponding regional anesthetic management warrant discussion.¹⁹ Several off-label applications of LMWH are of special interest to the anesthesiologist. LMWH has been demonstrated to be efficacious as a "bridge therapy" for patients chronically anticoagulated with warfarin, including parturients, patients with prosthetic cardiac valves, a history of atrial fibrillation, or preexisting hypercoagulable condition. The doses of LMWH are those associated with DVT treatment, not prophylaxis, and are much higher. An interval of at least 24 hours is required for the anticoagulant activity to resolve.

DABIGATRAN

Dabigatran etexilate is a prodrug that specifically and reversibly inhibits both free and clot-bound thrombin. The drug is absorbed from the gastrointestinal tract with a bioavailability of 5%.²⁰ Once absorbed it is converted by esterases into its active metabolite, dabigatran. Plasma levels

peak at two hours. The half-life is eight hours after a single dose and up to 17 hours after multiple doses. It is likely that once daily dosing will be possible for some indications because of the prolonged half-life. Because 80% of the drug is excreted unchanged by the kidneys, it is contraindicated in patients with renal failure.²¹ Dabigatran prolongs the aPTT, but its effect is not linear and reaches a plateau at higher doses. However, the ecarin clotting time (ECT) and thrombin time (TT) are particularly sensitive and display a linear dose response at therapeutic concentrations. Reversal of anticoagulant effect is theoretically possible through administration of recombinant factor VIIa, although this has not been attempted clinically.²¹ Indeed, product labeling suggests that dialysis may be considered for patients with significant bleeding due to dabigatran.

Given the irreversibility of dabigatran, the prolonged half-life and the uncertainty of an individual patient's renal function, dabigatran should be discontinued five days prior to neuraxial block. Consider documentation of reversal of anticoagulant effect (assessment of a TT or ECT) if less than five. Neuraxial catheters should be removed at least six hours prior to initiation of dabigatran therapy.²²

RIVAROXABAN

Rivaroxaban is a potent selective and reversible oral activated factor Xa inhibitor, with an oral bioavailability of 80%. After administration, the maximum inhibitory effect occurs one to four hours, however, inhibition is maintained for 12 hours. Rivaroxaban is cleared by the kidneys and gut. The terminal elimination half-life is nine hours in healthy volunteers and may be prolonged to 13 hours in the elderly due to a decline in renal function (hence a need for dose adjustment in patients with renal insufficiency and contraindicated in patients with severe liver disease).

Overall, clinical trials comparing rivaroxaban (5- 40mg mg daily, with the first dose six to eight hours after surgery) with enoxaparin (40 mg, beginning 12 hours before surgery) demonstrate similar rates of bleeding and a comparable efficacy.²³⁻²⁵ While a "regional anesthetic" was performed in over half of the patients included in the clinical trials, no information regarding needle placement or catheter management was included. Although there have been no reported spinal hematomas, the lack of information regarding the specifics of block performance and the prolonged half-life warrants a cautious approach.

A minimum of three days should elapse between discontinuation of rivaroxaban and neuraxial block. Indwelling neuraxial catheters are contraindicated due to the "boxed warning". Likewise, indwelling neuraxial catheters should be removed six hours prior to initiation of rivaroxaban therapy postoperatively.

APIXABAN

Apixaban inhibits platelet activation and fibrin clot formation via direct, selective and reversible inhibition of free and clot-bound factor Xa. The oral bioavailability is 50%. After administration, the maximum inhibitory effect occurs in three to four hours, however, inhibition is maintained for 12 hours. Apixaban is cleared by the liver and kidneys. The

terminal elimination half-life is 12 hours in healthy volunteers and may be prolonged in patients with renal impairment.

A minimum of three days should elapse between discontinuation of apixaban and neuraxial block. Indwelling neuraxial catheters are contraindicated and should be removed six hours prior to initiation of rivaroxaban therapy postoperatively.

ANTIPLATELET MEDICATIONS

Antiplatelet medications are seldom used as primary agents of thromboprophylaxis. However, many orthopedic patients report chronic use of one or more antiplatelet drugs. Although Vandermeulen et al² implicated antiplatelet therapy in 3 of the 61 cases of spinal hematoma occurring after spinal or epidural anesthesia, several large studies have demonstrated the relative safety of neuraxial blockade in both obstetric, surgical and pain clinic patients receiving these medications.²⁶⁻²⁸ In a prospective study involving 1000 patients, Horlocker et al²⁸ reported that preoperative antiplatelet therapy did not increase the incidence of blood present at the time of needle/catheter placement or removal, suggesting that trauma incurred during needle or catheter placement is neither increased nor sustained by these medications. The clinician should be aware of the possible increased risk of spinal hematoma in patients receiving antiplatelet medications who undergo subsequent heparinization.¹¹ Ticlopidine and clopidogrel are also platelet aggregation inhibitors. These agents interfere with platelet-fibrinogen binding and subsequent platelet-platelet interactions. The effect is irreversible for the life of the platelet. Platelet dysfunction is present for 5-7 days after discontinuation of clopidogrel and 10-14 days with ticlopidine.

Prasugrel is a new thienopyridine that inhibits platelets more rapidly, more consistently, and to a greater extent than do standard and higher doses of clopidogrel. In the United States, the only labeled indication is for acute coronary syndrome in patients intended to undergo percutaneous coronary intervention. After a single oral dose, 50% of platelets are irreversibly inhibited, with maximum effect two hours after administration. Platelet aggregation normalizes in 7-10 days after discontinuation of therapy. The labeling recommends that the drug "be discontinued at least 7 days prior to any surgery".

Ticagrelor represents a new class of nonthienopyridine platelet inhibitors designed to address the limitations of current oral platelet drugs. Ticagrelor completely reversibly inhibits ADP-induced platelet activation, unlike the thienopyridines (e.g. clopidogrel, prasugrel). Ticagrelor has been studied in acute coronary syndrome in combination with aspirin. Maintenance doses of aspirin above 100 mg decreased the effectiveness and should be avoided. The labeling recommends that when possible, ticagrelor should "be discontinued at least 5 days prior to any surgery".

Platelet glycoprotein IIb/IIIa receptor antagonists, including abciximab (Reopro[®]), eptifibatide (Integrilin[®]) and tirofiban (Aggrastat[®]), inhibit platelet aggregation by interfering with platelet-fibrinogen binding and subsequent platelet-platelet interactions. Time to normal platelet aggregation following discontinuation of therapy ranges from eight hours (eptifibatide, tirofiban) to 48 hours (abciximab).

Increased perioperative bleeding in patients undergoing cardiac and vascular surgery after receiving ticlopidine, clopidogrel and glycoprotein IIb/IIIa antagonists warrants concern regarding the risk of anesthesia-related hemorrhagic complications.

Draft recommendations from the 4th ASRA Practice Advisory on Anticoagulant and Antiplatelet Medications and Regional Anesthesia are included in the Table below.

Recommended Time Intervals Before and After Neuraxial Block or Catheter Removal*		
DRAFT		
Drug	Time <i>before</i> puncture/catheter manipulation or removal	Time <i>after</i> puncture/catheter manipulation or removal
Dabigatran	5 days	6 hours
Apixaban	3 days	6 hours
Rivaroxaban	3 days	6 hours
Prasugrel	7-10 days	6 hours
Ticagrelor	5-7 days	6 hours

*Developed at 4th ASRA Practice Advisory for Regional Anesthesia in the Patient Receiving Antithrombotic or Thrombolytic Therapy

ANESTHETIC MANAGEMENT OF THE ANTICOAGULATED PATIENT

The decision to perform spinal or epidural anesthesia/analgesia and the timing of catheter removal in a patient receiving thromboprophylaxis should be made on an individual basis, weighing the small, though definite risk of spinal hematoma with the benefits of regional anesthesia for a specific patient. Alternative anesthetic and analgesic techniques exist for patients considered to be at an unacceptable risk. The patient's coagulation status should be optimized at the time of spinal or epidural needle/catheter placement, and the level of anticoagulation must be carefully monitored during the period of epidural catheterization (Table 1). It is important to note that patients respond with variable sensitivities to anticoagulant medications. Indwelling catheters should not be removed in the presence of a significant coagulopathy, as this appears to significantly increase the risk of spinal hematoma.^{2,3} In addition, communication between clinicians involved in the perioperative management of patients receiving anticoagulants for thromboprophylaxis is essential in order to decrease the risk of serious hemorrhagic complications. The patient should be closely monitored in the perioperative period for signs of cord ischemia. If spinal hematoma is suspected, the treatment of choice is immediate decompressive laminectomy. Recovery is unlikely if surgery is postponed for more than 10-12 hours; less than 40% of the patients in the series by Vandermeulen et al.² had partial or good recovery of neurologic function.

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Sick Adult Patients and Day Surgery: The New Paradigm in Ambulatory Surgery

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CASE

A 65-year-old male with a BMI of 43.5 kg/m², history of heavy snoring and daytime somnolence, diabetes mellitus, and hypertension is scheduled for a hernia repair at a free-standing ambulatory surgery center (ASC). His medications include metformin and an ACE inhibitor. His vital signs and fasting blood sugar and HBA1c levels are within normal limits.

Is this patient suitable to undergo a surgical procedure in an ASC?

INTRODUCTION

Improvements in surgical and anesthetic techniques as well as modifications in postoperative care have increased the number of procedures being performed on an outpatient basis. Ambulatory surgery accounts for about 65-70% of all elective surgical procedures performed in the United States¹. In fact, surgical procedures and patient populations that were once considered inappropriate are increasingly being done in an outpatient setting². For day surgery to be safe and efficient, careful selection of patients and procedures is crucial³. However, there is an uncertainty amongst anesthesiologists, who must determine patient suitability for ambulatory surgery.

Clearly, identifying suitability for an ambulatory procedure is a dynamic process that depends on a complex interplay between surgical procedure, patient characteristics, expected anesthetic technique (e.g., local/regional vs. general anesthesia), and social factors, as well as the ambulatory setting, which will influence the ability to manage complex patients based upon the availabilities of personnel and equipment (Table 1). Although it may be difficult to quantify, appropriateness of patient selection may also depend on the experience and skill of the surgeon and the anesthesiologist. Therefore, attempts to address individual factors without consideration of others is fraught with flaws.

The literature on optimal patient selection for ambulatory surgery is sparse. Most studies have used the incidence of morbidity and mortality, cancellation of surgery, delayed surgical start, delayed recovery and discharge home, unplanned admission, and readmission after discharge home to determine appropriate patient selection. A recent study used the American College of Surgeons' National Surgical Quality Improvement Program (ACS-NSQIP) database from 2005-2010 to assess the morbidity and mortality within 72 hours of ambulatory surgery in adults (n=244,397)⁴. The most common morbidities included unplanned postoperative intubation, pneumonia, and wound disruption. The incidence of perioperative morbidity and mortality was 0.1% (1 in 1053 cases). The independent risk factors for increased perioperative morbidity, after controlling for surgical complexity, included

Table 1: Factors that influence patient and procedure selection for ambulatory surgery

Surgical procedure <ul style="list-style-type: none">• Minimal invasiveness• Moderate duration• Minimal blood loss not requiring blood transfusion• No specialized postoperative care required• No need for postoperative parenteral therapy• Postoperative pain manageable at home
Patient characteristics <ul style="list-style-type: none">• Stable and well controlled coexisting medical conditions• Disease unlikely to be adversely affected by surgery
Social factors <ul style="list-style-type: none">• Responsible adult escort and availability of a responsible caregiver• Patient understands instructions• Reasonable access to a telephone• Reasonable access to healthcare• Able to return to hospital within reasonable time frame• Not expected to care for children or perform hazardous tasks
Ambulatory setting <ul style="list-style-type: none">• Office-based• Free-standing ambulatory surgery center• Hospital-based ambulatory surgery center• Short-stay

high body mass index (BMI), chronic obstructive pulmonary disease (COPD), history of transient ischemic attack/stroke, hypertension, previous cardiac surgical intervention, and prolonged operative time. One of the limitations of this study is that the observed complication rate was low, resulting in inability to detect some of the clinically meaningful risk factors. Furthermore, these retrospective analyses may not always be relevant in the current rapidly changing surgical and anesthetic practice environment. Another study reported that the predictors of unplanned hospital admission included length of surgery more than one hour, advanced age (>80 years), increased BMI, and high (≥ 3) American Society of Anesthesiologists (ASA) physical status⁵.

This article will discuss the current literature that can guide rational selection for ambulatory surgery in high-risk adults patients.

AMERICAN SOCIETY OF ANESTHESIOLOGISTS PHYSICAL STATUS

Despite its inherent subjectivity, the ASA physical status has moderate inter-rater reliability in clinical practice and could be used as a marker of preoperative health status⁶. Thus, it can be used as an overall marker of perioperative risk rather than attributing risk to a specific disease process. There is a general agreement that patients with a high burden of comorbidities, particularly those with poorly stabilized medical conditions (e.g., ASA physical status 4) are not suitable for ambulatory surgery. On the other hand, ASA physical status 3 patients (i.e., patients with severe systemic disease or disease from whatever cause) may be considered

acceptable candidates for outpatient surgery if their medical conditions are optimized preoperatively.

AGE

The prevalence of cardiovascular disease, cerebrovascular disease, pulmonary, and diabetes mellitus increases with age. Therefore, one of the questions commonly posed is: Is there an age limit for ambulatory surgery? Retrospective analysis of the ACS-NSQIP database between 2007 and 2010 assessed the safety of ambulatory laparoscopic cholecystectomy in patients greater than 65 years (outpatients, n=7499 [48.9%] and inpatients, n=7799 [51.1%])⁷. Independent predictors of inpatient admission and mortality included congestive heart failure, ASA physical status 4, bleeding disorder, and renal failure requiring dialysis. Other studies have reported that the age greater than 80 years is an indicator of increased perioperative risk^{5,8}. However, age alone should not be used to determine suitability for ambulatory surgery. Of note, elderly outpatients may require a greater degree of post-discharge supervision and are more likely to have social issues (e.g., elderly or debilitated spouse) that need to be considered.

OBESITY

Several studies have identified obesity, which is associated with an increased prevalence of comorbidities, as a risk factor for perioperative complications after ambulatory surgery^{4,5,9,10}. Thus, one of the clinical questions posed with respect to selection of obese patients for ambulatory surgery is: Is there a weight (or BMI) limit above which ambulatory surgery is not appropriate? A systematic review revealed that BMI alone did not influence perioperative complications or unplanned admission after ambulatory surgery¹⁰. Although all the studies included in this systematic review were observational, they were representative of broad clinical practice and included both bariatric and non-bariatric surgical procedures. This systematic review revealed that there was a conservative approach to patient selection for non-bariatric surgical procedures, as the average BMI was only 30 kg/m². In contrast the patients undergoing bariatric surgery had a BMI of around 40 kg/m², which is known to have a higher burden of comorbid conditions including obstructive sleep apnea (OSA). However, the bariatric surgical population had rigorous preoperative evaluation and optimization of comorbid conditions.

Although weight or BMI should not be the sole determinant of patient selection for ambulatory surgery, patients with BMI of less than 40 kg/m² may be suitable for ambulatory surgery assuming that their comorbid conditions, if any, are optimized [10]. Also, it is necessary to consider the presence of sleep disordered breathing (i.e., OSA and obesity-related hypoventilation syndrome), as it has been associated with increased perioperative complications¹¹. The super obese (i.e., BMI >50 kg/m²) should be chosen carefully as they have higher incidence of perioperative complications. For patients with BMI between 40 and 50 kg/m², thorough preoperative assessment is necessary to identify obesity-related comorbid conditions (e.g., OSA, obesity-related hypoventilation syndrome, and pulmonary hypertension, as well as resistant hypertension, coronary artery disease, and cardiac failure).

OBSTRUCTIVE SLEEP APNEA

It is well documented that patients with OSA are at high risk of perioperative complications¹¹. Therefore, suitability of ambulatory surgery in patients with known or suspected OSA remains controversial. The ASA recently published updated guidelines regarding perioperative management of OSA patients, including selection for ambulatory surgery¹². Of note, the previous recommendation that ambulatory surgery is not recommended in patients undergoing airway surgery or upper abdominal surgery has been eliminated. The ASA guidelines also propose a scoring system, based on the severity of OSA, the invasiveness of the surgery, the type of anesthetic technique, and the need for postoperative opioids, that may be used to estimate whether an OSA patient is at increased risk of perioperative complications, and thus determine the suitability for ambulatory surgery. However, clinical utility of this scoring system is questionable, as it has not yet been validated.

A systematic review of published literature assessing perioperative complications in patients with OSA undergoing ambulatory surgery revealed that OSA patients with inadequately treated co-morbid conditions are not suitable for ambulatory surgery¹³. Based upon this systematic review, the Society for Ambulatory Anesthesia (SAMBA) consensus statement recommends that patients with a known diagnosis of OSA, who are typically prescribed positive airway pressure [PAP] therapy, may be considered for ambulatory surgery if their comorbid medical conditions are optimized and they are able to use a PAP device in the postoperative period (Figure 1). It appears that postoperative PAP therapy may be protective against opioid-induced respiratory complications.

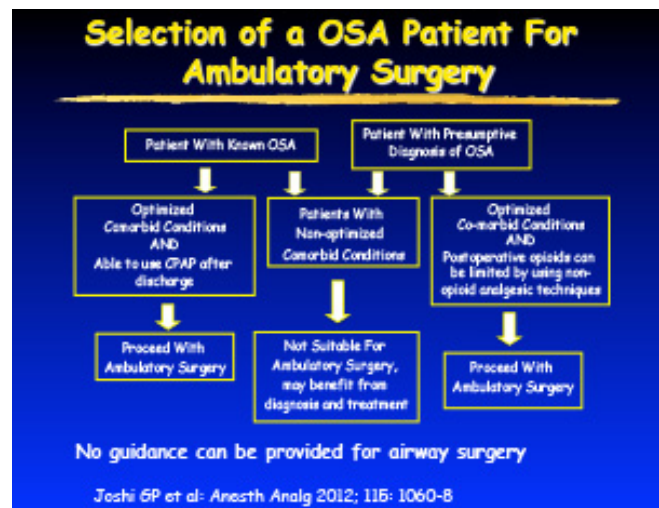


Figure 1: Selection of a patient with obstructive sleep apnea for ambulatory surgery. From Joshi GP, et al: Anesth Analg 2012; 115: 1060-8¹³.

On the other hand, patients who are unable or unwilling to use PAP device after discharge may not be appropriate for ambulatory surgery. Patients with a presumed diagnosis of OSA, based on screening tools such as the STOP-Bang questionnaire, can be considered for ambulatory surgery if their comorbid conditions are optimized and if postoperative pain relief can be provided predominantly with non-opioid analgesic techniques. It is also recommended that a screening tool be incorporated in a routine preoperative evaluation. The STOP-Bang questionnaire is simple to use; however, it is

recommended that a higher 'cut-off' (e.g., ≥ 5 or 6 positive indicators) should be used to determine presumption of OSA, rather than the original suggestion of a 'cut-off' of ≥ 3 ¹³.

Of note, the SAMBA consensus statement did not provide any guidance for OSA patients undergoing upper airway surgery due to limited evidence¹³. However, there is some recent evidence suggesting that airway surgery in this patient population can be performed in an ambulatory setting with complication rates similar to the inpatient population^{14,15}. A recent systematic review of 18 publications with 2160 patients assessed postoperative complication rates after OSA surgery performed on same day basis¹⁵. There were no deaths or major catastrophic events. The overall incidence of any adverse event was 5.3%, with the respiratory-related events rate of less than 1.5%. Most of the respiratory events were related to oxygen desaturations, which were not clinically significant. Exclusion of oxygen desaturation significantly reduced the overall adverse event rates. All the adverse events were related to the surgical procedure and not specifically to OSA. The re-admission rate was only 0.4%. The author concluded that OSA surgery performed on outpatient basis is generally safe and routine hospital admission is not necessary, except for patients undergoing tongue base surgery, those with a higher preoperative apnea/hypopnea index, or those with high postoperative opioid requirements. Other studies have also reported that most serious airway complications occur early after surgery (i.e., within 2 to 3 hours postoperatively)¹⁶. Potential postoperative complications include airway obstruction, post-obstructive pulmonary edema, and cardiac arrhythmia.

DIABETES MELLITUS

Although patients with diabetes mellitus often have several comorbidities, it is not an independent predictor of complication rate after ambulatory surgery. Nevertheless, it is necessary that the surgical facilities caring for this patient population have the necessary equipment to monitor blood glucose levels. The Society For Ambulatory Anesthesia (SAMBA) has published a consensus statement on perioperative blood glucose management¹⁷, which provides some guidance to address the question: Is there a preoperative blood glucose level (BGL) above which one should postpone elective surgery? Although there is insufficient evidence to specifically recommend a 'cut-off' BGL above which elective ambulatory surgery should be postponed, it may be acceptable to proceed with surgery in patients with preoperative hyperglycemia but with adequate long-term glycemic control, barring any significant complications of hyperglycemia such as ketoacidosis and hyperosmotic states. In patients with chronically poorly controlled diabetes mellitus, the decision to proceed with ambulatory surgery should be made in conjunction with the surgeon and take into account patient comorbidities and the risks of surgical complications.

CARDIAC DISEASE

Due to advances in medical and interventional cardiac care, as well as improvement in preoperative evaluation, patients with cardiac disease (e.g., hypertension, coronary artery disease [CAD], valvular heart disease, congestive heart failure, cardiomyopathy, cardiac implantable electronic

devices [CIED], coronary artery stents, and congenital heart disease) are much less at risk of adverse events after ambulatory surgery. Typically, ambulatory surgery carries a low risk of perioperative cardiac complications (defined by a cardiac risk of $<1\%$). However, individuals at high risk for perioperative cardiac events, including unstable or severe angina, recent myocardial infarction within 2 months, decompensated or newly diagnosed heart failure, high grade atrioventricular block or symptomatic arrhythmias, and severe aortic or mitral valve stenosis may not be suitable for procedures in an ambulatory setting¹⁸.

The risk of perioperative myocardial infarction or cardiac arrest (MICA) can be calculated by using a cardiac risk calculator (<http://www.surgicalriskcalculator.com>), derived from the ACS-NSQIP database. It incorporates patient variables (i.e., age, ASA physical status, functional status, and preoperative serum creatinine) and surgical procedure¹⁹⁻²¹ (Figure 2). The predictive performance of this cardiac risk

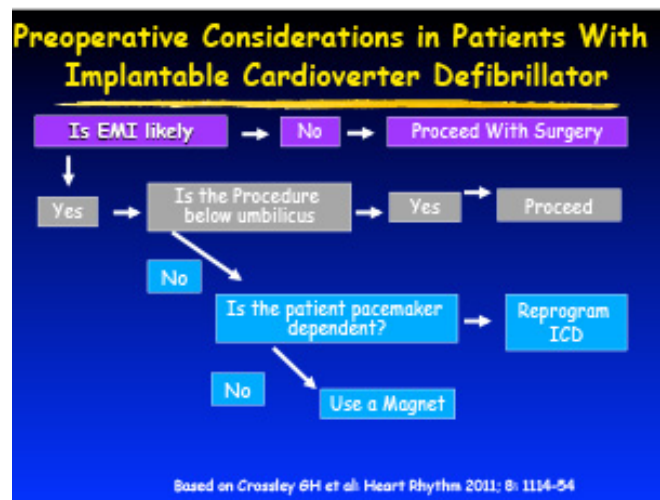


Figure 2: Preoperative considerations in a patient with implantable cardioverter defibrillator. Based on Crossley GH, et al. Heart Rhythm 2011; 8: 1114-54.²³

calculator is reported to be superior to that of the Revised Cardiac Risk Index (RCRI)^{19,22}. The RCRI include diabetes mellitus requiring insulin, creatinine ≥ 2 mg/dL, history of cerebrovascular accident or transient ischemic attack, ischemic heart disease and heart failure²². The presence of ≤ 2 clinical risk factors is considered at low risk of major adverse cardiac events (MACE)²². Patients at an elevated risk should be assessed for functional status, and those with a functional status of <4 METs or in whom functional capacity cannot be assessed should be considered for pharmacologic stress testing, if it will impact perioperative decision making or care¹⁸.

Patients with CIED may be at risk of perioperative arrhythmia and asystole. Also, in the case of implantable cardioverter defibrillators (ICD) there is a concern that electromagnetic interference may be misinterpreted as an arrhythmia leading to inappropriate shock. The recommendations of the Heart Rhythm Society jointly developed with the ASA, in collaboration with the American College of Cardiology (ACC), the American Heart Association (AHA), and the Society of Thoracic Surgeons (STS) provide excellent guidance for the management of patients with CIED^{18,23}. Overall, patients with CIED may safely undergo ambulatory

surgery assuming that appropriate equipment and support is readily available. However, the controversy in management of patients with CIED it related to the use of magnet to disable the ICD and the need for reprogramming (i.e., suspend ICD and pacemaker function), which requires an expert (e.g., a cardiologist, electrophysiology nurse, or device representative) and who may not be always available (Figure 3).

Figure 3: Surgical risk calculator for assessing the risk of perioperative myocardial infarction and cardiac arrest. From Rao A, et al: Am Coll Surg 2013; 217: 1038-48.¹⁸

Another challenging group of patients include those with coronary artery stents. The controversy in this patient population surrounds the need to continue the dual antiplatelet therapy to prevent coronary artery thrombosis. A joint advisory from several professional associations addresses the prevention of premature discontinuation of dual antiplatelet therapy in patients with coronary artery stents^{18,24} (Figure 4).

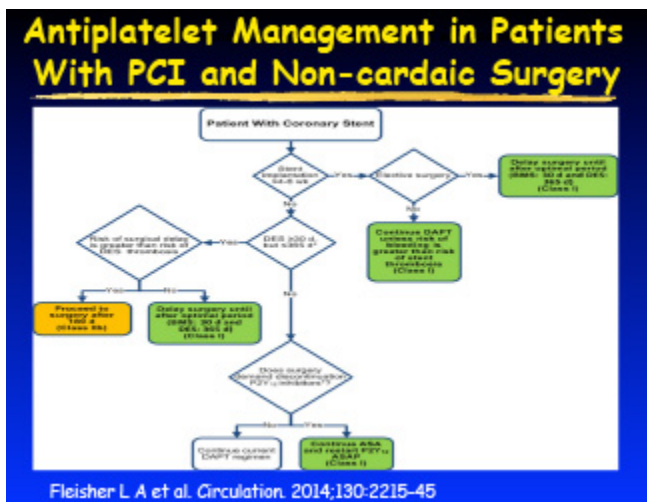


Figure 4: Antiplatelet management in patients with percutaneous cardiac intervention and coronary stents. Fleisher L, et al: Circulation 2014; 130: 2215-45.¹⁹

SUMMARY

As older and sicker patients undergo more complex surgical procedures in an ambulatory setting, patient selection has become the cornerstone of safe and efficient perioperative care. Developing and implementing protocols (or clinical pathways) for patient selection is the best way to improve perioperative outcome. This requires a multidisciplinary

approach in which the anesthesiologist should take a lead in collaborating with the surgeons and the perioperative nurses. Rather than considering the factors in isolation, the interaction of any disease(s) with the planned surgical procedure should also be considered.

The first step in determining appropriate patient selection includes preoperative assessment and identification of any comorbid conditions, which should be optimized to minimize risks. For any patient who is not completely healthy, the nature of any preexisting condition, its stability and functional limitation should be evaluated. The social situation should be evaluated to determine whether the patient has help at home for postoperative care. Outpatients should be capable of understanding instructions for pre- and postoperative care, and should be accompanied home by a responsible escort. Someone should also be available to care for the patient during the first night after surgery and be able to assist them in obtaining emergency medical care if needed. The anesthetic technique chosen should provide optimal intraoperative conditions, while ensuring a rapid return of consciousness and protective reflexes upon completion of the operation, minimal residual sedative effects (so-called “hangover” effect), little impairment of postoperative cognitive function, and the absence of side effects during the early recovery period. A pragmatic question to ask is: Will postoperative hospitalization influence patient care or perioperative outcome? If no improvement would be achieved, then the patient should undergo the procedure on an ambulatory basis. In the future, as more patients and surgical procedures are moved from inpatient facilities to outpatient facilities, it will be appropriate to develop exclusion criteria, rather than inclusion criteria, for patients that are not candidates for ambulatory surgery.

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Hospital-Acquired Anemia: A Hazard of Hospitalization?

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The World Health Organization defines anemia as a hemoglobin value less than 12g/dL in women and less than 13g/dL in men. In population-based and cohort investigations, the presence of anemia is associated with poor health outcomes. At the time of hospitalization, patients admitted with anemia (present on admission, POA anemia) are similarly at heightened risk for adverse morbidity and mortality outcomes. We defined hospital-acquired anemia as a patient who was admitted to the hospital with a normal hemoglobin value and who subsequently developed anemia during their course of hospitalization. We sought to study a large population of over 188,000 mixed medical and surgical hospitalizations in a quaternary referral health system to examine the prevalence, outcomes and healthcare implications associated with the development of hospital-acquired anemia. We subdivided anemia into grades of severity: mild anemia: hemoglobin values >11 and <12 g/dL in women and >11 and <13 g/dL in men; moderate anemia: hemoglobin values >9 and <11 g/dL; and severe anemia: <9 g/dL. Over 74% of patients developed hospital-acquired anemia: 40,828 developed mild anemia, 57,184 moderate anemia and 41,795 severe anemia. There were differences in baseline characteristics between patients who did and did not develop hospital-acquired anemia, however after risk adjustment for these differences, we reported a dose-dependent higher mortality, longer duration of hospital stay and greater overall hospital charges for patients who developed anemia during their hospital stay. We hypothesized a number of factors that related to why patients developed hospital-acquired anemia: excess phlebotomy, procedural blood loss and hemodilution. Figures 1-2.

As noted, patients who are admitted to the hospital with anemia are reportedly at higher risk for adverse outcomes. We investigated whether risk for patients admitted with POA anemia was related to, or further heightened by the development of hospital-acquired anemia, ie., going from bad – to – worse. Among over 43,000 mixed medical and surgical hospitalizations with POA anemia, we found POA anemia to be associated with increased risk for mortality, longer hospital length of stay and higher total charges. These patients went from bad-to-worse if they subsequently developed hospital-acquired anemia, that is, they had higher mortality and increased hospital resource utilization.

It was unclear to us whether the risk associated with anemia continued to the post-discharge setting in terms of placing patients at higher risk for 30-day hospital readmission. In general, 30-day readmissions for Medicare beneficiaries is approximately 19%. A recently published investigation on factors related to hospital readmission included lower hemoglobin values among a number of factors related to

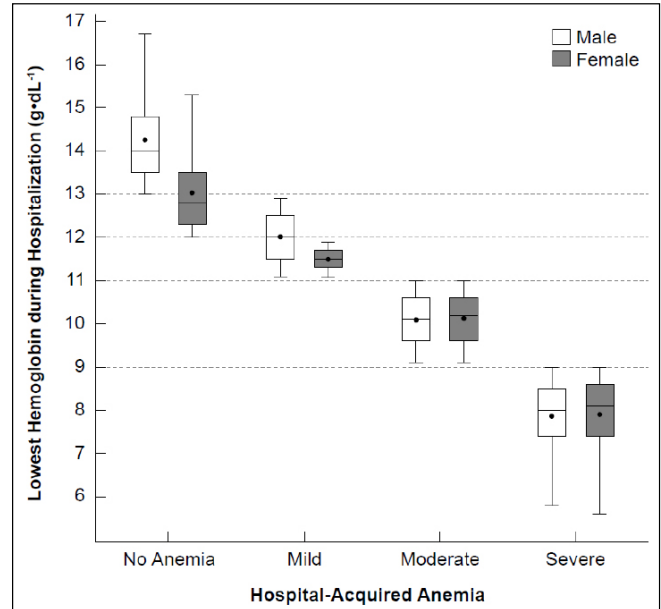


Figure 1. Lowest hemoglobin during hospitalization stratified by gender and hospital-acquired anemia groups. Lower and upper ends of boxes represent 25th and 75th percentiles, center lines and dots within boxes are median and mean, respectively, and vertical lines extending above and below boxes are minimum and maximum of the data. (From Koch et al., Hospital-acquired anemia: Prevalence, Outcomes and Healthcare Implications. Journal of Hospital Medicine 2013;8:506-512).

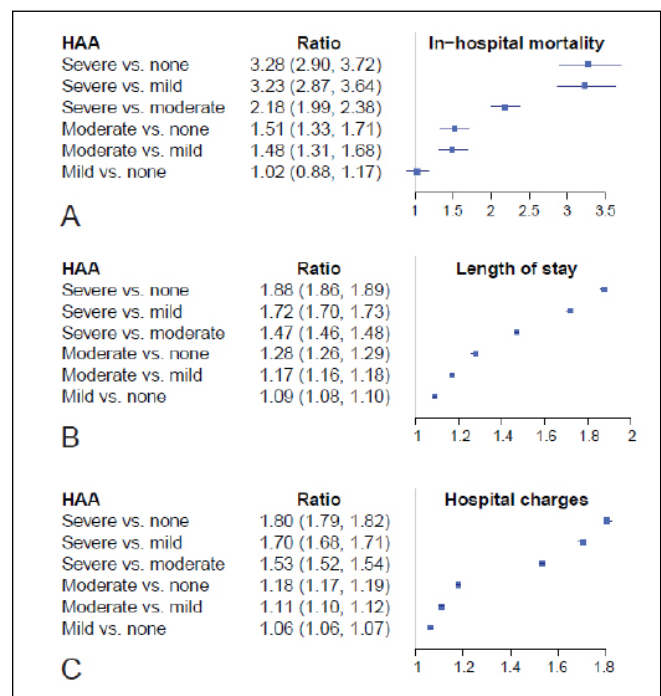


Figure 2. Forest plots of adjusted outcomes and hospital acquired anemia (HAA). Squares represent the effect size (ratio), and lines represent confidence intervals. (From Koch et al., Hospital-acquired anemia: Prevalence, Outcomes and Healthcare Implications. Journal of Hospital Medicine 2013;8:506-512).

increased risk for readmission. We sought to examine the prevalence and magnitude of anemia at the time of hospital discharge and determine whether it was associated with increased 30-day readmissions. We examined over 152,000 hospitalizations in a single health system and found over 70% of patients were discharged with anemia: 21% with mild, 35% with moderate and 17% with severe discharge anemia. We reported a severity – dependent increased risk for 30-day hospital readmission with increasing severity of anemia (odds ratio, OR and confidence limits, CL for 30-day readmission): mild anemia at discharge OR = 1.74 (1.65-1.82); moderate anemia OR= 2.76 (2.64-2.89); and severe anemia 3.47 (3.30-3.65). Figure 3.

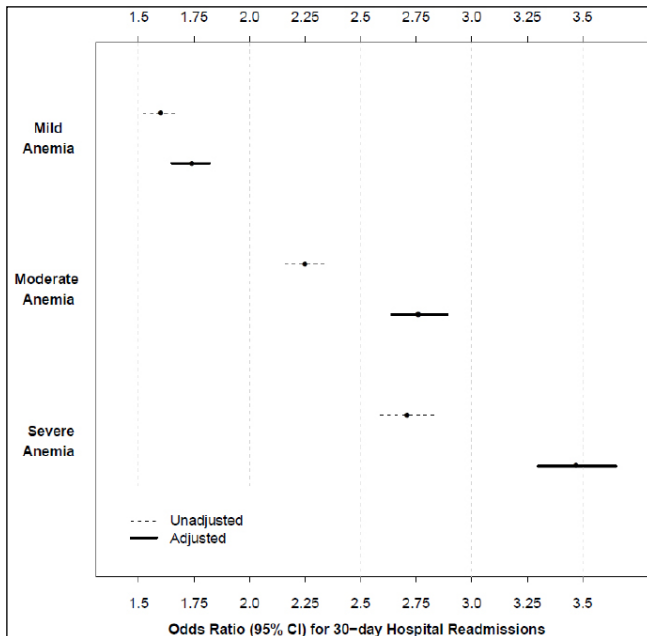


Figure 3. Magnitude of anemia at hospital discharge and unadjusted (dashed) and adjusted (solid) odds ratios and 95% confidence intervals (CI) for 30-day hospital readmission. (From Koch CG, et al., Magnitude of anemia at discharge increases 30-day hospital readmissions. *J Patient Safety* 2014).

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The Normalization of Deviance: Do We (Un)Knowingly Accept Doing the Wrong Thing?

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Anesthesia professionals recognize that perioperative care of both routine and seriously ill patients has the potential for devastating patient injury. The Institute of Medicine¹ and other reports suggest that many patients experience complications during the course of high-intensity care in the nation's 5000 acute care hospitals.

The last decade has witnessed multiple campaigns, efforts, and rhetoric aimed to improve the understanding of error and focus individuals and systems on procedures to improve safety outcomes. The last decade has also seen increased emphasis on economic productivity, driven in part by concern about endlessly increasing health care costs. Is the approach of "doing more with less" in the operating room (OR) any different from the "faster, cheaper, better" mantra of the National Aeronautics and Space Administration (NASA)? It is appropriate to ask whether economic pressure has affected patient safety.² More bluntly, are anesthesia professionals at risk of cascading down the slippery slope of faster rather than better?

LESSONS FROM SPACE

Theories of organizational safety, such as Normal Accidents Theory, describe the complexity of a system and the tight coupling of interactions between its subsystems. Both the Challenger and Columbia space shuttle accident investigation boards applied Normal Accidents Theory analysis to their investigations and asked similar questions. Why did NASA continue to fly the Challenger shuttle while O-ring erosion problems were documented numerous times before the cold January 1986 launch? Why did NASA continue to fly the Columbia shuttle despite knowing foam insulation was regularly striking vulnerable areas of the vehicle years before Columbia's fatal accident?

One explanation is that these mishaps had been "normalized" over many occurrences and many years until managers and engineers began to believe that these flaws were expected and therefore acceptable. Diane Vaughan,³ in her exhaustive book, *The Challenger Launch Decision*, coined this behavior the "normalization of deviance." This incremental process is a gradual erosion of normal procedures that would never be tolerated if proposed in 1 single, abrupt leap. Instead, small incremental deviations are observed and tolerated. Lacking an accident, they become "normalized."⁴ When the shuttle was originally designed, no allowance was made for the possibility that the Challenger would be launched in

subfreezing temperatures, leaving rocket booster O-rings to contract, weaken, and leak. Nor was it ever anticipated that insulating foam debris could fall off the main tank and strike the vehicle's wing. When these events were first experienced, the obvious safety implications were recognized. However, faulty analyses concluded that the vehicle could tolerate these abnormal events. Managers and engineers decided to either implement a temporary fix or simply accept the risk. This approach established a precedent for accepting safety violations as technical deviations that can be tolerated and managed.⁴ As the problems recurred and the shuttle kept flying, the fallacy that the errors were acceptable was reinforced. Thus, foam strikes were no longer even defined as safety violations. They had become "normalized": considered a normal part of a shuttle liftoff.⁴

Normalization of deviance breaks the safety culture, substituting a slippery slope of tolerating more and more errors and accepting more and more risk, always in the interest of efficiency and on-time schedules. This toxic thinking often ends with a mindset that demands evidence that these errors would destroy the vehicle (or harm a patient), instead of demanding proof that the shuttle (or patient) is safe and not being harmed. The boundaries are soon pushed to extremes without understanding where and why the original limits were established.⁴

LESSONS FROM THE OR: IS THERE A COLUMBIA/CHALLENGER DISASTER IN OUR FUTURE?

Anesthesiology shares a core value with space flight and aviation: safety. We in health care can pretend that what happened at NASA cannot possibly happen to us. As of 2003, space shuttles had flown 112 missions. Two of those missions ended catastrophically, a failure rate of 1.7%. Analysis of those 2 spectacular failures demonstrates the same normalization of deviance that we believe is incrementally undermining perioperative safety. Surely, the stakes for anesthesia and perioperative care are just as high as for NASA. Although our failures are not as spectacular as shuttle explosions, they are much more frequent and equally devastating to patients and their families. Therefore, we must avoid the temptation to normalize deviations from safety standards, such as the frequently observed behaviors noted in Table 1, while we acknowledge that correction or avoidance of routine equipment failures or human errors may be insufficient to avert complex mishaps and systemic failures.⁵ Nevertheless,

Table 1. Anesthesia Practices that Should Not Be “Normalized”

1. Removing vital monitors at the end of general anesthesia before the patient is awake, trachea is extubated, and homeostasis assured.
2. Handoffs of care at vital times (emergence, induction, separation from cardiopulmonary bypass, etc.).
3. Failure to follow recognized isolation procedures and protocols.
4. Failure to wash the hands before and after patient contact.
5. Failure to properly monitor effects of neuromuscular blocking drugs in every patient.
6. Failure to examine laboratory results before surgery.
7. Excessive noise from operating room personnel, industry representatives, students, and learners at the time of anesthesia induction, along with radio or other noise to levels where monitor sounds cannot be heard.
8. Titration of narcotics in postanesthesia care unit by rigid adherence to the pain score, without necessary modulation based on sound clinical judgment.
9. Nonsterile dressings placed on skin site for peripheral IVs, central catheters, arterial catheters, etc.
10. Failure to place standard monitors before performing a peripheral nerve block for regional anesthesia.

we advocate an attitude change that fundamentally opposes normalization of deviance. From 4 different institutions, academic and private practice, and from diverse regions around the country, we observe common practices that represent erosions of patient safety in the interest of efficiency. Three clinical vignettes illustrate our concerns.

EXAMPLE 1

Production pressure has promoted the practice whereby some, or all, standard anesthesia monitors are discontinued before the end of general endotracheal anesthesia. A recent Anesthesia Patient Safety Foundation Internet poll (www.APSF.org; Fig. 1) suggests that 1 anesthesia professional in 8 will remove blood pressure and/or electrocardiogram (ECG) cables before the patient's emergence from anesthesia and

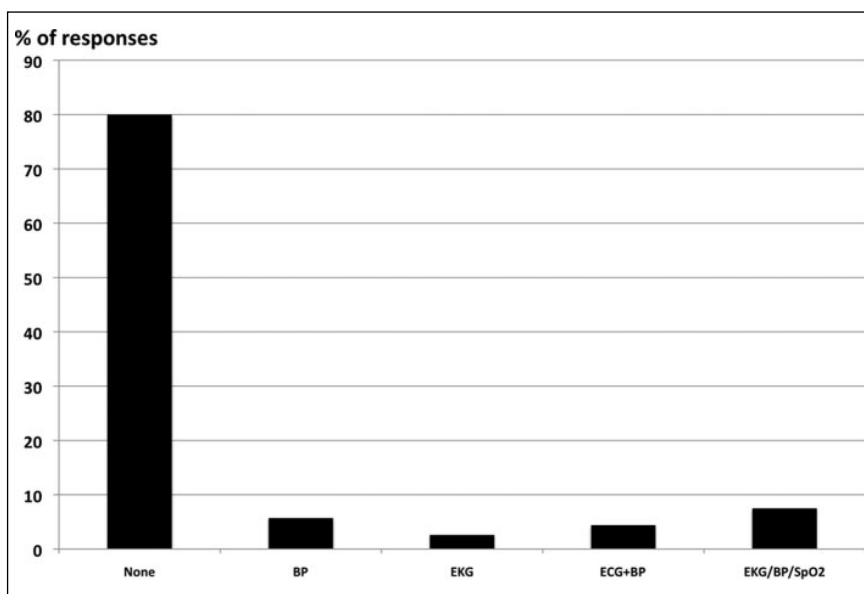


Figure 1. Columns represent percent responses to the Anesthesia Patient Safety Foundation Web poll that queried nurse anesthetists and anesthesiologists about removal of routine monitors at the end of surgery but before anesthesia emergence and tracheal extubation. One in 8 respondents removed 1 or 2 monitors, whereas 1 in 13 removed the triad of electrocardiogram (ECG), blood pressure (BP), and pulse oximetry standard monitors. SpO₂ pulse oximetry monitor. (Used with permission of Anesthesia Patient Safety Foundation Newsletter editor, and available at: www.apsf.org, 2009.)

tracheal extubation. A significant number, approximately 1 in 13 respondents, will also remove the pulse oximetry oxygen saturation (SpO₂) probe. Some practitioners believe this practice speeds OR turnover or contributes to “efficiency” in some way. We disagree. Nothing in the American Society of Anesthesiologists’ (ASA) or the American Association of Nurse Anesthetists’ guidelines supports such practice. Moreover, this maneuver removes vital monitors from patients during a period of intense physiological stress—the transition from surgical planes of anesthesia to return of consciousness with spontaneous ventilation, stable hemodynamics, and patient cooperation. As a representative anecdote, we recently observed a patient’s cardiac rhythm suddenly convert from normal sinus rhythm to a perfusing monomorphic ventricular tachycardia during this period of emergence. This life-threatening arrhythmia was unexpected and unheralded. But for direct observation of the ECG during this vulnerable transition period, a key diagnosis would have been missed and vital treatment delayed, exposing the patient to further rhythm deterioration and risk of significant morbidity or death. A pulse oximeter alone would have failed to capture this diagnosis, because the perfusing ventricular tachycardia produced no immediate interruption in the oximetry signal or display. Whenever clinical decisions are made that contradict or modify current practice, it is imperative that we ask not, “What is the evidence that this will hurt the patient?” but that we ask instead, “What is the evidence that this decision will not lower safety?” In the absence of such evidence, we should not assume the practice to be safe or acceptable.

EXAMPLE 2

The literature is replete with studies, surveys, commentaries, letters, and editorials that document the continued occurrence of perioperative residual neuromuscular blockade.^{6,7} Failure to recognize residual muscle weakness can be attributed to many interacting factors but ultimately can be traced to either a failure to monitor neuromuscular blockade or a lack of understanding in neuromuscular pharmacology.⁸ Current practice involves the use of modern, intermediate-acting neuromuscular blocking drugs with minimal potential for accumulation. In many instances, induction of general anesthesia proceeds without prior documentation of baseline neuromuscular responses, or, frequently, stimulating electrodes are never placed on the patient at all.

A recent case illustrates the multiple failures along the clinical continuum. On surgical closure after upper abdominal surgery, an elderly patient received full-dose pharmacologic reversal and then his trachea was extubated after documentation of “train-of-four (TOF) recovery without fade.” Although chart documentation may at first seem appropriate, the patient was actually received in the postanesthesia care unit with minimal respiratory effort,

low saturation (Spo₂ 88%), and hyperdynamic circulation indicative of hypercarbia. Reassessment of TOF at the ulnar nerve by objective monitoring (acceleromyography) documented a TOF of 0.36. On further investigation, it was noted that the intraoperative assessment consisted of visual assessment of TOF of the face muscles (jaw) and confirmation of “sustained tetanus” (delivered for approximately 2 seconds) through electrodes placed on the patient’s temple and forehead. Although technically the monitoring and assessment criteria fulfilled the medicolegal requirements, it is clear that multiple failures occurred: from reliance on subjective (visual) assessment, to lack of baseline response documentation, to inappropriate application of tetanic stimulation (for 5 seconds), to improper location of stimulating electrodes that induced direct muscle stimulation and provided a false index of recovery.

Unfortunately, this clinical scenario is not uncommon.⁷ It is likely that the transition from the “older generation” long-acting neuromuscular blocking drugs (e.g., curare, pancuronium, doxacurium, and pipecuronium) to the newer, intermediate-acting drugs that have much lower potential for residual paralysis has made us think that postoperative residual paralysis was no longer possible and has contributed to the current “normalization of deviance” from the basics of neuromuscular monitoring.

We must be proactive and realize that the impetus to learn the nuances of neuromuscular monitoring will continue to decrease, unless we stop accepting the deviance. As production pressure increases in proportion to the decrease in reimbursement, and as new, drug-specific antagonists of neuromuscular blocking drugs reach the market (e.g., sugammadex and cysteine),⁹ the perceived need for appropriate, timely, and continual monitoring of neuromuscular function will likely continue to decrease. Are we strong and perceptive enough to resist cascading down the slippery slope of “faster” rather than “better and safer?”

EXAMPLE 3

Improved understanding of the pharmacology of local anesthetics has contributed to a steady decrease in complications caused by local anesthetic toxicity during performance of peripheral nerve blocks.¹⁰ In addition, the use of real-time ultrasound to visualize needle location in proximity to neural and vascular structures, collateral anatomy, and the ability to visualize perineural spread of local anesthetic provide additional information to minimize potential complications. However, ECG rate, rhythm, and morphology, arterial blood pressure, and arterial oxygen saturation are sensitive indicators of local anesthetic toxicity.¹¹ Thus, it is concerning to see our profession “normalize” the practice of performing peripheral nerve blocks using only a single monitor, usually a pulse oximeter. Indeed, a survey performed by Corcoran et al.¹² revealed that monitoring practices varied at academic anesthesiology departments. There was no relationship between the monitoring technique and the number of peripheral nerve blocks performed per month or the level of training of the provider performing the block. The authors reported that 16% of the studied anesthesia departments used only a pulse oximeter.¹² This scenario parallels the perception that monitoring “shortcuts,”

eerily similar to our first example, are acceptable. We disagree. By way of example, we recently observed an elderly patient who became confused and lethargic immediately before cardiac asystole ensued during injection of local anesthetic for an interscalene plexus block in the perioperative holding area. Prompt detection of her (potentially) fatal arrhythmia led to immediate intervention, initiation of advanced cardiac life support, and a good outcome. Thus, we believe the safer practice, consistent with Anesthesia Patient Safety Foundation philosophy, is to place all standard ASA-recommended monitors on the patient before the injection of large volumes of local anesthetic for peripheral nerve block. Individual practitioners may claim impressive records in hundreds of patients. However, we know from the rule of 3 that when the numerator is 0, the real incidence may be as great as 3 over N. So, the “perfect practitioner” with 300 blocks without major complication may have a rate of major complications of 3 of 300 or as high as 1%!¹³ Thus, a long track record of deviations from accepted practice without adverse consequence is not adequate evidence to normalize the deviation. In the absence of large studies documenting that monitoring can be relaxed during placement of peripheral nerve blocks, we advocate adherence to ASA monitoring standards to maximize patient safety.

SUMMARY

There are many elements that contribute to errors within an industry or profession. Several human factors associated with safety breakdowns are outlined in Table 2. Experience and root-cause analyses usually document that 2 or more of

Table 2. Human Factors Contributing to Anesthesia Mishaps

Normalization of deviance
Poor communication
Production pressure
Fatigue and stress
Emergency operations
Inadequate anesthesia provider experience
Inadequate familiarity with equipment, device, surgical procedure, anesthetic technique
Lack of skilled assistance or supervision
Afferent overload (excess stimuli or noise)
Normalcy bias (assuming alarms are ‘false alarms’)
Faulty or absent policy and procedures

these factors coalesce to form a “perfect storm” leading to a mishap. For example, expecting a fatigued provider to care for an emergency patient with concurrent production pressure to maintain the elective schedule, while using new and unfamiliar equipment, is a potent mix of risk factors. As Gaba et al.¹⁴ pointed out, production pressure “is a reality for many anesthesiologists and is perceived in some cases to have resulted in unsafe actions.” One solution is to integrate standard protocols and expectations for safe practice and expected behavior throughout the practice. Other potential solutions may involve the design of better and “smarter” monitors that will reduce the noise pollution and attendant distractions in the OR, and variable priority training that helps clinicians focus on “optimal distribution of attention when performing multiple tasks simultaneously with the goal of flexible allocation of attention.”¹⁵ We have also observed

the phenomenon of intersecting curves of knowledge versus experience. When we exit our organized training period, our knowledge base is strong.

We have studied for specialty examinations, experienced the idealized purity of an academic environment, and have been taught the “right way” to practice by our mentors and role models. As the years pass, our minute, detailed knowledge may decrease, but our practical experience increases greatly, and patient care and safety are assured. However, as we are increasingly challenged to “do more with less,” the temptation will arise to “cut a few corners” where we can to achieve productivity and efficiency benchmarks. To that end, we caution our colleagues to avoid the slippery slope of accepting a decrease in vigilance and safety while striving for “faster, better, cheaper.” We encourage every individual to maintain vigilance, advocate for patient safety, aim for excellence and efficiency, and avoid the temptation of normalizing deviance from accepted safety standards.

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Pain and Prescription Opioids: From Panacea to Epidemic

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OVERVIEW

According to the 2011 report from the Institute of Medicine *Relieving Pain in America*, chronic pain affects about 100 million Americans, with an annual associated cost estimated to be \$560-635 billion. Pain affects each individual in a unique way and there is no universal antidote. Pain can be severe and can persist, not uncommonly as a lifelong burden. With chronic pain comes enormous personal suffering and lost productivity.

Opium is the dried latex that exudes from the scored seed pods of the opium poppy (*Papaver somniferum*), and use of this crude extract to treat pain and wide range of other ailments dates back to the Neolithic Age (~10,000 - ~2,000 B.C.). The phenanthrene alkaloids morphine, codeine, and to a lesser extent thebaine are present in opium in significant quantities, which have been enhanced through selective breeding. Thebaine serves as the raw material for the synthesis for hydrocodone, hydromorphone, and other semisynthetic opioids. Morphine base is easily extracted from the dried, brownish-black opium latex and then converted to diacetylmorphine (heroin), an opiate with twice the potency of morphine. Morphine and its relatives, termed *opiates* if derived directly from the natural plant extract or *opioids* if created semi synthetically or synthetically, all bind at the mu-receptor where they lead to a host of effects, including the production of profound and reliable analgesia. Because opioids are so successful in relieving pain, they became a routine part of medical practice as far back at the 17th century.

Until very recent years, the use of opioids for treating chronic pain has been limited, as the potential for adverse effects, including addiction and death due to overdose, has been known for as long as opium has been used. Several investigators challenged this conventional wisdom and demonstrated sustained pain relief with little risk of adverse effects in a small series of patients. This small demonstration of efficacy along with a burgeoning pharmaceutical industry producing new opioid formulations led to a dramatic increase in their use in the United States and Canada. With increased use of opioids, in ever-higher doses and for longer periods of time, has come an increase in prescription opioid abuse, diversion, and opioid-related deaths. Recognition of this new epidemic comes at the same time that analysis of the available scientific evidence has failed to demonstrate a clear long-term benefit for use of chronic opioid therapy in treating non-cancer pain. The pendulum is swinging back toward more conservative use. The task at hand is to define how best to identify and manage patients who will benefit from chronic opioid therapy and to tackle the difficult task of discontinuing this form of therapy for the large number of patients who continue to receive chronic opioids without demonstrable benefit.

Chronic Opioid Therapy for Treating Non-cancer Pain: A Panacea

“Of all the remedies it has pleased almighty God to give man to relieve his suffering, none is so universal and so efficacious as opium” —Thomas Sydenham (1624 – 1689)

As anesthesiologists, we witness the profound effectiveness of opioid analgesics for relieving pain in every day practice – they quickly and effectively relieve even the most severe pain associated with illness or injury. So, it seems logical to use this powerful tool whenever and wherever we encounter those suffering with pain.

“Opium gives, and opium takes away.”
—Thomas De Quincey (1785 – 1859)

We have known for centuries that it is not so simple. Thomas De Quincey, a journalist and editor who wrote about the wonders of the opium-induced state in *Confessions of an English Opium Eater* (1821). De Quincey also detailed how his addiction to opium frayed the fabric of his life, leaving him destitute and without friends. He would lie, cheat and steel, falling hopelessly in to debt and lying to his physicians and friends to get more of the medication he needed to fuel his addiction. Far more common than outright addiction (compulsive substance use despite harmful consequences) are the adverse effects associated with opioids. Some are simply annoying: pruritus, mental clouding, and constipation. Others can be life threatening, most notably the respiratory depression that is dose-dependent and can lead to complete cessation of respiration and result in death if artificial respiration is not provided promptly.

So, why then has the use of significant daily doses – often extremely high doses – of opioid analgesics for treating chronic non-cancer pain become so commonplace? Russell Portenoy and Katherine Foley, two pain specialists practicing in New York City in the late 1980s, published a series of 38 patients with chronic non-cancer pain, demonstrating that they could indeed be maintained on these agents over the long term with little problematic behavior and reports of significant analgesia without the appearance of overt addiction.² In 1988, Ronald Melzack told those attending his presidential address during the 5th World Congress of the International Association for the Study of Pain, “...these papers represent a phenomenon akin to ‘breaking the sound barrier.’ Our attitudes to narcotics are influenced by unfounded prejudice based on street addicts...”. Leading medical societies adopted policies supportive of chronic opioid therapy; pain specialists and patient advocacy groups successfully lobbied state Medical

Boards and legislatures to change statutes and regulations. With guidance from the Federation of State Medical Boards, many states developed model guidelines that allowed for much more permissive use of opioids for treating non-cancer pain, often with specific language that pointed out that there is no ceiling to the doses that might needed to control pain.⁴

As the attitude of organized medicine was changing toward greater acceptance of chronic opioid therapy, a number of novel drug delivery systems were developed for opioid analgesics, including systems that allowed for sustained release and transdermal drug delivery systems. The testing required for these new analgesics was limited to demonstrating superiority over placebo for a limited period of drug exposure, often a period as short as four to six weeks. The first agents were tested in patients with cancer-related pain, but once they reached the marketplace, they were rapidly deployed for the treatment of non-cancer pain (and, not uncommonly, they were aggressively marketed to practitioners for treating those with non-cancer pain). Until very recently, few of these agents were tested for sustained efficacy over the course of months or years so typical of what was actually happening in real patient care. Coupling modern medicine's plea for better pain treatment and recognition that opioids appear to be an effective, low risk therapy with the pharmaceutical industry's widespread promotion of use of their new formulations and the era of aggressive and free-wheeling use of opioids began.

From Troubling Trends to Full Scale Epidemic

In the years after the initial release of controlled-release oxycodone (OxyContin®) in 1998, there was a dramatic rise in the number of Emergency Department mentions associated with the drug oxycodone reported through the Drug Abuse Warning Network (DAWN). Asa Hutchinson, then Administrator of the United States Drug Enforcement Administration, in an April 2002 address United States Senate Caucus on International Narcotics Control discussed the concern about escalating prescription opioid abuse in the United States. The DAWN data clearly demonstrated a rise in both prescription and non-prescription drug abuse during the prior decade, but what stood out was the rapid and disproportionate rise in the DAWN ED episodes associated with oxycodone when compared with other prescription opioids. The disproportionate rise in abuse of oxycodone has now equalized with a steady and alarming ongoing rise in the overall rate of prescription opioid abuse related deaths (Figure 1).

An alarming array of findings have emerged as the epidemic has become apparent.⁶ Fifty two million people in the United States over the age of 12 have used prescription drugs non-medically in their lifetimes; 6.1 million people have used them non-medically within the past month. The

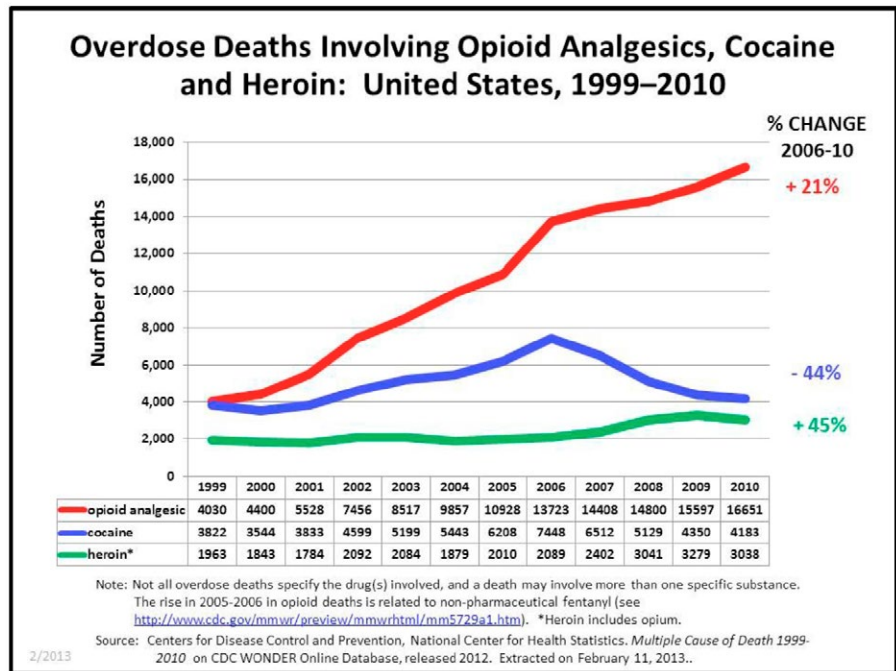


Figure 1. Overdose deaths involving opioid analgesics, cocaine and heroin in the United States, 1999-2010.

United States is 5% of the world's population and consumes 75% of the world's prescription drugs. Painkillers are the most abused prescription drugs, with 5.1 million abusers in 2010. Abused prescription drugs are most commonly (54% of the time) obtained for free from a friend or a relative. The most common reasons that teens give for abusing prescription drugs: 1) they are easy to get from parent's medicine cabinet; 2) they are available everywhere; 3) they are not illegal drugs.

Is Chronic Opioid Therapy Effective for Treating Chronic Non-Cancer Pain?

Much scrutiny has been aimed toward the existing data regarding the efficacy and safety of chronic opioid therapy for treating non-cancer pain in the past few years, and few clear answers have emerged. In an important article published in the *New England Journal of Medicine* in 2003, Ballantyne and Mao first brought widespread attention to the lack of evidence for efficacy of chronic opioid therapy, particularly at higher doses.⁷ They detailed the adverse effects that accompany chronic opioid therapy and called on practitioners to use caution, "It is therefore important that physicians make every effort to control indiscriminate prescribing, even when they are under pressure by patients to increase the dose of opioids." A recent Cochrane review of opioid therapy for chronic low back pain compared to placebo or other treatments examined 15 trials in a total of 5540 patients.⁸ The authors concluded, that there is some very low to moderate quality evidence for short-term (less than 4 months) reduction of pain and improvement in function in patients receiving chronic opioids. They found no evidence to demonstrate effectiveness and safety of long-term (longer than 4 months) opioid therapy. A series of similar analyses have appeared in the scientific literature, the most recent of which raises significant questions about both long-term effectiveness and safety of chronic opioid therapy.⁹ In this most recent analysis conducted for a National Institutes of Health workshop that centered on the prescription drug abuse epidemic, Chou and his colleagues did not find a

single study of chronic opioid therapy that evaluated long-term (>1 year) outcomes related to pain, function, quality of life, opioid abuse, or addiction. They pointed to a number of observational studies that suggest that opioid therapy for chronic pain is associated with increased risk for overdose, opioid abuse, fractures, myocardial infarction, and markers of sexual dysfunction and for some of these harms, higher doses was associated with increased risk. Anesthesiologists, who comprise the majority of subspecialists in the field of pain medicine, have seen the medico legal risks of prescribing chronic opioid therapy escalate dramatically during the past decade, with most of malpractice claims arising from drug-related deaths (from either intentional or unintentional drug overdose).¹⁰ The alarming public health crisis surrounding abuse of prescription opioid analgesics and greater clarity about the risks and benefits of this approach to treatment leave practitioners in an uncomfortable position. We must acknowledge the crisis, and develop strategies to reverse the current alarming trends.

Chronic Opioid Therapy for Non-Cancer Pain in 2015

In 2011, the Obama Administration laid out a detailed plan, *Epidemic: Responding to America's Prescription Drug Abuse Crisis*.¹¹ Their plan calls for expanded education of patients and health care practitioners with an urgent call for new research, the expansion of existing Prescription Drug Monitoring Programs (PDMPs), better means for disposing of unneeded prescription drugs, and tougher enforcement of existing laws focused on identifying and prosecuting practitioners who are "...prescribing these medications outside the usual course of professional practice or for illegitimate purposes." Obama's plan has set a five year goal of 15 percent reduction in non-medical use of prescription-type psychotherapeutic drugs among people 12 years of age and older.

At least two major questions immediately arise for pain medicine specialists. How do we appropriately select and manage patients with non-cancer pain for chronic opioid therapy to treat only those with the greatest chance to benefit while minimizing the risk to the individual who is treated and our society? How do we identify and best manage those patients receiving chronic opioid therapy who are not benefiting from this course of treatment?

Current guidelines for using chronic opioid therapy to treat chronic non-cancer pain are now widely available. The most recent guideline developed jointly by the American Pain Society and the American Academy of Pain Medicine was published in 2009 and are summarized below.¹²

Guidelines for Selecting and Monitoring Patients Receiving Chronic Opioid Therapy (COT) for the Treatment of Chronic, Noncancer Pain

PATIENT SELECTION

- Conduct a history, physical examination, and appropriate testing, including an assessment of risk of substance abuse, misuse, or addiction.
- Consider a trial of COT if pain is moderate or severe, pain is having an adverse impact on function or quality of life, and potential therapeutic benefits outweigh potential harms.
- A benefit-to-harm evaluation, including a history, physical examination, and appropriate diagnostic testing, should be performed and documented before and on an ongoing basis during COT

INFORMED CONSENT AND USE OF MANAGEMENT PLANS

- Informed consent should be obtained. A continuing discussion with the patient regarding COT should include goals, expectations, potential risks, and alternatives to COT.
- Consider using a written COT management plan to document patient and clinician responsibilities and expectations and assist in patient education.

INITIATION AND TITRATION

- Initial treatment with opioids should be considered as a therapeutic trial to determine whether COT is appropriate.
- Opioid selection, initial dosing, and titration should be individualized according to the patient's health status, previous exposure to opioids, attainment of therapeutic goals, and predicted or observed harms

MONITORING

- Reassess patients on COT periodically and as warranted by changing circumstances. Monitoring should include documentation of pain intensity and level of functioning, assessments of progress toward achieving therapeutic goals, presence of adverse events, and adherence to prescribed therapies.
 - In patients on COT who are at high risk or who have engaged in aberrant drug-related behaviors, clinicians should periodically obtain urine drug screens or other information to confirm adherence to the COT plan of care.
 - In patients on COT not at high risk and not known to have engaged in aberrant drug-related behaviors, clinicians should consider periodically obtaining urine drug screens or other information to confirm adherence to the COT plan of care.
-

Current guidelines for using chronic opioid therapy to treat non-cancer pain published by multidisciplinary expert groups such as the American Pain society and the American Academy of Pain Medicine or regulating organizations such as the Federation of State Medical Board focus on how to prescribe safely and efficiently, but do not provide practical advice on opioid discontinuation. In a recent review, our research group reexamined the existing literature and proposed a set of guidelines based on the published literature aimed at guiding practitioners as they identify patients who are not benefiting from chronic opioid therapy and begin the difficult process of discontinuing this therapy.

Watching the rapid expansion and sudden retreat from widespread use of chronic opioid therapy for treatment of chronic non-cancer pain during the course of my career has been a disorienting experience as a pain practitioner. It is difficult to establish personal standards of practice with so many groups offering disparate opinions about how best to approach the use of opioids for those with chronic pain. Nonetheless, now the burden is on our specialty to assist practitioners with less expertise in managing this often difficult population at the same time we continue the much-needed research to better care for our patients suffering with chronic pain.

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Obesity and Obstructive Sleep Apnea: A Combined Nightmare

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INTRODUCTION

Obesity is defined as a Body Mass Index (BMI) >30 kg/m², morbid obesity defined as >35 kg/m², super morbid obesity >50 kg/m² and ultra-obesity >70 kg/m². Obstructive Sleep Apnea (OSA) syndrome is a disease characterized by recurrent episodic cessation of breathing lasting \geq 10s during sleep. In this condition, there is exaggerated depression of pharyngeal muscle tone during sleep and anesthesia, resulting in a cyclical pattern of partial or complete upper airway obstruction with impaired respiration.¹ A significant number of patients with OSA are undiagnosed when they present for elective surgery.² Approximately 24% of surgical patients were found to be at high risk based on screening, of whom 81% had not been previously diagnosed with OSA.^{3,4} Obesity is an important risk factor for the development of OSA. The prevalence of OSA is 78% in morbidly obese patients scheduled for bariatric surgery.⁵ Obese patients may have significant comorbid conditions and cardiopulmonary diseases. Excess accumulation of fat in various locations in the body causes mechanical and metabolic problems. The mechanical problems like alteration in pulmonary function, obstructive sleep apnea and difficult airway challenge the anesthesiologist more than the metabolic problems like hypertension, dyslipidemia and insulin resistance.⁶ Though there is conflicting evidence about obesity alone as a risk factor for the perioperative morbidity, the combination of obesity and OSA has significant impact on the postoperative outcome.

OBESITY AND OSA INTERACTION

The prevalence of OSA among the general population aged 30 to 70 years is 5% in women and 14% in men,⁷ and is 78% in morbidly obese patients scheduled for bariatric surgery.⁵ Obesity is considered a major risk factor for the development and progression of OSA. Patients with mild OSA who gain 10% of their baseline weight are at a six-fold increased risk of progression of OSA, and an equivalent weight loss can result in a more than 20% improvement in OSA severity.⁸ Visceral obesity is common in subjects with OSA.⁹ Obesity is a major risk factor for OSA because it causes enlargement of soft tissue structures within and surrounding the airway, thereby contributing significantly to pharyngeal airway narrowing. Lung volumes are markedly reduced by a combination of increased abdominal fat mass and recumbent posture. Reduction of lung volume may decrease longitudinal tracheal traction forces and pharyngeal wall tension, which predisposes to narrowing of the airway. In addition, obesity-related leptin resistance may impair the neuroanatomic interactions necessary for stable breathing, thereby contributing to the genesis of OSA.¹⁰ Though OSA is not a component of metabolic syndrome (central obesity,

hypertension, hyperlipidemia and insulin resistance), there are experimental and clinical evidences to show the relationship between OSA and cardiometabolic syndrome.¹⁰ Since most of the OSA patients are undiagnosed, anesthesiologist has an important role of identifying OSA especially severe OSA. Male with central or android obesity are more prone to have OSA than the gynecoid type of obesity.

PATHOPHYSIOLOGICAL CHANGES WITH OBESITY AND OSA

Obesity has a significant effect on the physiology of breathing. There is significant reduction in lung compliance and functional residual capacity (FRC). Residual volume is relatively well preserved with minimal reduction in total lung capacity. Tidal volumes are often reduced in severe obesity, and breathing follows a rapid, shallow pattern. As BMI increases, there is a reduction in expiratory flow and a decrease in FEV1 and FVC. But the ratio of FEV1 to FVC is preserved. CO diffusing capacity is normal or increased due to increase in pulmonary blood flow. The airway resistance is also significantly higher in the obese and it is related to the reduction in lung volume rather than airway obstruction. This contributes to OSA. Subjects with simple obesity have an enhanced respiratory drive, while the respiratory drive of subjects with obesity hypoventilation syndrome is either depressed or inappropriately suppressed.¹¹

Obesity is independently associated with left ventricular hypertrophy, characterized by increase in both left ventricular cavity size and wall thickness. An increase in left ventricular size also leads to atrial fibrillation. Anorexigenic drugs used to facilitate weight loss are associated with mitral and aortic valve regurgitation. In addition, myocardial contractility is reduced with diastolic dysfunction. Abdominal obesity is a well-defined risk factor for the development of atherosclerotic coronary artery disease. In obese patients, stroke volume and cardiac output are both increased, due to the metabolic demand. Sympathetic activation likely results from sleep apnea and it prevent the normal nocturnal decline in blood pressure. In general, obesity leads to hypertension, the probable mechanism is activation of the renin-angiotensin system may occur directly via signals from adipose tissue.¹² Sleep apnea associated with obesity could lead to left ventricular hypertrophy, hypertension, increased sympathetic tone, chronic hypoxemia, and exaggerated swings in intrathoracic pressure during obstructive episodes. The increase in right ventricular cavity size and wall thickness is related to obstructive sleep apnea (OSA). OSA is one of the common reasons for resistance hypertension.¹³

POSTOPERATIVE OUTCOME IN OBESE PATIENTS WITH OSA

Chronic untreated OSA is an independent risk factor for increased all-cause mortality in the general population.^{14,15} Patients with OSA has 2 times higher risk of pulmonary complications after non-cardiac surgery.¹⁶ In bariatric surgical patients, the presence of OSA was found to be an independent risk factor for adverse postoperative events.¹⁷ Flink et al reported a 53% incidence of postoperative delirium in OSA patients vs. 20% in non-OSA patients.¹⁸ A recent meta-analysis showed that the presence of OSA increased the odds of postoperative cardiac events including myocardial infarction, cardiac arrest and arrhythmias (OR 2.1), respiratory failure (OR 2.4), desaturation (OR 2.3), ICU transfers (OR 2.8), and reintubations (OR 2.1).¹⁹ However, a recent study found that neither an OSA diagnosis nor suspected OSA was associated with increased 30-day or 1-year postoperative mortality.²⁰ Also, Mokhlesi et al examined large nationally representative cohorts in elective orthopedic, prostate, abdominal and CV surgery in 1 million patients.²¹ and 90,000 patients undergoing bariatric surgery.²² Both studies showed increased complications but not an increase in mortality. A recent large population study showed OSA patients are more likely to receive ventilatory support, more ICU, stepdown and telemetry services, consume more economic resources, and have longer lengths of hospitalization.²³ Recently in a matched analysis of polysomnography data and health administrative data, the risk of cardiovascular complications, primarily cardiac arrest and shock, was significantly different between undiagnosed OSA {2.2 (1.16-4.17)} and diagnosed OSA patients {0.75 (0.43to 1.28)}. Diagnosis of OSA and prescription of CPAP were associated with a reduction of postoperative cardiovascular complications.²⁴ Though there is strong evidence on OSA and adverse postoperative outcome, obesity alone is not a risk factor for postoperative complication. There are recent studies showing obesity paradox in the surgical population, In these studies, mild to moderate obesity has been shown to have a protective effect on the postoperative complication and cardiac morbidity.^{25,26} Morbidly obese parturients are at increased risk for antenatal comorbidities, failed labor analgesia, longer first stage of labor and operative delivery.²⁷ Metabolic syndrome is a risk factor for post-operative pulmonary complication, DVT, atrial fibrillation and CHF.^{28,29} A recent outcome study on the bariatric surgical population showed that pulmonary complications and metabolic syndrome were significantly associated with increased postoperative mortality.³⁰

PREOPERATIVE ASSESSMENT

Morbidly obese patients are considered at high risk for perioperative complications and often undergo extensive testing for preoperative clearance, including chest X-ray, pulmonary function tests, non-invasive cardiac testing, and blood work. Although recent data indicate that extensive preoperative testing may not be necessary for every severely obese patient undergoing gastric bypass surgery,³¹ basic screening tests are imperative to identify the additional risk factors.³² Further preoperative testing should be individualized based on the co-morbid conditions. Since nearly 70% of morbidly obese patients are prone to have

OSA, screening test to diagnose and quantify OSA has been suggested to be mandatory. The gold standard for diagnosing OSA is overnight polysomnography. The Apnea Hypopnea Index (AHI), defined as the average number of abnormal breathing events per hour of sleep, is used to determine the presence of and the severity of OSA. An apneic event refers to the cessation of airflow for 10s, while hypopnea occurs with reduced airflow with desaturation $\geq 4\%$. The American Academy of Sleep Medicine diagnostic criteria for OSA requires either an AHI ≥ 15 , or AHI ≥ 5 with symptoms, such as daytime sleepiness, loud snoring, or observed obstruction during sleep. OSA severity is mild for AHI ≥ 5 to 15, moderate for AHI 15 to 30, and severe for AHI >30 .³³

Since polysomnography is a time consuming and expensive test, the STOP-Bang questionnaire (Table 1) can be used as a screening tool.³⁴ The STOP-Bang questionnaire has the highest methodological validity and reasonable accuracy in predicting a diagnosis of OSA^{35,36} and a STOP-Bang score of 5–8 identified patients with a high probability of moderate-to-severe OSA.³⁷ The addition of serum HCO₃- level ≥ 28 mmol/L to a STOP-Bang score ≥ 3 improves the specificity for preoperative obstructive sleep apnea recognition.³⁸ For obese or morbidly obese patients, a STOP-Bang score of 4 or greater can be used as a cut-off.³⁹ Patients with a positive STOP-Bang score are more likely to have increased postoperative complications.⁴⁰ Also the Oxygen Desaturation Index from a high resolution nocturnal oximeter is a sensitive and specific tool to detect undiagnosed sleep disordered breathing in the

Table 1:
STOP-Bang Questionnaire

Yes <input type="radio"/>	No <input type="radio"/>	Snoring? Do you Snore Loudly (loud enough to be heard through closed doors or your bed-partner elbows you for snoring at night)?
Yes <input type="radio"/>	No <input type="radio"/>	Tired? Do you often feel Tired, Fatigued, or Sleepy during the daytime (such as falling asleep during driving)?
Yes <input type="radio"/>	No <input type="radio"/>	Observed? Has anyone Observed you Stop Breathing or Choking/Gasping during your sleep?
Yes <input type="radio"/>	No <input type="radio"/>	Pressure? Do you have or are being treated for High Blood Pressure ?
Yes <input type="radio"/>	No <input type="radio"/>	Body Mass Index more than 35 kg/m²?
Yes <input type="radio"/>	No <input type="radio"/>	Age older than 50 year old?
Yes <input type="radio"/>	No <input type="radio"/>	Neck size large? (Measured around Adams apple) For male, is your shirt collar 17 inches or larger? For female, is your shirt collar 16 inches or larger?
Yes <input type="radio"/>	No <input type="radio"/>	Gender = Male?

Scoring Criteria:

For general population

Low risk of OSA: Yes to 0-2 questions

Intermediate risk of OSA: Yes to 3-4 questions

High risk of OSA: Yes to 5-8 questions

Yes to 2 of 4 STOP questions + individual's gender is male

Yes to 2 of 4 STOP questions + BMI > 35 kg/m²

Yes to 2 of 4 STOP questions + neck circumference male 17"
female 16"

www.stopbang.ca Property of University Health Network

Modified from

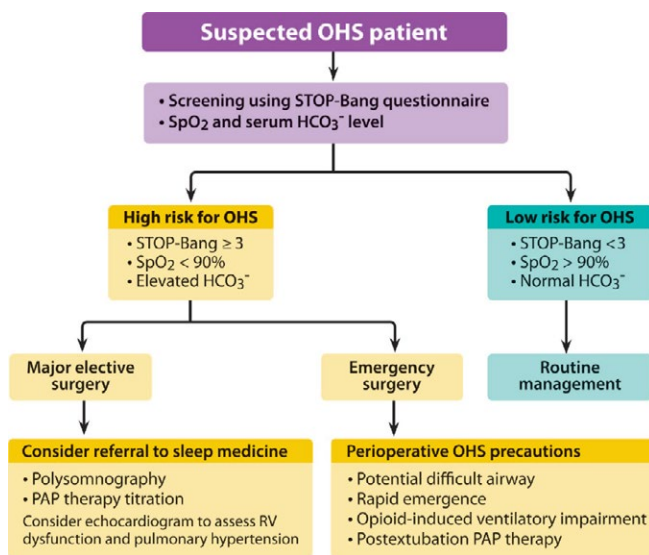
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surgical patients.⁴¹ Patients with preoperative mean overnight SpO₂ <93%, or oxygen desaturation index >29 events/h were recently shown to be at higher risk for postoperative adverse events.⁴² In the absence of other causes for hypoxemia, a baseline oximetry reading of $\leq 94\%$ on room air suggests severe long standing OSA. These screening tests do not differentiate OSA from other sleep disorders, such as obesity hypoventilation syndrome and central sleep apnea, and therefore a blood gas and polysomnography are indicated to diagnose hypercarbia and effortless apnea, respectively. Comorbidities associated with OSA are arterial hypertension, coronary artery disease, cerebrovascular disease, congestive heart failure, cardiac dysrhythmias and diabetes mellitus. Studies suggest that patients with OSA, who have been treated with CPAP preoperatively, have fewer perioperative complications than those untreated.⁴³ A functional algorithm could help to guide possible screening and the management of the obese patients with OSA.⁴⁴

Obesity hypoventilation syndrome (OHS) is defined by the triad of obesity, daytime hypoventilation and sleep disordered breathing without an alternative neuromuscular, mechanical or metabolic cause of hypoventilation. It is a disease entity distinct from simple obesity and obstructive sleep apnea. OHS is often undiagnosed but its prevalence is estimated to be 10-20% in obese patients with obstructive sleep apnea and 0.15-0.3% in the general adult population. Compared to eucapnic obese patients, OHS patients present with severe upper airway obstruction, restrictive chest physiology, blunted central respiratory drive, pulmonary hypertension and increased mortality. The mainstay of therapy is non-invasive positive airway pressure.⁴⁵ (Fig 1)



PREOPERATIVE PREPARATION

Preoperative sedative premedication should be avoided in morbidly obese patients with OSA. Obese patients have faster gastric emptying time, a large gastric volume and a high incidence of gastro-oesophageal reflux disease making them prone to aspiration. This risk increases further after post-bariatric surgery.⁴⁶ If concerned about the risk of acid aspiration, H₂-receptor antagonists or a proton pump inhibitor can be given. Gastric ultrasound is an emerging option to

measure the gastric content to avoid aspiration in morbidly obese patients.⁴⁷ Also, obese patients are at significant risk of venous and pulmonary thromboembolism and therefore mechanical and pharmacological method of perioperative thromboembolic prophylaxis must be considered.

The health care team should have special training in the issues relating to the care of morbidly obese patients. Patients should be encouraged to move themselves whenever possible. Operating table, trolley, bed and specific equipment like spine frame for spine surgery should be checked and labeled for its maximum weight bearing capacity. An “obesity pack” (including specific equipment, protocol guidelines and contact numbers) should be available for the emergency surgeries. Society of Obesity and Bariatric Anesthesia (SOBA) has published a comprehensive one sheet guideline for managing the obese patients. (www.SOBAuk.com)

INTRAOPERATIVE MANAGEMENT

In morbidly obese patients, oxygen saturation following preoxygenation falls more rapidly during apnea than in those with a normal BMI. This effect can be limited by a 25 degree head-up position during preoxygenation,⁴⁸ the combination of preoxygenation with a reverse Trendelenburg position and nasopharyngeal oxygen insufflation,⁴⁹ positive end-expiratory pressure (PEEP) of 10 cm H₂O⁵⁰ and noninvasive bi-level positive airway pressure.⁵¹ Rapid sequence induction remains essential in the morbidly obese patients with gastro-oesophageal reflux.⁵²

Airway management - Excess fatty tissue on the face, neck, breasts, thorax, and abdomen in an obese patient poses substantial airway challenges with bag and mask ventilation, tracheal intubation, oxygenation, and tracheotomy. The ASA closed claims database shows that obese patients disproportionately account for 37% of all airway-related complications occurring during induction.⁵³ The United Kingdom Fourth National Audit Project (NAP 4) reported a four-fold increase in the risk of serious complications in the morbidly obese patient vs. the non-obese patients.⁵⁴ Nineteen (25%) of the 77 obese patients reviewed in that study suffered brain damage or death. Positioning with the head, neck and shoulders elevated in the head elevated laryngoscopy position (“HELP”) facilitates direct laryngoscopy. The incidence of difficult intubation and difficult mask ventilation is high in obese compared to non-obese population. A neck circumference greater than 43 cm is associated with an increased risk of difficult intubation.⁵⁵ But, there is a conflicting evidence regarding the predictors of difficult intubation like neck circumference, severity of OSA, pretracheal soft tissue thickness and BMI.⁵⁶ A Mallampati score of 3 or 4 and male gender predicted difficult intubation.⁵⁷ The ratio of the neck circumference to thyromental distance (NC/TM), predicts difficult intubation in obese patients.⁵⁸ Obesity was found to be an independent predictor of failed use of a LMA requiring device removal and endotracheal intubation.⁵⁹ Double-lumen supraglottic airways, such as the LMA ProSeal™ and the LMA Supreme™, provide higher leak pressures and may be safer in patients with obesity.⁶⁰ During cannot intubate cannot ventilate scenario, the surgical airway plays a vital role. The emerging role of ultrasound in identifying airway anatomy presents the advantage of turning a blind technique

into one that is guided and offering the possibility to identify the cricothyroid membrane accurately in obese patients.⁶¹ Videolaryngoscopic guided intubation with the Glidescope, Storz V-Mac or McGrath systems has a high success rate in the morbidly obese patients with a difficult airway.⁶² The use of awake video laryngoscopy-assisted tracheal intubation has also been described as an alternate to flexible bronchoscopic intubation.⁶³ The Difficult Airway Society published guidelines in 2012 for management of tracheal extubation using a stepwise approach.⁶⁴ Patients with obesity and obstructive sleep apnea are stratified into a category of extubation “at risk” of a major complication. A recent multi-center study shows the incidence of difficult intubation was twice more frequently in ICU than in the OT and severe life-threatening complications related to intubation occurred 20-fold more often in ICU.⁶⁵

Whenever possible, patients should be extubated wide-awake in the sitting position. Morbidly obese patients are prone to have postoperative hypoxemia due to atelectasis.⁶⁶ Though intraoperative lung recruitment maneuver are important to avoid hypoxemia, CPAP in the PACU helps to improve the oxygenation. Patients with OSA should be instructed to bring their CPAP or non-invasive positive pressure ventilation equipment to the hospital. Compared with the venturi mask, the Boussignac CPAP mask improves the postoperative PaO₂/FIO₂ ratio in morbidly obese patients.⁶⁷ Perioperative auto-titrated continuous positive airway pressure treatment was shown to significantly reduce postoperative apnea hypopnea index and improved oxygen saturation in surgical patients with moderate and severe obstructive sleep apnea.⁶⁸

Obese patient with OSA should have perioperative precautions and risk mitigation to achieve the best possible outcome (Table 2).

VENTILATION STRATEGIES

Following induction of anesthesia, atelectasis increases from 1 to 11% of total lung volume in the morbidly obese patients.⁶⁹ Recruitment maneuvers (PEEP & Valsalva) can counteract these effects. Preoxygenation with non-invasive pressure support ventilation & PEEP with intraoperative early recruitment maneuver (40 cm H₂O for 40 s) improves arterial oxygenation and end-expiratory lung Volume.⁷⁰ A recent meta-analysis shows that recruitment maneuver added to PEEP compared with PEEP alone improves intraoperative oxygenation and compliance without adverse effects.⁷¹ During bariatric surgery, pressure-controlled ventilation improves oxygenation compared with volume-control.⁷² In a recent review by Silva et al., the authors recommended stepwise incremental recruitment maneuvers to reduce hemodynamic instability and found no evidence supporting pressure vs. volume control ventilation.⁷³ Morbidly obese patients have markedly reduced supine functional residual capacity, with further decrease in the Trendelenburg position and insufflation of the abdomen with CO₂ during laparoscopy surgery. In non-obese patients the difference in PaCO₂/ETCO₂ was high with large tidal volumes (800ml), but in the morbidly obese patients this difference was high with small tidal volumes.⁷⁴ The endotracheal tube moves down more in morbidly obese patients during laparoscopic surgery and this is aggravated by the Trendelenburg position.⁷⁵

Table 2: Perioperative Precautions and Risk Mitigation for OSA Patients

Anesthetic Concern	Principles of Management
Premedication	Avoid sedating premedication ⁶⁶ Consider Alpha-2 adrenergic agonists (clonidine, dexmedetomidine) ⁵⁷
Potential difficult airway (difficult mask ventilation and tracheal intubation) ^{58,59}	Optimal positioning (Head Elevated Laryngoscopy Position) if patient obese Consider CPAP preoxygenation ⁶² Two-handed triple airway maneuvers Anticipate difficult airway. Personnel familiar with a specific difficult airway algorithm ⁶¹
Gastroesophageal reflux disease ⁶⁴	Consider proton pump inhibitors, antacids, rapid sequence induction with cricoid pressure
Opioid-related respiratory depression ⁶⁶	Minimize opioid use Use of short-acting agents (remifentanyl) Multimodal approach to analgesia (NSAIDs, acetaminophen, tramadol, ketamine, gabapentin, pregabalin, dexmedetomidine, clonidine, Dexamethasone, melatonin) Consider local and regional anesthesia where appropriate
Carry-over sedation effects from longer-acting intravenous and volatile anesthetic agents	Use of propofol / remifentanyl for maintenance of anesthesia Use of insoluble potent anesthetic agents (desflurane) Use of regional blocks as a sole anesthetic technique
Excessive sedation in monitored anesthetic care	Use of intraoperative capnography for monitoring of ventilation ²⁶
Post-extubation airway obstruction	Verify full reversal of neuromuscular blockade ²⁶ Extubate only when fully conscious and cooperative ²⁶ Non-supine posture for extubation and recovery ²⁶ Resume use of positive airway pressure device after surgery ²⁶

Adapted from Seet E, Chung F Can J Anesth 2010; 57: 849-64

One lung ventilation is technically possible in the lateral position, since abdominal content falls away from the body and unloads the dependent diaphragm. A large tidal volume ventilation, intermittent alveolar recruitment, continuous positive airway pressure to the collapsed lung and positive end-expiratory pressure (PEEP) to the ventilated lung could help to avoid the hypoxia during one lung ventilation. In general morbidly obese patients are prone for post-operative pulmonary complication and it could be more with thoracic surgery.^{76,77}

REGIONAL ANESTHESIA

Regional anesthesia offers distinct advantages, which allows minimal airway manipulation, avoidance of anesthetic drugs with cardiopulmonary depression, reduced post-operative nausea and vomiting and reduced perioperative opioid requirements. However, the rate of block failure increased incrementally with a higher BMI.⁷⁸ Using ultrasound-guided regional anesthesia for peripheral nerve blocks in the obese population led to improved success rates.⁷⁹ Epidural analgesia should be considered in obese patients undergoing laparotomy to improve postoperative spirometry.⁸⁰ Ultrasound guided neuraxial anesthesia is a viable option to increase the successes in obese patients.⁸¹ Since 50-68% of post bariatric surgery patients are prone to have Vitamin K deficiency due to malabsorption,⁸² documentation of normal coagulation function is necessary for neuraxial blocks. In contrast to the previous studies, a

recent study showed no difference in spinal bupivacaine requirement between the obese and non-obese parturient.⁸³ For shoulder surgery, interscalene block in patients with OSA indicates careful evaluation. Phrenic nerve blockade may be minimized through using ultrasound, a small volume of local anesthetic, and a catheter technique for titrating the dose.⁸⁴ A recent study on 40,316 patients with sleep apnea diagnosis who underwent hip and knee arthroplasty, the use of neuraxial anesthesia vs. general anesthesia was associated with decreased odds for the need for mechanical ventilation, use of ICU, prolonged length of stay and cost.⁸⁵

POSTOPERATIVE DISPOSITION OF KNOWN AND SUSPECTED OSA PATIENTS AFTER GENERAL ANESTHESIA

All patients with known or suspected OSA who had received general anesthesia should have additional 30-60 minutes in PACU after the modified Aldrete criteria for discharge has been met.^{44,86} The occurrence of recurrent respiratory events in PACU (episodes of apnea \geq 10 seconds, bradypnea $<$ 8 breaths/min, pain-sedation mismatch, or repeated O₂ desaturation $<$ 90%) is another indication for continuous postoperative monitoring.⁸⁷ Any of the above events occurring repeatedly in separate 30-minute intervals may be considered recurrent PACU respiratory events. Patients with suspected OSA and who develop recurrent PACU respiratory events are at increased risk of postoperative respiratory complications.⁸⁷⁻⁸⁸ These patients may require postoperative PAP therapy with monitoring facility.⁸⁹ Monitoring with continuous oximetry is recommended with parenteral opioids due to possible drug induced respiratory depression.⁹⁰ Continuing PAP therapy in the postoperative period in the bariatric surgery patients may mitigate the risk of postoperative complications.⁹¹ Apart from oral or systemic administration of opioid sparing agents, other effective techniques include local anesthetic wound infiltration, peripheral nerve block catheters and neuraxial infusions of local anesthetic agents. If postoperative parenteral opioids are necessary, consideration should be made for the use of patient controlled analgesia with no basal infusion and a strict hourly dose limit, as this may help reduce the total amount of opioid used.

Recently, Swart et al published a PACU order-based approach to facilitate postoperative decision making for patients with sleep apnea. The orders prompt anesthesiologists to consider the factors and events associated with higher risk of complications from OSA, diagnostic follow-up and possible sleep medicine consult.⁹² (www.stopbang.ca) A recent study found that patients had no significant increase in postoperative complications if managed on the OSA risk management protocol.⁹³

The disturbances in sleep architecture were greatest on postoperative N1, night of surgery and breathing disturbances during sleep were greatest on postoperative N3.⁹⁴ Preoperative AHI, male gender and 72h opioid dose were positively associated with postoperative AHI.⁹⁵ Therefore, it is necessary to have appropriate monitoring based on the OSA risk.

AMBULATORY ANESTHESIA

At present there is a lack of evidence to recommend a cut-off BMI for ambulatory surgery. The Society for Ambulatory Anesthesia (SAMBA) indicates that BMI $>$ 50 kg/m² has increased risk of perioperative complication.⁹⁶ Currently more importance is given to the comorbid conditions than the BMI alone. In 2006 and 2014, the ASA developed guidelines on the perioperative management of patients with OSA^{97,98} based on the severity of OSA, the invasiveness of surgery, the type of anesthesia, and the need for postoperative opioids. In 2012, SAMBA published a consensus statement on the perioperative management of patients with obstructive sleep apnea.⁹⁹ The STOP-Bang questionnaire could be used as a screening tool, and patients with a known diagnosis of OSA who are compliant with continuous positive airway pressure (CPAP) and have optimized comorbid conditions may be considered for ambulatory surgery. Patients who are non-compliant with CPAP may not be appropriate for ambulatory surgery. Patients with a presumed diagnosis of OSA based on the screening tool and optimized comorbid conditions can be considered for most types of ambulatory surgery if postoperative pain relief can be provided predominantly with non-opioid analgesic techniques. In contrast to the ASA OSA guidelines, laparoscopic upper abdominal procedures (e.g., gastric banding) may be safely performed on an outpatient basis provided that the perioperative precautions are followed. Recurring adverse respiratory events in PACU is an indication for extended monitoring and admission.⁸⁷ A recent retrospective study did not find any difference in the incidences of postoperative hypertension, hypotension, hypoxia, cancellation of surgery, and unplanned hospital admissions between non-obese and morbidly obese patients undergoing ambulatory surgery.¹⁰⁰ Ideally, ambulatory surgical centers that manage patients with OSA should have the resources to handle postoperative problems associated with OSA and a transfer agreement with an appropriate inpatient facility.

CONCLUSION

Morbidly obesity and OSA is a challenging combination for anesthesiologists as these patients need extra care during the perioperative period. Understanding the risk about this combination and screening for the potential comorbid conditions is imperative to modify the anesthetic management for a better perioperative outcome. Advancement in anesthesia technology like video laryngoscopes, ultrasound and ventilatory modes in anesthesia workstations has made dramatic improvement in the peri-operative care of obese patients. At the same time advancement in minimally invasive surgery challenges the anesthesiologist, since most of the surgeries are being done as ambulatory procedures.

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How to Manage Disruptive Colleagues

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INTRODUCTION

Having disruptive people in your institution is not only irritating but may adversely affect patient care.¹ For that reason, institutions are required to address these behavior problems at multiple levels, medical student, resident, faculty and staff. Different organizations within organized medicine, (AAMC, ACGME, ASA, and ACS) all have policies regarding the management of disruptive individuals and your institution must have specific policies and procedures for that management.^{2,3,4,5}

The Joint Commission (JC) has published the Sentinel Event Alert No. 40 entitled "Behaviors that undermine a culture of safety."¹ They categorize them as unacceptable, inappropriate and disruptive and provide examples such as verbal abuse, physical threats, passive activities and refusing to answer questions, phone calls or pages. The AMA published a similar policy regarding this type of behavior, AMA H-225.956. Rosenstein et al conducted surveys at 100 hospitals, surveying physicians, nurses and administrators. They provided results of 4,530 surveys, published in the journal of the American College of Surgeons.^{6,7} Seventy-four percent of those surveyed had personally witnessed disruptive behavior among physicians, 56% of physicians surveyed has witnessed disruptive behavior. Among surgical specialties, General Surgeons had the highest incidence at 31% and the lowest were GYN at 6%, whereas in the medical specialties, Cardiology had the highest at 7% and Neurology the lowest at 4%. In this study strategies were developed to improve the culture of professional behavior with recommendations including raise awareness, develop policies and procedures, provide education, communication, developing committee among nurses and physicians, and identifying project champions. After these processes were implemented a follow-up survey was conducted which 50% of respondents found no change in behavior, where 35% thought it had improved and 15% actually thought it was worse.⁷

In this review I will cover several types of situations with differing severity and chronicity. These events will involve different levels of personnel and how they may be handled. Before these situations are presented, I will review some general rules which may be helpful when approaching these situations. Most of the content I will present is from my personal experience.

General Rules:

1. Good things in public, bad things in private. Always meet with the individuals involved in a private setting when having these discussions. Don't put anything in email that you don't want broadcast to your entire institution and beyond.

2. Know your institutional rules. That is, the policies and procedures associated with each of the organizations associated with each individual groups (i.e. residents, faculty, staff, etc.).
3. Get advice. The advice will come in the way of the leadership of the institution, the chief of the medical staff, the dean of the medical school, human resources and the legal staff of your institution. Remember, "misery loves company."
4. Document all interactions. Event, meeting with follow-up documentation and an accurate time-line may be needed upon future review.
5. Get all the facts from both sides of the story before you make any judgments or proceed with any action. The facts always change when you hear both versions of the same event.

The following situations will be described when dealing with residents, junior faculty or senior faculty, both in your department or another department. I won't be reviewing how hospital employees are dealt with for these are more complex situations which may involve union and institutional policy, which are beyond the scope of this talk.

Disruptive individuals can be classified, from my experience, into five types:

- 1) Immature, Inexperienced and Insecure
- 2) Out of Touch
- 3) Disgruntled (Negative Thought Leaders)
- 4) The Malignant Narcissist - the most difficult to manage

Situation One: It is brought to your attention by a resident that another resident is using the paging system inappropriately for "fun." This falls into the first category of immaturity. It is usually settled by having a talk with the individual; asking them to please meet you in your office. Here the two of you can discuss professionalism and how this type of behavior is not professional, not acceptable, and will not continue. In my experience this usually stops that behavior, especially when others in the program find out what happened to that individual. If it doesn't stop, things become more serious and you need further documentation and elevation to the institution's GME and Office of Clinical Affairs (OCA).

Situation Two: A nurse comes to you and states that a surgeon in the OR was speaking unprofessionally, losing control and "yelling at everyone." You contact the surgeon and again ask them to meet with you in your office. In discussing with the surgeon you ask them how they recalled the situation. The surgeon is a junior faculty and they described they were starting a difficult case they were doing for the first time so they were very anxious. The case had been delayed so the second shift of nurses were in the room who were unfamiliar

with the case and did not know the instrumentation, which made him extremely anxious and upset about how this case would proceed. In this situation I sympathized with the junior faculty and stated that it was clear why this would be a disturbing situation, but, his behavior in the room did not improve things. I told him that in the future he should state his concerns specifically, that is, that the nursing staff needs to be familiar with the procedure, especially when he was doing this for the first time. If he felt that he could not proceed at that time with that nursing staff scheduled for the room, he should discuss this with the OR Director and/or OR Nursing Director, request getting different nurses, even deferring the case, or ask assistance or advice from a senior surgeon. He would need to do what he thought was in the best interest of the patient. From his perspective it was an understandable reason to be upset. But, his behavior not only aggravated the situation but made other feels that he, the faculty, was not in control. I told him it would be to his benefit to apologize to the nurses for what he said and how he said it and he could explain to them why he was upset but that it did not justify his behavior. In my experience this can happen with junior faculty in surgery, anesthesia, or any service where they are put in a situation where they are responsible but feel that the staff support is not sufficient, which makes them anxious about the outcome of the intervention.

Situation one and two I call “first time offenders,” with less severe actions which can usually be resolved by a one-on-one discussion and requiring an apology within 24 hours to the individuals involved. The individuals need close monitoring to ensure this is indeed a one-time event and does not recur.

Situation Three: A nurse comes to your office complaining of inappropriate contact, overtly over familiar by an older faculty to a younger nurse. After a one-on-one discussion with the faculty, the senior faculty was shocked that the nurse took this as inappropriate behavior and thought he was being a “friendly” father figure and did not mean anything by it. I explained the nurse did not take this as friendly but was embarrassed and felt very awkward. The faculty was just as embarrassed and awkward and offered to apologize in person if that would help the situation. In this case the nurse did not want to be singled out and wanted this to be anonymous. That was ok with the senior faculty. He said he would stop this behavior toward any individuals. I discussed the response of the senior faculty with the nurse and she was satisfied. This I would classify, hopefully, as a Class Two, the out of touch faculty. This again resolved the situation, but as with the others required monitoring to ensure it did not recur. If it reoccurs, it must be immediately elevated to OCA.

Situation Four: A new department chair comes to the institution and within a few months of reorganizing the clinical and financial structure, several of the senior faculty become very upset and spend much of their time complaining about the new leadership and how it is ruining the department. This small, but vocal, group of senior faculty is causing significant morale problems within the entire department. They become known as the “Negative Thought Leaders.” Younger faculty and other faculty are not sure who to believe and they are not sure if what the chair is doing may or may not be as fair. Once the facts of the situation are investigated it turns out that the senior faculty had a special clinical and financial deal under

the previous administration. The new chair had been trying to right the ship and make the clinical effort and financial reward more fair and balanced. The senior faculty who had had a better deal could not state to the faculty at large that they had lost their special deal so they resorted to undermining the new leadership. This situation required the involvement of the institution’s leadership. It is the institution’s responsibility to back the new department chair and let the older disgruntled faculty know their disruptive behavior would not be tolerated, that the new chair was in charge and they could either move forward with the new program or seek employment elsewhere. As stated, situations such as these require leadership from the institution’s highest level to reinforce the position of the new chair.

There are ways of managing disgruntled faculty (whether young or old) that may prevent escalation. This involves open conversations to those and others in the department about the changes in workload, academic time, also understanding the difficulties in managing heavy clinical responsibilities as faculty become more senior. Those senior faculty who may be anxious about their careers coming to an end need to be managed and mentored just as aggressively as junior faculty who are starting their careers. These discussions should be open, unthreatening, and inclusive. It is good to develop a phased retirement plan as an option to allow them to enjoy the latter part of their career. It is helpful to develop committees, which include them, in helping resolve these situations and prevent a division of faculty between the young and the old, clinical and research, etc.

Situation Five: One of your faculty comes to speak with you about a surgeon who repeatedly states that he cannot proceed with a procedure because the anesthesiologist has given a vasopressor. This surgical faculty is a recognized otolaryngologist who specializes in free-flap repairs for cancers of the head and neck. He conducts long, detailed, free-flap procedures lasting 6-12 hours and in some cases even longer. During the reanastomosis he is very concerned about the vascular perfusion of the free-flap. He feels that any vasopressor given to the patient at any time during the case will adversely affect the free-flap. There is no literature to base this impression, he just feels that way. These patients are very old with significant cardiovascular disease and therefore it is not uncommon after induction to have some episode of hypotension. When these episodes occur the anesthesiology faculty and resident are required to treat it with a vasopressor. The surgical faculty became very upset and threatened to cancel the case because five milligrams of ephedrine was given post-induction. This was at least three to four hours prior to any dissection of the free-flap. This is not the first time; it is one of many times this surgical faculty argues with the anesthetic management of the case. On other occasions, with patients with base tongue tumors and neck radiation, the surgeon argues the patient does not need an awake fiberoptic. At times this discussion occurs in front of the patient and family where this surgeon would state “an awake fiberoptic is totally unnecessary.” This is immediately after the anesthesia faculty has evaluated the airway, looked at the images, and determined it would be safest to proceed with an awake fiberoptic. When the surgeon is approached about these issues he states that “he is doing what is best for the patient and if

there is a bad outcome it will be the fault of the anesthesia care.”

In an attempt to address the vasopressor and flap survival issue, the two departments meet to propose a retrospective review of the previous five years of free-flap cases and vasopressor use. This faculty, who was at the meeting, stands up and states “I know what you are up to and want nothing to do with this,” and then leaves the room. This individual is a classic malignant narcissist.

Ultimately, managing this individual requires full institutional involvement: the surgeon’s chair, chief of medical staff and the institution’s lawyer. This surgeon was required to enter the Pulse program, this will be described below. In the end, the individual showed some signs of improvement after one year in the program, but eventually decided to leave the institution.

This is the most difficult and challenging type of individual – the malignant narcissist. These are usually “frequent flyers” and have a severely destructive effect on your institution. You will need help managing these individuals from the legal and administrative departments. Managing these individuals involves engaging the bureaucracy from the very start. Malignant narcissists have classic symptoms:

- 1) Grandiose sense of self-importance
- 2) Preoccupation with success, power and brilliance
- 3) Belief in personal specialness
- 4) Need for excessive recognition
- 5) Strong sense of entitlement
- 6) Exploitation of others
- 7) Lack of genuine empathy
- 8) Arrogant, haughty in their behaviors and attitudes.

Discussing issues with them does not work in the usual way, that is, the one-on-one meeting with them in your office will not work. Do not meet with them alone. You will need legal help and an excessive paper trail, with written expectations. They have major insight deficient. You will usually hear “I’m only trying to do what’s best for my patients,” or, “that person has it out for me.” “I can’t believe anyone would take offense at that.” You must remember that a true narcissist has a deep sense of entitlement and little insight to how the rest of the world perceives him or her; so you have little chance to satisfy his or her demands. These individuals are prevalent in academic centers and in many large institutions. They are commonly in the surgical disciplines, but not necessarily. At the University of Michigan we use an organization called The Pulse Program, which provides professional help in dealing with these individuals with counseling and 360 degree evaluations.⁸ This pulse program will try to provide them insight from those around them, but will only work if the institution backs them in the requirement to undergo this treatment. Individuals such as these are the ones that caused the Joint Commission to require institutions to have policies in dealing with disruptive behavior because these individuals are the most disruptive to the institution.

Finally, there are practical tips to help you manage all these situations.

1. Keep everything you discuss with them in confidence.
2. Your offenders will likely not do the same.

3. Your actions will seem unjustified to them; they may be threatened, they may threaten innocent bystanders, they may unify reactionary forces.
4. Be prepared with your trusted advisors.

Final Checklist:

Before you proceed with managing any of the above situations:

- a. What are the facts?
- b. Is this a pattern or a change?
- c. What is happening in his or her life?
- d. What are the system contributors?
- e. What is the potential impact or urgency?
- f. What resources do I need to intervene?

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Ten (10) Things You Always Wanted to Know About Obstetric Anesthesia

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ABSTRACT

This review course lecture will review 10 aspects of obstetric anesthesia care. These include 1) sterile technique (skin preparation and practitioner garb), 2) testing neuroblockade sensory level (to ensure appropriate surgical anesthesia), 3) concentration/volume of epidural solution (influence on the extent and quality of neuroblockade), 4) density of labor analgesia neuraxial block (influence on the progress of labor), 5) programmed intermittent bolus (PIEB) (advantages in maintaining epidural labor analgesia, 6) neuraxial analgesia-associated fetal bradycardia (etiology and treatment, 7) vasopressors and spinal hypotension (ephedrine vs. phenylephrine), 8) spinal anesthesia after failed epidural (risk of high or total spinal anesthesia), 9) external cephalic version (evidence for improved outcomes with neuraxial analgesia/anesthesia), 10) transversus abdominis plane (TAP) block (indications and complications). Evidence to support suggested care will be presented.

1. Sterile technique

An analysis of injuries to the neuraxis in obstetric regional anesthesia claims in the American Society of Anesthesiologists (ASA) Closed Claims Database from 1980 to 1999 determined that 46% of the claims were for infection (half abscess, half meningitis).¹ In contrast, infections made up only 6% of nonobstetric neuraxial claims. Reynolds² estimated that the risk of neuraxial infection in obstetric patients who receive neuraxial procedures is 1:302,757. The most common bacterium found in spinal-epidural abscesses following neuraxial anesthesia is *Staphylococcus aureus*, a skin contaminant. Rigorous studies of skin preparation before neuraxial procedures have not been conducted, but there is good quality evidence from vascular lines and surgical wounds that alcohol-based chlorhexidine antiseptic solutions significantly reduce the risk of infection compared with other solutions. Both the American Society of Regional Anesthesia and Pain Medicine (ASRA) and the ASA recommend use of this alcohol-based chlorhexidine solution for skin preparation before neuraxial procedures.^{3,4}

Unlike community-acquired meningitis, the primary cause of bacterial meningitis after neuraxial procedures is streptococcus viridans species. Meningitis following childbirth is always associated with neuraxial techniques, i.e., it is always iatrogenic. In the anesthesiology, radiology, and neurology literature, it is frequently reported in clusters, suggesting the provider factors (poor technique), not patient characteristics, are risk factors for this potentially catastrophic outcome. For example, in 2010, the Centers for Disease Control (CDC) reported five cases of meningitis following neuraxial labor analgesic procedures (spinal and combined spinal-epidural [CSE]) from two anesthesiologists.⁵ The causal bacteria in 4

of 5 patients were matched to *Streptococcus salivarius* from the nasopharynx of the two anesthesia providers. One patient died. These cases illustrate the importance of adhering the CDC and ASA guidelines that including wearing a mask for all neuraxial procedures, removing jewelry and washing hands.⁴

2. Testing neuroblockade sensory level

It is traditionally taught that a T6 to T4 sensory level is required to provide adequate anesthesia for cesarean delivery; however, practitioners use of variety of stimuli to test for sensory level, including cold, sharp, and touch. Differential sensory blockade exists to these modalities following initiation of spinal anesthesia. The sensory level to touch is consistently lower than the sensory level to cold, often by several dermatomes.⁶ In a study of 102 women undergoing cesarean delivery with spinal anesthesia with hyperbaric bupivacaine and diamorphine, a T6 sensory level to touch with 100% sensitive for identifying women with satisfactory anesthesia (requiring no intraoperative supplementation). Another study found the determined sensory level is dependent on the question the anesthesiologist asks the patient.⁷ For example, asking the patient when the sharp stimulus is the same as a control sharp stimulus will identify a different sensory level than asking the patient when she first perceives a sharp stimulus. In this study, block assessments using the “first perception of sharp” were equivalent to “touch same as control.”

3. Concentration/volume of epidural solution

Epidural catheters for labor analgesia are typically sited in a midlumbar spinal interspace. Sensory blockade from T10 to S4 is required for childbirth. A number of studies have shown that analgesia is superior using high volume/low concentration solutions compared with low volume/high concentration solutions. For example, in a study of patient-controlled epidural analgesia (PCEA) using 3 solutions: 0.25% plain bupivacaine, 0.125% bupivacaine with fentanyl and 0.0625% bupivacaine with fentanyl, analgesia was superior and the total bupivacaine dose was significantly lower with the two lower bupivacaine concentration solutions.⁸ In another study, the ED50 for epidural bupivacaine was significantly lower for 0.125% bupivacaine than 0.25% bupivacaine. Simply stated, there is more bang (analgesia) for the buck (bupivacaine dose) with low concentration/high concentration solutions.

4. Density of labor analgesia neuraxial block

A number of studies suggest that density of neuraxial blockade may affect the outcome of labor. Neuraxial techniques using high concentration local anesthetic solutions are associated with a higher rate of instrumental

vaginal delivery than techniques using low concentration solutions.⁹ In the PCEA study cited above,⁸ the instrumental vaginal delivery rate was higher in the 0.25% bupivacaine group than the 0.125% and 0.0625% groups (the bupivacaine dose was also greater). In a 2013 systematic review comparing high to low concentration solutions ($\leq 0.1\%$ bupivacaine or 0.17% ropivacaine), low-dose solutions were associated with a lower risk for instrumental vaginal delivery (odds ratio (OR) 0.70, 95% CI 0.56 to 0.86).

5. Programmed intermittent bolus (PIEB)

The required dose of local anesthetic, and thus the density of neuroblockade, may also depend on the mode of delivery of the epidural solution. Bolus delivery compared with a continuous infusion results in a lower total dose. Up until recently, bolus doses were administered by either the anesthesiologist or patient (PCEA). Recent studies have compared programmed intermittent epidural boluses (PIEB) (the epidural pump is programmed to administer regular bolus doses) to continuous infusion for the maintenance of analgesia. For example, in a study by our group at Northwestern, the total bupivacaine dose and breakthrough pain were lower, and patient satisfaction was greater in patients randomized to receive PIEB compared with a traditional PCEA technique with a basal infusion.¹⁰ In a 2013 systematic review and meta-analysis comparing the two techniques, the OR for anesthesia provider intervention was 0.56 (95% CI 0.29 to 1.06) and the OR for instrumental vaginal delivery was 0.59 (95% CI 0.35 to 1.00).¹¹

6. Neuraxial analgesia-associated fetal bradycardia

Fetal bradycardia has been observed after the initiation of neuraxial labor analgesia. A 1994 sentinel report suggested that bradycardia was associated with uterine tachysystole.¹² The authors hypothesized that the tachysystole resulted from an altered balance between tocodynamic and tocolytic forces resulting from initiation of labor analgesia. Initiation of analgesia causes a marked decrease in circulating maternal epinephrine levels¹³ and epinephrine, via its β_2 -adrenergic effects, is tocolytic. The decrease in tocolytic effect after initiation of analgesia results in uterine tachysystole and fetal bradycardia. Observational studies are inconsistent regarding whether CSE analgesia is an increased risk for fetal bradycardia compared with epidural analgesia. A 2009 randomized controlled trial found an increased rate of nonreassuring fetal heart rate (FHR) tracings and increase in intrauterine pressure in CSE compared with epidural analgesia;¹⁴ however, the study conclusions are limited because FHR tracings were only assessed for 15 min after the initiation of analgesia and peak analgesia occurs later with epidural than CSE analgesia.¹⁵ In contrast to this finding, a 2014 secondary analysis of a randomized trial comparing CSE to epidural analgesia found no difference in nonreassuring FHR tracings between groups, but in both groups there was an increase in nonreassuring tracings in the 60 min interval after initiation of analgesia compared to 30 min before.¹⁶ Standard in utero resuscitation measures should be undertaken if fetal bradycardia is observed (check maternal blood pressure, change maternal position, intravenous fluid bolus, discontinue exogenous oxytocin infusion, and consider tocolytic administration if uterine tachysystole is present).

7. Vasopressors and spinal hypotension

Traditionally, ephedrine was considered the drug of choice to prevent and treat spinal anesthesia-induced hypotension in women undergoing cesarean delivery because animal studies demonstrated a decrease in uteroplacental blood flow with α -adrenergic agonists. However, clinical trials have demonstrated higher umbilical artery pH values in mothers who receive phenylephrine compared with ephedrine.¹⁷ The use of phenylephrine makes more sense from a physiologic standpoint. Noninvasive assessment of hemodynamic parameters after the induction of spinal anesthesia show that cardiac output increases and systemic vascular resistance (SVR) decreases. Thus, a vasoconstrictor reverses the fall in SVR and returns cardiac output toward baseline.¹⁸ Although the traditional teaching has been to treat hypotension when it falls to less than 80% of baseline, maintaining blood pressure at baseline compared to 80% of baseline results in higher umbilical artery pH values and less maternal nausea.¹⁹ In a randomized trial of phenylephrine infusions at 0, 25, 50, 75 and 100 $\mu\text{g}/\text{min}$, the median absolute performance error (MDAPE) was lowest for phenylephrine 50 $\mu\text{g}/\text{min}$ and the 25 and 50 $\mu\text{g}/\text{min}$ infusion rates were associated with fewer anesthesiologist interventions for treatment of hemodynamic abnormalities.²⁰

8. Spinal anesthesia after failed epidural

Options for anesthesia after failed epidural anesthesia for cesarean delivery include general anesthesia, repeat epidural anesthesia, spinal anesthesia and CSE anesthesia. Each technique has its advantages and disadvantages. There have been multiple reports of high or total spinal anesthesia following failed epidural anesthesia.²¹ Possible mechanisms included compression of the dural sac by fluid in the epidural space,²² leakage of local anesthetic solution in the epidural space through the newly made dural puncture, presence of subclinical anesthesia before the initiation of spinal anesthesia, and anatomic aberration, explaining both the failed epidural anesthetic and high spinal anesthesia.

9. External cephalic version

External cephalic version (ECV) of fetuses in the breech position has been shown to decrease the need for cesarean delivery. Studies comparing neuraxial to no or intravenous analgesia have assessed whether the success rate of ECV is improved with analgesia. Several systematic reviews and meta-analysis suggest that neuraxial analgesia/anesthesia is associated with a higher ECV success rate (RR 1.44; 95% CI 1.16 to 1.7923). Sensitivity analysis indicates that studies that used anesthetic doses of neuraxial local anesthetics had a higher risk ratio than studies that used analgesia doses. Further study is warranted to directly compare anesthetic and analgesia doses. Cost analysis modeling indicates that neuraxial analgesia for the ECV is cost effective provided it is associated with an increased rate of successful ECV.²⁴

10. Transversus abdominis plane (TAP) block

Transversus abdominis plane (TAP) block provides analgesia to the anterior abdominal wall after cesarean delivery. Studies comparing TAP block to spinal morphine analgesia have found that spinal morphine provides superior

and longer-lasting analgesia.^{25,26} Therefore, TAP blocks are indicated for women who cannot/do not receive spinal morphine or have breakthrough pain after spinal morphine. Rigorous dose-response studies for TAP blocks have not been performed, but study suggests that serum levels of local anesthetics after performance of bilateral TAP blocks approach levels of concern for local anesthetic systemic toxicity (LAST), even when low concentration solutions (e.g., 0.25% ropivacaine) are used.²⁷ Indeed, there have been several reports of LAST in obstetric patients who received a TAP block postcesarean delivery.^{28,29} Patients should be observed for symptoms of LAST for 45 min after TAP block.

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