

Perioperative Management of the New Anticoagulants: Novel Drugs and Concepts

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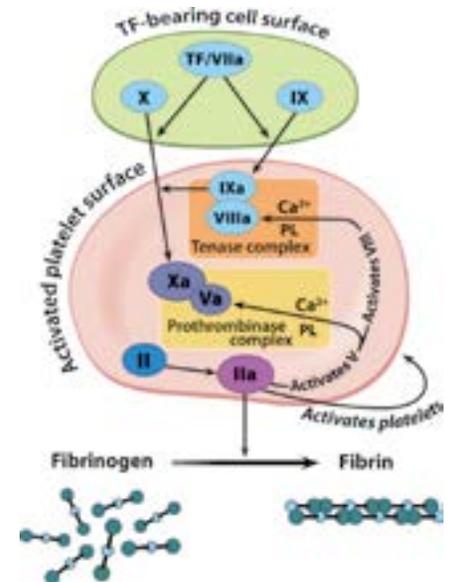
Introduction

The increasing use of the direct oral anticoagulants (DOACs) has provided clinicians and patients with alternatives to warfarin for the treatment of venous thromboembolism (VTE), the prevention of cerebrovascular embolic stroke in patients with atrial fibrillation, and thromboprophylaxis in patients undergoing surgery. Four DOACs are currently approved in most countries and have added a novel paradigm for anticoagulation management. However, providers should be aware of perioperative management strategies regarding patients on these agents for both elective and emergency surgery. Currently, a specific reversal agent, idarucizumab, is available for dabigatran, and clinical trials are currently underway for reversing apixaban, rivaroxaban, and edoxaban. In this review, a group of international experts will review perioperative management strategies that include when to stop these drugs for elective surgery or invasive procedures, how to assess and monitor their anticoagulant effects, current protocols for temporary discontinuations of DOAC therapy, and the utility of specific DOAC reversal agents.

Direct Oral Anticoagulants Currently Available

The currently available non-vitamin K DOACs include the direct thrombin inhibitor dabigatran etexilate (Pradaxa[®], Boehringer-Ingelheim Pharma), and direct factor Xa inhibitors, rivaroxaban (Xarelto[®], Johnson and Johnson/Bayer HealthCare), apixaban (Eliquis[®], Bristol Myers Squibb/Pfizer), and edoxaban (Savaysa[®], Daiichi Sankyo). The advantages of the DOACs include a rapid onset of action, with a peak effect two to four hours following oral administration, predictable anticoagulant/pharmacodynamic effects, minimal drug interactions, and no present requirement for routine laboratory monitoring. The particular use of each individual agent depends upon multiple factors including current approval, labelling of the drugs, availability, and country-specific approved dose regimens. Of note, there are multiple reviews related to these agents, and a growing body of literature.¹⁻³

One of the important consistent findings from multiple publications is that, compared with warfarin, DOACs have a lower risk for intracranial bleeding and as low or a lower risk for other types



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Figure 1. The coagulation cascade. TF = tissue factor; PL = phospholipids.

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Robert C. Morell, MD, Immediate Past APSF Newsletter Editor-in-Chief, Reflects on Past Accomplishments

by APSF Newsletter Co-Editors Lorri A. Lee, MD, and Steven B. Greenberg, MD

In October of 2016, Dr. Robert C. Morell bid the APSF farewell as he stepped down as the second editor-in-chief of the *APSF Newsletter* after 23 years of dedicated service to patient safety and the APSF. Dr. Morell joined the editorial staff of the *APSF Newsletter* in 1994. Dr. John Eichhorn, the founding editor of the *APSF Newsletter*, quickly realized Dr. Morell's talents and

dedication and appointed him associate editor from 1997 to 2000.

Dr. Morell became editor-in-chief in 2001. His numerous accomplishments were driven by his incredible enthusiasm for patient safety, his creativity, and a strong desire to keep the anesthesia community informed regarding emerging clinical issues that could impact patient safety.

Dr. Morell obtained his undergraduate degree from the University of Virginia and his MD from the Medical College of Virginia. He then attended Bowman Gray School of Medicine (currently known as Wake Forest School of Medicine) for his residency in anesthesiology, serving as chief resident in 1986, followed by a regional fellowship at

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NEWSLETTER

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guide for authors

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International Experts Weigh in on Perioperative DOAC Management

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of bleeding.⁴ Warfarin, a vitamin K antagonist, produces an anticoagulant effect by reducing circulating levels of coagulation factors II, VII, IX, and X.⁵ Although giving vitamin K is a logical reversing agent, its effect is not immediate and time is required to reverse the INR, and it takes 24 to 72 hours to restore adequate levels of functional coagulation factors. On the other hand, the DOACs are reversible direct pharmacologic inhibitors of either thrombin or factor Xa, two critical targets of the hemostatic cascade that have a pharmacologic effect similar to other commonly used parenteral anticoagulants such as low-molecular-weight heparin (LMWH), heparin, or other direct thrombin inhibitors (i.e., bivalirudin, argatroban).³

Although, in general, DOACs have a lower risk of bleeding,⁶⁻⁸ managing anticoagulation in the perioperative period is problematic because all anticoagulants can cause bleeding.⁹ Despite their apparent safety compared with warfarin, perioperative management strategies for patients receiving DOACs require specific considerations. In a recent international survey, we observed that physicians had limited knowledge about the peri-

operative management of patients treated with DOACs.¹⁰ The evaluation of DOAC-treated patients for procedural interventions should include documenting the timing of the last DOAC dose, renal function that influences elimination time, and the procedure-associated bleeding risk that affects interruption timing. DOACs require specific coagulation assays to measure anticoagulation levels accurately (i.e., dilute thrombin time for dabigatran, anti-Xa levels for oral Xa inhibitors), although standard coagulation screening tests (i.e., prothrombin time [PT] for rivaroxaban, activated partial thromboplastin time [aPTT] for dabigatran) may provide a qualitative assessment if there is a residual DOAC anticoagulant effect.

Specialty societies have endorsed general recommendations for patient management to promote hemostasis in anticoagulated patients requiring surgery or other invasive procedures. These include general stopping rules (such as ≥ 24 hours for low bleed-risk procedures and ≥ 48 hours for high bleed-risk surgery in patients with normal renal function) for elective procedures. Switching to LMWH, in general, is not required during peri-procedural DOAC interruption because of the rapid offset and onset of DOACs.²

Preoperative Management of Patients Receiving DOACs

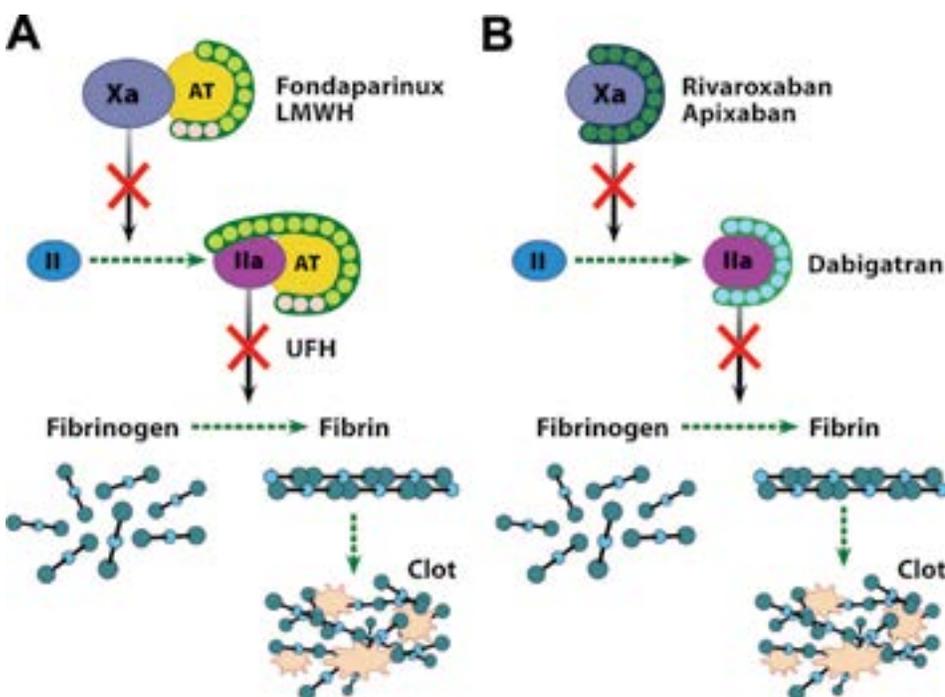
Specific considerations for the preoperative management of DOAC-treated patients include pharmacokinetics of the particular drug, renal function, and specific considerations regarding whether the surgery requires emergency intervention or is elective, and the particular risk of thrombosis and bleeding of the individual surgical procedure. Based on the availability of idarucizumab as a specific antidote for dabigatran, patients can be readily managed if they require emergent or urgent surgical or procedural interventions. Although other reversal strategies for oral Xa inhibitors are under investigation, none of them today have been studied in patients requiring emergent procedural interventions. Other potential off-label therapies have been evaluated and will be considered subsequently.

Dabigatran etexilate is the only oral direct thrombin inhibitor. Dabigatran is a prodrug that is encapsulated to allow for absorption in the gut and its major mechanism of metabolism is via renal elimination (~80%). Apixaban, rivaroxaban, and edoxaban are direct factor Xa inhibitors, and are primarily hepatically metabolized (~65–70%). Clinicians should consider the half-life of the DOACs approximately 12 hours in most patients unless they have reduced renal function. Dabigatran elimination is the most dependent on renal function, and preoperative interruption should be based on creatinine clearance (CrCl) calculated according to the Cockcroft-Gault formula.^{11,12} Renal function is less an issue with rivaroxaban, apixaban, and edoxaban unless there is severe renal insufficiency.¹³

Multiple recommendations for perioperative management of DOAC-treated patients exist but such recommendations should be considered as potential therapeutic guidance statements given that prospective standardized management protocols are still in development, and are also based on specific drug recommendations as well.^{2,14,15} These recommendations are based on an international group of physicians, many of whom are authors of the present article. Readers should examine the American Society for Regional Anesthesia (ASRA) guidelines for discontinuation of anticoagulants prior to regional anesthesia. (<https://www.asra.com/advisory-guidelines/article/1/anticoagulation-3rd-edition>).

In general, management is based on procedure-related bleeding risk. Selected minimal bleeding risk procedures are likely to be safely undertaken without DOAC interruption (e.g., minor dental procedures, cataract surgery, pacemaker implantation, skin biopsies) although prospective validation studies are needed. Other

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Figure 2. The primary mechanism of action of the established anticoagulants (unfractionated heparin [UFH], low-molecular-weight heparin [LMWH], and fondaparinux) via antithrombin-dependent binding (A) and the new anticoagulants (rivaroxaban, apixaban, and dabigatran etexilate) via antithrombin-independent binding (B). UFH also inactivates factors Xa, IXa, XIa, and XII via antithrombin, but to a lesser extent than inactivation of thrombin. LMWH also inactivates thrombin via antithrombin, but to a lesser extent than inactivation of factor Xa. AT = antithrombin.

Normal Coagulation Studies Don't Exclude Residual DOAC Effects

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procedures can be classified as low bleeding risk (e.g., laparoscopic cholecystectomy or hernia repair), or high bleeding risk (e.g. cardiovascular, intracranial or spine surgery, major cancer surgery, any surgery with spinal or epidural anesthesia).

The European Society of Anaesthesiology and the French Working Group on Perioperative Haemostasis (GIHP) recommend interruption of DOAC therapy ~24 hours (two or three half-lives) before an elective low bleeding risk procedure (non-regional anesthesia related), and 5 days before a medium or high bleeding risk procedure. These recommendations also account for patient's renal function.^{16,17} The European Heart Rhythm Association's guide to DOAC use for elective surgery suggests a general stopping rule of ≥ 24 hours for low-risk procedures and ≥ 48 hours for high-risk surgery. However, longer interruption intervals are suggested for patients with CrCl < 80 mL/min on dabigatran and those with CrCl 15 to 30 mL/min on oral Xa inhibitors.^{2,18} Other expert consensus documents recommend a 24- to 48-hour interruption interval based on the specific DOAC, renal function, and procedural bleeding risk.^{19,20} However, as a reminder, caution should be considered for preoperative bridging of any oral anticoagulant with LMWH as noted in recent recommendations and clinical trials.^{20,21}

Additional studies to assess standardized perioperative management protocols in DOAC-treated patients are ongoing.^{19,22} The management of patients who are receiving DOACs and require emergency surgery or other procedural intervention due to trauma or other emergencies continues to evolve as we develop additional management strategies that will be subsequently discussed.

Measurement of Anticoagulation with the DOACs

One of the major advantages of the DOACs is that routine anticoagulation monitoring is not presently required due to predictable pharmacokinetic and pharmacodynamic properties. However, following acute traumatic injury or in patients who require emergency surgical or otherwise procedural intervention, anticoagulation monitoring may be helpful.^{23,24} Other information important to obtain for the clinician to guide potential interpretation and management of the results includes the history of when the last dose of anticoagulant was taken, the patient's renal function, and other potential concomitant medications including potential antiplatelet therapies.²³

In dabigatran-treated patients, standard coagulation testing can be used to determine potential effects. The aPTT assay is an effective screening assay to determine a potential anticoagulation effect due to dabigatran, and a prolonged aPTT is

consistent with an anticoagulant effect as reported. (http://www.nejm.org/doi/suppl/10.1056/NEJMoa1502000/suppl_file/nejmoa1502000_appendix.pdf). However, a normal aPTT does not exclude residual anticoagulant effect. A normal thrombin time or diluted thrombin time will exclude an anticoagulant effect of dabigatran. In addition, the dilute thrombin time provides a more reliable and precise measurement of the anticoagulant effect of dabigatran, an assay not currently cleared by FDA but available in specialized centers.^{25,26} In Europe, the calibrated Hemoclot[®] thrombin inhibitor assay (Hyphen BioMed, Neuville-sur-Oise, France) is recommended as the method of assessing anticoagulation in dabigatran-treated patients.²⁷ In Europe, the ecarin clotting time (ECT) assay is also commonly used in specialized centers to evaluate anticoagulation in dabigatran-treated patients.²⁸

Monitoring and/or assessing the effects of the anti-Xa “xaban” agents is more complicated despite their growing use as the mainstays of DOAC therapy. Although the INR is used routinely to monitor anticoagulation with vitamin K antagonists, it is not a dependable or specific assay for assessing the anticoagulant effects of the DOACs.²⁵ Following traumatic injury or major surgery, patients routinely have a prolonged PT due to multiple causes and, therefore, it is an insensitive assay of the anticoagulant effects of Xa inhibitors, especially apixaban.²⁹⁻³¹ If levels are required, then specific drug-calibrated

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Save the Date
Wednesday, September 6, 2017



Stoelting Conference
Royal Palms Resort and Spa, Phoenix, AZ

Perioperative Handoffs: Achieving Consensus on How to Get it Right

Handoffs in health care are potential patient safety risks, but are also opportunities to identify missed problems. Perioperative handoffs, including those occurring intraoperatively, from the OR to PACU or OR to ICU, have both common and unique issues. In this one-day consensus-building workshop, APSF aims to identify critical elements of handoff processes, including how to conduct handoffs safely and how to implement new handoff processes that work locally.

Jeffrey B. Cooper, PhD, and Meghan B. Lane-Fall, MD, MSHP, will be the co-moderators of this workshop, which will include expert presentations and panel discussions. The primary focus of this meeting will be achieving consensus about key issues through closely facilitated working groups. If you have expertise or an interest in helping to improve handoffs, consider participating.

If you are interested in attending, please contact Janet Henderson, APSF administrator, at henderson.janet@mayo.edu. Space is limited.



Jeffrey B. Cooper, PhD



Meghan B. Lane-Fall, MD, MSHP

Reversal Agents for DOAC Anticoagulation are Emerging

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factor Xa assays, similar to those used to determine low molecular weight heparin concentrations are available in some institutions. These potential quantitative measurements of the “xabans” are calibrated in anti-Xa units and have been reported for rivaroxaban and apixaban,^{32,33} and edoxaban.³⁴ These assays are not widely available, require specific calibration to each individual agent, and are rarely available on an urgent basis outside of specialized centers.^{25,31} The different coagulation assays currently available for each DOAC are listed in Table 1.

Interruption of Oral Anticoagulation and Bridging/Switching Between Anticoagulants

Previously reported guidelines for periprocedural and/or preoperative management of patients on warfarin anticoagulation included discontinuing warfarin and proceeding with the use of LMWH or unfractionated heparin to bridge patients with atrial fibrillation who were at increased risk for thromboembolic events.^{35,36} More recent data on anticoagulant bridging to allow for procedural interventions and invasive procedures to proceed has been called into question.^{37,38} Guidelines from the American Academy of Neurology report that bridging therapy with heparin is associated with increased risk of bleeding compared to warfarin discontinuation.³⁹ In a large, randomized study of atrial fibrillation patients reported by Douketis *et al.* in 2015 from the BRIDGE investigators, stopping warfarin without LMWH bridging was non-inferior to bridging therapy for arterial thromboembolism when warfarin treatment was interrupted for an elective operation or other elective invasive procedure and was associated with a significant decrease in post-procedural major and minor bleeding.²¹

For patients anticoagulated with DOACs, the limited data currently available suggest that perioperative bridging with LMWH during DOAC interruption provides no therapeutic benefit and can lead to increased major bleeding. In a recent sub-analysis of data from the RE-LY trial, where

dabigatran-treated patients who had treatment interruption for an elective procedure, experienced more major bleeding events with bridging therapy than patients who did not receive bridging therapy, with no significant effect on arterial thromboembolism.⁴⁰ As a result, bridging therapy is not indicated when anticoagulation needs to be interrupted for short intervals of approximately 24 to 48 hours in advance of an invasive or surgical procedure.²⁸ Similar guidance and recommendations are also suggested for apixaban.^{41,42} Treatment with apixaban, rivaroxaban, and edoxaban should be stopped at least 24 hours before an invasive or surgical procedure of low risk, but may require longer discontinuation intervals for procedures with a moderate to high risk of bleeding. There is ongoing interest regarding whether certain procedures, particularly pacemaker or defibrillator implantation, can be done without DOAC interruption. Randomized controlled trials currently underway, such as BRUISE CONTROL-2, are expected to inform best practices for such patients.⁴³

Reversal of DOAC-induced Anticoagulation With Specific Agents

When anticoagulated patients present for emergency surgery or following traumatic injury, bleeding is an expected and feared risk in DOAC- or warfarin-treated patients among those perioperative providers caring for them. Therefore, specific reversal agents are under development for all DOACs.

For patients on dabigatran, idarucizumab, a specific reversal agent, is currently approved in many countries for dabigatran reversal in cases of serious bleeding or emergency surgery/procedures. Idarucizumab is a humanized monoclonal antibody that selectively binds dabigatran and reverses dabigatran-induced anticoagulation. In the REVERSE-AD study, idarucizumab reversed the anticoagulant effects of dabigatran in patients with a major bleeding event, or in need of an urgent invasive procedure (within the next 8 hours).^{44,45} Following intravenous administration, idarucizumab reversal is immediate and lasts for at

least 24 hours. Idarucizumab was approved in 2015 by the United States Food and Drug Administration for the reversal of dabigatran-related anticoagulation in cases where emergency surgery and/or urgent procedures are required, or in cases of life-threatening or uncontrolled bleeding.⁴⁶ An American Heart Association report suggested that a 5 g dose of idarucizumab resulted in immediate and complete reversal of dabigatran anticoagulation in 82–99% of critically ill elderly patients taking dabigatran who presented with life-threatening emergencies, and intraoperative hemostasis was judged by surgeons as “normal” in 93% of the surgical/procedural patients. This study included approximately 200 complex, critically ill patients undergoing a multitude of orthopedic, surgical, and other procedures in a high-risk patient population.⁴⁷

Andexanet-alfa is in phase III clinical trials as a specific reversal agent for emergency reversal of apixaban, edoxaban, rivaroxaban, fondaparinux, and the low molecular weight heparins such as enoxaparin.^{48,49} It is important to realize that andexanet-alfa has not been studied for reversal of anticoagulation in surgical patients to date. Andexanet-alfa is a bioengineered human factor Xa decoy protein. By binding to circulating factor Xa inhibitors, andexanet-alfa makes endogenous factor Xa available to contribute to the coagulation cascade.^{49,50} Ciraparantag is another drug in early evaluation as a reversal agent for factor Xa inhibitors and low molecular weight heparin, but is not currently available.^{51,52}

Currently, when DOAC-treated patients present for emergency surgery or procedural interventions receiving one of the anti-Xa agents, management strategies are needed. Growing data from case reports, *in vitro* studies, and volunteers suggest some efficacy for the ability of prothrombin complex concentrates (PCCs) to reverse DOACs.⁵¹⁻⁵³ At least one registry trial is underway to assess outcomes in bleeding patients or those requiring urgent care treated with DOACs and reversed with PCCs, and other potential agents. As previously discussed, in emergency situations where patients are bleeding and have taken anti-Xa agents, the

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Table 1. Assays for Monitoring Direct Oral Anticoagulant Activity^{1,2}

Drug	Quantitative Assays (Provides an Estimate of Anticoagulant Drug Levels)	Qualitative Assays (to Indicate Presence or Absence of Drug Effect)	Not Recommended
Direct Factor Xa inhibitors (apixaban/rivaroxaban/edoxaban)	Specific, calibrated anti-Factor Xa assays	None currently available	Prothrombin time (except rivaroxaban where there may be a dose-related prolongation), activated partial thromboplastin time, dilute thrombin time or thrombin time assays, or heparin-specific assays such as the activated clotting time assay
Direct thrombin inhibitor (dabigatran)	Dilute thrombin time assay (available in some specialized centers in US, ecarin clotting time (not available in US))	Activated partial thromboplastin time, thrombin time	Chromogenic anti-Factor Xa assays, heparin-specific assays such as the activated clotting time assay

Prothrombin Complex Concentrates for DOAC Reversal: Data is Limited!

“Anticoagulants,” From Preceding Page ability to rapidly measure therapeutic effects or drug levels with the Xa inhibitors is limited.

One particular noteworthy study evaluated a 5 mm punch biopsy in healthy subjects receiving a single dose of 60 mg edoxaban. The authors noted that four factor-prothrombinase complex concentrate (4F-PCC) produced a dose-dependent reversal of edoxaban's effect on bleeding duration, bleeding volume, and thrombin generation and normalized values to baseline levels before anticoagulation using a 50 IU/kg dose of 4F-PCCs.⁵³ However, PT was only partially reversed and this is a consistent finding in all of the PCC reversals of anti-Xa agents.⁵³ In the volunteers who underwent reversal of anticoagulation, there were no safety issues and no thromboembolic events. Notably, this is the only study to evaluate a specific bleeding parameter associated with DOAC reversal using a four factor PCC.⁵³

Summary:

The DOACs have provided important additional therapeutic approaches for anticoagulation in patients. The benefits as previously discussed include predictable pharmacokinetics, no present requirement for routine monitoring, and overall the potential for fewer risks of bleeding and improved outcomes as noted in the multiple studies that led to approval by the Food and Drug Administration. As with any anticoagulants, the drug should be stopped for high-risk surgical procedures in patients at increased risk for bleeding, and for all the agents, renal function should be considered. Monitoring can be used in elective surgical interventions, but for emergencies, the availability and need for emergent or urgent surgery is an important consideration. For dabigatran, idarucizumab is a specific reversal agent that has been studied in a multiplicity of surgical patients. For the “xbans,” currently there is no approved agent available for specific reversal, and andexanet has not been studied as of yet in surgical patients. Therefore, clinicians need an alternative therapeutic approach, and off-label use of prothrombin complex concentrates has been reported, but all procoagulants pose thrombotic risks as well. Nonetheless, clinicians need therapeutic approaches when dealing with emergencies and bleeding in surgical patients. In managing patients who are bleeding, standard approaches should always be considered, including hemostatic and hemodynamic support, and with life-threatening hemorrhage, the use of massive transfusion protocols.

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Dr. Morell Establishes High Impact Safety Columns—*Dear SIRS* and Q&A

“Morell,” From Cover Page

Virginia Mason Medical Center. He has over 30 years of practice experience in both academic and private practice institutions, rising to the rank of Associate Professor at Wake Forest University. Dr. Morell is currently in private practice in Niceville, FL. His experiences in both settings allowed him to bridge the gap that sometimes exists between these groups. His strong voice for

private practice experience at the APSF Executive Committee meetings enabled the group to make recommendations that could work in both academic and private practice settings. Dr. Morell ensured that the *APSF Newsletter* maintained high-quality content and disseminated the latest breaking research and development impacting patient safety. Perhaps one of his most important and enduring contributions was the creation of

the *Dear SIRS* column, along with Dr. Michael Olympio, which brought anesthesia professionals and manufacturers together to solve problems concerning medications and devices in a collaborative spirit. During his tenure as editor-in-chief from 2001 to 2016, the *APSF Newsletter* distribution list has grown from approximately 34,000 to more than 122,000 anesthesia professionals and affiliated industries.

Robert C. Morell, MD, Reflects on His Time With the APSF and as Editor of the APSF Newsletter

My first involvement with the APSF occurred in 1993 when the FDA added a black box warning to the package insert for succinylcholine, warning of the potential for hyperkalemia due to unrecognized myopathic conditions in children and adolescents. There was significant push back due to concerns that this would force anesthesia professionals, particularly those who only occasionally administered pediatric anesthetics, toward unfamiliar induction techniques that might result in greater risk. Being one of those “occasional pediatric anesthesiologists,” I was also concerned that this black box warning was misdirected, as it was unlikely that adolescents would have undiagnosed muscular dystrophies compared to younger children. After reading the *APSF Newsletter*, I felt that an article should be written on the topic and that the APSF should send a representative to the pending FDA/Anesthetic Drug and Life Support Advisory Committee meeting. I phoned Rick Siker, then APSF executive director, to share my concerns and request APSF involvement. That was my first interaction with this pioneer of patient safety. Dr. Siker quickly agreed with me and suggested that I attend the meeting and write the article, giving me contact information for Dr. John Eichhorn, who was the founding and current editor of the *Newsletter*. Dr. Eichhorn served as a mentor to me for that first safety reporting assignment, which resulted in a pro/con column published in the *APSF Newsletter* in 1994 (<http://www.apsf.org/newsletters/html/1994/spring/#art2>). Dr. Eichhorn encouraged my involvement in the *Newsletter* and provided me the opportunity to continue to contribute. We formed a warm and solid relationship. John continued as my mentor for several years, gradually giving me more responsibility, allowing me to attend the editorial board and executive committee meetings and introducing me to Dr. Ellison C. (Jeep) Pierce. It was a tremendous honor to be allowed to work alongside such dedicated and brilliant pioneers in patient safety. Drs. Pierce, Siker, and Gravenstein were also incredibly gracious to a newcomer and were always willing to listen to my ideas, some of which were good and some not so much. As my experience grew, I moved from editorial board member to associate editor and eventually editor-in-chief of the *APSF Newsletter*.

The opportunities for creativity were simply wonderful. I was supported in taking the *Newsletter* from green and black and white to full color. Photographic opportunities abounded. In 1997, John Eichhorn and I edited and published the first textbook



Robert C. Morell, MD

on patient safety entitled, *Patient Safety in Anesthetic Practice*. It was such an honor to have Dr. Jeep Pierce author the forward, and Dr. Leroy Vandam contribute the first chapter on the historical aspects of patient safety. It was very gratifying that esteemed experts and authors such as Drs. Steve Hall, Jonathan Benumof, John Butterworth, J.S. Gravenstein, Steve Howard, Jan Ehrenwerth and Richard Prielipp were so excited and willing to contribute to the book.

While taking a long walk along the piers in San Francisco at an ASA meeting, Dr. Michael Olympio, then chair of the APSF Committee on Technology, and I had the joint inspiration for the *Dear SIRS* (Safety Information Response System) column, as well as the Q and A column, both of which have continued as very popular regular columns in the *Newsletter*. The *Dear SIRS* column has addressed some very hot topics in anesthesia including the inaugural *Dear SIRS* issue in 2004 regarding a common gas outlet concern that resulted in a corrective action by the manufacturer. Other topics have included an incorrect network connection simultaneously crashing multiple anesthesia machines and anesthesia circuit obstruction by CO₂ absorbent wrappers. For many years Dr. Olympio, followed by Dr. William Paulsen, as chairs of the Committee on Technology, provided their invaluable expertise on anesthesia equipment for this column.

Over my 23 years of involvement with the APSF, I was fortunate to participate in many important APSF initiatives that have greatly improved patient safety. The *Newsletter* has always been, and continues to be, the face of the APSF, the means of communicating important, and often, critical information, as well as serving as a wide-reaching educational tool. The *Newsletter* enjoys the largest

circulation of any anesthesia publication in the world. None of this would have been possible without the continued support of Dr. Bob Stoelting, the Executive Committee, the Board of Directors and most importantly, the Editorial Board. Jan Ehrenwerth, Joan Christie, Jeff Vender, Glenn Murphy, and John Eichhorn have inspired and authored many important articles. Wilson Somerville, PhD, and Addie Larimore have provided incredible editorial support. Bonnie Burkert has been the brains and brawn of production before, during, and after my tenure. In the spirit of my initial mentoring, I was so very fortunate to meet and recruit, first, Dr. Lorri Lee (a world-renowned expert in many safety areas such as postoperative visual loss and neuroanesthesia) and subsequently, Dr. Steve Greenberg (part of the prestigious Northwestern and present NorthShore University HealthSystem [Evanston, IL] legacy, with great expertise in critical care, cardiac anesthesia, and neuromuscular blockade.) My ability to step down was made possible by the dedication of Dr. Lee as my co-editor and Dr. Greenberg as assistant editor. Their enthusiasm, creativity, knowledge base, and editorial expertise have allowed, and will continue to allow, the *Newsletter* to remain the fresh, relevant, and critically important face of the APSF. I thank all those who put up with me, encouraged me, corrected me, and helped me over these many years. The opportunity to have collaborated with such wonderful people, to be supported in my creativity and evolution of the *Newsletter*, to have contributed to important safety initiatives and to have facilitated the dissemination of safety information has been profoundly meaningful to me. This has truly been a rewarding journey.

Dr. Morell remains active in private practice in Niceville, FL, and is a local champion for patient safety in his institution, having served as chair of the department of surgery and currently serving as chief of staff at Twin Cities Hospital. He has just achieved one of his most important lifetime accomplishments—that of becoming a grandfather to beautiful baby girl, Brylee, in February of this year!



Spotlight on Infection Prevention: Safe Injection Practices

by Terri Lee Roberts, BSN, RN, CIC, FAPIC

Safe injection practices are part of Standard Precautions, providing for patient safety and health care provider protections. According to the Centers for Disease Control and Prevention (CDC), syringe reuse and misuse of medication vials over the past decade have resulted in dozens of infectious outbreaks and the need to alert more than 100,000 patients to seek testing for infection with hepatitis B virus, hepatitis C virus, and HIV. This harm is preventable!

For more information, please visit the CDC's Injection Safety website:

<http://www.cdc.gov/injectionsafety>



The One & Only Campaign

The Centers for Disease Control and Prevention and the Safe Injection Practices Coalition lead the One & Only Campaign, a public health initiative to increase awareness of safe injection practices. Its goal is to eliminate infections resulting from unsafe injection practices. Remember "One Needle, One Syringe, Only One Time" for each and every injection! For example, use a new syringe and new needle when drawing up more propofol for an infusion. Never re-use tubing for infusions between patients, even if it is auxiliary tubing inserted upstream into the patients main i.v. line.

For more information, please visit the One and Only Campaign website.

<http://www.oneandonlycampaign.org>

Sharps Disposal Containers

Used sharps need to be disposed of immediately into a sharps container approved by the U.S. Food and Drug Administration (FDA). These containers have been evaluated for safety and effectiveness to help reduce the risk of injury and infections from sharps. FDA-cleared sharps disposal containers are made from puncture-resistant materials with leak-resistant sides and bottom and a tight fitting, puncture-resistant lid. These containers are labeled to warn of hazardous waste and marked with a line to indicate when the container is considered full. Close and properly dispose of the container when it is full.

For more information, please visit the CDC's Stop Sticks Campaign website and the FDA's Medical Devices website.

Drug Diversion is a Patient Safety and Infection Prevention Event

According to the U.S. Department of Justice Drug Enforcement Agency (DEA), the abuse of controlled substances is a serious problem, and health care providers are as likely as anyone else to abuse drugs. Drug-impaired health care providers are a source of controlled-substances diversion. Health care providers have easy access to controlled substances and some will divert and abuse these drugs to self-medicate, relieve stress, or improve mental alertness and work performance.

If a health care provider tampers with injectable drugs, they must do so quickly to avoid detection. It is likely sterile technique is not used and the needle used to inject the drug is not replaced. If the health care provider is infected with hepatitis B virus, hepatitis C virus, and/or HIV, the exposed patients are at risk of developing infection.

Drug-diversion programs for health care facilities include

- Policies to prevent, detect, and report drug diversion

- Processes to observe and audit use of controlled substances
- Immediate attention to suspicious audits
- Collaborative relationships with public health and regulatory officials
- Staff education on drug diversion

For more information, please visit the DEA Diversion Control Division website and the CDC's Injection Safety website.

Terri Lee Roberts, BSN, RN, CIC, FAPIC, is an infection prevention analyst with the Pennsylvania Patient Safety Authority.

Disclosure: The author has no financial conflicts of interest to disclose for this article.

Additional Resources

Prevent the occurrence of bloodborne disease transmission associated with unsafe injection practices. *Pa Patient Saf Advis* [online] 2011 Jun. Retrieved from [http://patientsafetyauthority.org/ADVISORIES/AdvisoryLibrary/2011/jun8\(2\)/Pages/70.aspx](http://patientsafetyauthority.org/ADVISORIES/AdvisoryLibrary/2011/jun8(2)/Pages/70.aspx).

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DANGEROUS MISPERCEPTIONS

Here are some examples of dangerous misperceptions about safe injection practices.

Myth	Truth
Changing the needle makes a syringe safe for reuse.	Once they are used, both the needle and syringe are contaminated and must be discarded. A new sterile needle and a new sterile syringe should be used for each injection and each entry into a medication vial.
Syringes can be reused as long as an injection is administered through IV tubing.	Syringes and needles should never be reused. The IV tubing, syringe, and other components represent a single, interconnected unit. Distance from the patient, gravity, or infusion pressure do not ensure that small amounts of blood won't contaminate the syringe once it has been connected to the unit.
If you don't see blood in the IV tubing or syringe, it means that those supplies are safe for reuse.	Germs such as hepatitis C virus and staph or MRSA are invisible to the naked eye, but can easily infect patients even when present in microscopic quantities. Do not reuse syringes, needles, or IV tubing.
It's okay to use leftover medicine from use single-dose or single-use vials for more than one patient.	Single-dose or single-use vials should not be used for more than one patient regardless of how much medicine is remaining.

Injection Safety is Every Provider's Responsibility!

The One & Only Campaign is a public health effort to eliminate unsafe medical injections. To learn more about safe injection practices, please visit OneandOnlyCampaign.org.

For the latest news and updates, follow us on Twitter @injectionsafety and Facebook/OneandOnlyCampaign.

This material was developed by CDC. The One & Only Campaign is made possible by a partnership between the CDC Foundation and Lilly USA, LLC.

One of the resources available on www.cdc.gov/injectionsafety.

APSF Joins NPSF in National Multidisciplinary Effort to Reduce Preventable Health Care Harm

The Anesthesia Patient Safety Foundation (APSF) strongly supports the goals and direction of the National Patient Safety Foundation's (NPSF's) Call to Action and widespread adoption of the public health framework described in "Preventable Health Care Harm Is a Public Health Crisis and Patient Safety Requires a Coordinated Public Health Response."

The APSF serves as the primary safety organization for more than 100,000 anesthesia professionals in the United States and is dedicated to improving the safety of all patients undergoing surgical and diagnostic procedures while anesthetized and during their perioperative care. These anesthesiologists, nurse anesthetists, and anesthesiologist assistants are involved in the full spectrum of perioperative care, ranging from pre-operative assessment through intraoperative care to the provision of critical care services and pain management. Since its inception in 1985, the APSF has provided more than \$10 million to support perioperative patient safety research. Through its publications and conferences, the APSF has a worldwide impact and works closely with health care professional societies to advocate for practices that improve perioperative patient outcomes.

In joining the NPSF in their patient safety endeavors, the APSF Newsletter, website (www.apsf.org), and other social media sources will periodically disseminate updates from the NPSF for this coordinated effort among multidisciplinary groups at reducing patient harm.

Sincerely,



Mark A. Warner, MD
President

The APSF continues to accept and appreciate contributions.

Please donate online by clicking the Donate button below or make checks payable to the APSF & mail donations to

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NPSF National Patient Safety Foundation®



CALL TO ACTION

Preventable Health Care Harm Is a Public Health Crisis and Patient Safety Requires a Coordinated Public Health Response

Information and technical review provided by the Centers for Disease Control and Prevention.

Summary

Preventable harm in health care is a public health crisis, with estimates placing it as a leading cause of death in the United States.¹⁻⁴

The National Patient Safety Foundation (NPSF) calls on health care leaders and policymakers to initiate a coordinated public health response^{5,6} to improve patient safety and drive the collective work needed to ensure that patients and those who care for them are free from preventable harm (see figure 1). Such an approach has already contributed to significant reductions in health care-associated infections (HAIs).⁷

As outlined below, NPSF believes that a public health response — one that draws on the experience and expertise of public health professionals and public health organizations — will accelerate progress in the prevention of harm and establish the critical infrastructure needed to address this challenge across the US health care system consistently and sustainably.

Building on successful efforts to reduce HAIs^{5,8-13} and taking advantage of critical lessons learned,⁷ NPSF proposes the following public health framework to guide efforts. This evidence-based approach identifies effective, replicable interventions for effective propagation across the health care system.

NPSF urges greater collaboration among all stakeholders to address preventable health care harm and recommends widespread adoption of our public health framework to guide collective efforts (figure 1). Too often, efforts to blame individuals and organizations for preventable harm diverts attention and resources away from a more effective and sustainable collective response.

Read more >>>

Figure 1.

Public Health Framework for the Prevention of Harm in Health Care

Policymakers and Health Care Leaders
Define the Problem and Set National Goals

Stakeholders Collaborate to
Coordinate Activities

Inform
the Community

Measure
and Monitor

Identify Causes
and Interventions

Educate
and Train

The National Patient Safety Foundation's vision is to create a world where patients and those who care for them are free from harm. A central voice for patient safety since 1997, NPSF partners with patients and families, the health care community, and key stakeholders to advance patient safety and health care workforce safety and disseminate strategies to prevent harm. NPSF is an independent, not-for-profit 501(c)(3) organization.

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NPSF Urges Call to Action on Preventable Health Care Harm

We will all be patients someday, yet evidence suggests that preventable harm in health care is a leading cause of death and morbidity in the US. As a reflection of APSF's commitment to advancing safe care and elevating patient and workforce safety as a core value, we are among the early endorsers of the National Patient Safety Foundation's new Call to Action: Preventable Health Care Harm Is a Public Health Crisis and Patient Safety Requires a Coordinated Public Health Response. The Call to Action builds on successful efforts to reduce health care-associated infections and takes advantage of critical lessons learned. NPSF pro-

poses a public health approach to guide collective efforts and calls on health care leaders and policymakers to initiate a coordinated response to drive the collective work needed to ensure that patients and those who care for them are free from preventable harm. By initiating a public health approach and working together to implement it, health care leaders and policymakers can accelerate progress in patient safety and establish the infrastructure needed to ensure that patients and the health care workforce are free from preventable harm across the health care spectrum.

Read more and download the full NPSF Call to Action document at http://c.ymcdn.com/sites/www.npsf.org/resource/resmgr/pdf/NPSF_CallToAction_PubHealth.pdf?hhSearchTerms=%22preventable+and+harm%22.



Unintended Discharge of an ICD in a Patient Undergoing Total Knee Replacement

Q Dear Q&A,

This brief communication questions the current recommendations for perioperative management of cardiovascular implantable electronic devices (CIED) which include pacemakers, implantable cardioverter defibrillators (ICDs), and cardiac resynchronization therapy (CRT) devices. This case pertains to the ICD.

There are two strategies for patient's undergoing surgeries who also have an internal cardiac defibrillator (ICD) to prevent inappropriate discharge of the device in the presence of electromagnetic interference (EMI). The first is to program the device to "off" by using a manufacturer's specific programmer. The other, simpler strategy is to place a doughnut magnet directly over the devices' generator. This will inhibit the devices' tachyarrhythmia therapy function, not its bradyarrhythmic therapy (pacemaker) function.

The 2011 HRS/ASA expert consensus statement suggested inactivating the ICD for all surgeries above the umbilicus.¹ However, the document implied that it was unnecessary to do so for surgeries below the umbilicus, as the risk of EMI being detected, and hence of discharge of the device, was very low and in fact never documented to have occurred.¹ We recently cared for a patient undergoing lower extremity surgery—total knee replacement—whose ICD discharged during surgery despite appropriate placement of the electrocautery grounding pad.

The patient was an 82-yr.-old male (height: 5' 6", weight: 146 lbs.) with a history of coronary artery disease and an ischemic cardiomyopathy (ejection fraction=25%). The patient also had a CIED (St. Jude Medical; Little Canada, MN. Quadra Assura™ 3365-40Q CRT-D; RV lead: maximum sensitivity setting, 0.5 mV; autosense mode "on") located in the left pectoral region. Neither a magnet nor reprogramming was used to disable the device's antitachyarrhythmic therapy function. He subsequently underwent a right total knee replacement under spinal anesthesia. The

See "Q&A," Next Page

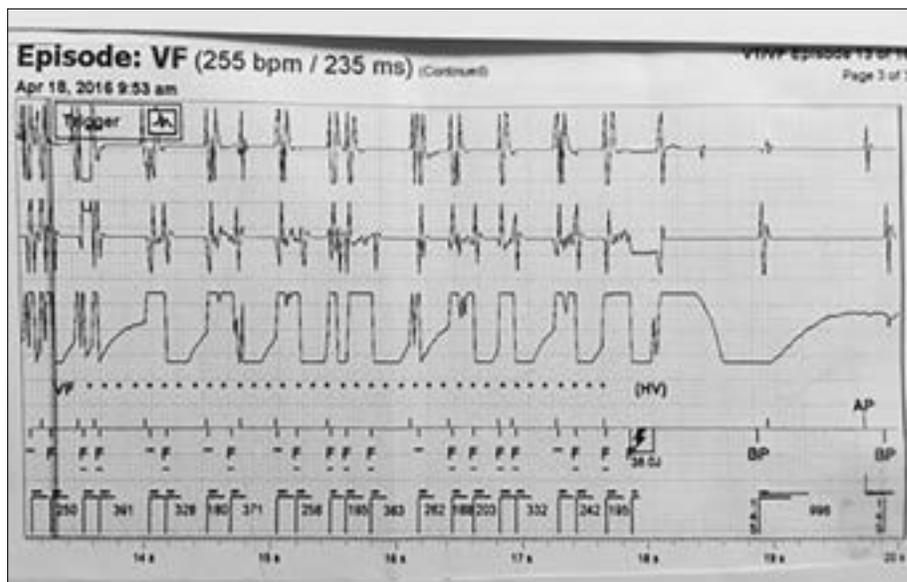


Figure 1. Top tracing: Atrial sense lead. Middle tracing: Ventricular sense lead. Bottom tracing: Discrimination (channel) lead. Atrial, ventricular, and discrimination channel leads show similar rapid wave form signals suggesting to the ICD that this is ventricular fibrillation. The device senses this and then analyzes the wave form during a programmable duration delay of approximately eight seconds. It determines that this is ventricular fibrillation, and then charges for approximately 5 seconds—while continuing to analyze the waveforms—and then discharges. The point is that the discharge event was set in motion many seconds before the actual discharge.

VF *** Device charging ⚡ Lightning bolt symbol indicates discharge

VT/VF Episodes	Date / Time	Type	Rate (bpm)	Duration (M S)	Therapy Delivered	Alerts
	Apr 18, 2016 10:00 am	VF	342	00:09		⚡x2
	Apr 18, 2016 9:57 am	Non-sustained		00:06		⚡x2
	Apr 18, 2016 9:53 am	VF	315	00:11		⚡x1
	Apr 18, 2016 9:53 am	VF	255	00:13	36J	⚡x1
	Apr 18, 2016 9:47 am	Non-sustained		00:08		⚡x3
	Apr 18, 2016 9:47 am	VF	444	00:21		⚡x2
	Apr 18, 2016 9:39 am	VF	307	00:09		⚡x1
	Apr 18, 2016 9:27 am	Non-sustained		00:16		⚡x2
	Apr 18, 2016 9:17 am	VF	268	00:13		⚡x2
	Apr 18, 2016 9:13 am	VF	210	00:14	ATP	⚡x1
	Apr 18, 2016 9:07 am	Non-sustained		00:06		

Figure 2. Table depicts events of interest, including the event leading to device discharge (electrogram shown in Fig. 1), as well as their duration. The "VF" event at 09:47 consists of several short epochs of high frequency wave forms whose total duration is 21 seconds, but with no shock delivered. The device identifies some epochs as ventricular fibrillation, but correctly identifies most as high frequency "noise" and, therefore, the device does not discharge (electrogram not shown).

The APSF sometimes receives questions that are not suitable for the Dear SIRS column. This Q and A column allows the APSF to forward these questions to knowledgeable committee members or designated consultants. The information provided is for safety-related educational purposes only, and does not constitute medical or legal advice. Individual or group responses are only commentary, provided for purposes of education or discussion, and are neither statements of advice nor the opinions of the APSF. It is not the intention of the APSF to provide specific medical or legal advice or to endorse any specific views or recommendations in response to the inquiries posted. In no event shall the APSF be responsible or liable, directly or indirectly, for any damage or loss caused or alleged to be caused by or in connection with the reliance on any such information.

ICD Inadvertently Fires During Total Knee Arthroplasty

“Q&A,” From Preceding Page

surgery involved the use of a monopolar electro-surgical unit (ESU). The return pad was placed on the patient's left thigh. The anesthesia-surgical course was unremarkable. However, approximately two months after his surgery, routine surveillance interrogation of the device suggested that it had discharged intraoperatively (Fig. 1 and Fig. 2) while functioning normally.

In patients undergoing surgery, inactivation of the anti-tachyarrhythmic function of the ICD is recommended in order to prevent electromagnetic interference (EMI) from discharging the device. Unintended discharge could lead to a life-threatening arrhythmia. Two strategies are typically utilized to deactivate the device for surgeries performed above the umbilicus—either via a doughnut magnet, or programmed deactivation.² Deactivation of the device using a doughnut magnet, however, is not foolproof. It assumes that the magnet is properly positioned and that there is appropriate contact. However, expert consensus does not necessitate using these strategies during surgery performed below the umbilicus—and particularly during lower extremity procedures—since the ICD is unlikely to sense any EMI, and therefore unlikely to inappropriately discharge. Therefore, in patients undergoing lower extremity surgery, as in our case, inactivation of the ICD via magnet application or reprogramming is not particularly recommended. In fact, the ASA Practice advisory from 2011 discourages the use of magnets in general.³ In a study comparing the efficacy of two perioperative strategies—magnet deactivation vs. program deactivation—the ICDs in the group undergoing lower extremity surgery did not record any instance of EMI.² Our case, to the best of our knowledge, is the first documented case of ICD activation (and therefore recording of EMI) in a patient undergoing lower extremity surgery. Therefore, while the risk of ICD activation in the lower extremities is admittedly rare, it is not zero. This case calls into question prior expert consensus opinion as to the management of ICDs during surgery on the lower extremities.

Another related safety issue has arisen with the introduction of very large, nondisposable, return electrode pads (Mega Soft Dual Cord™ or Mega2000™, Megadyne Medical Products, Draper, UT) that are placed on the operating table instead of the patient. These pads are typically 36 x 20 inches for adults and utilize the principle of capacitive coupling. This large surface area for a return pad increases the risk that the ICD electrodes might be within the electric field generated by the

monopolar ESU (area between the electrocautery surgical site and the return pad)—even during lower extremity surgery. If the electrodes from the ICD are in the electrical field generated by the monopolar ESU, then the risk of unintentional discharge is high. This potential safety hazard was initially cited by the NHS Foundation Trust,⁴ but has not received wide dissemination. The increased use of the Megadyne™ return pads is another reason why the authors believe that an update to the most recent expert opinion is needed.

Magnet application over a CIED to temporarily deactivate the tachyarrhythmic therapy function (ICD) is a simple procedure. We believe that new guidelines or consensus statements should consider whether a magnet should be placed over the ICD of all patients undergoing any surgery in which a monopolar ESU will be used provided the following three caveats are met:

- 1) The magnet response is known and “on”;
- 2) the magnet is confirmed to be in the appropriate position (which in the absence of an audible tone can be difficult to determine);
- 3) and the magnet is in a stable position such that it will not be displaced (i.e., when patient is in the prone or lateral positions).

If these conditions cannot be met, consideration should be given to reprogram the device “off” and appropriate precautions taken. This recommendation is particularly important for patients undergoing surgery in which Megadyne™ return pads are used.

Drs. Bruce Kleinman, Sam Ushomirsky, and John Murdoch, are staff anesthesiologists at the Edward Hines Jr. VA Hospital, Hines, IL. Dr. James Loo is Chief of Anesthesiology at Edward Hines Jr. VA Hospital, Hines, IL. Jeanette Radzak is an electrophysiology nurse practitioner at Edward Hines Jr. VA Hospital, Hines, IL. Dr. Joseph Cytron is Associate Professor of Cardiology, Loyola University Medical Center.

None of the authors have any financial interest in any of the devices mentioned in the report. The opinions expressed are solely those of the authors, and are not to be construed in any way as representing the opinions of the Department of Veteran's Affairs or the APSF.

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A Dear Dr. Kleinman:

(From the Editors: The APSF does not have a formal position on the issue re: modification of the existing guidelines for perioperative management of CIEDs. We have recruited Dr. Streckenbach who is an expert on the perioperative management of implantable cardioverter defibrillators [ICDs] and pacemakers to provide a response to this very interesting report.)

As the number of patients with implantable cardioverter defibrillators (ICDs) presenting to the operating room for surgery has rapidly increased over the last decade, it appears that the resources readily available to help anesthesia professionals manage these devices have dwindled. Cardiologists, electrophysiologists (EP), and EP technicians along with company representatives have traditionally helped provide perioperative management of ICDs; however, the availability of this group has declined over the past several years, presumably caused by budgetary constraints. This often leaves anesthesia professionals in a difficult situation—having to manage the ICDs by themselves. There are two published guidelines that many use to help guide perioperative ICD management, the ASA Practice Advisory and the Heart Rhythm Society (HRS)/ASA Expert Consensus Statement.^{1,2} Both documents are very helpful, but neither can cover every scenario. In this month's APSF publication, Kleinman *et al.* describe a patient who sustained an ICD shock during knee surgery despite correct placement of the bovie pad. The HRS/ASA Statement suggests that patients having knee surgery should not get shocked since “the risk of false arrhythmia detection is considered so low for surgical procedures on the lower extremities that neither reprogramming nor magnet application is considered mandatory.”¹⁻² Yet, Kleinman *et al.* reported that their patient had knee surgery and according to the data presented had an ICD shock during the surgery.

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Expert Weighs in on ICD Firing During Surgery Below Umbilicus

“Q&A,” From Preceding Page

However, this shock is not exactly surprising. This author has records of two other patients (unpublished) who received unexpected shocks during hip surgery. In both cases, as in Kleinman’s, the anesthesia professionals were not aware of the shock at the time of the surgery. Kleinman’s report should certainly get everyone thinking about how to manage ICDs during lower extremity surgery. Their case is very instructive, but a quick review of how ICDs detect and treat ventricular fibrillation (VF) will be helpful before analyzing that event.

An ICD senses intrinsic R-waves through the RV sensing/pacing lead. The ICD determines the patient’s rhythm by measuring the time interval between successive R-waves. When the heart rate is 60, the interval between beats is 1000 msec (60,000 msec/60 beats). When the patient has ventricular fibrillation the heart rate is much higher—usually above 200 bpm—and the interval between beats decreases to 300 msec or less (60,000 msec/200 beats). The ICD measures each successive R-R interval and defines that interval as normal if the interval is long enough and as VF if the interval is too short. Each patient’s ICD is programmed to define what interval gets labeled as a “VF” interval. Once an ICD detects a “VF” interval, a counter starts. If enough of the subsequent intervals (for example, 12 of the next 16) meet the VF criterion, then the ICD declares the patient to be in VF. When this occurs, the ICD charges its capacitor for a shock. During charging, many ICDs will deliver anti-tachy pacing (ATP) if the HR is in a programmable range (for example 180–210 bpm). Occasionally the ATP will break the dysrhythmia obviating the need to deliver the shock. More often, however, the ATP fails and the ICD continues to charge until it is ready to deliver the shock. The charge time is approximately 4–12 seconds depending on the charge setting and the battery life. Just before delivering the first shock, most ICDs will re-assess the rhythm to confirm that the patient is still in VF. If yes, a shock is delivered. If no, the shock will be aborted, and the capacitor will slowly dissipate its charge.

It is not uncommon during electrocautery use for an active ICD to detect what it believes is VF and charge, but then abort because the cautery was not in use during the short reconfirm phase. The author is aware of cases where patients’ ICDs charge multiple times during a surgical procedure, but only deliver one or two shocks due simply to the timing of the cautery use. It is very important to understand that it takes as few as 3–4 seconds of cautery to “fool” the ICD into

thinking the patient is in VF. In fact, it does not even need to be 3–4 seconds of continuous cautery—it just has to be enough bursts of cautery for the device to detect a small programmable number of very short R-R intervals. Figure 1 (see page 17) demonstrates how quickly cautery can be detected as VF during thoracic surgery. A magnet was used to inhibit the ICD in this case, but the magnet was displaced intermittently. Cautery was misinterpreted as VF in 3 seconds.

It is also worth pointing out that ICDs are more likely to sense far-field or distant cautery than pacemakers. The RV lead sensitivity setting of an ICD is high in order to detect the low amplitude fibrillation beats. Pacemaker sensitivity is lower (4–5 times typically) as pacemaker RV leads only have to detect the higher amplitude intrinsic R-waves. Thus ICDs would be more likely to sense cautery in the lower extremities than a pacer would.

To summarize, ICDs measure R-R intervals. If enough short R-R intervals occur in a short time period, the ICD detects VF and charges its capacitor. If the VF is still present when the charging ends, a shock is delivered. If it is not, the charge is aborted.

Given this simplified explanation of ICD function, the analysis of what likely transpired during the case of Kleinman *et al.* will be discussed. The anesthesia team followed the HRS/ASA Statement recommendations and chose to leave the ICD active for the lower extremity surgery. The electrocautery return pad was placed on the contralateral thigh. Thus cautery energy travelled from the patient’s knee up toward the waist and crossed over to the opposite leg. As electrical energy moves from its source to its destination it spreads out. How far the electrical energy spreads superiorly as it travelled to the other leg is hard to know, but my guess is that it might have gotten near the umbilicus in this particular case. The distance between the umbilicus and the RV sensing lead in this 5’6” patient is approximately 6 inches. Since the sensitivity of the ICD’s RV sensing lead is high (and thus the required amplitude of the signal required is low), the low amplitude electrocautery signal was presumably detected as if it represented intrinsic R-waves. Since the frequency at which these “R-waves” were occurring was high, the ICD quickly detected enough short R-R intervals to fulfill the VF criterion. In fact, this happened 7 times between 9:13 am and 10:00 am (see Figure 2 in the report by Kleinman *et al.*). While charging ensued during the 9:13 am episode, ATP was delivered by the ICD. ATP was delivered only in the 9:13 am episode because the detected average HR was above the ATP range in the other VF episodes. The

anesthesiologist might have noticed a series of rapid pacing spikes with paced R-waves, but only if he or she had been looking at the monitor at this time, and if cautery were not being used. In that same episode, when the charging completed, the ICD did not sense the electrocautery so the shock was aborted. Shortly thereafter, during a 9:53 am VF episode, the ICD confirmed VF at the end of charging, and shocked the patient with 36 joules.

In Figure 1 (see page 10) of Kleinman *et al.*’s report, notice the electrocautery signals are being detected as VF intervals (the “F”s). Charging occurred coincident with the asterisks. It took approximately 5 seconds for the charge (this duration was likely shortened by the prior charge without complete charge dissipation at 9:47 am). When charging completed at the last asterisk, the next interval (195 msec) says “F” indicating that cautery was detected at that moment, and the ICD presumed that the dysrhythmia persisted. It therefore delivered the 36-joule shock to a heart presumably in sinus rhythm. The anesthesiologist might have noticed this shock depolarization on the EKG if he or she were looking at the monitor devoid of cautery noise, but it would have been very short in duration. The patient who had a spinal most likely would have moved somewhat, the intensity dependent on the patient’s muscle mass. Again the anesthesiologist may have been charting and did not notice it—or could have thought it was a cough. The surgeons too may have noticed it but presumed the motion to indicate a cough or just random patient movement.

An ICD misinterpreting cautery as VF is problematic for several reasons. First, ATP or a high voltage asynchronous shock, during sinus rhythm, can actually induce ventricular fibrillation. Second, the ICD battery can be significantly depleted. Each shock can diminish the battery by an estimated 30 days according to manufacturer technical support staff. Moreover, a charge even without a shock diminishes battery life. There is a report of total ICD battery depletion during a surgical procedure related to this issue.³ Third, patient movement from a shock during a critical moment could cause a surgical complication. Finally, there is evidence that shocks, appropriate or inappropriate, cause myocardial injury and increase mortality.⁴

So what should the readers do with the knowledge of the case presented by Kleinman *et al.*? I think readers should understand that whether an ICD will sense electrocautery or not depends on more than just the location of the surgery. It significantly depends on the location of the electrocau-

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Article Review

Medication Safety: An Important APSF Initiative Revisited

by Tricia Meyer, PharmD

Medication errors have been estimated to occur in approximately 5% of medication administrations during surgery with a large majority of them being preventable.¹ High-quality evidence-based literature on preventative measures is limited.

Medication utilization in the perioperative area is fundamentally different from the typical hospital patient care units. The anesthesia professional is the only practitioner involved with the total medication process of prescribing, preparing, dispensing, and administering the medications without the advantage of an extra check of other health care professionals such as pharmacists or nurses. Additionally, many of the drugs used in anesthesia are high-risk drugs with a narrow therapeutic index which contributes to the potential for a harmful medication error to occur.

In a recent review article entitled, "Medication safety in the operating room: literature and expert-based recommendations," Wahr and colleagues undertook a rigorous literature review of publications and guidelines on medication errors/medication safety in the operating room to identify strategies to improve medication safety. This study is an update of a 2004 systematic review by Jensen that also identified evidence-based strategies for preventing drug administration errors during anesthesia.¹

Medication errors in the operating room are not uncommon and most are considered preventable. Interestingly, the researchers found in their review similar medication error rates or near miss rates across the globe, indicating a shared problem and concern of the profession.¹ New Zealand identified an error or near miss rate of 1:133 anesthetics; South Africa 1:274 anesthetics; Japan 1:450 anesthetics. The errors occurring most frequently were miscalculations of dose, concentration, or infusion rates; syringe or vial swaps; additional or missed dose(s). In the studies evaluated, the harm from these errors was found to be low; however, the authors did review a worrisome number of case studies that reported potentially lethal or lethal errors. These included wrong route, dilution or concentration errors, pump programming errors, allergic reaction of a known allergic drug, and failure to flush lines after drug administration. More concerning is a recent study, published in 2016, that found a higher rate of errors of 1 error in every 2.2 surgeries.²

The authors, who included human factors engineers, physician anaesthetists, and one pharmacist,

searched peer-reviewed articles published over a 20-year span between 1/1/1994 and 1/1/2014. The inclusion criteria encompassed articles that contained recommendations on medication safety or that cited contributing factors for errors. Further searches were conducted for guidelines or consensus statements from the National Guidelines Clearinghouse and from reviewed publications describing guidelines or statements on medication safety recommendations.

Recommendations were rated corresponding to the type of publication. A point scale was modified by the human factors engineers from the Jensen article and was used to grade the recommendation findings.

After an extensive review of the publications, the researchers found 74 articles to include in the development of the guidelines in addition to 6 guidelines or sets of recommendations specifically addressing medication safety in the operating room. The researchers noted that there was a shortage of high-quality, randomized, controlled studies to guide intraoperative medication safety tactics and the authors depended on expert opinions. The guideline/recommendation sets that were used in the review were

1. Association of perioperative Registered Nurses (AORN)—2006
2. Anesthesia Patient Safety Foundation (APSF)—2010
3. American Society of Health-Systems Pharmacists (ASHP)—1999**
4. Center for Disease Control (CDC)—2007
5. Institute for Healthcare Improvement (IHI)—2013
6. Institute for Safe Medication Practices, Canada (ISMP)—2008

** Currently under final revision for updated recommendations**

The total number of recommendations collected from the review was 138. The recommendations were further refined to 44 and, from this point, a modified Delphi process was used to exclude elements that were determined not to be important to safety or items that could not be measured. The resulting number of recommendations after the process was 35 and the authors felt this list was more inclusive than previous recommendations based on an approach to include strategies to prevent common and uncommon errors.

Although the list of recommendations was primarily developed from expert opinion from

either a review of a voluntary reported errors, solicited expert opinions, or formal consensus statement/guidelines, the authors carefully used a defined search strategy with inclusion and exclusion criteria, a systematic review process, a focus group review, and a mechanism for scoring the recommendations.

Many strategies proposed on medication safety have not been tested in randomized clinical trials. The number and variety of errors reported with contributing events and the cost of randomized controlled studies make it challenging if not virtually impossible to research each specific recommendation. Wahr *et al.* presented the recommendations with the most solid support of experts in the field. The items on the medication safety strategies list suggest possible tactics to lower medication errors. The outline of recommendation themes are as follows:

Patient Information
Drug Information
Cart Inventory
Administration
Pharmacy
Culture

The reader can access the complete list of the recommended medication safety strategies by accessing the publication. The authors emphasize that the lack of well-designed, randomized, controlled trials should not be used as an excuse to do nothing or to be misled into thinking the present status is acceptable. They also would like operative/anesthesia services to use the list of recommendations as a tool or checklist to analyze their capacity for errors and then develop improvements.

Tricia Meyer MS, PharmD, FASHP, FTSHP, is Regional Director of Pharmacy at the Scott & White Medical Center-Temple and Associate Professor of Anesthesiology at Texas A&M University College of Medicine.

The author reports no conflicts of interest for this article.

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Congratulations to a True Pioneer in Simulation



David M. Gaba, MD

David M. Gaba, MD, Professor of Anesthesiology, Perioperative and Pain Medicine and Associate Dean for Immersive and Simulation-based Learning and Director of the Center for Immersive and Simulation-based Learning (CISL) at Stanford University School of Medicine was recently awarded the high honor of the 2017 4th Annual Pioneer in Simulation Award at the International Meeting on Simulation in Healthcare. Dr. Gaba is



David M. Gaba, MD, (left) receiving the 2017 4th Annual Pioneer in Simulation Award at the International Meeting on Simulation in Healthcare.

also a staff physician and founder of the Simulation Center at the VA Palo Alto Health Care System (VAPAHCs). He has had a faculty appointment at both Stanford and the VAPAHS since 1983.

Dr. Gaba is responsible for creating the technology for one of the original human patient simulators and has been an innovator in integrating simulation in health care to enhance health care

provider teamwork. He is also honorably serving his 27th year as a member of the Executive Committee of the APSF. Thank you, Dr. Gaba, for helping to make our patients safer everyday by facilitating improved training for health care providers. Below is the link to the tribute to Dr. Gaba's lifetime of incomparable work.

<https://vimeo.com/207549992/e1925da3f1>

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Expert Perspective on Perioperative Management of ICDs

“Q&A,” From Page 12

tery return pad. If the return pad can be placed on the ipsilateral leg (e.g., on the left calf during left hip surgery) the likelihood of an ICD detecting the cautery is very low—consistent with the statement made in the HRS/ASA Consensus Statement. However, if the return pad is placed on the contralateral leg, especially in a small patient, one may have to consider the risk of an inappropriate shock to be higher than suggested by the Consensus Statement. Certainly, if the return pad is placed on the patient’s back, the risk of an inappropriate shock is very high. Finally, I think it is also important to remember that some OR nurses may not be so acutely aware of the relevance of the position chosen to place the electrocautery return pad. Certainly if you plan to leave an ICD on during a surgical procedure that will include electrocautery, you should discuss the placement of the return pad preoperatively with the circulating nurse.

In the second half of this paper, I will make a few recommendations intended to improve the anesthesia professional’s ability to manage patients who have ICDs. First, I recommend that you read the HRS/ASA Consensus Statement in its entirety if you have not already. It provides excellent electrophysiology education as well as guidance for perioperative device management. It has concise summaries of the questions you should ask about the patient’s device, and it includes charts that describe the function of both ICDs and pacemakers. Whenever colleagues ask what they should read to learn more about perioperative electrophysiology, I always tell them to start with this paper.

Second, I recommend that you become a magnet specialist if there is any chance you will ever choose to use a magnet in the OR. In other words, I suggest that you learn in great detail exactly how ICDs from each of the manufacturers interact with a magnet. Table 1 (see page 18) provides my summary of these magnet-ICD interactions. You should notice that a properly placed magnet will inhibit the anti-tachy therapy of all ICDs. The only possible exception to this statement would be a very rare Boston Scientific or St. Jude ICD that was programmed to ignore a magnet—see below. When the magnet is removed from any of the ICDs, the anti-tachy therapy resumes.

Next, notice how a magnet affects the pacemaker component of each ICD, remembering that all ICDs have an integrated pacemaker. A magnet is ignored by the pacer component of every brand of ICD except for Sorin (the base

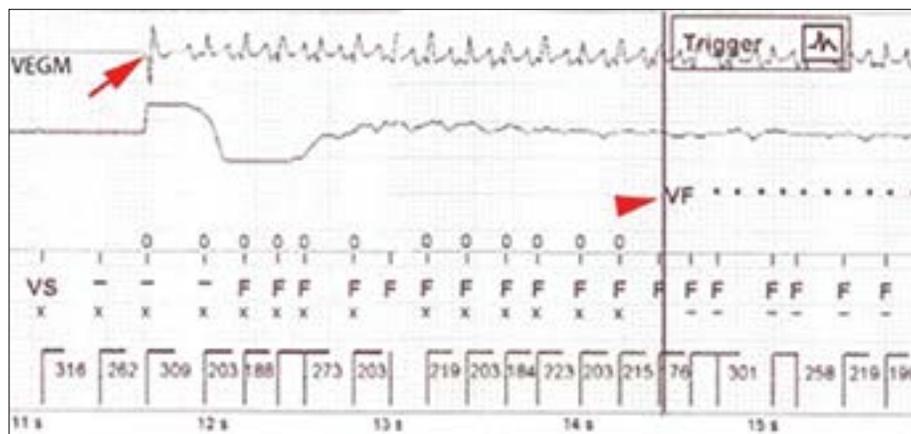


Figure 1: ICD sensing electrocautery during thoracic surgery when magnet was displaced. Arrow defines onset of cautery. Arrowhead defines detection of VF approximately 3 seconds later.

rate increases). In no situation will a magnet convert an ICD’s integrated pacer to an asynchronous pacing mode as a magnet routinely does with stand-alone pacers. The only way to make the ICD’s pacer asynchronous is to re-program the ICD using a company-specific programmer.

Next, notice that ICDs differ in the tone each emits when a magnet is applied (see Table 1, page 18). It is very important that you understand these differences. Boston Scientific ICDs emit a beeping tone (every second or coincident with the R-wave) for as long as the magnet is on the ICD. This tone can be heard even in the noisy operating room by applying one’s stethoscope over the hole in the magnet. This tone can help confirm the proper magnet location throughout an entire procedure. Medtronic ICDs emit a tone that lasts for 10–15 seconds after placement of a magnet. A continuous 10–15 second tone indicates that the anti-tachycardia component of the ICD is inhibited. The Medtronic tone can at least confirm your initial magnet placement, but it does not facilitate intermittent checking during the procedure. The other devices (St. Jude, Biotronik and Sorin) do not emit a tone. This means that one cannot confirm that the magnet is properly positioned initially or throughout the entire surgical procedure with these latter three ICDs. This issue is particularly worrisome if the patient is obese and the ICD is difficult to palpate, or if the patient is in a lateral or steep Trendelenburg position. The author has 5 records of patients whose ICDs were presumably inhibited with a magnet during a procedure who nevertheless got intraoperative shocks. Two of these patients were in the lateral position and one was obese.

Finally notice, as mentioned above, that ICDs differ in their ability to potentially ignore a magnet. Boston Scientific and St. Jude ICDs can be programmed to ignore a magnet; Medtronic, Biotronik and Sorin ICDs cannot. Thankfully, ICDs are very rarely programmed to ignore a magnet, but one should always confirm that the ICD would respond to a magnet before the surgery begins. In my experience, the typical EP or cardiology follow-up note does not define this magnet response. If your patient has a Boston Scientific device, you can place the magnet over the ICD, and if you hear beeping tones, you can be assured that the ICD is responding to the magnet and therefore will inhibit the ICD’s anti-tachy therapy. To know for certain that a St. Jude ICD will respond to a magnet, you will need to get that specific information from the patient’s cardiologist, or you will need to use a programmer to interrogate the device.

Anesthesia professionals who choose to use a magnet to inhibit an ICD perioperatively certainly should know precisely how the ICD will respond to a magnet. They must be very careful to ensure that the magnet position relative to the ICD is appropriately maintained. Defining the border of the ICD with a marking pen before securing the magnet over the ICD makes periodic monitoring easier. They should also remember that if a patient develops VF while the ICD is inhibited with the magnet, they might still want to use an external defibrillator. If they choose to remove the magnet so that the ICD can treat the dysrhythmia, it will take 3–4 seconds to detect the VF and another 5–10 seconds for the ICD to charge before the shock can be delivered. Watch-

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Anesthesia Professional Organizations Could Develop Online ICD Training Programs

“Q&A,” From Preceding Page

ing VF for up to 15 seconds in the OR waiting for the internal ICD to shock the patient is not ideal.

My last recommendation intended to improve the ability to manage patients with ICDs relates to device programmers. Although there are few of them, trained anesthesia professionals can use a programmer to disable the ICD’s anti-tachy therapy. Each company’s programmer is different, but it is still relatively easy to turn off the anti-tachy therapy, especially for Boston Scientific, St Jude, and Biotronik ICDs. In fact, only one step is required to turn off the anti-tachy therapy of a Biotronik ICD (Figure 2). Manufacturing representatives are very skilled at training anesthesia professionals on how to use their programmers and appear willing to provide a programmer for perioperative use. With practice, typically with EP colleagues, motivated anesthesia professionals should be able to learn very basic programming such as suspending anti-tachy therapy and changing pacing modes.

Disabling the ICD’s anti-tachy function with a programmer prevents inappropriate shocks and obviates the need to use a magnet during a procedure. This reprogramming is a good alternative to using a magnet especially in obese patients, or those who will not be supine throughout the procedure. Using the programmer also provides the

option to change the pacing mode of an ICD when indicated. In fact, one has to use the programmer in order to convert the pacemaker function of an ICD to asynchronous pacing (e.g., DOO). An asynchronous pacing mode is only programmable after the anti-tachy therapy is suspended with the programmer.

A downside of reprogramming the ICD’s anti-tachy therapy is that the device will not be readily able to treat an intraoperative dysrhythmia. Therefore, cardiac monitoring and immediate availability of external defibrillation are essential once the ICD is suspended. Also, the ICD must be reactivated prior to the patient being discharged from the hospital. The advantage of anesthesia professionals doing the programming is that they can typically turn off the ICD when the patient is already in the OR and fully monitored. As soon as the surgery is done, an anesthesia professional is typically available to reactivate the ICD before the patient goes to the recovery room. This process minimizes the time during which the ICD is off and decreases the risk of a patient getting discharged with the ICD suspended. This is exactly how I manage the majority of the patients at my hospital.

Anesthesia professionals who understand basic electrophysiology and know how to utilize the device programmers may be able to effectively

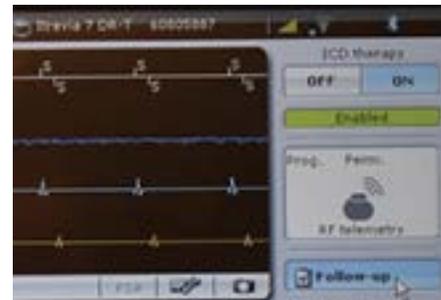


Figure 2: Biotronik ICD programmer screen upon initial interrogation depicting one-touch anti-tachy disabling option.

manage CIEDs in the perioperative period. The anesthesia professional can be aware of the cautionary needs, the positioning issues, the ability to use a magnet based on the surgical site, and the patient’s medical history. More importantly, the anesthesia professional is in the OR with the patient. A recently published article demonstrated that anesthesia-driven care of CIEDs can be safe and time saving.⁵

Obviously not every anesthesia professional can be expected to learn how to use a programmer. However, hospitals could support the training of a few motivated individuals who could then

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Table 1: Summary of Impact of Magnet Application to Five Brands of ICDs

Manufacturer	Response to Magnet	Effect on Pacer Component of ICD	Tone Emitted	Can ICD be programmed to ignore magnet?	Miscellaneous
Boston Scientific	ICD inhibited until magnet removed	None	Yes, beeping tone synchronous with R-wave or every sec	Yes (Very rare)	Older ICDs that could be permanently deactivated with a magnet are gone. Sub Q ICD responds to a magnet
Medtronic	ICD inhibited until magnet removed	None	Yes, monotone for 10–15 seconds only. High-low tone indicates device malfunction	No	Patient alerts can be programmed to emit an on-off tone with magnet application
St. Jude	ICD inhibited until magnet removed	None	No	Yes (Very rare)	
Biotronik	ICD inhibited until magnet removed	None	No	No	Magnet will inhibit ICD for 8 hours only. Would have to remove and replace ICD to extend inhibition
Sorin	ICD inhibited until magnet removed	Converts pacer rate to 96→80 depending on battery life. Pacing mode unchanged	No	No	No option to convert to an asynchronous pacing mode even when the ICD is inhibited with a programmer

MGH Works Towards Collaboration Between EP Services and Training Process

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develop the framework necessary for such an endeavor. Professional organizations for anesthesia providers could develop online training programs that could be used by anesthesia professionals who have less access to manufacturing representatives and EP services. At the MGH, we are in the middle of this training process, closely collaborating with our EP service and its rewards for patient safety and throughput are abundantly clear.

Dr. Scott Streckenbach, is presently Assistant Professor, Harvard Medical School and Director of Periop-

erative Electrophysiology in the Division of Cardiac Anesthesia and in the Department of Anesthesia, Critical Care, and Pain Medicine, Massachusetts General Hospital.

Disclosure: Dr. Streckenbach reports no financial conflicts of interest for this article.

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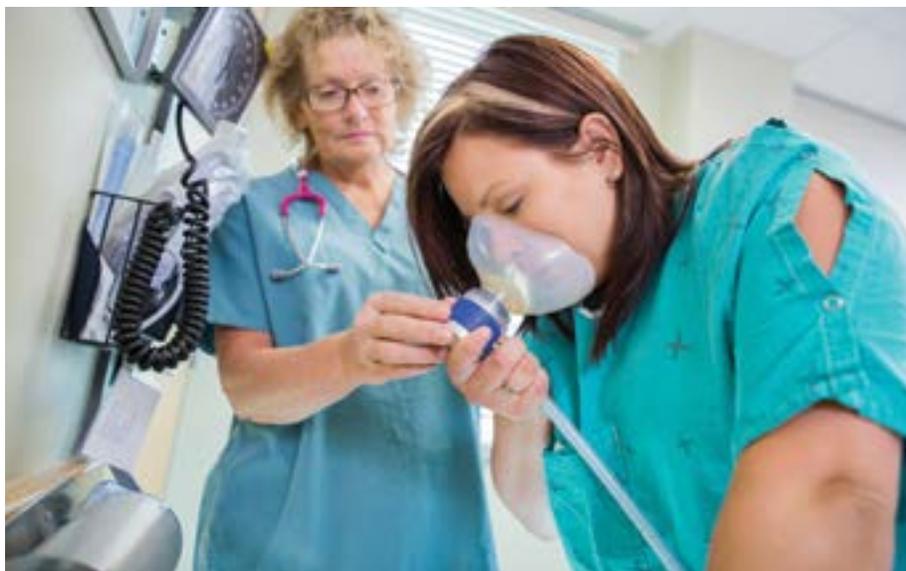
Nitrous Oxide for Labor Analgesia: Is It Safe for Everyone?

Q Dear Q&A,

Is it feasible to use self-administered nitrous oxide for labor analgesia?

Nitrous oxide is used extensively for labor analgesia in the United Kingdom, Canada, Australia, Finland, and Sweden.¹ Historically, the use of nitrous oxide in the United States for this purpose has been significantly more limited. However, there has been a dramatic growth of this service in the last couple of years as commercially available delivery systems have reemerged onto the market.

Our institution was asked if we would explore expanding options for labor analgesia to include nitrous oxide. After consulting with other institutions offering nitrous oxide for labor analgesia, we agreed to move forward with this initiative. At the time, the only FDA-approved delivery system for nitrous oxide was the Nitronox™ system by Porter Instrument Division, Parker Hannifin Corporation, which had recently acquired the rights and began manufacturing units again. The device delivers nitrous oxide in a 50:50 ratio with oxygen through a demand valve attached to either a mouthpiece or a standard anesthesia face mask.



Patients are instructed to exhale into the mask or mouthpiece where waste gas is evacuated through a connection to the central vacuum system.

Prior to launching the service, there were significant concerns expressed among our staff regarding environmental exposure to nitrous oxide. As

part of a plan to assuage worries and ensure that we remained below National Institute for Occupational Safety and Health (NIOSH) recommended exposure limits (25 ppm, time-weighted average), we required dosimeters (Assay Technology passive nitrous oxide badges) be worn for anyone anticipated to be in a patient’s room for more than 15 minutes while nitrous oxide was being used. In addition, dosimeters were placed within the patient’s room while nitrous oxide was being used to monitor ambient levels.

The results from our first trial period are illustrated in the Table where samples ranged from <2.8 to 140 ppm (time-weighted averages). We

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Delivery System	Trial	Total Samples	Samples above NIOSH recommended levels	Percent exceeding NIOSH levels
Nitronox™	1	25	17	68%
	2	31	15	48%
Pro-Nox™	1	5	2	40%
	2	14	10	71%

Potential Solutions to High Nitrous Oxide Concentrations in L&D

“Q&A,” From Preceding Page

opted to suspend this service while we investigated possible causes. After discussions with the manufacturer and additional patient education efforts that emphasized ensuring a tight mask seal, and advocating that staff remain out of the patient's immediate space while nitrous was being used, we reinitiated the service. Repeat testing (see table on page 19) again showed that 48% of samples were above recommended thresholds. The decision was made to terminate the use of the Nitronox™ delivery system.

Given continued interest in offering nitrous oxide to our parturients, we explored an alternative delivery system, the Pro-Nox™ system by CAREstream Medical. Following additional educational sessions for staff, we reinitiated a nitrous oxide option for labor analgesia. Samples were sent off (Liberty Mutual Industrial Hygiene Laboratory, Hopkinton, MA) after the first two patients used the service. Results were consistent with our previous experience and ranged from 1.2 to 180 ppm (Table, page 19). The service was again temporarily suspended while we investigated ways to mitigate further exposure. A second trial of the Pro-Nox™ delivery system yielded similar results with 71% above the NIOSH recommended limits. The decision to suspend nitrous oxide as an option for labor analgesia indefinitely was unanimous among our workgroup.

Although nitrous oxide for the management of labor pain has enjoyed decades of seemingly innocuous use, there has been a paucity of quality literature regarding its safety and effectiveness. A systematic review of nitrous oxide for the management of labor pain was recently published,² which sought to review the existing evidence for the effectiveness of nitrous oxide for labor analgesia, the influence of nitrous oxide on maternal satisfaction with the birth experience, and adverse effects associated with nitrous oxide. The authors identified 58 publications that met their criteria; however, the majority (46/58) of them were deemed of poor quality. The evidence for occupational harm associated with nitrous oxide is limited, and many of the studies that do exist were performed prior to modern scavenging techniques making evaluation of possible risk difficult. However, it should be noted obstetrical suites may not be designed with scavenging and ventilation systems that are present in modern operating rooms and dental suites.

The available data is insufficient to make evidence-based statements regarding maternal, fetal, or occupational health risks associated with exposures to nitrous oxide during labor. However, the

NIOSH recommended exposure limit of 25 ppm for health care workers is the current U.S. standard. We found that despite numerous attempts to decrease nitrous exposure to health care professionals, we were unable to consistently adhere to these guidelines resulting in the elimination of nitrous for labor analgesia at our institution.

We hope our experience will prompt other institutions that utilize nitrous for labor analgesia to routinely monitor levels for both the safety of the patients and health care personnel and prompt further research in this area. Until prospective, multicenter trials studying the short- and long-term effects of nitrous oxide for use in the obstetrical suites are conducted, we recommend frequent monitoring of nitrous oxide levels and adherence to NIOSH guidelines.

Benjamin Morley, MD
Lebanon, New Hampshire

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A Dear Dr. Morley:

The first point concerns a proper mask fit and recognition that a good mask fit requires skill and is critical to maintaining the lowest possible level of N₂O in an operating room.^{1,2,3} In the surgical suite the excess inspired and exhaled gases are collected from the circle breathing system or one of the Mapleson circuits. In this case the patient receives 50/50 nitrous oxide from a demand valve, which is closed until a negative pressure from the patient opens the valve and provides the 50/50 nitrous oxide mixture for the patient to inhale, very similar to functioning of the self-contained underwater breathing apparatus regulator (SCUBA). If the flow rate on the demand valve exceeds the patient's inspiratory flow rate, a poor mask fit will enable nitrous to escape into the room. A possible solution to the problem of a mask leak is to use a double mask as described by Reiz *et al.*⁴ However, mask leak is probably not the most significant source of trace nitrous oxide.

In the case of self-administered nitrous analgesia, one of the sources of environmental nitrous oxide is from the patient's exhaled breath. The patient is now exhaling significant amounts of

nitrous into the room to be taken up by anyone surrounding the patient. After the patient inhales the nitrous oxide and puts the mask aside, the exhaled gas will contain large quantities of nitrous oxide. Byhahn *et al.* demonstrated that mean concentrations of exhaled anesthetic gases in the recovery room and intensive care unit following surgery, exceed governmental standards for personnel exposure.⁵ If the patient emerges from anesthesia in the operating room, the concentration of anesthetic agents and nitrous oxide are often low enough to be unmeasurable by clinical monitoring systems as the patient is moved to the PACU. In this case, however, the exhaled breath starts at high concentrations of nitrous oxide, much greater than those in the PACU or ICU after surgery, and is exhaled into the patient's environment.

The solution to this problem may be found in the labor room air turnover rate and the use of non-recirculated air that is properly heated and humidified for each parturient's room. Each labor room, like each operating room, should have a very high fresh gas turnover rate using non-recirculated, conditioned (temperature and humidity) air. Design and construction of non-recirculated and conditioned air for each labor room may solve the problem of trace nitrous oxide concentrations, but may be prohibitively expensive.

A. William Paulsen, PhD, AA-C Chair, APSF Committee on Technology.

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A Rational Approach to Lymphedema Risk Reduction Practices

Q Dear Q&A,

We are writing to inquire about the Anesthesia Patient Safety Foundation's position on peripheral intravenous (IV) catheter placement or non-invasive blood pressure readings taken on the ipsilateral arm in patients who have undergone prior breast surgery. Historically, these patients have been taught to never allow the arm on the affected side to be used for any of these procedures due to concerns of causing lymphedema.

In our institution there are two policies in place reinforcing this practice of no blood draws, IV, or blood pressure cuff use on the affected arm, irrespective of whether the patient has any pre-existing lymphedema. These policies are directed towards our lab technicians who draw blood samples and our allied health care staff who manage the patients with peripheral intravenous catheters. Our institutional process includes placement of laminated warning cards on the front of the patient's chart and text in their electronic medical record stating no blood pressure cuff readings or IVs on the affected arm.

This issue can cause significant distress and confusion among this patient group and the medical support staff caring for them. Frequently, our anesthesia professionals have to spend a significant amount of time discussing the issue with the patients. This discussion often takes place at a time when the patients are already under duress from their impending surgery. Furthermore, our breast cancer surgeons at our institution do not feel there is any evidence to preclude using the IV or blood pressure cuff on the affected side in the absence of pre-existing lymphedema.

A recent prospective study done at Harvard by Ferguson *et al.* looked at 632 mastectomy patients with invasive breast cancer over a period of 5 years and did not show any link between IV placement or blood pressure cuff placement and lymphedema.¹ The accompanying editorial in the same journal issue also questions the current practice and suggests it is time to abandon old practices.

Our local perioperative quality committee is in the process of revisiting our current policies regarding this issue. It will require significant education and change management amongst many levels of health care providers within our institution. Perhaps a position statement or guideline from our anesthesia governing bodies (using this high-grade evidence) would help support implementing these changes. In light of this recent evidence in the literature, does the APSF know of or have any such policies or guidelines?



Figures 1A and 1B: Fig. 1A figure depicts a patient with significant lymphedema. Fig 1B depicts a patient with lymphedema wearing a compression garment.

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Gregory R. Dobson, MD, FRCPC, Director of Quality and Patient Safety, Dept of Anesthesia, Dalhousie University, Halifax, NS, Canada.

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A Dear Dr. Milne:

(From the Editors: The APSF does not have a formal position on this issue. We have recruited Drs. Feldman and Nudelman who are experts on the topic of lymphedema to provide a response to these concerns.)

The risk of developing Breast Cancer Related Lymphedema (BCRL) is a major concern to breast cancer patients. The necessity of adhering to lymphedema risk reduction practices has been questioned and rebutted.^{1,2} Drs. Milne and Dobson cite the Ferguson Massachusetts General Hospital observational study where patients undergoing treatment for breast cancer between 2005 and 2014 had bilateral arm volume measurements pre and postoperatively using a Perometer. The authors implied that a 10% increase in volume was synonymous with BCRL. Perometry criterion will not diagnose lymphedema in patients with subclinical or mild lymphedema, variable changes, or lymph-

edema in the hand, breast, or trunk. The conclusion was that venipuncture, injections, blood pressure readings, and air travel "may not" be associated with arm volume increases, a narrow finding and not a definitive conclusion. Debunking the long-standing practices of lymphedema risk reduction practices is not warranted based on the available evidence.

Lymphedema is an inflammatory edema that can occur due to disruption of lymph flow secondary to axillary node dissection or axillary radiation and results in the development of interstitial fibrosis and subcutaneous adipose deposition.³ The lymphedema not only involves the arm but can involve the adjacent trunk and, if conserved, the breast. Other risk factors include cellulitis, BMI >25, and possibly a genomic risk.⁴ One of the lymphatic system's main functions is host defense. There is an increased risk of cellulitis in at-risk individuals and individuals with lymphedema. Erysipelas may be the first sign of subclinical lymphedema.⁵

The protective measures are based on the physiological principles of taking care not to do anything that puts the reduced transport capacity at risk or that may increase the lymphatic load.⁵ Risk reduction practices include avoiding taking blood pressure readings and avoiding invasive procedures in the at-risk extremity. They are also based on years of experience treating at-risk individuals and lymphedema patients.⁶ The risk reduction practices have been called "burdensome" to

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Decision to Override Lymphedema Risk Reduction Practices is a Multidisciplinary, Clinical One

“Q&A,” From Preceding Page

patients and clinicians but certainly less of a burden than living with lymphedema.

Although BCRL usually occurs within 3 years postoperatively, there is a lifelong risk of developing lymphedema.⁷ Lymphedema can be latent or obvious. Lymphedema can cause physical symptoms such as limb heaviness and discomfort and possibly reduce arm function. Diagnostic sensitivity is increased with validated symptom surveys and clinical assessment. Breast conservation and radiation therapy (RT) can be associated with breast lymphedema. Lymphedema creates an economic and emotional burden.⁸ There is no cure for lymphedema although the condition can be managed by a certified lymphedema therapist through an individualized program of complete decongestive therapy (CDT), wearing compression garments (see Figure 1B, page 21), and a lymphedema exercise program.

The risk of developing lymphedema is less for SLNB (Sentinel Lymph Node Biopsy) patients than for ALND (Axillary Lymph Node Dissection) patients, but the risk is not zero. A recent publication stated that the overall two-year cumulative incidence of lymphedema was 10% for SNLB + RT compared with 19.3% for ALND-no RT and 30.1% ALND + RT.⁹

The methodology for detecting lymphedema is far from perfect and there are no universal diagnostic criteria. Lymphedema is a clinical diagnosis, but in an effort to introduce objective criteria, various volume calculations and tissue fluid measurements have been adopted. Lymphedema can be present without volume increases and no objective volume increase has been proven to accurately diagnose lymphedema. There is no agreement on what deviation from baseline measurements represents a significant increase. Various investigators have considered increases ranging from 3% to 10% to be significant.¹⁰ Recent direct studies of the lymphatic pump demonstrate that at-risk women have high pump function in both arms, but this objective measurement is not widely available.

Arm volumes can be calculated from the arm measurements, by direct volumetry using the water displacement method or perometry. Perometry is not widely available due to equipment cost and does not measure hand or chest volume. Bioimpedance measurements can also help detect early fluid accumulation, but there is limited access to this technology due to cost.

The National Lymphedema Network (NLN) position paper on Lymphedema Risk Reduction Practices offers a rational approach to risk reduction.¹¹ Ideally, a member of the cancer treatment team or a lymphedema professional should discuss the lymphedema risk factors and the risk reduction practices with the at-risk individual. Recognizing that medical necessity may override the precautions, the NLN position paper summary states that “If possible, avoid punctures such as injections and blood draws,” and “If possible, avoid having blood pressure taken on the at-risk extremity, especially repetitive pumping.” The decision to override the risk reduction practices has to be based on weighing the multiple factors unique to the at-risk individual. Földi and Földi state, “In an emergency, the anesthesiologist’s attention should not be diverted for a single second.”¹²

Cellulitis is a known lymphedema risk factor.¹³ The most common bacteria associated with cellulitis is *β-Streptococcus*. In patients with lymphedema or at risk, especially patients with a history of cellulitis, perioperative antibacterial treatment will decrease the risk of cellulitis.

The recent article by Ferguson *et al.* drew a narrow conclusion that in the minority of women who experienced at-risk behaviors, cellulitis was significantly associated with swelling in both the univariate and multivariate analyses, while trauma approached significance in the univariate analysis ($p = 0.08$). Another prospective study showed venipuncture associated with swelling.¹³ There are no objective criteria to document immediate damage or triggering of lymphedema by iatrogenic trauma to the at-risk arm/quadrant, but clinical experience and the literature show that infection, venipuncture, and trauma can provoke swelling. Therefore, the prudent medical approach should be to limit unnecessary trauma to the at-risk arm/quadrant. Patients and providers should be thoroughly educated on the risks, the limitations of knowledge, the limitations of diagnosis of the condition, the possible delay in developing lymphedema, and, with this full knowledge, engage in shared decision-making. The current state of knowledge is that some risk is involved with traumatizing an at-risk limb and that no objective criteria exists for diagnosis. If an incurable disease can be prevented by limiting iatrogenic trauma, medical providers should strive to avoid these actions. Traumatizing an at-risk limb has not been proven to never provoke swelling and/or lymphedema, and clinical guide-

lines should reflect the evidence and clinical experience that indicates risk.

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The authors report no conflicts of interest for this article.

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To Err is Human; To Tolerate, Inhumane

by Joe Kiani and Thornton Kirby

“The greatest danger for most of us isn’t that our aim is too high and we miss it, but that it is too low and we reach it.”

—Michelangelo

Technology and pharmacology have transformed health care in our modern world. We are fortunate to live in an age when dedicated health care professionals have at their disposal the tools that enable them to deliver the miracle of healing. Yet despite these gains, too many patients still suffer from preventable human errors that result in permanent harm or death.

In 1999, the Institute of Medicine (IOM) published the report “To Err is Human,” and concluded nearly 100,000 patients die from medical errors annually in the United States.¹ A recent study by Dr. Martin Makary and colleagues at Johns Hopkins University puts the devastating number at over 250,000 annually.² Makary calls for the Centers for Disease Control and Prevention to increase the pressure to reduce patient harm by adding medical errors to the CDC’s annual list of the leading causes of death.

Despite these sobering statistics there is cause for optimism. Our two organizations have encountered exceptional colleagues who have demonstrated that it is possible to improve patient care and reduce the frequency of harm in health care settings. We have also discovered that it is easy to get caregivers to embrace a philosophical goal of zero harm, but it is a much more daunting task to have them establish zero as their operational goal.

Today health care organizations take a more proactive approach to preventing harmful events such as health care-associated infections, yet we have a long way to go if we are to catch up with our counterparts in other industries. Consider the following comparison between commercial aviation and hospitals by Dr. Mark Chassin, president of The Joint Commission and a champion of high reliability in health care.³

Between 1990 and 2001, United States commercial airlines flew 9.3 million flights per year and had 129 deaths per year, equivalent to a death rate of 13.9 deaths per million flights. In response, U.S. airlines retooled their operations based on a safety culture built on the principles of high reliability organizations. Between 2002 and 2010, airlines flew 10.6 million flights per year with 18 deaths per year,

equivalent to 1.74 deaths per million flights representing an 87% reduction in merely a decade.

In 1999, the Institute of Medicine estimated that as many as 98,000 deaths occurred in hospitals each year due to errors in care.¹ Estimated deaths corresponded to 34.4 million hospitalizations per year, equivalent to a death rate of 2,800 deaths per million hospitalizations. If we apply Dr. Makary’s recent estimate of 250,000 annual deaths against the same 34.4 million hospitalizations, we would calculate a rate of 7,300 deaths per million hospitalizations. In these comparisons between aviation and hospital settings we note a stark difference. Clearly there is work to be done.

Preventable errors still happen far too often. In 2001, the National Quality Forum (NQF) disseminated a list of what they coined “Never Events”—errors that should never occur in any hospital, no matter the setting.⁴ As of 2011, the list includes 29 events grouped into 6 categories.⁵ Most notable, although rare, are wrong-site, wrong-patient, and wrong-procedure surgeries. Other more frequent events include medication errors, falls, and pressure ulcers. In 2007, the Centers for Medicare and Medicaid Services (CMS) announced that they would no longer pay for additional costs associated with preventable errors.⁶

One of the contributing factors to health care’s poor safety record is how organizations set improvement goals. Most hospitals set annual goals to reduce harm by some percentage over the previous year. However, there is a fundamental flaw in this approach: it implies that some number of harm events is acceptable, although the intent in setting improvement goals is quite to the contrary.

Generally speaking, fear of failure and lack of leadership commitment seem to be the two greatest obstacles. Let’s consider the most frequent objections and how they can be most effectively countered.

Frequent Objections

“Zero harm is not possible.” The most frequent objection to zero harm goals is grounded in science and statistics. Many health care professionals acknowledge they wish they could eradicate patient harm, but they do not believe it’s possible to completely eliminate medical errors.

“Our compensation system penalizes zero goals.” An increasing number of health systems have established executive compensation incentives tied to quality indicators. Therefore executives may be reluctant to set goals of zero harm for fear of being penalized.

“I can’t control the front-line providers.” A few hospital executives refuse to set zero harm goals because they cannot control the front-line clinicians who must deliver the outcomes.

“We can’t achieve zero harm across the board.” There are some leaders who mistakenly believe that establishing a zero harm goal necessarily requires establishing zero as the goal for all patient harm indicators tracked by the organization.

Successful Responses

Start by setting a goal of Zero Preventable Deaths (not harm). This strategy was adopted by the Board of Trustees at Children’s Hospital of Orange County (CHOC), CA, with the support of the entire team. Clinicians and hospital administrators feel it is more manageable to strive for zero preventable deaths than to achieve zero harm across the board.

Zero harm is possible. The South Carolina Hospital Association (SCHA) has partnered with The Joint Commission Center for Transforming Healthcare to pursue high reliability. The Memorial Hermann Health System in Houston has been on this journey for years, and presents zero harm awards to its hospitals when they demonstrate 12 consecutive months without harm. The SCHA created a similar “Certified Zero Harm Award,” and in the first 3 years received 258 awards.

Compensation systems should be redesigned to encourage zero harm goals. Rather than establishing compensation incentives that require perfect performance, it may be more prudent to set goals of zero preventable deaths, and tie compensation incentives to progress toward the goal.

Pursuing zero harm is not about controlling behavior, it’s about building a culture of safety. One of the defining characteristics of high reliability organizations is a culture of safety, and that message comes from the top. Once the expectation has been articulated and reinforced, individual behaviors begin to change throughout the organization without constant oversight by leadership.

Start with a goal of zero in one area, and build on that. Although zero harm is the ultimate goal, a complex medical system is unlikely to achieve zero on all harm indicators at once. Instead, hospitals should choose one area of strong performance, and strive to eliminate harm in that area.

Implement processes to prevent human errors from becoming fatal to patients. If your hospital is reluctant to set zero as the objective, then ask them to implement the processes that can help avoid

See “Zero Harm,” Next Page

Obstacles/Potential Solutions to Achieving Zero Harm

“Zero Harm,” From Preceding Page

preventable deaths.⁷ Implement good processes and save lives.

These are the most frequent objections we’ve encountered, but our list is not exhaustive. We are not naïve enough to think preventable harm will be forever eliminated in health care settings, but we have seen firsthand the significant progress being made in a small number of organizations in the pursuit to zero.

To err is human, but to tolerate error (by refusing to adopt processes known to prevent human errors from causing harm or death) is inhumane.

The authors wish to express our gratitude and respect for the caregivers who have been so open with us in exploring this topic. Few clinicians or leaders in health care have been willing to set goals of zero, so we are deeply grateful to those who have dedicated themselves to helping us learn what it will take to set the right bar for our industry’s performance.

Thornton Kirby is president and CEO of the South Carolina Hospital Association, an organization committed to zero preventable harm by adopting high reliability principles in a health care setting. Thornton is also a Regional Chair of the Patient Safety Movement Foundation.

Joe Kiani is chairman and CEO of Masimo and founder of the Patient Safety Movement Foundation, a commitment-based and collegial organization that has established a goal of zero preventable deaths by 2020. For more information on processes you can use to eliminate preventable deaths, go to: www.patientsafetymovement.org or <http://patientsafetymovement.org/>

challenges-solutions/actionable-patient-safety-solutions-apss/)

Conflicts of interest: Joe Kiani is an employee of Masimo Corporation and is the founder of the Patient Safety Movement Foundation. Mr. Kiani is also a board member at the Children’s Hospital of Orange County, CA. Thornton Kirby is an employee of the South Carolina Hospital Association, and is a regional chair of the Patient Safety Movement Foundation.

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Letter to the Editor:

TAVRs under MAC: Debate Continues!

To the Editors:

In the February 2017 article entitled “The Anesthesia Professional’s Role in Patient Safety During TAVR (Transcatheter Aortic Valve Replacement),”¹ Drs. Novak and Parulkar concisely elucidate a number of points in the care of TAVR patients. In particular, they present a thoughtful analysis of the current data on choice of anesthetic for these cases. While performing TAVR under sedation seems to be growing in popularity, there are lingering concerns as to whether this is truly the best practice. In addition to the authors’ points, I would opine that there is an element of added risk attendant to employing sedation rather than general anesthesia.

While TAVR under MAC appears safe, and serious problems are infrequent, they are problems for which we should be ready. Almost nothing in our daily practice is usually a problem, but prudent anesthetic practice means preparing for worst-case sce-

narios, not just the usual scenarios. In a TAVR, that worst-case scenario is cataclysmic hemodynamic collapse necessitating emergent cardiopulmonary bypass. Neglecting to secure the airway and monitor with TEE leaves us unequivocally under-prepared for that scenario, in which seconds truly matter.

*Sincerely,
Nathaniel F. Simon, MD
Chief, Department of Anesthesia
Sutter Medical Center Sacramento
Sacramento, CA*

Dr. Simon has no disclosures.

Reference:

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Letter to the Editor:

Anesthesia Safety Concerns for CT-Guided Tumor Cryoablation and the Risk of the Frozen Instrument

by Medhat S. Hannallah, MD, Raj Parekh, MD, and Shahine Baghai, MD

Cryoablation is increasingly used to treat unresectable malignant tumors. During cryotherapy it may not be possible to immediately remove the freezing element from an organ in an emergency without active thawing. We recently cared for a patient that illustrated the risk of the frozen instrument during cryotherapy of the kidney in the prone position and the benefits of proactive communication.

A 65-year-old man was scheduled for a computed tomography (CT)-guided percutaneous cryoablation of a right kidney tumor. The patient had multiple medical problems including obesity, obstructive sleep apnea, and a difficult airway. The procedure, which was to include multiple advancements and withdrawals of the patient inside and outside of a CT scanner, was to be performed under general anesthesia with an endotracheal tube and in the prone position.

Once the freezing process was initiated, the patient could not be immediately turned supine in the event of an emergency.¹ Therefore, the interventional radiology (IR) team agreed to verbally notify the anesthesia team who would perform a quick check to rule out any airway or hemodynamic issues. The treatment was concluded uneventfully and the patient was turned to the supine position and his trachea was extubated upon full awakening.

Percutaneous cryoablation is increasingly utilized to treat small renal masses that are concerning enough to warrant treatment but reside in poor surgical candidates.² Renal masses are frequently approached posteriorly which requires the patient to be in the prone position. The probes will be firmly anchored to the patient's tissues during the tumor freezing process. They are either allowed to thaw spontaneously, which takes approximately 10 minutes, or they are actively thawed, which takes up to 2–3 minutes. Any attempt to forcibly remove the probes prior to complete thawing may result in tissue avulsion and hemorrhage.³

This patient had multiple comorbidities that increased his risk of complications in the prone position. The fact that the frozen probes could not be immediately removed in an emergency meant that the patient could not be immediately turned supine. The IR team, therefore, alerted the anesthesia team each time freezing was about to start.

Cryoablation of kidney tumors is sometimes performed with the patient placed in the decubitus position with the treatment side down.⁴ The decubitus position allows access to the airway but



*John E Eberts, HealthTronics, Inc, Austin, TX

Figure 1: Four cryoablation probes placed through dermal incisions with patient in the prone position.

would compromise the efficacy of cardiopulmonary resuscitation.

During cryotherapy the anesthesia professional needs to be familiar with the potential risk of the frozen instrument. Communication with the proceduralist before the start of each freezing cycle is important for patient safety.

Dr. Hannallah is an Associate Professor in the Department of Anesthesiology at Medstar Georgetown University Hospital in Washington, DC.

Dr. Parekh is a resident physician in the Department of Anesthesiology at Medstar Georgetown University Hospital in Washington, DC.

Dr. Baghai was an interventional radiology fellow in the Department of Radiology at Medstar Georgetown University Hospital, and is currently employed with Mid-Atlantic Permanente Medical Group, Rockville, MD.

Drs. Hannallah, Parekh, and Baghai report no conflicts of interest for this article.

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Erroneous Placement of Antimicrobial-Impregnated Central Venous Catheter in a Patient Susceptible to an Allergic Reaction

by Diosdado Baja, MD, Terry Vien, DO, and Neil Ray, MD

Introduction

Central line-associated bloodstream infections (CLABSI) have been associated with thousands of preventable deaths and billions of dollars of additional costs to the US health care system.¹ Many institutions in recent years have prioritized preventing such infections. However, a substantial number of CLABSIs continue to occur, especially in high-risk areas of the hospital. An advancement widely implemented by many institutions is the use of antimicrobial-impregnated central venous catheters (CVC) to decrease the incidence of CLABSI and its associated morbidity and excess cost.² We report a case of an antimicrobial coated CVC that was erroneously placed in a patient, who was susceptible to an allergic reaction.

Case Report

A 33-year-old male with congenital hypertrophic obstructive cardiomyopathy status post myomectomy and subaortic resection with aortic valve repair, presented with acutely progressive shortness of breath, lightheadedness, and chest pain. He was notably noncompliant with therapy and a poor historian. Our providers elicited a sulfa allergy but the patient was unsure of the specific reaction. He was scheduled for a surgical aortic valve replacement requiring a redo sternotomy. Central venous access was indicated for central venous pressure (CVP) monitoring and infusion of vasoactive medications post cardiopulmonary bypass. A CVC impregnated with chlorhexidine/silver sulfadiazine was placed in the patient after the induction of general anesthesia. He did not manifest any clinical signs of an allergic response to the sulfa containing CVC. Upon identifying the error, the line was converted to a non-antimicrobial impregnated CVC before the end of the procedure. The patient was extubated on postoperative day (POD) #0 in the CTICU, weaned off vasoactive medications by POD#2, and was discharged on POD#8.

Discussion

Two types of antimicrobial coated CVCs are available on the market and for certain indications (such as CVCs expected to remain in place for >5 days in institutions where CLABSI rates are not decreasing despite implementation of CLABSI reducing strategies), carry a Category 1A recommendation from the CDC to reduce infections: minocycline/rifampin, and chlorhexidine/silver sulfadiazine.³ It has been our experience that anesthesia providers are often unaware of

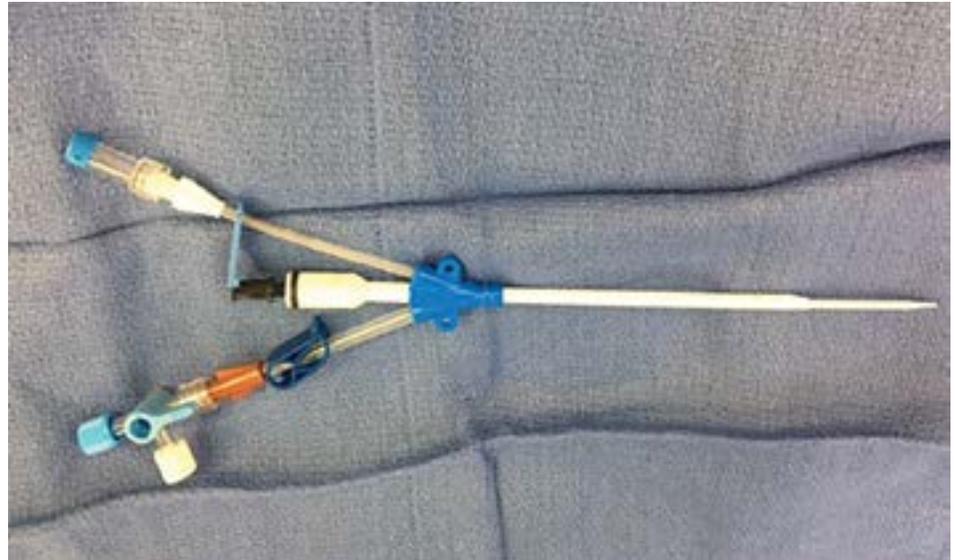


Figure 1. Central Line.

which specific type of antimicrobial coating is used at their institution. Furthermore, we have noted that the packaging of CVC does not clearly elucidate the risks of allergic reactions. This incident represented a medication error that resulted in a “near miss.” It also led to the separation of antibiotic and non-antibiotic coated central line catheters at our institution’s trauma and cardiac operating rooms. Their present use is based on the discretion of the surgical and anesthesia teams. Furthermore, our department as a whole became more cognizant of the indications and contraindications for antibiotic/antiseptic-coated CVC use. Other institutions may benefit from reviewing their guidelines for CVC use as this may have significant impact on patient safety.

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Dr. Vien is a Pain Fellow at UC Davis Medical Center, Sacramento, CA.

Dr. Ray is Assistant Professor at UC Davis Medical Center, Sacramento, CA.

The authors have no financial interest or other conflicts of interest to disclose.

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Letter to the Editor:

The Role of Capnography to Prevent Postoperative Respiratory Events

To the Editor:

Dr. Geralemou and colleagues make an excellent argument for capnography monitoring in the postoperative period for evidence of hypoventilation in their October 2016 *APSF Newsletter* article entitled "The Role of Capnography to Prevent Postoperative Respiratory Adverse Events." However, that doesn't necessarily mean capnography should be recommended as a standard outside the operating room. In the postoperative setting, there is little published data on the sensitivity, specificity, and predictive value of capnography, nor its relative merit as compared to other respiratory monitoring techniques such as acoustic monitoring or plethysmography. In my own personal experience, the use of capnography is associated with a very high false alarm rate, which could naturally result in alarm fatigue. An aggressive pursuit of research to assess the value of postoperative respiratory monitoring on patient outcomes should commence. Until then, caution should be used to definitively anoint capnography as a recommended standard based upon our current knowledge.

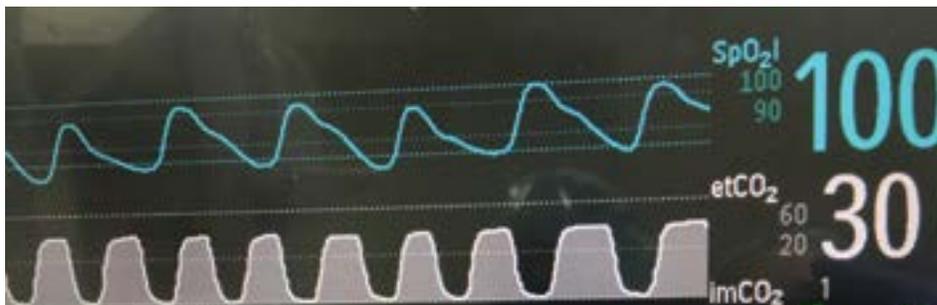


Figure 1. Pulse oximetry and capnography waveforms.

*David Bronheim
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In Reply:

Dear Dr. Bronheim:

I agree that capnography is not perfect and our experience in the operating room cannot be easily translated to non-critical care areas. There is a large body of evidence to suggest that spontane-

ously ventilating patients can be monitored effectively when using the correct sampling lines. I think that use of capnography in non-critical care areas requires a significant education for those taking care of the patients. I do agree that other methods such as acoustic monitoring of breath sounds, plethysmography, microwave radar, and other techniques have not been compared to capnography in order to establish the techniques with the best sensitivity and specificity.

*Bill Paulsen, PhD
Chair, APSF Committee on Technology*



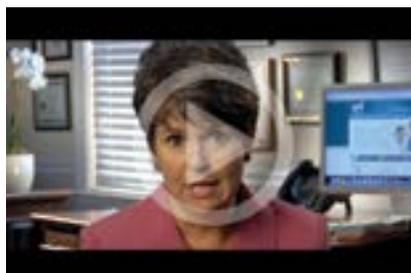
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