

## About Bloody Time!

### *Interventional Spine and Pain Procedures in Patients on Antiplatelet and Anticoagulant Medications: Guidelines From the American Society of Regional Anesthesia and Pain Medicine, European Society of Regional Anaesthesia and Pain Therapy, American Academy of Pain Medicine, International Neuromodulation Society, North American Neuromodulation Society, and World Institute of Pain*

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In this issue of *Regional Anesthesia and Pain Medicine*, Narouze et al,<sup>1</sup> representing the American Society of Regional Anesthesia and Pain Medicine (ASRA), the European Society of Regional Anaesthesia and Pain Therapy, the American Academy of Pain Medicine, the International Neuromodulation Society, the North American Neuromodulation Society, and the World Institute of Pain, have published a guideline for Interventional Spine and Pain Procedures in Patients on Antiplatelet and Anticoagulation Medications. This groundbreaking article is the first guideline tailored to the performance of pain procedures in patients taking antiplatelet and anticoagulant medications and the first multisociety guideline addressing this topic. The American Society of Regional Anesthesia and Pain Medicine is the recognized leader in this area and published the first guideline addressing neuraxial procedures for anesthesia and postoperative analgesia as a supplement to the journal in 1998.<sup>2</sup> The first guideline was created in response to a US Food and Drug Administration (FDA) request after multiple spinal/epidural hematomas were reported via the FDA MedWatch Program in patients taking low-molecular-weight heparin (enoxaparin) for deep venous thrombosis prophylaxis after its introduction to the United States. The ASRA guidelines have become the generally accepted standard of practice. The American Society of Regional Anesthesia and Pain Medicine has gone on to publish updated guidelines in 2003<sup>3</sup> and 2010<sup>4</sup> with a fourth edition scheduled to be published in 2015. Each of these guidelines used research data when available, pharmacology for new agents, and experience with existing agents gathered during the publication intervals to strengthen recommendations and expand their reach. Initially, the guidelines focused solely on neuraxial anesthesia and analgesia, but, as time went by and the performance of peripheral nerve blocks expanded; recommendations were modified and guidance was offered regarding the performance of peripheral nerve blocks in the presence of antiplatelet and anticoagulant agents. In concert with the growth in regional anesthesia/analgesia, the field of pain medicine experienced significant growth in the number of practitioners; the number, type, and complexity of procedures being performed; and the number of complications being reported, including complications related to antiplatelet and anticoagulant medications. In most cases, pain practitioners simply adopted the ASRA guidelines and applied them to their pain practices. However, many practitioners felt the guidelines were neither conservative enough for patients undergoing certain types of pain procedures or procedures performed in certain locations nor liberal enough in some circumstances (eg, procedures for the terminally ill) and modified their practices to address their concerns. In most cases, existing guidelines were sufficient for low- and intermediate-risk procedures. However, many felt that a guideline specifically addressing high-risk pain procedures was needed to improve patient safety.

An open forum addressing anticoagulation/antiplatelets and pain procedures was held during the 11th Annual ASRA Pain Meeting, November 15 to 18, 2012, in Miami, Florida. During this forum, a survey was conducted to assess current practice and identify areas of concern. Most of the respondents (98%) followed the ASRA regional anesthesia guidelines for anticoagulants but not for antiplatelet agents.<sup>1</sup> In particular, there was marked variation in protocols regarding aspirin or nonsteroidal anti-inflammatory

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drugs. In addition, there were variations depending on the type and location of the procedure. Respondents were more conservative for procedures being done in the cervical or thoracic spine or for advanced procedures requiring large needles or multiple manipulations within the spinal canal such as kyphoplasty or spinal cord stimulation trials and implants. The survey also identified a general lack of awareness regarding the anticoagulant effects of selective serotonin reuptake inhibitors on platelets and bleeding risk. In 2014, Benzon and Huntoon<sup>5</sup> posed the question “Do We Need New Guidelines for Interventional Pain Procedures in Patients on Anticoagulants?” in their editorial addressing 2 manuscripts reporting spinal epidural hematomas in patients whose only apparent risk factor was the use of aspirin (ASA). In their editorial, the authors highlighted 9 publications reporting spinal hematoma after interventional pain procedures in addition to those being published in the journal at that time. In response to the survey results and the expressed need for a set of guidelines specifically designed to improve patient safety during the performance of interventional spine and pain procedures, the ASRA Board of Directors recommended that the society’s journal, *Regional Anesthesia and Pain Medicine*, appoint a committee to develop a separate set of guidelines for pain interventions.

There is no question that interventional pain procedures are associated with significant risks. The relative risks of interventional pain therapies have been increasing in concert with advances in pain therapies and the increased medical judgment and technical skill necessary to perform them safely and effectively. In addition to the technical risks associated with interventional pain procedures, pain patients frequently have other risk factors including significant anatomic abnormalities; prior surgical procedures; hormonal changes; and renal, hepatic, and metabolic abnormalities. The increased frequency of complications associated with pain procedures has been evident in growing numbers of published case reports, case series, and malpractice suits. In a 2004 publication derived from data maintained within the American Society of Anesthesiologists (ASA) Closed Claims Project, Fitzgibbon et al<sup>6</sup> identified and described issues and trends in liability related to chronic pain management by anesthesiologists. The authors reviewed the closed claims database between 1970 and 1999 to identify liability related to chronic pain management. They excluded all claims related to acute pain management. They compared outcomes and liability characteristics of 284 pain management claims to 5125 surgical/obstetric claims. Claims related to chronic pain management increased over time in concert with the growth in pain medicine. They accounted for 2% of all claims in the 1970s, 3% in the 1980s, and 10% in the 1990s. Payments for chronic pain management claims were lower than surgical/obstetric claims from 1970 to 1989. During the 1990s, there was no difference in size of payments between chronic pain management and surgical/obstetric claims. Almost one third of chronic pain management claims resulting in payment in the 1990s involved a permanent and disabling injury as compared with only 17% from 1979 to 1989, although this difference was not considered statistically different. In 64% of chronic pain management claims, the injury became apparent after discharge from the treatment facility. Of the 284 chronic pain management claims in the database, 276 involved invasive procedures. Epidural steroid injections accounted for 83% of injections and 40% of all chronic pain management claims. In 2010, Rathmell et al<sup>7</sup> compared cervical procedures with other chronic pain claims collected from 2005 through 2008 in the ASA Closed Claims Database. The data in this article are notable for not only the dramatic number of claims related to cervical procedures, but also the fact that more chronic pain claims were entered in a 4-year period than in the entire previous review of chronic pain claims for

a 30-year period. The ASA Closed Claims database and the individual case reports and case series published in the medical literature represent only a fraction of the total number of complications occurring with the millions of interventional pain procedures performed each year. The true picture of complications is obscured as there is no readily identifiable source of data regarding the overall incidence of complications and no other professional society maintains a closed claims database examining pain procedures like the ASA. In addition, the impact of the enormous growth in the overall number or complexity of procedures being performed or the relative risks associated with who was performing the procedure (eg, a non-pain-trained interventional spine physician, other physicians without formal pain training, or non-physicians with no pain training) has not been examined.

The role of training and knowledge in the incidence and severity of complications related to interventional pain procedures has not been examined, but the ASRA survey performed in 2012 clearly identified some knowledge deficits related to anticoagulant effects of medications that may contribute to increased risk. In addition to anatomic, pharmacologic, and physiologic risk factors, the technical aspects of performing procedures play a role in the risk of complications related to bleeding and limiting the number of needle or catheter manipulations will reduce the risks. The range of training received before the performance of interventional pain procedures is variable and ranges from fellowship-trained pain medicine physicians with board certification to physicians with some exposure during residency to non-physician providers with no formal pain training. In most cases, the public lacks sufficient sophistication to inquire about the extent of training or board certification before undergoing procedures and, in some cases, there is active misrepresentation of credentials. The importance of addressing all of the potential risk factors related to the performance of interventional pain procedures to improve patient safety is underscored by this article.

The authors have exerted a monumental effort in creating this guideline. They assembled a diverse, well-respected group of authors to perform an exhaustive review of the medical literature and create a guideline that is based on evidence where available, pharmacology, and consensus opinion. The recommendations are made in the context of procedure type, anatomic location, anatomic and physiologic risk factors, drug characteristics, pharmacokinetics, and pharmacodynamics. The article is extensively referenced, including 420 references to build the case and support the recommendations. The body of the article provides an extensive and detailed rationale for each of the recommendations addressing each of the drug classes and the nuances of the risks associated with each drug. The authors have created tables summarizing the article’s high points. Table 1 categorizes common pain procedures into high-, intermediate-, and low-risk procedures that put the recommendations into context. Tables 2 through 7 address each of the various drug classes and provide recommended discontinuation intervals for each of the drugs that have effects on coagulation. Table 8 provides an overview of recommended procedural management for patients taking antiplatelet and anticoagulant therapy. Finally, Table 9 summarizes all of the recommendations into one place with columns highlighting the drug, when to stop for high-, intermediate-, and low-risk procedures and when to restart the drug. Although the entire article should be required reading for all physicians performing interventional pain procedures, the information assembled in Table 9 provides a fast and easy summary to guide clinical practice.

As with any guideline or set of recommendations, there will be those who disagree with the content, the process, and the final product. However, this work represents a very solid and long-overdue starting point to improve patient safety for patients taking

antiplatelet and anticoagulant medications who will be undergoing interventional pain procedures. The absence of randomized studies or large numbers of patients from pooled databases to serve as the basis of this guideline does not diminish the need for the guideline or the effort put forth by the authors to create a reasonable set of recommendations to guide clinical practice. The guideline will be tested in the crucible of actual clinical practice and future editions will be modified on the basis of outcomes observed in the interval between now and the next edition. I believe that this article should be required reading for all interventional pain practitioners interested in practicing state-of-the-art medicine. I challenge ASRA and the other contributing societies to provide forums for feedback on the implementation and outcome of these new guidelines so that revisions can be made in a timely and ongoing fashion to keep up with the rapidly changing face of pain medicine and the ever-changing pharmacologic world of antiplatelet and anticoagulant medications. The authors and societies have much to be proud of and should be thanked for taking on this gargantuan task. Products like this multisociety guideline will help us all achieve our shared goal of improving both safety and outcome.

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