Pain Physician 2010; 13:109-116 • ISSN 1533-3159

Perspective

A Perfect Storm in Interventional Pain Management: Regulated, but Unbalanced

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Disclaimer: There was no external funding in the preparation of this manuscript.
Conflict of interest: None.

Manuscript received: 03/02/2010
Accepted for publication: 03/10/2010

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Interventional pain management now stands at the crossroads at what is described as "the perfect storm." The confluence of several factors has led to devastating results for interventional pain management. This article seeks to provide a perspective to various issues producing conditions conducive to creating a "perfect storm" such as use and abuse of interventional pain management techniques, and in the same context, use and abuse of various non-interventional techniques. The rapid increase in opioid drug prescribing, costs to health care, large increases in death rates, and random and rampant drug testing, can also lead to increases in health care utilization. Other important aspects that are seldom discussed include medico-legal and ethical perspectives of individual and professional societal opinions and the interpretation of diagnostic accuracy of controlled diagnostic blocks.

The aim of this article is to discuss the impact of several factors on interventional pain management and overuse, abuse, waste, and fraud; inappropriate application without evidence-based literature support (sometimes leading to selective use or non-use of randomized or observational studies for proving biased viewpoints — post priori rather than a priori), and issues related to multiple professional societies having their own agendas to push rather than promulgating the science of interventional pain management.

This perspective is based on a review of articles published in this issue of *Pain Physician*, information in the public domain, and other relevant articles. Based on the results of this review, various issues of relevance to modern interventional pain management are discussed and the viewpoints of several experts debated.

In conclusion, supporters of interventional pain management disagree on multiple aspects for various reasons while detractors claim that interventional pain management should not exist as a speciality. Issues to be addressed include appropriate use of evidence-based medicine (EBM), overuse, overutilization, and abuse.

Key words: Interventional pain management, interventional techniques, physician payment reform, fraud, abuse, evidence-based medicine, health care costs, comparative effectiveness research, bias

Pain Physician 2010; 13:109-116

Manchikanti et al (1) in this issue describe the confluence of many factors leading to devastating results for interventional pain management. This issue also contains multiple other manuscripts describing the role of urine drug testing, alleged interference to access due to the policies of urine drug testing, medical-legal perspectives of individual opinions, and making sense of the diagnostic accuracy of controlled diagnostic blocks (2-5).

Manchikanti et al (6,7) described the escalating pace of innovation in health care and interventional pain management with the constant addition of broad and complex areas of interventions. They also described the role of pervasive and persistent unexplained variability in clinical practice and high rates of perceived inappropriate care, combined with increased expenditures, fueling a steadily increasing demand for evidence of clinical effectiveness, to oppose unbalanced growth in interventional pain management (8-11). Consequently, a body of evidence has been demanded regarding safety, effectiveness, appropriate indications, cost-effectiveness, and other attributes of medical care. Failure to understand which services work best under which circumstances, and for which type of patients, contributes to the increasing cost of care, patient safety, and the avoidable loss of life, with any type of practice of medicine. While the United States has the most expensive health care system in the world by a large margin, it has been claimed by many measures of public health that it ranks lower among the western nations (12). Manchikanti et al (1) describe the impact on interventional pain management based on payment systems (physician office, ambulatory surgical center, and hospital outpatient department payments); overuse, abuse, waste, and fraud; inappropriate application without evidence-based literature; and organizational issues related to multiple societies.

Allegations of Lack of Evidence for Interventional Pain Management

Interventional pain management has been criticized for lack of evidence demonstrating an increasing prevalence of chronic pain in general and, in particular the lack of effectiveness of interventional techniques. As detailed by Manchikanti et al (1,13), there is substantial evidence with regards to escalating disabilities and the economic impact of chronic pain. In fact, a recent study by Freburger et al (14) showed an annual increase of 11.6% in the overall prevalence of low back pain across all demographic groups. In addition, the controversial issues of duration and chronicity of pain have been resolved based on extensive literature illustrating that chronic pain lasts for months to years with tendencies to recur and relapse (1,13). Even then, the literature concerning interventional pain management continues to be controversial with claims of ineffectiveness and inappropriate care (1,6,7,15-32). However, advances in the understanding of the structural basis of chronic spinal pain, the principles of evidence-based medicine (EBM), and comparative effectiveness research (CER) may have increased utilization with increased access (6,7,33-78). Manchikanti et al (1,6,7) have shown the inappropriate utilization of EBM principles and their application to deny evidence for interventional techniques. At times, "the lack of evidence" has been incorrectly interpreted as "evidence for the lack of effectiveness."

Bogduk and Fraifeld (19) despite their contribution and claim to guardianship of research in interventional pain techniques, fall short and join others (20-32) who continue to attempt to derail interventional pain management. Their view may be influenced by individual as well as specific group bias, academic advancement, lack of understanding of procedural aspects with undue focus on methodology, and societal and individual politics. Surprisingly, many authors continue to exclude selectively some of the well designed studies and therefore provide a biased and incomplete evaluation of evidence. This in part is due to a lack of understanding the differences among multiple randomized trials with consideration of local anesthetic effect in a closed space or over a nerve as placebo. Finally, some opinions are based on pure financial impact (29-32). In a recent editorial, Bogduk and Fraifeld (19) described that interventional pain management faces a crisis — the same concern shared by Manchikanti et al (1) and numerous interventional pain management physicians. This shared concern becomes significantly divided when reviewing the evidence which is already present and the methodology of evidence creation. Basically, Bogduk and Fraifeld (19) claim that there is no solid evidence (randomized controlled trials) in support of interventional techniques and it is an expensive proposition to produce any such evidence. They present sample costs of randomized trials and detail multiple challenges and hurdles facing the generation of good evidence which will be acceptable to policy makers and insurers. They propose a reversal of the long-standing value and credibility of randomized controlled trials which are considered as the gold standard. Instead they recommend implementation of (less costly and less complicated) observational evidence. Therefore, they not only fall short of recognizing the existence of randomized controlled trials and observational evidence, but also retreat to a less credible methodology of evidence generation. One might question the soundness of this proposal amid their admittance of challenges facing the acceptance of current randomized controlled trials that are not replicated or performed in a specific group of patients. Obviously, selective inclusion and exclusion of evidence,

especially when combined with biases for or against a specific organization, entity, individual, or technique will lead to erroneous and biased conclusions.

In the same issue of *Pain Medicine Journal* as Bogduk and Fraifeld's article, Richeimer (20) makes his "case against the Interventional Pain Medicine label" under the section of "Perspective," which is based on "having practiced as psychiatrist, anesthesiologist, and pain medicine specialist." The author takes out his frustrations on the creation of interventional pain management as a subspecialty and even "the new subspecialty society of American Society of Interventional Pain Physicians." He wrongfully implies that interventional pain physicians are viewed as technicians and not as "doctors for diagnosis, consultation, and comprehensive treatment planning" and advises we should not become like interventional radiologists who are "simply filling orders of other physicians!" At the same time, one has to agree with the authors' recommendation on teaching interventional procedures along with comprehensive evaluation and management to those seeking fellowship training in pain medicine. This view is shared by the American Society of Interventional Pain Physicians (ASIPP) and is reflected in its review course teachings, publications, and diversity of its membership.

The authors also advocates prescribing pain medications (opioids) to avoid big jury awards for untreated pain and suffering and he implies if pain doctors do not prescribe them, they "should stop calling themselves pain specialists." This view seems less biased than one expressed recently by a senior editor of the same journal advocating opioid prescription: "at some point, we must say if you are going to be a doctor, you must treat pain" (79). Despite extensive abuse, the appropriate use of opioids based on peer-reviewed guidelines has been recommended by interventional pain physicians, and focused review courses on opioids followed by a certification exam have been long implemented by the American Board of Interventional Pain Physicians (ABIPP) (80-92). The National Survey on Drug Use and Health (NSDUH) reported that in 2007, an estimated 5.2 million (2.1% of the population age 12 and older) used prescription pain medications for nonmedical purposes in the last month (93). According to statistics released by the US Centers for Disease Control and Prevention's (CDC) National Center for Health Statistics (NCHS), the number of fatal poisonings involving opioid drugs more than tripled between 1999 and 2006 (94). The role of opioid diversion in such deaths has been established in certain geographic areas. Between 1999 and 2004, in West Virginia, more than 93% of deaths caused by unintentional medication overdose were related to opioid analgesics (90). The United States constitutes only 4.6% of the world's population, consumes 80% of the global opioid supply, and 99% of the global hydrocodone supply, as well as two-thirds of the world's illegal drugs (81). The serious safety issues surrounding opioid prescription has prompted some to recommend careful screening and close monitoring of patients by their physicians in order to prevent diversion (91), which in itself may escalate health care costs and illustrates one avenue for overuse, abuse, and fraud. Kuehn (79), in a recent perspective in *JAMA*, notes that the proposal for safe opioid prescription has met resistance from health care worker organizations and other groups, which argue that mandatory physician training would ultimately limit patient access to pain medication. Thus, it seems different standards apply to pain medicine versus interventional pain management, with the issue of increasing deaths linked to opioid medication not being addressed as either a health issue or an economic one (cost of lives lost). Thus, it is essential to balance the need for opioid treatment with serious safety issues, personal biases and advocacy opinions set aside. This balanced approach needs to be based on establishing medical necessity through careful evaluation of each patient.

In the age of CER, depicted as the natural progression of EBM, the authors claims credibility for most of his "perspective" based on 8 years of experience as chief of pain medicine in an academic setting, even though interventional pain management has been recognized for a longer period of time. He does not hesitate to adhere to anecdotal evidence and openly claims that "money appears to be a key issue" with regards to interventional pain medicine (20). Richeimer (20) also questions the need for independent interventional pain organizations and proposes those societies "would best be part of one of the existing pain organizations such as the American Pain Society or the American Academy of Pain Medicine." By doing so, the author ignores the existence of the International Spine Intervention Society (ISIS), which transformed from the International Spinal Injection Society. In fact, he also ignores the existence of ASIPP, which is larger than any other pain society. Many of its members belong to multiple societies.

Inappropriate Utilization

Inappropriate utilization of interventional techniques has been a topic of discussion in recent years

(6,7,9-11).

Substantial growth has been attributed to the explosive growth of physicians performing these procedures without training, lack of enforcement of local coverage determinations (LCDs), lack of LCDs, and finally economic incentives. However, these issues will not be resolved based on the exclusion of the literature and the inappropriate methodologies applied with personal biases. While the American Pain Society (APS) guidelines show that they are prepared as APS-AAPM (American Academy of Pain Medicine) guidelines, AAPM claims no role in preparation of these guidelines.

Gilbert et al (2,3) painstakingly show alleged interference to the access of care for patients without urine drug testing. Based on Gilbert et al (2,3), if a patient receives 3.4 tests per year it is expected, based on these manuscripts, without interference from regulators, that in-office urine drug testing and laboratory confirmation will cost approximately $450 minimum per test and per patient a minimum $1,530 per year. In contrast, the cost for an average number of epidural injections for a patient over a period of one year is less when it is performed in an office or ambulatory surgery center (ASC) setting, as if it is performed in a hospital outpatient department, which can be slightly more expensive. Further, as described in the manuscripts, if these drug tests are performed during each visit the cost can easily exceed $6,000 per year equivalent to a single person's health care premium in the United States. Such behaviors bring up the issue of exploding health care costs in the United States.

One of the other reasons mentioned quite frequently is medical liability costs. Medical liability costs are predominantly blamed on attorneys; however, the responsibility for costs rests upon not only the trial attorneys, but also physicians who practice poor medicine and finally physicians who knowingly or unknowingly, with or without bias and with or without financial interests may be contributing by their so-called my-way-or-the-highway philosophy. Helm et al (4) show the consequences of such behaviors. The issue of expert testimony by the board members against other members was brought to the attention of the board of directors at the ISIS annual meeting (95). The call made for creation of an ethics committee was rejected by the board of directors, in part because "ISIS does not have the resources to fully fund and maintain a separate ethics committee or section." Consequently, the president of ISIS was assigned by the executive committee to investigate the matters personally and provide a report to the membership. The data gathered provided "no prima facie evidence of bias or excesses" and concluded that providing expert testimony "does not constitute any breach of ethics."

Much has been written about the value and validity of diagnostic blocks with one spectrum stating many types of pain, including discogenic, facet joint, and sacroiliac joint pain, may not even exist and others stating that it is highly prevalent and no diagnostic blocks or single diagnostic blocks with 50% pain relief are appropriate as a controlled diagnostic block. In general, precision diagnostic blocks are used to clarify multiple challenging situations, such as determining the pathophysiology of clinical pain, the site of nociception, and the pathway of afferent and neural signals. Diagnostic facet joint nerve blocks have been shown to have significant evidence classified as moderate to strong in the diagnosis of low back pain without radiculitis or disc herniation, utilizing multiple studies with strict criteria of 80% pain relief with ability to perform previously painful movements with controlled diagnostic blocks (5,18,45,63,64,66). These studies showed the prevalence of lumbar facet joint pain in 21% to 40% in the heterogenous population with chronic low back pain, 34% to 48% in thoracic pain, 36% to 67% in neck pain, with false-positive rates of 17% to 49% in the lumbar spine, 42% to 58% in the thoracic spine, and 27% to 63% in the cervical spine. At the end of one year, the diagnosis was confirmed in 75% of the group with 50% relief (5), whereas it was 93% in the group with 80% relief. At the end of the 2-year follow-up, the diagnosis of lumbar facet joint pain was sustained in 51% of the patients in the group with 50% relief, whereas it was sustained in 89.5% of the patients with 80% relief (5). The results differed between 50% relief and 80% relief with a prevalence of 61% facet joint pain with dual blocks with 50% relief, and 31% with dual blocks with 80% relief; whereas with only a single block, the prevalence was 73% with 50% relief and 53% in the 80% relief group (5).

Further, Manchikanti et al (5) clearly demonstrate that it is not prudent to utilize mediocre standards and continue to perform treatments which will be ineffective. Other studies also have shown the reliability of these interventions with multiple variables (96-102). Manchikanti et al (5) illustrated the implications of 50% relief, 80% relief, single block, or controlled diagnostic blocks. They concluded that controlled diagnostic lumbar facet joint nerve blocks are valid utilizing the criteria of 80% pain relief and the ability to

perform previously painful movements, with sustained diagnosis of lumbar facet joint pain in at least 89.5% of the patients at the end of 2-year follow-up. In contrast, the diagnosis was sustained in 51% of the patients with 50% relief at the end of 2 years and the prevalence was 61% with dual 50% blocks and 31% in patients with 80% or greater pain relief. Utilizing similar protocols, a single block and ≥ 50% relief, the prevalence will be 73% and 53% in ≥ 80% relief. Thus, using a criteria of ≥ 80% relief and use of a double diagnostic paradigm leads to a "precision" diagnostic decrease in prevalence from 73% to 53% with one block and a decrease to 31% in double diagnostic blocks. It is our firm belief that employing such strict criteria in double diagnostic blocks and utilizing the ≥ 80% pain relief criteria as a cutoff will lead to improved diagnostic accuracy and less misutilization of the healthcare system as related to facet interventions.

Recently, Cohen et al (103) compared 0.25 mL versus 0.5 mL in the diagnostic cervical facet joint nerve blocks. Yet, in another controversy, the results of patients receiving 0.25 mL showed 54.5% of patients demonstrated pain relief, whereas specificity was better with 0.25 mL. In contrast, patients receiving higher volumes (0.5 mL) showed reduction in prevalence by 50% (25% versus 54.5%) based on pain relief. Therefore, based on the work of Cohen et al (103) 0.25 mL may lead to unnecessary radiofrequency neurotomies or other therapeutic interventions.

In summary, while supporters of interventional pain management continue to disagree on multiple aspects of their practice for various reasons, detractors are claiming victory. As a young medical specialty, interventional pain management needs to address numerous vital issues including EBM, CER, overuse, over utilization, and abuse leading to increases in cost and reimbursement, which in turn may result in serious consequences threatening our very future. In the process, we need to adhere to our principles and partner with our informed patients to reduce pain and suffering while improving function and quality of life, using the best available evidence in the most cost effective way.

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