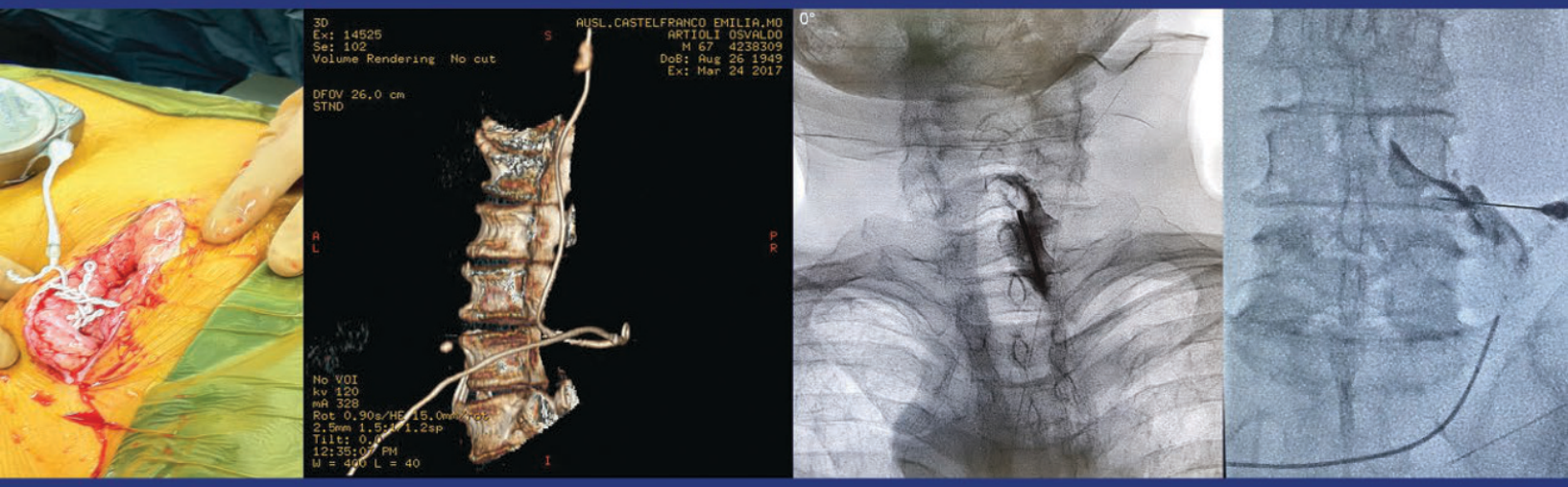
Complications of Pain-Relieving Procedures

An Illustrated Guide



Edited by: Serdar Erdine ▪ Peter S. Staats

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This edition first published 2022

Registered Office
John Wiley & Sons Ltd, The Atrium, Southern Gate, Chichester, West Sussex, PO19 8SQ, UK

Editorial Office
9600 Garsington Road, Oxford, OX4 2DQ, UK

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A catalogue record for this book is available from the Library of Congress

Hardback ISBN: 9781119757276; ePub ISBN: 9781119757290; ePDF ISBN: 9781119757283; oBook ISBN: 9781119757306

Cover image: Courtesy of Peter Courtney, Courtesy by Cristina Mastronicola, Courtesy of Ashish Chakravarty, Courtesy of Grace Tsai
Cover design by Wiley

Set in 10/12pt Warnock Pro by Integra Software Services Pvt. Ltd, Pondicherry, India

We would like to dedicate this book to Professor Prithvi Raj, the founding father of World Institute of Pain,a friend, an innovator, a mentor to us all. The memory of Dr Raj continues to inspire us to improve our care of patients suffering with chronic pain.

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Foreword

There have been many pioneers in interventional pain and during my tenure I was welcomed into a Texas family of Anesthesiologists and Interventional Pain Physicians fairly rapidly. I was invited by Dr. Pepper Jenkins to visit the University of Texas Southwestern Medical Center as a visiting professor. There, I met Prithvi Raj. We became lifelong friends and he mentioned that he was writing an extensive book on interventional pain procedures. I encouraged him and told him that it was a great idea. Our friendship remained throughout the years, and we kept in contact during his multiple moves. I always felt that somehow, we would work together one day. I caught up with him on his last move and encouraged him to join me at Texas Tech in the Anesthesiology department. Prithvi remained productive and a vital part of interventional pain. His vision of a Texas Pain Society (TPS) and a World Institute of Pain (WIP) became a reality. Together, with the involvement of the WIP founders David Niv, Serdar Erdine, Ricardo Ruiz Lopez and myself, we also had to make major decisions on the educational process of future practitioners. He authored numerous papers and books; always striving to be safer and better. This book is dedicated to Prithvi Raj for his first-class way of achieving so much in very fine organizations; let it be the example for others.

The contents and distribution of topics in this book has been very well written by the editors. Understanding the various complications, and learning from them, not only makes a better skilled clinician, but protects you from potential lawsuits where you may only be protected by a competent lawyer. It becomes expensive. Thou shalt not have bad outcomes and complications because of ignorance!

During my experience with between 350–400 medical legal cases, I came to recognize that we should continue to learn; one man's experience is not enough. When I was a resident in anesthesia, the incidence of mortality were 1 in 10 700. And look at the tremendous impact that came from monitoring the delivery of oxygen, CO_2, alarms, safer medications etc., every one of them becomes relevant to lower the morbidity. Look at the first large-scale study on radiofrequency procedures of the Gasserian ganglions with a remarkably high success rate, yet the first 7000 patients' outcomes reported two deaths and multiple hemorrhages from the use of sharp needle tips. Looking at the literature, there has not been any reports of blunt needles penetrating nerves or arteries. Scanlon, in his national survey of complications following transforaminal cervical injections, stated that the proposed way to reduce morbidity and mortality "is to **'use blunt needles'".**

The frequency of post-procedural disasters tends to occur on Fridays with the complications surfacing hours or days later. In particular, on Fridays followed by National Holidays. Slow bleeds have resulted in paralysis in combination with obstructed neural foramina. The incidence of huge problems can be rare and communication over weekends with any system brings in lower quality medical providers. These providers may not be at all familiar with increased pressure, loculation and hyper osmolar solutions

that may draw additional fluid volume. What about rescheduling any other day than a Friday…?

You are only getting better the more you remain current in relevant publications. One's man's experience is no experience. Bad outcomes from pain procedures should be taken more seriously and long-lasting pain relief should be recognized.

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Foreword

Ever since its inception in 1993 The World Institute of Pain (WIP) has defined and included into its Bylaws the education, training and certification of Pain Interventionalists as a main goal according to the Latin original text: "to help, or at least do no harm "Every therapy in the physician´s or surgeon´s skills is double-edged as every remedy is potentially harmful.

From the initial reference of August Bier in 1889, many distinguished colleagues like John Bonica, Prithvi Raj, Philip Bromage and Sampson Lipton improved Regional Anesthesia and Pain Management, pioneering a broad array of invasive techniques for the effective alleviation of pain, all constituents for the implementation of a well-established "corpus of knowledge" as a new Surgical Medical Specialty; Interventional Pain Management.

Especially in the last decades, the introduction of Gate Control Theory in the pain field by Ronald Melzack and Patrick Wall led to the initial attempts providing electrical stimulation to the spinal cord and paved the way to a tremendous evolving technology with multiple clinical applications called as Neuromodulation which are promising in the future as well.

The discovery of opioid receptors provided and built on the basis for infusional intrathecal therapies. Despite the long way and efforts carried out there is still much to be discovered in the setting up of clear boundaries for these therapies and their applications.

The application of neuroablation, first using controlled a substitute of chemical agents such as alcohol and phenon, then of radiofrequency thermocoagulation since the 1960s has made it possible to use and the wide expansion of this technology covering all areas of human body. The discovery of pulsed radiofrequency (PRF) by Menno Sluijter in 1998 introduced a new tool for neurostimulation to pain practitioners and surgeons, avoiding deafferentation pain as it could occurs with conventional – thermal – uses of conventional radiofrequency.

Special mention is deserved here of the introduction during the last two decades of vertebral augmentation, endoscopic transforaminal therapies for disc excision and various techniques of tissue removal from the spinal canal by means of the epiduroscopy, initiated by Heavner, or without direct vision, including the lysis of adhesions by Gabor Racz, as well as recent percutaneous technologies that a modern Interventional Pain Specialist should master for completion of an updated chronic pain practice.

Notwithstanding recent innovations to perform spinal surgical procedures such as percutaneous lumbar extraforaminotomy (PLEF) percutaneous spinal fusions, spinal endoscopic procedures and interspinous spacers for treating spinal stenosis, all of them define the new field of Minimally Invasive Spine Surgery (MISS), some concerns must be raised about the potential dangers to patient care.

This means there is momentum for continuous education and training on surgical complications for the experienced Pain Specialist practicing spine interventional therapies, fostering education of core competencies on failures, complications, successes and ongoing treatments, including the role of the Pain Interventionists in a multidisciplinary team integrated by other specialties including Spine Surgery and Neurosurgery.

In addition, the new field of Regenerative Medicine using plasmatic biologic agents and mesenchymal stem cell therapies is providing new tools to the Interventional Pain Specialist in order to regain effectiveness in the alleviation of pain from various degenerative disorders arising in different origins whether osteoarticular, muscular or vertebral.

There are many examples of complications, mostly through legal cases, though relatively few have been collected in the literature. The Pain Specialist must keep in mind that warning signs may differ in individual patients and, therefore, should be trained to recognize abnormal imaging for quick recognition. These skills require appropriate training in radiographic or ultrasonography anatomy in order to clearly distinguish the well-known and the unexpected or aberration imaging.

It must be highlighted that well-established protocols have not been followed or correct techniques have not been used in all the known cases of complications. Therefore, it is essential to pay attention to detail by the Specialist to avoid complications.

The initiative from Serdar Erdine and Peter S. Staats compiling this *Book of Complications in Interventional Pain Therapy* fills an important gap in the methodological study of the modern Interventional Pain Specialists which is called to be a seminal publication and useful tool in the Education and training of the future fellows. Thus, the Editors, co-Editors, and all contributing authors deserve warmest recognition from our community and sincere gratitude for having updated, with excellence, this important pending compilation of the most difficult area that nowadays Interventional Specialists must face in their clinical practices.

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Preface

"If you can't stand the heat, get out of the kitchen".

This was the advice given to (PS) early in my career by a neurosurgeon and close friend when starting the pain division at Johns Hopkins. I was first anesthesiologist at Johns Hopkins University to have surgical privileges and was of course concerned about complications. Would I know what to do if the patient had an acute bleed in the spine? Would I be able to manage an infection? These were among the concerns I had as I decided to embark on this journey to improve pain care worldwide. I did not have internal champions from my specialty that I could turn to if I got into trouble. Would I know what to do? To whom could I turn? There were no texts devoted to complications in Pain Management. No academic anesthesiologist had been granted surgical privileges and thus consideration of complications was deferred to the surgeons and was not a broad concern in our field.

Similarly, when SE became an associate professor at the age of 31, I had to develop a pain program or department, and of course grapple with complications on a systemic level. Being able to perform a procedure was not enough. We had to do it safely. It was clear that the management of complications needed to be given the same thoughtful and comprehensive approach as we did in OR anesthesia. I started the Department of Algology in the Medical Faculty of Istanbul with this vision in mind, (John Bonica liked the word Algology, which was why we chose it instead of Pain Medicine) in part to achieve this goal. Many years later, Algology became a unique subspecialty in Turkey. Years ahead of many of our peer countries.

It is now commonplace, and in fact standard, for Physical Therapy and Rehabilitation Anesthesiologists and Neurosurgeons to perform a wide range of interventional pain procedures that cross traditional barriers or specialties. However, the background and training of these specialties are quite different. Some have years of surgical training, while others have not cauterized tissue since medical school. In addition, our field is unique in the gross number of procedures an average pain physician performs. Unlike in other surgical specialties, where only a few procedures are performed on a limited area of the body, IPM, physicians are now performing literally hundreds of different types of procedures throughout the body, each requiring a deep fund of knowledge. These procedures vary greatly and may include injection of cement, use of biological agents such as stem cells, implanting devices for modulation of pain, ablation of nerves, or injections into highly complicated areas of the body. The knowledge of anatomy, physiology and surgical techniques is unparalleled when compared to other disciplines in medicine. Without this knowledge, and discipline in providing a safe environment for our patients, the rate of complications would be unacceptable.

There is consensus in the pain management community that practice of pain management has now become a specialty on its own and requires careful nurturing of its growth, specialist training of pain physicians and the creation of acceptable standards of practice guidelines for all physicians. As part of the growth of the specialty there is a recognition that complications certainly do occur, and we need a comprehensive approach to address this problem.

Development of our field came from a recognition that pain is undertreated worldwide, a universal recognition that opioids are not the answer for all patients, and that large and complex spinal

procedures are limited in their applicability. Many patients require a more nuanced approach, with understanding of their diagnosis, the range of options that exist, and careful weighing of the risks and benefits of a variety of approaches including invasive approaches which are highlighted here. Hundreds of new approaches to managing chronic pain have developed over the years. Over the past 30 years, we have developed minimally invasive approaches that are currently replacing more conventional approaches to managing complex pain. A whole new discipline of interventional pain management has been born to foster these minimally invasive approaches, while improving the care of patients. IPM doctors now cross train and must understand radiology, rehabilitation medicine, neurosurgical and orthopedic approaches, as well as anesthetic techniques as foundational while we invent new strategies to managing pain. There have been scores if not hundreds of books on the science and techniques of interventional pain management, but few have concentrated on the risks and how to avoid them. As this field has developed, we replace many more invasive procedures, with minimally invasive approaches.

If a surgeon performs only a few procedures, they become proficient quickly, practicing the same procedure over and over. From peripheral occipital nerve stimulation to regenerative medicine approaches requiring the use of ultrasound. This inherently means that the physician needs to be familiar with a wide range of approaches, normal and abnormal anatomy and, of course, the surgical implications and complications of each. So, with this advancing breadth of training required have we expanded the fellowship and training programs? Are medication strategies safer? In a word, no.

Over the past several years, as the number of interventional procedures for pain management have increased, so has the number and type of complications that occur. When we entered the field of pain medicine, there were few therapeutic strategies available to the pain physician, and patients suffered in silence, or underwent far more invasive and much less effective strategies than we have to date. In fact, the field of pain medicine was in such a state of infancy that randomized controlled trials (RCTs), and long-term follow up was considered rare. As the field has expanded in terms of the breadth of what pain physicians offer, the complexity of therapies and frank number of procedures offered, so has the rate of complications increased. The length of training has not expanded, making the rate of knowledge acquisition far quicker than was expected a mere 20 years ago.

Several textbooks cover the techniques, indications, contraindications and mechanisms of action for interventional pain management techniques, but only a few textbooks have focused on the complications, how to avoid them, their impact on patients and the psychology of the treating team, as well as any medicolegal consequences. The combination of interventional pain physicians with quite diverse training backgrounds and the recent significant increase in the use of interventional diagnostic and therapeutic techniques raises the potential for increased complications. Unfortunately, there are major limitations in the analysis of complications. This text intends to provide pearls and strategies to avoid complications, as well as strategies on how to treat them and avoid long-term injury.

As part of our Hippocratic oath, we want to help those, but "do no harm. Having proper technique, a thorough understanding of the normal and abnormal anatomy, patient co-morbid disorders, recognizing the complications that inevitably will occur early, and managing them aggressively will lead to improved outcomes.

We have both been blessed to have the opportunities to open the doors of the proverbial kitchen, made some fabulous meals (and we have helped a lot of people along the way) but we unfortunately recognize that complications do occur. Creation of this text was a work of passion, intending to improve safety of all patients across the globe. We are grateful to the worldwide experts who have devoted their time expertise and efforts in helping us all understand that while complications do occur, the risks can be mitigated, and adverse events can be treated

Serdar Erdine
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Acknowledgments

Grateful thanks is given to the following who have given permission for their photograph collection to be used:

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Section 1

Basic Principles

1

The Importance of Studying Complications in Pain Medicine

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It is terrifying to have complications following procedures performed to help patients. A complication can be as minor as a local skin infection, or much more severe with hematomas, paralysis and even death following a neuraxial or visceral nerve block. No physician ever goes to work, thinking "Today, I am going to injure someone". Rather, physicians may believe that a complication is simply an unfortunate event that was just unavoidable or unlucky. But luck favors the prepared. Even without mal-intent, the truth is, many complications are avoidable. With an appropriate understanding of indications contraindications, anatomy, physiology, and techniques, the risk of most complications can be mitigated.

Over the past several years, as the number of interventional procedures for pain management has increased, so has the number and types of complications that occur. When we entered the field of pain medicine, there were few therapeutic strategies available to the pain physician, and patients suffered in silence, or underwent much more invasive and far less effective strategies than we have to date. In fact, the field of pain medicine was at such a state of infancy that randomized controlled trials (RCTs), and long-term follow up was considered rare. As the field has expanded to the breadth of what pain physicians offer, the complexity of therapies and the frank number of procedures offered, so has the rate of complications. The length of training has not increased, making the rate of knowledge acquisition much quicker than was expected a mere 20 years ago.

While some complications are relatively minor, others can be severe and debilitating. Unfortunately, these complications are rarely reported. The medicolegal system discourages reporting of complications, and physicians may be embarrased or fearful of legal or disciplinary action. For this reason, many physicians under report the true complications. Thus, the true incidence and severity of complications is also likely to be under reported. In order to provide true informed consent and make the most appropriate recommendation to patients, it is important to understand the scope and severity of any problems. Moreover, if we understand the scope of the problem, we can proactively develop safer tools and approaches to avoid such complications.

Several textbooks cover the techniques, indications, contraindications, and mechanism of action of interventional pain management techniques, but only a few textbooks have focused on the complications, how to avoid them, their impact on patients, and the psychology of the treating team, as well as their medicolegal consequences. The combination of interventional pain physicians with quite diverse training backgrounds, as well as the recent significant increase in the use of interventional diagnostic and therapeutic techniques, raises the potential for increased complications. Unfortunately, there are major limitations in the analysis of complications. This text intends to provide pearls and strategies to avoid complications, as well as strategies to treat them and avoid long-term injury.

Historically, physicians have a tendency not to report poor outcomes; therefore, the true incidence of complications is not fully known. Only a fraction of the total number of complications that occur following procedures are reported. Health privacy issues and fear of litigation prevent some physicians from reporting the complications of interventional techniques. Further, any complications may be reported to

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different databases, making a general analysis even more difficult. Although the overall incidence of significant complications in interventional pain medicine is low, some catastrophic complications do occur.

Interventional pain management physicians and staff must clearly explain these complications in layman's terms to the patient so as to reduce the occurrence of claims. Written preoperative instructions explaining the procedure and potential complications should be given and signed by the patient before the procedure, allowing time for review. The informed consent before all procedures should include a discussion about the indications, complications, risks, and available alternative therapies.

Most importantly, complications are inevitable and it is imperative to identify and treat these problems promptly to minimize their impact when they do occur and to communicate these issues with the patient.

Although pain medicine is now an established subspeciality in many countries, residency or fellowship training in the field of interventional pain medicine does not universally exist. Without a universally accepted curriculum necessary for establishing competency in the specialty, greater variability in indications, techiques, and outcomes will be noted. This of course will also translate into great variability in the occurence of complications.

There are several ways for physicians entering the field of pain medicine to gain necessary experience. Of course a full fellowship curriculum is ideal, with hands-on training, slowly increasing responisibility and complexity of training over time. However, many physicians are learning a specific technique, which may involve simple observation of experienced physicians, taking a weekend cadaver course, or careful review of techniques written in interventional pain procedures techniques. Over several decades, we have seen a dramatic increase in the number of physicians performing interventional pain procedures, with a concomittent exponential increase in the performance of procedures to treat pain. This has, unfortunately, also led to a rise in the number of complications [1] and an increase in malpractice claims [2].

Interventional pain procedures may be minimally invasive but have the potential to be maximally dangerous. Serious complications are devastating for the patient, devastating and expensive for the physician and are often avoidable.

However, the incidence of complications from interventional pain procedures remains unknown. Interventional complications, by virtue of their nature, do not lend themselves well to prospective studies. As such, reported complication rates are extrapolated for the most part from observations in prospective studies or anecdotally from case reports, retrospective reviews and closed claim studies [3]. Nevertheless, considerable and useful information on complications and potential approaches to their prevention can be gained from such reports [3].

Nonetheless, not all pain therapy complications are the result of preventable medical mistakes.

Whenever there is an adverse event or complication, it is important to protect the evidence, document the incident, report the incidence, and analyze it in order to prevent any recurrence of such an event [4].

Another important barrier to improvement of safety of patients and procedures is that adverse event protocols for interventional pain treatment are not widely promoted. Interventional pain practitioners need to be aware of the potential complications, know how to avoid and more importantly, how to treat them, should they occur. Adverse events can be as minor as tenderness in the puncture site or as catastrophic as an epidural hematoma causing severe neurologic disease or even respiratory and cardiac arrest leading to death [5].

For physicians who perform interventional pain therapies, the question is not if but when a complication will occur. Despite appropriate training, experience, patient selection, and safeguards, there will be times when a near miss (a complication without a negative outcome), an accidental injury or even a serious or life-threatening complication occurs.

Complications can be classified in several ways; 1) by their severity; 2) by their source (human error, equipment failure, drug- or treatment-related); or 3) by whether they are preventable or unpreventable.

Preventable complications result from either the failure of a system (equipment failure, notification error in reporting an abnormal test result) or human error. Patients and their family members usually perceive preventable complications. Unpreventable complications involving injury or medical complications are errors that, while they may or may not be expected, cannot be avoided.

Examples of unpreventable complications are drug reactions or the effects of certain procedures that are probable and even foreseeable in some cases. Nonetheless, they are unfortunate occurrences.

In order to prevent "preventable complications" physicians should be trained in a way that they have all precautions taken, all facilities including intensive care at their disposal, a team including an anesthesiologist, nurses, and other healthcare personnel are around helping and supporting in case of any complications.

The first step in preventing complications is the history taking. The history taking for a patient to be prepared for an interventional pain procedure differs

from a general history taking. The history should include factors related to age, bleeding disorders, cardiopulmonary status, medication allergies/anaphylaxis, neurologic and musculoskeletal status, and any history of difficult airway problems. Properly preparing the patient prior to the procedure will prevent most complications. There are special areas of concern such as the cranium, occcipital region, neck, and thorax. For procedures on these areas, the technique to be performed should be carefully chosen. In particular, for symphathetic blocks in that region, the patient should be prepared for an iatrogenic hypotension prior to the procedure.

Past medical history is also important for discovering conditions that make the outcome of an interventional procedure hazardous. Any complications arising during previous operations or interventional procedures may prevent future complications. Allergic reactions which occured any time in the history of the patient are red flags and the patient should be prepared accordingly.

Previous psychological or psychiatric problems the patient may have had are important for deciding any procedure in these patients as there may be secondary gain after performing any procedure.

Medication history is important as it impacts a patient's response to the procedure. Thus, all medications the patient uses, especially antiplatelet medications should be recorded and stopped prior to the procedure, according to the drug used.

The physical exam is important for placing the patient on the table for the procedure. Close attention should be paid to the airway if sedation is considered during the procedure. Morbidly obese patients require more attention than the others.

A careful preoperative screening is mandatory to discover and prevent complications before they occur. During this preoperative screening, any allergy to any drugs, bleeding disorder, replacements within the body, e.g. pacemaker, drugs such as antiinflammatories, antiplatelet medications, and recent local and systemic infections, should be recorded. If the patient answers affirmatively to any of the above questions, the injectionist must carefully consider options before proceeding.

Perioperative Prevention of Complications

One should bear in mind that interventional pain procedures should be recognized as minimally invasive surgery and all precautions should be taken prior to the procedure. All procedures should be performed in the operating room with all facilities for emergency with the presence of an anesthesiologist or intensive care specialist. The patient should be monitored throughout the whole procedure. Even if the physician performing the procedure has a background in anesthesia, a second anesthesiologist should be present during the procedure for sedation, analgesia, monitoring, and emergency situations. This allows the surgeon to concentrate on the technique of the procedure to optimize the patient outcome.

As the first step, the patient's name, diagnosis, procedure to be performed, and the side or location of the body must be confirmed. Patient's positioning on the table is vital and a bolster should be placed under the patient allowing the belly to hang in a pendulous manner for spinal procedures.

One of the most common complications is infection. Important methods to decrease complications, or infections include appropriate sterile technique and use of antibiotics. This will include appropriate face coverings, handwashing, and patient preparation. The entrance area should be prepped with aseptic technique with povidone iodine or chlorhexidine. The scrub should last at least five minutes and should be allowed to dry.

The table on which all syringes with medications to be injected, needles, and electrodes should be ready prior to the procedure in a well-prepared fashion. All syringes should either be prepared by the physicians, or nurse and must be labeled. Failure to do so may result in a life-threatening event.

The physician who will perform the procedure should be prepared as a surgeon, with hood, face mask, surgical gown, and sterile glows. In cases where fluoroscopy will be used, the physician should wear a radiation gown, under their surgical gown, a thyroid shield, radiation eyeglasses, and radiation gloves.

Fluoroscopy is an important tool for performing interventional procedures. The physician should be aware of all radiation safety rules. In order to decrease the amount of radiation received by the physician, they should use the flouroscopy pedal for shooting the image themselves.

Correctly interpreting images by fluoroscopy during the procedure is one of the main rules to prevent complications. The first step, while using fluoroscopy, should be to identify the target in the best position with the optimal image. To see the image instantly may mislead and cause complications. Interpreting the spread of the dye is the second step. Any inadvertent arterial, venous injection, inadverdent puncture of the dura or spread of the dye to unexpected areas such as the lungs or esophagus, should be identified by the physician.

While introducing and advancing the needle, the physician should know where the tip of the needle is, either on the bone, ligament or a potential space. The previous image should be saved while advancing the needle. The patient should not be heavily sedated so that the response of the patient is available in case of inadverdent nerve or spinal cord injury. In critical procedures, aspiration of either blood or cerebrospinal fluid (CSF) is mandatory. In case of aspiration of blood, the tip of the needle may be replaced and, if bleeding continues, the procedure should be terminated. In case of CSF aspiration, if an epidural block is planned, the procedure is terminated. In case of any doubt, first stop, then inject contrast material again, check both in AP and lateral view, and if you still have doubt, cease the procedure. To explain why you stopped the procedure is far better than trying to explain a complication.

Vasovagal syncope at the beginning of the procedure is the most common risk. Signs and symptoms include sweating, cold or clammy skin, bradycardia, hypotension, nausea and vomiting, disorientation, pallor, and loss of consciousness. In such a case, the patient should immediately be turned supine, administer oxygen, IV bolus fluid and bear in mind other medication used during an emergency may be required. This is the reason for insisting on the presence of an anesthesiologist in the ward during the procedure.

Postoperative Management

Once the procedure is over, the patient should be taken by a gurney to the recovery unit. They should be observed for several hours until they are awake, have vital signs and can communicate. All motor functions should be tested and full recovery should be documented.

The patient should never be discharged alone; an accompanying person should be present, the patient must be told not to drive and to take bed rest depending on the type of the procedure. The patient should be instructed to notify the treating physician or go to the emergency room immediately if any of the following symptoms occur: fever, chills, a change in mental status, severe neck or back pain, difficulty breathing, a prolonged and severe headache, numbness and/or weakness in the arms or legs, loss of control of the bladder and/or bowel, excessive redness, swelling, or drainage from the area of the injection.

Conclusions

A serious complication is devastating for the patient, devastating for the physician and, in many cases, avoidable. The wise interventional pain physician should anticipate any problems, be prepared for them, react appropriately to an emergency and, with appropriate intervention, can avoid disaster.

In order to avoid complications; the physican should know the appropriate indications and contraindications of any proposed procedures, learn the relevant anatomy and perform the procedures in the safest manner possible. The physician should practice within their abilities and, if they are in doubt, they should not proceed with the planned procedure. The physician should obtain the best training possible. The physician should not try to fit a procedure to the patient, they should know which patient should not have a procedure. The physician must remember that each procedure may carry its own possible complications, so they should try to anticipate these and avoid any complications from happening. The physician should explain all possible complications to the patient and their companion in detail, from the simplest to the most severe, then the patient should make their own fully informed decision on whether to proceed, at which point, the physician must ensure they obtain signed, informed consent from the patient.

During the procedure, meticulous attention to the technique is necessary. In order to do this, the physician should verify all drugs and contrast agents. Appropriate monitoring of equipment, personnel, and resuscitation equipment is crucial for the success of the procedure. The physician should never be over-confident.

Do not forget that many serious complications are done by very experienced physicians. Thus, the physician should know when to stop. Lastly, the physician should not walk away from a complication, they must sort it out and resolve it.

References

1 Manchikanti, L. (2004). The growth of interventional pain management in the new millennium: A critical analysis of utilization in the medicare population. *Pain Physician* 7: 465–482.

2 Manchikanti, L. and Singh, V. (2003). Interventional pain management: evolving issues for 2003. *Pain Physician* 6: 125–137.

3 Hayek, S.M. (2007). Complication: a painful entity for patient and physician. *Techniques in Regional Anesthesia and Pain Management* 11: 121.
4 Sitzman, T. (2008). Adverse event protocol for interventional pain medicine: the importance of an organized response. *Pain Medicine* 9 (S1): 108–112.
5 De Andrés Ares, J. (2014). Complications in interventional pain treatment. *Techniques in Regional Anesthesia and Pain Management* 1 (8): 1.

2

History of Interventional Pain Procedures

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Introduction

Interventional pain management dates back to the origins of neural blockade and regional analgesia [1]. The invention of the hollow needle and syringe may be accepted as the first step in the history of interventional pain procedures. Sir Francis Rynd performed the first nerve block using morphine dripped through a cannula in a patient with trigeminal neuralgia in The Meath Hospital in Dublin, in 1844 [2].

Alexander Wood improved the hollow needle in 1853 and Charles Pravaz, the hypodermic syringe, known as the Pravaz syringe, in 1853 [3] (Figures 2.1 and 2.2).

The origins of the neural blockade and regional anesthesia date back to 1884. Although Freud and Koller were working together on cocaine, Karl Koller is accepted as the father of regional anesthesia as he was the first to publish the local anesthetic effect of cocaine for eye surgery. Koller was just 27 years old [4] (Figures 2.3 and 2.4).

In 1899, Tuffer described the use of spinal cocaine to control pain from sarcoma of the leg [5]. It soon became apparent that cocaine was a very toxic substance, and between 1884 and 1891, 200 cases of toxicity had been reported and as many as 13 deaths had occurred [6].

Caudal Block

Sicard first described injection of dilute solutions of cocaine through the sacral hiatus into the epidural space in 1901 to treat patients suffering from severe,

Figure 2.1 The Pravaz hypodermic syringe.

Figure 2.2 Alexander Wood (1817–1884).

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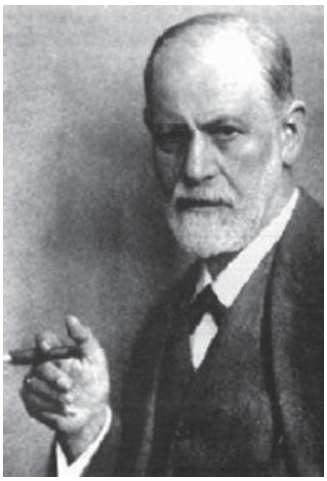

Figure 2.3 Sigmund Freud (1856–1939).

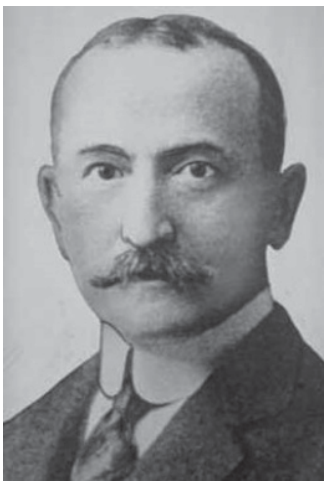

Figure 2.4 Karl Koller (1857–1944).

intractable sciatic pain or lumbago [7]. Cathelin also described caudal administration of local anesthetic not only for surgical procedures, but also for the relief of pain due to inoperable carcinoma of the rectum [8]. Pasquier and Leri, in 1901, independently reported the use of caudal epidural injection for sciatic pain [9].

After 1952, corticosteroid was added to the local anesthetic for acute and chronic pain by Robecchi and Capra in 1952 and Lievre in 1957.

Spinal Subarachnoid Approaches

Leonard Corning, a neurologist, was the first person to perform spinal anesthesia, but apparently was not fully aware that he had done so at the time. He injected 1.18 mL of 2 % cocaine hydrochloride into the space "situated between the spinous processes of two inferior dorsal vertebrae" on a dog. He carried out a similar test on a human being and the same happened, whereby he concluded that cocaine was absorbed by the veins and "then transferred to the substance of the cord and gave rise to anesthesia of the sensory and perhaps motor tracts of the same" [10].

Corning published one of the first textbooks on Local Anesthesia in 1886, and the first textbook on pain in 1894 [11, 12] (Figure 2.5).

Discovery of Spinal Anesthesia by August Bier

The first spinal anesthesia in a human was performed by August Bier in 1899 [13]. He used 10–20 mg of cocaine and the first of these experiments was carried out on August, 16, 1898. He asked his colleague Hildebrandt to perform spinal anesthesia on him. Hildebrandt was not successful. Then Bier successfully performed a lumbar puncture on his colleague and injected 5 mg of cocaine and obtained a very satisfactory spinal block. Both suffered headaches, nausea, and vomiting as well as dizziness as a result of CSF leakage and this was relieved by laying down. This is the first case report of post-dural puncture headache (Figures 2.6 and 2.7).

Epidural Anesthesia

Sicard and Cathelin injected cocaine into the epidural space caudally in 1901 [7, 14]. Fidel Pages-Mirave described the lumbar approach to the epidural space in 1923 [15]. Dogliotti popularized

Figure 2.5 James Leonard Corning (1855–1923).

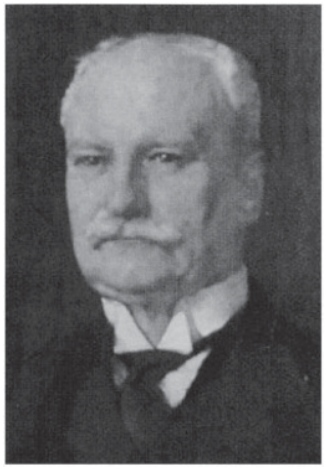

Figure 2.6 August Bier on his 75th birthday in 1936.

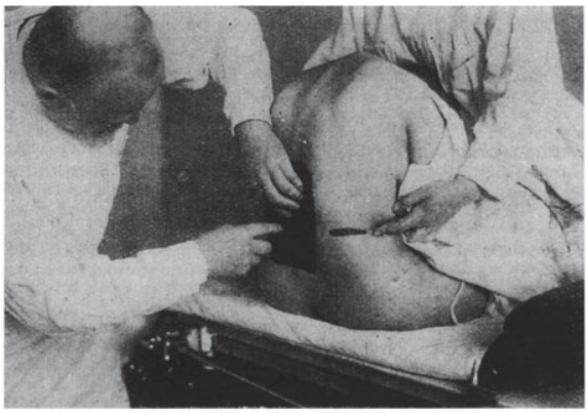

Figure 2.7 August Bier performing spinal anesthesia in 1920.

Figure 2.8 Jean-Athanase Sicard (1872–1929).

Figure 2.9 A.M. Dogliotti (1897–1966).

the technique in the 1930s when he described the "loss of resistance technique" [16] and Curbelo introduced continuous epidural anesthesia in 1949 [17] (Figures 2.8 and 2.9).

Cervical epidural block was also defined by Dogliotti in 1933.

Radiofrequency Procedures

Use of radiofrequency (RF) procedures for the treatment of chronic pain dates back to 1931 by Kirscher where he used a direct current of 350 mA with a 10-mm uninsulated needle, for the treatment of trigeminal neuralgia [18].

Sweet wrote his famous article in 1953, together with Vernon Mark, showing that the use of very high-frequency current (in the RF range) has decisive advantages over direct current lesion procedures [19].

Bernard J. Cosman made parallel pioneering contributions to the design and engineering of RF lesion generators and electrodes [20] (Figure 2.10).

The use of RF in pain management dates back to 1965 by Rosomoff for percutaneous lateral cordotomy to treat unilateral pain in cancer patients [21].

The first use of RF current for spinal pain was reported by Sheally, who performed RF lesioning of the medial branch for lumbar zygapophyseal joint pain in 1975 [22].

In 1980, a very important development was the use of small-diameter electrodes, known as the Sluijter Mehta Kit (SMK) system, which were introduced for the treatment of spinal pain by Slujter and Mehta. The system consists of a 22-gauge (22G) disposable cannula with a fine thermocouple probe inside for temperature measurement. The smaller electrode size diminished discomfort during the procedures [23].

Figure 2.10 Bernard J. Cosman (1914–1993).

Figure 2.11 Menno Slujter (1933–).

Pulsed RF was developed, in part, as a less destructive alternative to CRF and was introduced by Menno Slujter in 1998 [24] (Figure 2.11).

Historical Background by Procedure

1) Gasserian ganglion blocks

In 1903, Schloesser was the first to report the use of alcohol injection into the peripheral nerves in the treatment of trigeminal neuralgia [25].

Härtel, in 1914, described the percutaneous insertion of a needle through the foramen ovale via an extraoral approach, which is still used today [26].

In 1974, Sweet and Wepsic introduced RF lesioning of the trigeminal rootlets in the Meckel cave [27] (Figure 2.12).

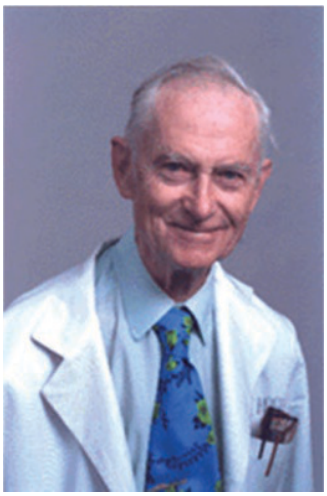

Figure 2.12 W.H. Sweet (1891–2001).

In 1981, Hakanson introduced percutaneous retrogasserian glycerol chemoneurolysis [28].

In 1983, Mullan and Lictor, introduced the technique of percutaneous balloon compression of the gasserian ganglion [29].

2) Glossopharyngeal block

Weisenburg first described pain in the distribution of the glossopharyngeal nerve in a patient with a cerebellopontine angle tumor in 1910. In 1921, Harris reported the first idiopathic case and coined the term glossopharyngeal neuralgia. He suggested that blockade of the glossopharyngeal nerve might be useful in palliating this painful condition. Early attempts at permanent treatment of glossopharyngeal neuralgia and cancer pain in the distribution of the glossopharyngeal nerve consisted principally of extracranial surgical section or alcohol neurolysis of the glossopharyngeal nerve.

3) Sphenopalatine ganglion block

The spehnopalatine ganglion (SPG) has been involved in the pathogenesis of pain since Sluder first described sphenopalatine neuralgia in 1908 and treated it with an SPG block.

4) Occipital nerve block

The term "occipital neuralgia" was first used in 1821, by Beruta y Lentijo and Ramos. The technique of occipital nerve block seems to have been first described by Bonica in 1953.

Brachial Plexus Block

Halsted performed a brachial plexus block in a patient in the United States in 1884; the same year in which Koller used cocaine [30] (Figure 2.13).

Figure 2.13 W. Halstead (1852–1922).

Celiac Plexus Block

In 1912, Kappis described paravertebral somatic blocks for surgery and pain relief [31]. In 1922, Läwen used paravertebral somatic block in the diagnosis of abdominal disease [32]. Celiac plexus block was first described by Braun, utilizing an anterior surgical approach in 1906, followed by Kappis in 1914, utilizing a posterior approach [33]. In 1920, Gaston Labat modified the technique of Kappis [34].

Gaston Labat published *Regional Anesthesia-Techniques and Application* (on the basic principles of regional anesthesia) in 1922. This textbook is still considered to be one of the classic textbooks ever published on regional anesthesia. Labat was a leader during the formation of the first American Society of Regional Anesthesia (ASRA) in 1923, which was dissolved in 1939 (Figure 2.14).

In 1983, Stefano Ischia described the transaortic approach [35].

In 2002, Prithvi Raj described the RF lesioning of the splanchnic nerve [36] (Figure 2.15).

Transforaminal Epidural Block

Transforaminal epidural block was first described through the S1 posterior sacral foramen, in 1952, by Robecchi and Capra. Lievre, in 1953, reported improvement in five out of 20 patients when treated with caudal epidural hydrocortisone. The

Figure 2.14 Gaston Labat (1876–1934).

Figure 2.15 Prithvi Raj 1931–2016. (*Source*: P. Raj, S. Erdine, 2010.)

use of fluoroscopy facilitated the use of the transforaminal route [37, 38]. Derby and Bogduk reviewed the technique in 1993, and Kikuchi described the anatomic variants of the dorsal root ganglia in 1994.

Facet Joint Injections

In 1911, Goldthwait was the first to recognize the role of facet joints as a source of back pain [39]. In 1933, Ghormley introduced the term "facet syndrome" [40]. In 1941, Badgley was the first to associate facet arthritis with nerve root irritation as a cause of low back pain and sciatica. In 1963, Hirsch demonstrated that low back pain along the sacroiliac and gluteal regions with radiation to the greater trochanter could be induced by injecting hypertonic saline in the region of the lumbar facet joints [41]. In 1971, Rees

proposed a surgical approach to severing the posterior primary rami. In 1975, Shealy first described RF denervation of the medial branch of lumbar facet joints [22].

Symphathetic Blocks

Selective block of the sympathetic trunk was first reported by Sellheim and, shortly after, by Kappis in 1923 and Brumm and Mandl in 1924.

Stellate ganglion and cervical/thoracic sympathetic block were described by Labat [42]. In 1924, Brunn and Mandl, described therapeutic block in the management of visceral pain [43]. Kappis also described the technique of lumbar sympathetic block and surgical resection of the lumbar sympathetic nerves about this time [44].

Reid and colleagues, in a large series published in 1970, described a more lateral approach that avoids contact with the transverse process.

In 1926, Swetlow reported long-term pain relief by neurolytic injection of alcohol to the paravertebral sympathetic nerves in the treatment of severe intractable pain, particularly pain of malignant disease [45]. Superior hypogastric block is defined by Ricardo Plancarte in 1990 [46].

Spinal Cord Stimulation

The introduction of Melzack and Wall's [47] "Gate Control theory" may be accepted as the beginning of neuromodulation. This concept was tested in 1967 by Wall and Sweet, who stimulated their own infraorbital nerves [48]. Sweet recruited Roger Avery, an engineering colleague at Massachusetts Institute of Technology (MIT), to make an implantable stimulator, which he and Wepsic used to treat chronic pain by peripheral nerve stimulation, and the field of neuromodulation for pain management was born [49, 50].

In 1967, Norman Shealy had the idea to stimulate the large nerve fibers where they were uniquely gathered in the dorsal columns of the spinal cord. By 1981, battery technology had improved to the point where Medtronic was able to provide a fully implantable spinal cord stimulator [51] (Figure 2.16).

In 1973, shortly after the introduction of spinal cord stimulation, Hosobuchi reported the successful use of chronic stimulation of the somatosensory thalamus for the treatment of denervation facial pain, anesthesia dolorosa, and the field of deep-brain stimulation (DBS) was born [52].

Figure 2.16 C. N. Shealy (1932–).

In 1985, Augustinsson used spinal cord stimulation for pain of peripheral vascular disease and witnessed that this not only resulted in pain relief but often also improved circulation and showed improvement in signs of ischemia [53].

Intraspinal Analgesics

In 1901, Dr. Katawata from Japan injected 10 mg of morphine combined with 20 mg eucaine, into the subarachnoid space of two patients with uncontrollable back pain [54]. However, this technique was not used again for the next 75 years. In 1973, Pert and Snyder demonstrated the presence of opiate receptors in the nervous tissue [55]. Also in 1979, Behar et al. and Cousins et al. reported that injection of morphine in the epidural space afforded similar pain relief in cancer patients [56, 57].

Epidural Lysis of Adhesions

Lievre reported the first use of corticosteroids injected into the epidural space for the treatment of sciatica in 1957 [38]. Hypertonic saline was first administered by Hitchcock in 1967 for the treatment of chronic back pain when he injected cold saline intrathecally [58]. Racz and Holubec in 1989 reported the first use of epidural hypertonic saline to facilitate lysis of adhesions [59] (Figure 2.17).

Figure 2.17 Gabor Racz (1937–).

Figure 2.18 Y. Kanpolat (1941–2016).

Discography and Intradiscal Procedures

Lindblom demonstrated the presence of radial annular fissures upon injecting a dye into the disc of a cadaver. He described concordant pain provocation with saline discal distention [60].

In 1948, Hirsch injected procaine into a herniated disc and reported relief of sciatica [61].

In 1963, Smith injected chymopapain inside the disc. Among all the intradiscal procedures only chymopapain injection is approved by FDA. However, it has not been produced in the USA since 1999 [62].

Intradiscal electrothermal therapy was first used by Sall and Sall in 1997 [63].

Vertebroplasty

Vertebroplasty was described in 1984 by Galibert et al. In the beginning, vertebroplasty was used in the surgical treatment of vertebral tumors [64]. The first report on the analgesic effect and its use in augmentation of osteoporotic vertebral fractures was in 1994 [65].

Epiduroscopy

Studies on epiduroscopy were started by Burman on cadaver vertebras using rigid arthroscopic systems in 1931. Ooi developed endoscopy for intradural and extradural use between 1960 and 1970. Epiduroscopic technology with flexible optics has been used in clinical application on patients since the early 1990s [66].

In 1991, Heavner et al. reported on endoscopic examination of the epidural and spinal space of rabbits, dogs, and human cadavers using a flexible endoscope [67].

In 1996, Schutze published the first report on epiduroscopically assisted SCS electrode implantation [68].

Percutaneous Cordotomy

In 1912, Drs. William Gibson Spiller and Edward Martin [2] described the first "open" cordotomy for the treatment of pain due to a tumor of the lower spinal cord [69].

Percutaneous cordotomy was introduced by Mullan in 1963 under flouroscopic guidence [70] (Figure 2.18).

Kanpolat introduced the CT-guided cordotomy in 2009 and this technique has been used widely instead of fluoroscopic guidance [71].

References

1 Manchikanti, L., Boswell, M.V., Prithvi Raj, P. et al. (2003). Evolution of interventional pain management: an historical review. *Pain Physician* 6: 485–494.

2 Rynd, F. (1845). Neuralgia-introduction of fluid to the nerve. *Dublin Medical Press* 13: 167–168.

3 Wood, A. (1855). New method of treating neuralgia by direct application ofopiates to painful points. *Edinburgh Medical and Surgical Journal* 82: 265–281.
4 Koller, K. (1884). On the use of cocaine for producing anesthesia on the eye. *Lancet* 2: 290–292.
5 Tuffer, T. (1900). Anesthésie medullaire chirurgicale par injection sousarachnoidienne lombiare de cocaine; technique et resultats. *Semaine Medicale* 20: 167.
6 Die, G.G. (1919). Entdeckung der Lokalanästhesie. *Der neue Tag* 1 (137): S6.
7 Sicard, M.A. (1901). Les injections medicamenteuse extraduraqles per voie saracoccygiene. *Comptes Renues des Senances de la Societe de Biolgie et de ses Filliales* 53: 396–398.
8 Cathelin, F. (1901). Mode d'action de a cocaine injete daus l'escapte epidural par le procede du canal sacre. *Comptes Rendies des Senaces de la Societe de Biologic et de ses Filliales* 53: 452–453.
9 Pasquier, N.M. and Leri, D. (1901). Injection intra-et extradurales de cocaine a dose minime daus le traitment de la sciatique. *Bulletin of Gene Therapy* 142: 196.
10 Corning, J.L. (1885). Spinal anesthesia and local medication of the cord. *New York Medical Journal* 42: 483–485.
11 Corning, J.L. (1886). *Local Anesthesia*. New York: Appleton.
12 Corning, J.L. (1894). *Pain in Its Neuro-pathological, Diagnostic, Medico-legal, and Neuro-therapeutic Relations*. Philadelphia: J.B. Lippincott.
13 Bier, A. (1899). Versuche uber Cocainisierung des Ruckenmark. *Deutsche Zeitschrift fur Chirurgie* 51: 361–368.
14 Cathelin, F. (1901). A new route of spinal injection; a method of epidural injections by way of the Sacral Canal; application to man. *Royal Society of Biology* 53: 452.
15 Mirave, F.P. (1961). Segmental anesthesia. *Survey of Anesthesiology* 5: 326.
16 Dogliotti, A.M. (1939). *Anesthesia: Narcosis, Local, Regional, Spinal*. Chicago: S.B. Debour.
17 Curbelo, M. (1949). Continuous peridural segmental anesthesia by means of a ureteral catheter. *Current Researchers in Anesthesia & Analgesia* 28: 13–23.
18 Kirschner, M. (1931). Zür electrochirugie. *Archiv fur Klinische Chirurgie* 167.
19 Sweet, W.H. and Mark, V.H. (1953). Unipolar anodal electrolyte lesions in the brain of man and rat: report of five human cases with electrically produced bulbar or mesencephalic tractotomies. *A.M.A. Archives of Neurology and Psychiatry* 70: 224–234.
20 Cosman, E.R. Sr., Cosman, E.R. Jr. (2012). Principles and descriptions of special techniques; radiofrequency lesions. In: *Pain Relieving Procedures, The Illustrated Guide* (eds. Raj, P and Erdine, S), 68–78. Chichester: Wiley-Blackwell.
21 Rosomoff, H.L., Brown, C.J., and Sheptak, P. (1965). Percutaneous radiofrequency cervical cordotomy: technique. *Journal of Neurosurgery* 23 (6): 639–644.
22 Shealy, C.N. (1975). Percutaneous radiofrequency denervation of spinal facets. *Journal of Neurosurgery* 43: 448–451.
23 Sluijter, M. and Metha, M. (1981). Treatment of chronic back and neck pain by percutaneous thermal lesions. In: *Persistent Pain, Modern Methods of Treatment* (ed. S. Lipton), 141–179. London: Academic Press.
24 Sluijter, M.E., Cosman, E.R., Rittman, W.B. III. et al. (1998). The effects of pulsed radiofrequency field applied to the doral root ganglion–A preliminary report. *The Pain Clinic* 11: 109–117.
25 Schloesser, H. (1903). Heilung periphärfer Reizzustände sensibler und motorischer Nerven. *Klinische Monatsblatter fur Augenheilkunde* 41: 255.
26 Härtel, F. (1914). Über die intracranielle Injektionsbehandlung der Trigeminusneuralgie. *Medizinische Klinik* 10: 582–584.
27 Sweet, W.H. and Wepsic, J.G. (1974). Controlled thermocoagulation of trigeminal ganglion and rootlets for differential destruction of pain fibers. 1. Trigeminal neuralgia. *Journal of Neurosurgery* 40: 143–156.
28 Häkanson, S. (1981). Trigeminal neuralgia treated by the injection of glycerol into the trigeminal cistern. *Neurosurgery* 9: 638–646.
29 Mullan, S. and Lichtor, T. (1983). Percutaneous microcompression of the trigeminal ganglion for trigeminal neuralgia. *Journal of Neurosurgery* 59: 1007–1012.
30 Halsted, W. (1885). Practical comments on the use and abuse of cocaine suggested by its invariably successful employment in more than a thousand minor surgical operations. *New York Medical Journal* 42: 294–295.
31 Kappis, M. (1914). Erfahrungen mit Lokalanästhesie bei Bauchoperationen. *Verhandlungen der Deutschen Gesellschaft fur Chirurgie* 43: 87.
32 Läwen, A. (1922). Ueber segmentäre Schmerzaufhebung durch papavertebrale Novokaininjektionen zur Differentialdiagnose intra-adbominaler Erkrankungen. *Medizinische Wochenschrift* 69: 1423.
33 Braun, H. (1905). Ueber einige neuer örtliche Anaesthetica (Stovain, Alypin, Novocain). *Deutsche Klinische Wochenschrift* 31: 1667.

34 Labat, G. (1922). *Regional Anesthesia: Its Technic and Application*. Philadelphia: WB Waunders.

35 Ischia, S., Luzzani, A., and Ischia, A. (1983). A new approach to the neurolytic celiac plexus block; the transaortic aproach. *Pain* 16: 333–341.

36 Prithvi Raj, P., Şahinler, B., and Lowe, M. (2002). Radiofrequency lesioning of splancnic nerves. *Pain Practice* 2 (3): 241–247.

37 Robecchi, A. and Capra, R. (1952). L'idrocortisone (composto F): prime esperienze cliniche in campo reumatologico. *Minerva Medica* 98: 1259–1263.

38 Lièvre, J.A., Bloch-Michel, H., Pean, G. et al (1953). L'hydrocortisone en injection locale. *Revue du Rhumatisme et des Maladies Osteo-articulaires* 20: 310–311.

39 Goldthwait, J.E. (1911). The lumbo-sacral articulation. An explanation of many cases of "Lumbago," "Sciatica" and Paraplegia. *Boston Med and Surgical Journal* 164: 365–372.

40 Ghormley, R.K. (1933). Low back pain. With special reference to the articular facets, with presentation of an operative procedure. *JAMA* 101: 1773–1777.

41 Badgley, C.E. (1941). The articular facets in relation to low-back pain and sciatic radiation. *The Journal of Bone & Joint Surgery* 23: 481–496.

42 Labat, G. (1924). Circulatory disturbances associated with subarachnoid nerve block. *Long Island Medical Journal* 21: 573.

43 Brunn, F. and Mandl, F. (1924). Die paravertebral Injektion zur Bekäampfung visceraler Schmerzen. *Wiener Klinische Wochenschrift* 37: 511.

44 Kappis, M. (1912). ueber Leitungsanästhesie an Bauch, Burst, Arm und Hals durch Injektion ans Foramen intervertebrale. *Münchener Medizinische Wochenschrift* 1: 794.

45 Swetlow, G.I. (1926). Paravertebral alcohol block in cardiac pain. *American Heart Journal* 1: 393.

46 Plancarte, R., Amescua, C., Patt, R.B. et al (1990). Superior hypogastric plexus block for pelvic cancer pain. *Anesthesiology* 73: 236–239.

47 Melzack, R. and Wall, P.D. (1965). Pain mechanisms: a new theory. *Science* 150: 971–979.

48 Wall, P.D. and Sweet, W.H. (1967). Temporary abolition of pain in man. *Science* 155: 108–109.

49 Sweet, W.H. and Wepsic, J.G. (1968). Treatment of chronic pain by stimulation of fibers of primary afferent neuron. *Transactions of the American Neurological Association* 93: 103–107.

50 Philip, L. (2006). Gildenberg, history of electrical neuromodulation for chronic pain. *Pain Medicine* 7: 7–13.

51 Shealy, C.N., Mortimer, J.T., and Reswick, J.B. (1967). Electrical inhibition of pain by stimulation of the dorsal columns. Preliminary clinical report. *Anesthesia & Analgesia (Cleveland)* 46: 489–491.

52 Hosobuchi, Y., Adams, J.E., and Rutkins, B. (1973). Chronic thalamic stimulation for the control of facial anesthesiadolorosas. *Archives of Neurology* 29: 158–161.

53 Augustinsson, L.E., Carlsson, C.A., Holm, J. et al. (1985). Epidural electrical stimulation in severe limbischemia. Pain relief, increased blood flow, and apossible limb-saving effect. *Annals of Surgery* 202: 104–110.

54 Matsuki, A. (1983). (Editorial). Nothing new under the sun - a Japanese pioneer in the clinical use of intrathecal morphine. *Anesthesiology* 58: 289–290.

55 Pert, C. and Snyder, S. (1973). Opiate receptor: demonstration in nerve tissue. *Science* 179: 1011–1014.

56 Behar, M., Olshwang, D., Magora, F. et al. (1979). Epidural morphine in treatment of pain. *Lancet* 1: 527–528.

57 Cousins, M.J., Mather, E., Glynn, C.J. et al. (1979). Selective spinal analgesia. *Lancet* 1: 1141–1142.

58 Hitchcock, E. (1967). Hypothermic subarachnoid irrigation for intractable pain. *Lancet* 1: 1133–1135.

59 Racz, C.B. and Holubec, J.T. (1989). Lysis of adhesions in the epidural space. In: *Techniques of Neurolysis* (ed. G.B. Racz), 57–72. Boston: Kluwer Academic.

60 Lindblom, K. (1948). Diagnostic puncture of the intervertebral discs in sciatica. *Acta Orthopaedica Scandinavica* 17: 231–239.

61 Hirsch, C. (1948). An attempt to diagnose level of disc lesion clinically by disc puncture. *Acta Orthopaedica Scandinavica* 18: 131–140.

62 Smith, L., Garvin, P.J., Gesler, R.M. et al. (1963). Enzyme dissolution of the nucleus pulposus. *Nature* 198: 1311–1312.

63 Saal, J.A., Saal, J.S., and Ashley, J. (1997). Targeted intradiscal thermal therapy: preliminary feasibility results. Presented at the anual meeting of the international society for the study of the lumbar spine, Singapore.

64 Galibert, P., Deramond, H., Rosat, P. et al. (1987). Preliminary note on the treatment of vertebral angioma by percutaneous acrylic verte-broplasty. *Neurochirurgie* 33: 166–168.

65 Gangi, A., Kastler, B.A., and Dietemann, J.L. (1994). Percutaneous vertebroplasty guided by a combination of CT and fluoroscopy. *American Journal of Neuroradiology* 15: 83–86.

66 Saberski, L.R. (2007). The history of epiduroscopy (spinal canal endoscopy). *The Pain Clinic* 19 (4): 141–148.

67 Heavner, J.E., Chokhavata, S., and Kizelshteyn, G. (1991). Percutaneous evaluation of the epidural and subarachnoid space with the flexible fiberscope. *Regional Anesthesia* 85: 1551.

68 Schütze, G. (1996). Epiduroscopically guided percutaneous implantation of spinal cord stimulation electrodes. Management of pain a world perspective II. In: *Management of Pain* (ed. P. Raj, S. Erdine, and Niv), 301–304. Bologna: Monduzzi Editore S.p.A.

69 Spiller, W. and Martin, E. (1912). The treatment of persistent pain of organic origin in the lower part of the body by division of the anterolateral column of the spinal cord. *JAMA* 58: 489–490.

70 Mullan, S., Harper, P.V., Hekmatpanah, J. et al. (1963). Percutaneous interruption of spinal-pain tracts by means of a strontium90 needle. *Journal of Neurosurgery* 20: 931–939.

71 Kanpolat, Y., Ugur, H.C., Ayten, M. et al. (2009). Computed tomography-guided percutaneous cordotomy for intractable pain in malignancy. *Neurosurgery* 64: ons187–ons193; discussion. 193–194.

3

Ethics of Interventional Pain Management

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> *Medicine must relieve the pain of the sick, and lessen the violence of their diseases …*
>
> —Hippocrates

Interventional pain management is defined by the Medicare Payment Advisory Commission as "minimally invasive procedures including percutaneous precision needle placement, with placement of drugs in targeted areas or ablation of targeted nerves; and some surgical techniques such as laser or endoscopic discectomy, intrathecal infusion pumps and spinal cord stimulators; for the diagnosis and management of chronic, persistent or intractable pain" [1].

Ethics has been a subject of medicine since the beginning of humankind both for physicians and patients. The Hippocratic Oath has existed since the times of ancient Greece [2]. However, pain medicine still does not have ethical guidelines although, in recent years, the principles of ethics are considered more as the number of interventional pain procedures is increasing.

Ethical and morality theories of biomedical ethics should be a part of pain medicine. Beauchamp and Childress in their *Principles of Biomedical Ethics*, have described four principles essential for biomedical ethics: respect for autonomy, non maleficence, beneficence, and justice [3].

Respect for autonomy: Patients with capacity are free to make their own healthcare decisions. Health professionals should act in a way that respects patients' beliefs and decisions, values, and culture. This may be realized by obtaining the patient's valid consent for any intervention. If the patient is without the capacity to present their desires, or cannot decide for themselves, they should be more protected [4].

Non malefaisence: Health professionals should act with the intent of avoiding harm, or first do no harm, "primum non nocere". Performing an interventional procedure on a patient which may provide only short-term pain relief but cause severe problems in the long term may also be considered as a violation of non maleficence.

Benefaisence: Physicians are responsible not only for refraining from harmful acts but also for promoting the good of the patient (bene facere).

Justice: Health professionals act with the intent of ensuring fair allocation of resources among those who have need, and distribute benefits and inconveniences equally.

Since Descartes, the physician has seen the body as a machine, and himself as a mechanic who fixes its broken parts. The patient applies to the medical system and is transformed into an object, then reduced to a symptom, syndrome, MRI image or a laboratory finding. There is great discrepancy between the physician's narrow vision of finding and treating the disease and the demand of the patient clearly asking for a better quality of life by treating the disease. This is called the biomedical model.

The biopsychosocial model, which emerged in the 1980s, provides a framework for understanding how diverse biologic (e.g., injury, infection), psychologic (e.g., negative mood, coping), and social/environmental (e.g., social support, access to services) factors can interact to influence a person's overall experience of pain [5].

A patient is a human being living in their society with a cultural, religious, societal background and history. As they become a chronic pain patient, and apply to the medical system, they are not only a

Complications of Pain-Relieving Procedures: An Illustrated Guide, First Edition. Edited by Serdar Erdine and Peter S. Staats.

syndrome or a complaint although the biomedical system "pushes" them in that direction.

Pain physicians are frequently confronted with the dilemma of scientifically unproven techniques, with treatments largely out of their control, and with lack of outcome assessment.

Inappropriate utilization of interventional techniques has been a topic of discussion in recent years. Benyamin et al. highlighted the "explosive growth of physicians performing these procedures without training" [6, 7]. Manchikanti et al. described the ethical issues of interventional pain management in the following terms: overuse, abuse, waste, and fraud; inappropriate application of EBM; and organizational issues related to multiple societies [8].

Overuse: There was an explosive growth in the number of Spinal Interventional Pain Management Techniques between 2000–2011. The total number was 1 469 498 in 2000 while it was 4 815 673 in 2011. The increase from 2000 to 2011 is 228% with an annual geometric average change equal to 11.4%. There was also an exponential increase in facet joint and sacroiliac joint injections [9, 10].

The number of injections varied according to physician speciality. While there was an increase in total of 228 % for Anesthesiology, the increase was 1212 % for Radiology, and 838 % for Physiatry [11]. All these numbers confirm the overuse of these techniques in recent years.

Industry relationships have also affected pain management in a negative fashion. While competition among pain medicine practitioners was increasing and new technologies and high-paying procedures were preferred, there was a reduction in less profitable treatment options [12].

Widespread use of inadequately tested or unnecessary pain procedures decreased the use of some treatments with well-documented effectiveness, and the lack of adequate pain education is a major concern [13].

A conflict of interest is a situation in which someone in a position of trust, such as a physician or a medical research scientist, has competing professional or personal interests that have the potential to influence patient care or other professional primary obligations such as research and education. Conflicts of interest can create self-serving biases that can be unconscious and unintentional, and that do, ultimately, influence patient care.

Traditionally, disclosing potential conflicts has been seen as an appropriate way to manage them; however, recent evidence suggests disclosure might do little to mitigate the potential conflict. Rather, disclosure unfairly places the burden of managing the conflict on those to whom the disclosure is made, charging them with determining how skeptical to be about the objectivity of the individual with the potential conflict [14].

The secondary interest of practice profit may play a large role in interventional pain management [15].

Consultants and advisory boards: Consultants to industry are essential to aid in product developement. However, consultants can be either be true experts or "token" consultants who are selected because they are high users or potential users of a drug, product, or medical device.

CME: Industry can and does play a large, legitimate, and significant role in continuing medical education (CME). It is ethical, reasonable, and necessary to rely on funding from industry for the purposes of education. However, CME programs must follow strict guidelines to minimize industry influence on CME content.

Technophilism and technocentricism: The industrial revolution in the twentieth-century to improve quality of life has led to technophilism and technocentricism. As technology progresses, the responsibilities to utilize or not to utilize for good and non-harm should also progress. The importance of not rejecting the evidence-based low-tech pain management tools that are already a part of our armamentarium simply because high-technology tools are becoming available is vital, and we should recognize the dangers of technophilism.

Patient–physician relationship: Many patients have been through the "medical mill", frustrated by previous providers who have not been able to cure their malady or worse, who have aggravated their condition. The vulnerable, often desperate, nature of many pain patients makes them very susceptible to trying anything that all-too-willing practitioners might do. Given the great multitude of interventions available today, desperate individuals with unremitting pain may find pain specialists who may take advantage of a patient by doing unnecessary or overly extensive procedures.

Chronic pain patients face many difficulties including lack of relief exacerbated by iatrogenic or traumatic injuries. The ethical dictum of non maleficence, or do no harm, is strongly tested under these conditions. Most interventions used today by pain centers have not been shown to be efficacious from a scientific perspective. The preceding issue becomes more pronounced when considering the increasing economic pressures of pain clinics. This has increased incentives to carry out more invasive and profitable interventions. The ethical principle of non maleficence may be seriously taxed with this conflict.

Another trend seen in the practice of pain medicine is lack of scientific rigor. Within this subset of

anecdotal practice exists a significant amount of care that disregards the literature and peer-reviewed consensus. This is not unique to pain medicine and occurs within all specialties in medicine [16].

Pellegrino provides the following guidelines for collective action on the part of the medical profession [17]:

1) Physicians are physicians first, not managed care functionaries.
2) Physicians must remain stewards of quality of care, the consideration of which results in every policy, rule, or regulation put forward by the managed care organization.
3) Physicians must insist on the integrity of the physician–patient relationship and on a medical ethics independent of social whim or government fiat.
4) Physicians must oppose systems using financial or other incentives to modify physician behavior that can harm patients.
5) Physicians must always maintain the primacy of the patient's good.
6) Physicians must encourage, support, and participate in studies of therapeutic efficacy.

As physicians, we are required to practice self-effacement. Very few have an understanding of what correct pain practice is. Today, the management of pain is still a vital area of physician education that is not dealt with adequately.

The opportunity presents itself for these organizations to have a significant impact on creating the appropriate rules and guidelines for pain practice. If the pain societies do not rise to this occasion, it will be a missed opportunity which could steer their own future. From the viewpoint of the average physician or organization, pain medicine appears to be a confusing realm of scattered methodologies with little common theme.

References

1 Medicare Payment Advisory Commission (2001). Report to the congress: paying for interventional pain services in ambulatory settings. Washington, DC: MedPAC. https://search.library.ucdavis.edu/discovery/fulldisplay?vid=01UCD_INST:UCD&mode=advanced&tab=Everything&isFrbr=true&docid=alma990027359550403126&query=sub,exact,%20Pain%20,AND&context=L&adaptor=Local%20Search%20Engine&lang=en (accessed 23 November 2021).

2 Dubois, M.Y. (2005). Editorial. The birth of an ethics charter for pain medicine. *Pain Medicine* 6 (3): 199–273.

3 Beauchamp, T.L. and Childress, J.F. (1994). *Principles of Biomedical Ethics*, 4e. Oxford: Oxford University Press.

4 Loeser, J.D. (2005). Pain: disease or dis-ease? The John Bonica lecture: presented at the third world congress of World Institute of Pain, Barcelona 2004. *Pain Practice* 5 (2): 77–84.

5 Novya, D.M. and Aigner, C.J. (2014). The biopsychosocial model in cancer pain. *Current Opinion in Supportive and Palliative Care* 8 (2): 117–123.

6 Benyamin, R.M., Datta, S., and Falco, F.J.E. (2010). A perfect storm in interventional pain management: regulated, but unbalanced. *Pain Physician* 13: 109–116.

7 Manchikanti, L., Falco, F.J.E., Boswell, M.V. et al. (2010). Facts, fallacies, and politics of comparative effectiveness research: part1. Basic considerations. *Pain Physician* 13: E23–E54.

8 Manchikanti, L., Singh, V., and Boswell, M.V. (2010). Interventional pain management at crossroads: the perfect storm brewing for a new decade of challenges. *Pain Physician* 13: E111–E140.

9 Manchikanti, L., Singh, V., Pampati, V. et al. (2009). Analysis of growth of interventional techniques in managing chronic pain in the medicare population: a 10-year evaluation from 1997 to 2006. *Pain Physician* 12: 9–34.

10 Manchikanti, L., Falco, F.J.E., Singh, V. et al. (2012). Utilization of interventional techniques in managing chronic pain in the Medicare population: analysis of growth patterns from 2000 to 2011. *Pain Physician* 15: E969–E982.

11 Friedly, J., Chan, L., and Deyo, R. (2007). Increases in lumbosacral injections in the Medicare population 1994 to 2001. *Spine* 32 (16): 1754–1760.

12 Taylor, M.L. (2011). The impact of the "business" of pain medicine on patient care. *Pain Medicine* 12: 763–772.

13 Dana, J. and Loewenstein, G. (2003). A social science perspective on gifts to physicians from industry. *JAMA* 290 (2): 252–255.

14 Wazana A. (2000). Physicians and the pharmaceutical industry: is a gift ever just a gift? *JAMA* 283 (20): 373–380.

15 Schofferman, J. (2006). Interventional pain medicine: financial success and ethical practice: an oxymoron? *Pain Medicine* 7 (5): 457–460.

16 Lebovits, A. (2001). Ethics and pain: why and for whom? *Pain Med* 2 (2): 92–96.

17 Pellegrino, E.D. (1994). Ethics. *JAMA* 271: 1668–1670.

4

Clinical Assessment of Patients to Decrease Risk

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Introduction

The incidence of complications in interventional pain management remains difficult to estimate. A high number of procedures are performed each year worldwide, but a low incidence of complications is generally reported with some of these being catastrophic, as inferred from the ASA Closed Claims Project Database 1970–2000 [1]. In a recent study on 26 061 consecutive interventional pain procedures, an overall complication rate of 1.9% was reported and no major complications such as permanent neurologic deficit, clinically significant bleeding or epidural hematoma [2] were observed. This improvement is likely due to the implementation of standardized patients' clinical assessment before interventional procedures in order to minimize the risk of complications and to improve patient outcomes. Therefore, collecting physical, medical, and pharmacologic information and drawing conclusions through clinical observation, instrumental tests, and psychologic evaluation is essential before scheduling any interventional pain procedure.

Medical and Pharmacologic Assessment

A thorough medical and pharmacologic assessment is mandatory in all patients undergoing interventional pain treatments, regardless of type of procedure. In addition to the identification of drug and material allergies (NSAIDs, steroids, local anesthetics, antibiotics, iodine or gadolinium contrast-medium, latex, and others), evaluation of patients' co-morbidities is pivotal. For instance, in diabetic patients, corticosteroid injections have proven to worsen control of glucose levels and post-procedural hyperglycemia [3]. In this set of patients, a thorough evaluation of disease severity and viable treatments is necessary, aiming toward a reduction in corticosteroid dosage, as advocated by some authors for epidural steroid injections [4].

Bleeding diathesis due to both platelet aggregation and coagulation disturbances requires specific and accurate preoperative evaluation, even with specialist consultation [5]. Regarding platelet count, the most recent evidence recommends a platelet count of > 80 000 μL for low- to medium-risk invasive procedures and a platelet count of >100 000 μL for high-risk procedures [6].

The same caution is required in patients' post-operative infective risk stratification. Surveillance data on Spinal Cord Stimulation (SCS) and Intrathecal Drug Delivery System (IDDS) revealed that 38% and 70% of patients respectively suffering from post-procedural infections showed pre-existing medical co-morbidities that would increase their infective risk. Among these co-morbidities were older age, poor nutritional status, diabetes, smoke addiction, obesity, remote-site moderate to severe infections, *Staphylococcus aureus* colonization, and immune status dysregulations [7]. Both patient-related infective risk screening and correction of modifiable factors (blood glucose optimization, tobacco cessation for at least four weeks, optimization of viral load in HIV patients, minimizing/avoiding perioperative oral steroids, and treatment of remote infections) are the gold standard in the preoperative period. In the case of non-modifiable

Complications of Pain-Relieving Procedures: An Illustrated Guide, First Edition. Edited by Serdar Erdine and Peter S. Staats.

factors, increased infective risk should be discussed and accepted by the patient prior to intervention. Nonetheless, neuroinvasive procedures in patients with an active infection requiring antibiotics should be postponed because of the potential risk of bacteremia or bacterial spread into the epidural or subarachnoid space. Regarding patients with cardiovascular disease, preoperative evaluation and risk stratification must thoroughly comply with the most recent guidelines on the topic [8].

Moreover, both structural and functional abnormalities possibly impacting on either the anesthesiologic interventional procedure itself or the response to anesthetics (through conscious sedation or general anesthesia) must be highlighted. The health professional might want to inquire specifically about spinal deformities, severe obesity, osteoporosis, dyskinesia, and other neurologic diseases, local malignancies, cognitive dysfunction, pregnancy, and cardiopulmonary diseases.

Evaluation of current drug therapy must include past and present analgesic drug consumption. Antithrombotic and anticoagulant treatments need to be reported due to the significant bleeding risk associated with several interventional procedures. Such treatments must be amended according to the most recent guidelines, thus taking into account drug type, bridging modalities, and procedure-related bleeding risk [9]. A complete pain medication history must be collected including dosages, associations, effectiveness, and any related adverse events with particular attention to drug abuse, diversion, and misuse. The shift to intrathecal opioid delivery is an option for those patients who seem to be unresponsive to systemic opioids. It is still controversial whether or not it provides proper analgesia to switch to opioids intrathecal administration when systemic high doses have failed. According to some authors, in these patients, IDDS should be performed with medications other than morphine, e.g., ziconotide [10]. Finally, evaluation of pain medication overuse is a mainstay in chronic headache treatment. In these patients, detoxification is mandatory but may induce withdrawal symptoms lasting 2–10 days, with no pharmacologic strategies proven to be effective in preventing rebound symptoms [11]. Therefore, invasive interventions such as greater occipital nerve (GON) blocks or onabotulinum toxin A infiltrations might be efficaciously performed prior to drug withdrawal [12].

Pain Assessment

Pain therapists are often the last specialists to evaluate a patient with chronic pain and although the first request is that of a prompt pain relief, their mission is far more challenging. In real-life settings, history of previous pain patient's evaluations often shows a lack of crucial information including clinical objectivity, instrumental and laboratory examinations, quality of life (QoL), and diagnosis in terms of "pain generator" identification [13]. Therefore, the aim of careful evaluation in a specialized pain center must settle some crucial questions such as the accuracy of pain physiopathologic classification, the relationship between clinical evidence and patients' symptoms, including their severity, and functional limitations and appropriateness of performed investigations.

Further, one must consider whether a correct pain diagnosis has been made or an alternative one needs to be taken into consideration. Health professionals should thereafter ensure that previous treatments were up-to-date, evidence-based and carried out according to the correct pain diagnosis. Physiopathologic classification remains a mainstay of pain assessment, particularly in patients eligible for invasive interventions. To date, the categorical way of classifying human pain as nociceptive or neuropathic according to whether there is or is not a detectable neural lesion is still considered appropriate. Nonetheless, nociceptive and neuropathic mechanisms may coexist in mixed pain syndromes, for which no consensus on specific diagnostic criteria has yet been reached [14].

In preparation for an invasive procedure, however, chronic pain disorders with a neuropathic component (e.g., low back pain [LBP]) should not be mistaken for chronic nociplastic pain, i.e., pain arising from altered nociception with no evidence of tissue or somatosensory system damage [15]. In such a clinical entity as Fibromyalgia Syndrome (FMS), invasive procedures are by large consensus not recommended by international treatment guidelines [16]. Similarly, invasive procedures must be avoided in patients with pain of unknown origin (PUO), psychogenic pain and somatization disorders [13].

Indication for Interventional Procedures

As regards interventional procedures for pain management, these are performed in cases of unresponsiveness to conservative treatments or severe to unbearable side effects of the latter. However, each clinical case needs to be handled individually, applying the aforementioned recommendations accordingly. While opioid treatment is a pivotal tool in oncologic pain treatment, neuropathic, bone, spontaneous and breakthrough pain may result almost completely in being unresponsive to opioids. In these settings, nonpharmacologic treatments play an important role, even in the early stages of the disease [17]. Moreover, some oncologic diseases demonstrate partial responsiveness

to opioids. For instance, in pancreatic cancer-related pain, invasive procedures might be considered as an early-stage treatment option in order to increase analgesia and reduce painkiller consumption and related adverse events [18].

On the other hand, the more intense type of pain related to advanced or end-stage pancreatic cancer may induce pain therapists to avoid neuroablative procedures of which the analgesic effect has proven to be negligible [19]. In non-cancer pain treatment, the situation has changed dramatically over the last few years in relation to the opioid epidemic and its deleterious sanitary consequences in some countries [20]. Attention to these concerns was raised by Pain Practitioners Societies, suggesting to start treating non-cancer pain with lower opioid doses together with interventional techniques [21].

Further, most recent guidelines highlighted the strong recommendation that when considering chronic non-cancer pain treatment, optimization of non-opioid and non-pharmacologic therapy, if viable, is mandatory and preferable rather than a trial of opioid medications [22]. Unfortunately, the role of interventional techniques is still poorly outlined in some diffuse pain syndromes such as LBP or osteoarthritis (OA). This is mostly due to methodologic concerns, although worldwide, these procedures are scheduled and performed daily [23, 24].

Neuroablative procedures must be taken into consideration in patients with pain of uncertain etiology. Demolitive treatments are contraindicated in syndromes such as idiopathic persistent facial pain (IPFP), where the risk of subsequent neuropathic refractory pain and neurologic dysfunction is relevant [25].

Similar considerations must be undertaken in other pain syndromes such as chronic pelvic pain of unknown or multifactorial origin or chronic abdominal idiopathic pain [26]. In these patients, neuroinvasive procedures such as SCS showed a rapid increase in applications thanks to new technologies. While indications for SCS are generally limited to specific chronic pain syndromes (Complex Regional Pain Syndromes [CRPS] and Failed Back Surgery Syndrome [FBSS], peripheral ischemic limb pain, and refractory angina pectoris), emerging evidence indicates the potential role in different pain etiologies refractory to conservative treatments, given the possibility to perform trial periods and the total reversibility of the procedure if ineffective, however, taking into account any possible complication [27, 28].

With regard to a patient's age, except for cancer-related pain, neuroablative procedures must be considered with caution in younger patients, given that these patients are at higher risk of developing post-procedural neuropathic pain. The actual risk of inducing long-lasting and refractory post-procedural pain or neurologic disturbances is a significant issue when performing percutaneous treatments in trigeminal neuralgia [29]. In older patients affected by chronic non-cancer pain, the quality of medical literature on the efficacy of interventional therapies remains poor. Nevertheless, considering the relevant risk of painkiller-related side effects in elderly patients, some authors suggest offering therapeutic nerve blocks or low-risk neuroablative procedures prior to strong opioids, as well as including invasive techniques in a multimodal pain approach [30].

Psychiatric Assessment and Expectations

Evaluation of a patient's psychiatric condition is of major concern in interventional pain management, particularly in chronic non-cancer pain. It is well-known that these patients frequently display psychopathologic features such as depressive and/or anxiety disorders, somatization disturbance, drug dependence and personality traits [31]. Irrespective of the unresolved questions concerning the role of psychologic and behavioral components in determining the impact and intensity of pain in different individuals and clinical scenarios, researchers' attention has been focusing on the relationship between specific pre-existing psychologic patterns and outcomes following interventional pain procedures. Most of the published studies address some specific invasive procedures such as SCS and IDDS. As to SCS, among 150 patients screened with psychologic questionnaires prior to implant for neuropathic pain states like CRPS and FBSS, depression and anxiety symptoms were detected in 63% and 23% of patients respectively; even higher if compared with the general population.

Moreover, the majority of patients with depression had not been identified and managed prior to pain clinic consultation [32]. A review of published studies on psychologic predictors of SCS outcomes revealed that the predictive values of psychologic testing varied with the tools used and the outcomes measured. However, depression was shown to be predictive of SCS negative outcomes in some studies while body concerns, autonomous coping, diminished feeling of joy, demoralization and aberrant negative thoughts, substance abuse, and emotional internalizing disorders were associated with worse outcomes [33].

In this context, a psychologist referral may be useful for assessing mental health, setting expectations for pain relief and to prepare patients who were

initially deemed unsuitable for SCS by providing recommendations and potential access to clinical care addressing psychologic issues in chronic pain [34]. Although an accepted panel of psychologic screening or evaluation was not clearly established, most recent guidelines stated that the psychologic assessment to address psychiatric co-morbidities before proceeding with SCS is mandatory. Moreover, patients with underlying untreated major psychiatric co-morbidities or history of painkiller abuse or with inadequately managed psychiatric co-morbidities should not be treated with SCS [35]. In patients scheduled for IDDS for cancer pain, a psychologic screening is not considered appropriate, as palliation is the primary goal of therapy. For non-cancer pain patients, the literature suggests a partnership between psychologists and pain physicians to evaluate patients' expectations for treatment.

Moreover, ziconotide delivery is contraindicated in patients with a history of psychosis and alternatives should be sought [36]. In general, patients eligible for IDDS should not present with psychiatric abnormalities and/or history of substance abuse (alcohol, drugs), although psychometric tests cannot be used as the sole assessment criterion. The instruments selected will depend on health professionals' judgment according to each individual case [37]. Eventually, the assessment of patients' expectations for pain relief before invasive procedures remains a controversial issue. Some observations suggest that, while exaggerated expectations were always believed to be a negative predictor of success after procedures, considering the different types of expectations could be crucial, taking into account other QoL indicators [38]. Global impression of change (GIC) was in fact demonstrated as a better mediator of the association between expectations and outcomes rather than changes in pain intensity alone, thus implying the fact that pain treatments are able to improve functioning, emotional state, and overall QoL even with limited pain relief [39].

Clinical and Instrumental Documentation

Interventional pain physicians should be able to interpret a wide load of clinical documentation, including radiologic investigations (MRI, CT, Ultrasound, X-ray), neurophysiologic and laboratory tests. Unfortunately, the growing overall complexity of diagnostic procedures and findings and ambitiously, often unattainably extensive knowledge, would be requested by pain therapists. Therefore, depending on the specific field of interest, an accurate review of the available imaging must be performed prior to intervention, particularly in interventional spine procedures, considering that errors and discrepancy are reported in radiologic practice in 3–5% of studies [40].

This obviously requires indepth study and ongoing training or expert radiologic consultation. Regarding neurophysiologic tests, results from investigations must be thoroughly evaluated. As an example, electromyography (EMG) requested in patients with radiculopathy may be useful, while clinical signs do not often correspond to EMG evidence, depriving this examination of absolute diagnostic value [41]. In conclusion, principles, indications and keys to correctly interpreting diagnostic examinations must be part of the cultural background of interventional pain therapists from the beginning of the training process [42].

Family Support, Malingering and Litigation

Lack of social or family support and difficult access to medical care may represent a strong barrier to performing interventional pain procedures, particularly if, in the post-operative period, close monitoring is required or frequent in-hospital consultation and visits are scheduled. Even although in both SCS and IDDS the poor quality of social and family support is included in patient selection protocols, this evaluation is not clearly detailed and the judgment on such a crucial aspect is apparently delegated to the pain therapist's perception [36, 43].

Moreover, secondary gain must be taken into careful consideration before interventional procedures in chronic non-cancer pain, even if a diagnostic clarification must be performed by psychologists or psychiatrists [44]. Malingering, best known as conscious falsification of medical symptoms, is also possibly evident in pain management, even if particularly associated with the medicolegal context [45]. While the impact of malingering in interventional pain management is not actually well specified, malingering suspicion must be thoughtfully excluded through appropriate psychologic or psychiatric evaluation. Bottom line, patients with ongoing litigation related to worker's compensation claims for industrial injuries, personal injury claims for accidents, medical malpractice, workplace harassment or discrimination or even criminal proceedings may request interventional treatments. These patients represent a unique challenge for pain physicians due to the psychologic aspects that might influence the outcome of pain treatments [46].

References

1 Araujo, M., More-O'Farrall, D., and Richeimer, S.H. (2008). Complications of interventional pain management procedures. *Advances in Anesthesia* 26: 1–30.

2 Carr, C.M., Plastaras, C.T., Pingree, M.J. et al. (2016). Immediate adverse events in interventional pain procedures: a multi-institutional study. *Pain Medicine* 17: 2155–2161.

3 Nguyen, V.H., Goel, A.P., Yerra, S. et al. (2018). Use of a screening questionnaire to identify patients at risk of hyperglycemia prior to steroid injection therapy. *Pain Medicine* 19: 2109–2114.

4 Kim, W.H., Sim, W.S., Shin, B.S. et al. (2013). Effects of two different doses of epidural steroid on blood glucose levels and pain control in patients with diabetes mellitus. *Pain Physician* 16: 557–568.

5 Raj, P.P., Shah, R.V., Kaye, A.D. et al. (2004). Bleeding risk in interventional pain practice: assessment, management, and review of the literature. *Pain Physician* 7: 3–51.

6 Jones, M.R. (2019). letter to Editor. Role of platelet concentration in bleeding complications of interventional techniques. *Pain Physician* 22: E361–E367.

7 Provenzano, D.A., Hanes, M.C., and Deer, T.R. (2018). Interventional pain procedures and the risk of infection. In: *Essentials of Pain Medicine*, 4e (ed. H. Benzon, S.N. Raja, S.M. Fishman et al.), 813–824. Philadelphia: Elsevier.

8 Fleisher, L.A., Fleischmann, K.E., Auerbach, A.D. et al. (2014). ACC/AHA guideline on perioperative cardiovascular evaluation and management of patients undergoing non-cardiac surgery. A report of the American College of Cardiology/American Heart Association Task Force on practice guidelines. *Circulation* 130: e278–e333.

9 Kaye, A.D., Manchikanti, L., Novitch, M.B. et al. (2019). Responsible, safe, and effective use of antithrombotics and anticoagulants in patients undergoing interventional techniques: American Society of Interventional Pain Physicians (ASIPP) guidelines. *Pain Physician* 22: S75–S128.

10 Pope, J.E., Deer, T.R., Bruel, B.M. et al. (2016). Clinical uses of intrathecal therapy and its placement in the pain care algorithm. *Pain Practice* 16 (8): 1092–1106.

11 Kristoffersen, E.S. and Lundqvist, C. (2014). Medication-overuse headache: epidemiology, diagnosis and treatment. *Therapeutic Advances in Drug Safety* 5 (2): 87–99.

12 Bendtsen, L., Sacco, S., Ashina, M. et al. (2018). Guideline on the use of onabotulinum toxin A in chronic migraine: a consensus statement from the European Headache Federation. *The Journal of Headache and Pain* 19 (1): 91.

13 Cahana, A., Mavrocordatos, P., Van Gessel, E. et al. (2004). The role of interventional pain management in chronic pain. *Journal of Anesthesia* 18: 29–35.

14 Freynhagen, R., Arevalo Parada, H., Calderon-Ospina, C.A. et al. (2019). Current understanding of the mixed pain concept: a brief narrative review. *Current Medical Research and Opinion* 35 (6): 1011–1018.

15 Kosek, E., Cohen, M., Baron, R. et al. (2016). Do we need a third mechanistic descriptor for chronic pain states? *Pain* 157: 1382–1386.

16 Thieme, K., Mathys, M., and Turk, D.C. (2017). Evidenced-based guidelines on the treatment of fibromyalgia patients: are they consistent and if not, why not? Have effective psychological treatments been overlooked? *The Journal of Pain* 18 (7): 747–756.

17 Fallon, M. (2008). When morphine does not work. *Supportive Care in Cancer* 16: 771–775.

18 Arcidiacono, P.G., Calori, G., Carrara, S. et al. (2011). Celiac plexus block for pancreatic cancer pain in adults. *The Cochrane Database of Systematic Reviews* (3): CD007519.

19 Cornman-Homonoff, J., Holzwanger, D.J., Lee, K.S. et al. (2017). Celiac plexus block and neurolysis in the management of chronic upper abdominal pain. *Seminars in Interventional Radiology* 34: 376–386.

20 Skolnick, P. (2018). The opioid epidemic: crisis and solutions. *Annual Review of Pharmacology and Toxicology* 58: 143–159.

21 Manchikanti, L., Abdi, S., Atluri, S. et al. (2012). American Society of Interventional Pain Physicians (ASIPP) guidelines for responsible opioid prescribing in chronic non-cancer pain: part 2 – guidance. *Pain Physician* 15: S67–S116.

22 Busse, J.W., Craigie, S., Juurlink, D.N. et al. (2017). Guideline for opioid therapy and chronic noncancer pain. *Canadian Medical Association Journal* 189: E659–666.

23 Foster, N.E., Anema, J.R., Cherkin, D. et al. (2018). Prevention and treatment of low back pain: evidence, challenges, and promising directions. *Lancet* 391: 2368–2383.

24 Kolasinski, S.L., Neogi, T., Hochberg, M.C. et al. (2020). 2019 American College of Rheumatology/Arthritis Foundation guideline for the management of osteoarthritis of the hand, hip, and knee. *Arthritis Care & Research* 72 (2): 220–233.

25 Broggi, G., Ferroli, P., Franzini, A. et al. (2005). The role of surgery in the treatment of typical and atypical facial pain. *Neurological Sciences* 26: S95–S100.

26 Priya, K. and Rajaram, S. (2016). Is idiopathic chronic pelvic pain a treatable entity: a comment. *Reproductive System & Sexual Disorders* 5: 4.

27 Kapural, L., Gupta, M., Paicius, R. et al. (2020). Treatment of chronic abdominal pain with 10-khz spinal cord stimulation: safety and efficacy results from a 12-month prospective, multicenter, feasibility study. *Clinical and Translational Gastroenterology* 11 (2): e00133.

28 Roy, H., Offiah, I., and Dua, A. (2018). Neuromodulation for pelvic and urogenital pain. *Brain Sciences* 8: 180.

29 Bick, S.K.B. and Eskandar, E.N. (2017). Surgical treatment of trigeminal neuralgia. *Neurosurgery Clinics of North America* 28: 429–438.

30 Abdulla, A., Adams, N., Bone, M. et al. (2013). Guidance on the management of pain in older people. *Age and Ageing* 42: i1–i57.

31 Manchikanti, L., Fellows, B., and Singh, V. (2002). Understanding psychological aspects of chronic pain in interventional pain management. *Pain Physician* 5 (1): 57–82.

32 Shamji, M.F., Rodriguez, J., Shcharinsky, A. et al. (2016). High rates of undiagnosed psychological distress exist in a referral population for spinal cord stimulation in the management of chronic pain. *Neuromodulation* 19: 414–421.

33 Fama, C.A., Chen, N., Prusik, J. et al. (2016). The use of preoperative psychological evaluations to predict spinal cord stimulation success: our experience and a review of the literature. *Neuromodulation* 19: 429–436.

34 Stephens, K.A. and Ward, A. (2014). Patient selection for spinal cord stimulators: mental health perspective. *Current Pain and Headache Reports* 18: 398.

35 Sitzman, B.T. and Provenzano, D.A. (2017). Best practices in spinal cord stimulation. *SPINE* 42 (14S): S67–S71.

36 Deer, T.R., Pope, J.E., Hayek, S. et al. (2017). The Polyanalgesic Consensus Conference (PACC): recommendations on intrathecal drug infusion systems best practices and guidelines. *Neuromodulation* 20 (2): 96–132.

37 De Andres, J., Asensio-Samper, J.M., and Fabregat-Cid, G. (2014). Intrathecal delivery of analgesics. *Methods in Molecular Biology* 1141: 249–278.

38 Geurts, J.W., Willems, P.C., Lockwood, C. et al. (2017). Patient expectations for management of chronic non-cancer pain: a systematic review. *Health Expectations* 20: 1201–1217.

39 Cormier, S., Lavigne, G.L., Choiniere, M. et al. (2016). Expectations predict chronic pain treatment outcomes. *Pain* 157 (2): 329–339.

40 Brady, A.P. (2017). Errors and discrepancy in radiology: inevitable or avoidable? *Insights into Imaging* 8: 171–182.

41 Chirchiglia, D., Chirchiglia, P., Murrone, D. et al. (2018). Discrepancy between clinical-neurophysiological-neuroimaging examinations in lumbar spine degenerative disease: to the neurosurgeon the choice. *Interdisciplinary Neurosurgery* 14: 188–190.

42 McElroy, K., Cuccurullo, S.J., Perret-Karimi, D. et al. (2014). Interventional pain management skills competency in pain medicine fellows. a method for development and assessment. *American Journal of Physical Medicine & Rehabilitation* 93 (8): 724–731.

43 Thomson, S., Huygen, F., Prangnell, S. et al. (2020). Appropriate referral and selection of patients with chronic pain for spinal cord stimulation: european consensus recommendations and e-health tool. *European Journal of Pain* 24: 1169–1181.

44 Fishbain, D.A. (1994). Secondary gain: concept definition problems and its abuse in medical practice. *The American Physical Society Journal* 3 (4): 264–273.

45 Greve, K.W., Ord, J.S., Bianchini, K.J. et al. (2009). Prevalence of malingering in patients with chronic pain referred for psychologic evaluation in a medico-legal context. *Archives of Physical Medicine and Rehabilitation* 90: 1117–1126.

46 Jacobs, M.S. (2013). Psychological factors influencing chronic pain and the impact of litigation. *Current Physical Medicine and Rehabilitation Report* 1: 135–141.

5

Medical Legal Issues in Pain Management

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Introduction

Pain management is founded upon three principles: efficacy, access and, safety. In accordance with the dictate, First of All, Do No Harm, safety is the most important of these three. If this is so, how is it that pain management physicians can and frequently do find themselves facing medicolegal problems? There are many events that lead to the final common pathway of medicolegal concerns. The most common sources of problems for physicians come from adverse outcomes from procedures or prescriptions and from interactions or reviews by regulatory agencies, such as Medical Boards or the Drug Enforcement Agency (DEA). This chapter discusses the medicolegal issues faced by pain physicians, with the hope that these issues can be avoided or at least minimized.

Pain management procedures are generally safe. As so many procedures take place around the central nervous system (CNS), adverse events can lead to significant morbidity. Despite this fact, the incidence of adverse events from pain management procedures remains low [1]. Interlaminar epidural steroid injections have a malpractice claim rate of less than one per million procedures. In contrast, regional anesthesia procedures have a 4 in 10 000 risk of neurologic complications and anywhere from a 0.4% to 5.2% risk of respiratory depression with intravenous (IV) patient-controlled analgesia [2].

What Is a Malpractice Lawsuit?

Pain management physicians are generally concerned with litigation and lawsuits. In order to be sued, the plaintiff must show that four hurdles have been cleared:

1) Duty.
2) Breach of duty (negligent act or omission).
3) Injury suffered by the plaintiff.
4) Causal link between the negligence and the injury [3].

Duty starts when the doctor–patient relationship is established. The doctor–patient relationship is established when the physician examines, diagnoses, or treats the patient [4]. For the pain management physician, duty generally begins at the time of the first consultation, but not at the time when a patient has been scheduled but not seen.

A special issue for pain management physicians is the scenario where another physician has examined the patient and determined that the pain management physician should perform a specific injection. For cost reasons, the initial consult at which the pain management physician might confirm the need for that injection might be waived, so that the first encounter occurs at the facility where the procedure is performed. By meeting the patient at the facility, duty is established.

As a part of duty, physicians have an obligation to provide informed consent, discussing treatment

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options and risks associated with each of these options [5]. While informed consent can be provided during an initial meeting in the preoperative area, this limited ability to establish rapport, rather than duty, puts the physician at risk in that a patient's decision to sue is often associated with a perceived lack of caring or collaboration [6].

The second issue necessary to proceed with a lawsuit is negligence, which is an act or omission that represents a departure from the standard of care. The standard of care varies by jurisdiction, but a reasonable definition for pain management physicians is "use the level of skill, knowledge, and care in diagnosis and treatment that other reasonably careful pain management physicians would use in the same or under similar circumstances" [7].

It is important to differentiate between the standard of care and best practice or guidelines. Guidelines, according to the Institute of Medicine, are recommendations intended to optimize patient care based upon systematic reviews of the evidence [8]. Best practice is optimal care. While best practice would be within the standard of care, the Institute of Medicine recognizes that care in the community lacks best practice, meaning care below best practice can still be compliant with the standard of care. It is common to see experts alleging non-existent departures from the standard of care based upon best-practice arguments, either drawn from guidelines or created *de novo* by the opposing expert.

The third issue of a lawsuit is that the patient suffered injury or damage. If patient were to feel transient pain during the transforaminal injection of an inflamed nerve root, there would be no damage, as that is a component of the procedure. However, excessive pain or other complications can be compensatable damages.

The fourth issue is that of causation: did a departure from the standard of care lead to the injury?

Causation can be difficult to prove despite what some might see as a clear case of medical malpractice. First is that the patient can suffer harm with no departure from the standard of care. It appears that the cause of fulminant hematomas following cervical interlaminar epidural steroid injections is related to venous anatomy [9]. This information has not yet been widely disseminated. A patient could suffer catastrophic neurologic injury from an epidural injection without a departure from standard of care.

The second area where experts can become confused with causation is that of irrelevant criticisms. The absence of naloxone in the office may be alleged to be a departure from the standard of care; if there is no issue of opioid overdose, that absence is irrelevant to the malpractice claim.

Occasionally, treating physicians can confuse the issue of causation by publishing articles about a case before it is resolved. The conclusions of the treating physicians may be incorrect, with the court reaching a different conclusion. Articles about cases in litigation should be deferred until the case is resolved.

Sometimes, a physician needs to terminate the doctor–patient relationship. The doctor–patient relationship is based not only upon acceptance of the patient into the practice, but mutual trust and acceptance between the patient and the physician. This is exemplified by the concept of shared decision-making, in which the physician and patient combine to apply evidence, clinical judgment and patient preference to come up with a treatment plan [10].

An example as to when a pain management physician should terminate the relationship would be when the patient evinces a lack of confidence in the physician's ability because of a difference between the patient and the physician as to what medicines should be prescribed. Further, a patient who uses language that shows a lack of confidence in the physician, one example being the patient stating that the physician is a "quack" should not have any interventional procedures by that physician as the patient is predisposed to believing that the physician has caused harm. If there is not good physician–patient communication, the patient would be better served under the care of a doctor with whom the patient has trust. The absence of that trust leads to less effective care, even if the treatment is best practice, as the patient doubts the efficacy and that doubt can impact the response.

How to terminate the physician–patient relationship varies between jurisdictions, but would generally entail notifying the patient via certified mail of the decision, indicating that you were willing to provide emergency care for a limited time, maintenance of medications during the transition period and information as to how to find other providers. Providers can research with their State's medical board for the State-specific requirements on how to properly discharge a patient. Another good resource is the doctor's malpractice insurance carrier, as they have typically helped doctors in the past with discharge language and requirements.

Administrative and Other Hearings

In addition to malpractice suits, administrative, and other hearings are potential areas where physicians can face legal action. Administrative hearings are the most common issue faced by physicians. With the exception of the treatment of opioid substance abuse

disorder, regulation of medical affairs is delegated to individual States and their medical licensing boards [11]. With the transition which has occurred from concern regarding the undertreatment of pain to the need to respond to the increase in deaths from opioid overdose, medical boards have become very aggressive in reviewing physicians for their prescribing patterns and initiating disciplinary actions.

A medical board review can be started by a complaint, which can be filed by anyone, for any reason. A patient dissatisfied with not receiving the amount of opioids they want, a family member who may or may not have been close to the patient, or any anonymous source can file a complaint. Some medical boards receive information from coroners regarding deaths which the coroners attribute to opioids. Coroners are often overworked and their conclusions as to whether the cause of death was related to opioids can often warrant review, both in terms of whether the levels comply with the literature regarding toxic levels or whether there were co-morbidities which might better explain the cause of death. Regardless, once the coroner has determined that opioids were involved, the cases will be forwarded to these medical boards for further review.

When a complaint is made to the medical board, the physician will generally be informed of the complaint and given an opportunity to respond in the form of a written summary of care, a copy of the records, and any other information the respondent wishes to provide.

Physicians should contact their malpractice carriers when they receive a notice of letter of complaint from the medical board. Malpractice generally covers these allegations and one is generally better served having legal counsel when dealing with medical boards. Medical boards do not consider it to be a sign of "guilt" when a provider utilizes the assistance of counsel.

The medical board may have an investigator interview the complainant and they will frequently review the physician's prescribing patterns on the physician's State's prescription drug monitoring program.

The medical board will have a physician consultant, not necessarily pain management, review the records. They may also identify prescribing patterns/medication combinations for other patients based on the physician's prescription drug-monitoring program profile. This can lead to investigators contacting additional patients seeking permission to obtain their records, leading to an expanded investigation. Once a review is started, there is no limit as to how many patients the medical board can ask to review. Patients deserve to know that they can protect their privacy and do not need to sign an authorization, and no records should be produced without a signed authorization or in compliance with a subpoena.

If the consultant feels that the case warrants further review, the physician will have an interview during which they can present their position and answer questions. Take any request for an interview very seriously.

The results of the investigation and the interview will then be referred to a medical board expert, who will be a pain management specialist. The expert will prepare a report summarizing the care provided to the patients. One common format is to identify a specific medical issue, perhaps knowledge of how to perform a specific procedure, discuss what the standard of care is, and then provide an analysis of the care provided in light of the standard of care. Finally, there would be a summary conclusion: no departure from the standard of care; a simple departure, meaning that you can understand how it happened; an extreme departure, meaning that you cannot understand how it happened; or lack of knowledge. Unlike in a medical malpractice action, causation is not a defense in a medical board matter.

Based upon this report, the physician's lawyer will discuss with the deputy attorney general for the State whether to dismiss the charges, accept a public letter of reprimand, probation for a defined number of years, or loss of the physician's license. Physicians on probation are generally excluded by most insurers except Medicare. It is financially very difficult to survive a probation if the physician plans to continue in the clinical practice of medicine.

If an agreement cannot be reached, the physician will have a hearing in front of an administrative law judge. Administrative law judges tend to be very equitable and competent; a hearing in front of them is warranted if the physician is unable to satisfactorily negotiate with the Attorney General's office. However, and this can vary from State to State, the medical board retains power to accept or reject the judge's proposed decision.

In order for the medical board's case against a physician to proceed, the physician's patients need to give permission for the medical board to have their files. Where the patients refuse to give medical boards permission to review their files, medical boards can issue subpoenas to obtain access, using the argument that public safety outweighs patient privacy [12]. A provider or a patient can object to the subpoena and, if the medical board is determined to proceed, this can end up before a judge to rule if there is good cause to order a release of the records. These cases have been adjudicated both ways, but courts give a lot of discretion to medical boards.

The Drug Enforcement Administration (DEA) will occasionally bring administrative action against a physician because, at a Federal level, the DEA provides permission for a physician to prescribe opioids. The DEA is interested in compliance with the Controlled Substances Act of 1970 (CSA), which requires that prescriptions be provided for a legitimate medical purpose in the usual course of medical practice. A licensed provider needs to determine that the patient has a medical need for the prescription and then prescribes the medication.

Up to a 90-day supply can be given at one appointment as the DEA recognizes that it can be difficult and expensive for patients to come in monthly, but there must be some sort of interaction between patient and provider when the prescription is made. Having the patient pick up the prescriptions from the medical assistant at the second and third month with no interaction with licensed personnel is not within the usual course of medical practice.

Physicians can face criminal charges, at local and Federal levels. Lisa Tseng, D.O.'s 2016 conviction for second-degree murder is well-known, but is an unusual event [13]. More common are either allegations related to running pill mills, often prosecuted as CSA violations or, at the Federal level, improper prescribing for the treatment of opioid substance use disorder. Attorney Generals have also been active nationally with allegations that physicians have prescribed because of payment from manufacturers [14].

Do You Want To Be An Expert?

Being a medical legal expert is an intellectually challenging and rewarding field. It is like teaching in its ability to expand the expert's knowledge by broadening his or her exposure to medical complications or treatment practices. At their best, medical experts provide honest opinions well substantiated by the medical literature. These opinions can support either plaintiff or defense positions. If an expert limits the review for one side or the other, they expose themselves to impeachment as either the inconsistency or unreasonableness of their positions will be exposed. As an expert, you should hope to have an opposing expert who is competent, as the more competent they are, the more well-founded their opinions should be. The basis for the opposing experts' opinions should be apparent to you as an expert, leaving you well-grounded in the literature and in a good position to refute and supplant the opposing experts' views. An opposing expert whose views are not grounded in sound scientific knowledge is frustrating in that you are obligated to explain why the views are so poorly formed.

The issue in many medicolegal cases is not the adverse event, but how it is responded to. Often, there is one event which can be identified where the departure occurred. This specificity can make it easier for a lay jury to understand the case and why a departure did or did not occur.

In addition to malpractice, the multijurisdictional, multidefendant cases brought by Attorney Generals against opioid manufacturers and wholesalers for inappropriately marketing and distributing opioids provides a deep and broad need for medical experts [15].

There is no one way to be hired as an expert. One of the easiest ways is to work with attorneys you know or let your insurer know you are interested. There are sites on which you can pay to list yourself as an expert, but their efficacy is not clear. There are also firms that obtain experts for law clients. Some of these firms are insurance company driven and are highly focused on the cost of your reviews. If an expert is comfortable providing opinions within these constraints, these firms can be useful to work with. If faced with the choice of an honest opinion or a budget, choose the opinion. Other firms locate the expert, generally allowing the expert to work closely with the attorneys. This type of cooperation generally yields the best results because of a better understanding of the needs and strategies of the various parties.

Conclusion

While pain management procedures are generally quite safe, they can be associated with catastrophic outcomes. Regardless of the outcome, patients can allege malpractice, but there the four hurdles of duty, standard of care, injury, and causation that they must establish for a malpractice suit to be successful. Physicians can also face administrative and criminal charges.

There is a need for qualified medicolegal experts. Interested physicians are encouraged to become involved.

References

1 Abrecht, C.R., Saba, R., Greenberg, P. et al. (2019). A contemporary medicolegal analysis of outpatient interventional pain procedures: 2009–2016. *Anesthesia and Analgesia* 129: 255–262.

2 Benzon, H.T., Grider, J.S., and Provenzano, D.A. (2019). Considerations to reduce medicolegal claims in interventional pain procedures. *Anesthesia and Analgesia* 129 (1): 19–22.

3 Bal, B.S. (2009). An introduction to medical malpractice in the United States. *Clinical Orthopaedics and Related Research* 467: 339–347.

4 Blake, V. (2012). HEALTH LAW: when is a patient-physician relationship established? *American Medical Association Journal of Ethics* 14: 403–406.

5 Gittler, G.J. and Goldstein, E.J.C. (1996). The elements of medical malpractice: an overview. *Clinical Infectious Diseases* 23: 1152–1155.

6 Beckman, H.B., Markakis, K.M., Suchman, A.L. et al. (1994). The doctor-patient relationship and malpractice: lessons from plaintiff depositions. *Archives of Internal Medicine* 154: 1365–1370.

7 Judicial Council of California Civil Jury Instructions, Sacramento, 2020.

8 Institute of Medicine (2011). *Clinical Practice Guidelines We Can Trust*. Washington, D.C.: The National Acadamies Press.

9 Helm, S., Noe, C.E., and Racz, G. (2020). Cervicothoracic epidural venous anatomy explains fulminant hematomas. *Pain Medicine* 21 (10): 2613–2615.

10 Lewis, J. (2020). Getting obligations right: autonomy and shared decision making. *Journal of Applied Philosophy* 37: 118–140.

11 *Oregon vs. Ashcroft*, 546 US 243, (1960).

12 *Grafilo vs. Wolfsohn*, No. B287080, (2019).

13 CBS News (2016). Calif. doctor sentenced for prescriptions that left three dead. https://www.cbsnews.com/news/doctor-hsiu-ying-lisa-tseng-sentenced-for-painkiller-prescriptions-that-left-three-dead (accessed 25 November 2021).

14 Dyrda, L. (2019). New York physician convicted of accepting $300,000 in kickbacks from Insys. https://www.beckersasc.com/asc-news/new-york-physician-convicted-of-accepting-300-000-in-kickbacks-from-insys-4-details.html#:~:text=A%20Manhattan%20jury%20convicted%20a%20New%20York-based%20physician,as%20speaker%20fees%2C%20but%20in%20actuality%20were%20bribes (accessed 25 November 2021).

15 *New York vs. Purdue Pharma*, No. 400016, (2018).

6

Complications of Opiate Therapy

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Introduction

History of Opiate Therapy

Opium is an extract from the opium poppy, *Papaver somniferum*, which was cultivated in Mesopotamia and Egypt around 3400 BCE [1, 2]. Opium contains morphine (named after the god of dreams, Morpheus [3]), among other chemicals. Early uses of opium for the treatment of acute and chronic pain go back to 1500 BCE when it was used for the treatment of baby colic according to ancient papyrus records [2] and 1170 BCE when sponges soaked in opium were held over the patient's nose for surgical procedures [1].

Opioid vs. Opiate vs. Opium

Opiates are narcotic analgesics derived from the opium poppy, and therefore are found in nature; this includes morphine and codeine. Opioids are narcotic analgesics that are at least in part synthetic; this includes oxycodone, hydrocodone, and hydromorphone.

Opioid Receptors

There are three opioid receptors: mu (found in the cerebral cortex, thalamus, periaqueductal gray: responsible for the analgesic, euphoric, respiratory, and gastrointestinal [GI] effects of opioids, and physical dependence); kappa (found in the hypothalamus and periaqueductal gray: responsible for analgesic effects), and delta (found in basal ganglia; responsible for analgesic effects). All three receptors are also present in the dorsal horn of the spinal cord [4]. Opioid receptors are also expressed in cardiovascular, GI, neuroendocrine (pituitary, adrenals), immune, and ectodermal tissues [5], which explains why opioids have a wide range of side effects [6]. Opioid receptors belong to the GPCR (g-protein coupled receptor) family, and activation of these receptors leads to membrane hyperpolarization, which inhibits subsequent release of glutamate and neuropeptides such as substance P and calcitonin gene-related peptide [4].

Common Adverse Effects

Adverse opioid effects can be classified in more than one way: acute vs. chronic, non-life threatening vs. life-threatening. The occurrence of these side effects is influenced by various factors including drug-related factors (dose, frequency, route of administration), patient-related factors, and disease-related factors [7].

Route of administration can also explain some of the variance. According to some studies, transdermal fentanyl causes less constipation, nausea, and sedation when compared to sustained-release oral morphine [8, 9]. There is some evidence that epidural administration of opioids causes higher levels of pruritus and nausea compared with parenteral administration [10].

A potential confounding factor in certain studies relates to study population, as there may be a gender difference (according to one study, women have

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higher incidence of nausea and vomiting compared to men after general anesthesia) [11].

Another patient-specific factor is age, as declining renal function can lead to increased metabolite accumulation and therefore more side effects [12].

Nausea

Nausea occurs in about 30–60% of patients treated with opioids [13]. Its mechanism includes stimulation of the chemoreceptor trigger zone (CTZ), reduced GI motility, or enhanced vestibular sensitivity [14, 15]. According to some studies, fentanyl has a lower risk of causing nausea than other opioids [16].

Constipation

Constipation is the most common side effect of opioids (40–95%); it is dose-dependent, and there is no tolerance to this side effect [17, 18]. In addition to impacting quality of life, long-term effects of constipation can include abdominal pain, cramping, bloating, hemorrhoids, rectal pain, bowel obstruction, and rupture. The mechanism of opioid-induced constipation includes central (opioids may alter autonomic outflow to the gut) and peripheral effects (stimulation of opioid receptors in the enteric nervous system), ultimately leading to inhibition of GI motility and secretion. Some studies have looked at the degree to which some opioids lead to constipation, and it appears that morphine is more constipating than transdermal fentanyl [19], and tramadol is more constipating than tapentadol [20]. Various studies have shown that transdermal fentanyl is a better option for patients where the limiting factor is the constipating side effect of opioids [21, 22], especially when compared with oxycodone.

Sedation

Sedation occurs in 20–60% of patients on opioids and it is dose-dependent [12]. The mechanism of the sedation seems to be the anti-cholinergic effects of opioids [1]. It is sometimes accompanied by dizziness. According to some studies, tramadol use may increase the risk of delirium, whereas hydromorphone and fentanyl have a protective effect [23].

Pruritus

The incidence of pruritus is 2–10% [7] and is more common when opioids are administered via epidural or intrathecal injections [24]. The mechanism is related to histamine release [14].

Immunomodulatory Effects

Although the traditional view is that opioids have an immunosuppressive effect (e.g., leading to decreased resistance to bacterial infections [1]), the data on this topic is mixed, and recent studies show that opioids can have a variety of effects on the immune system: immunosuppressive, immunostimulatory, or dual effect [25]. Further complicating this, is the fact that some opioids have no effect on the immune system, and that for those that do, the effect can be positive for short-term administration and negative for long-term administration.

Hormonal Effects

Opioids can have both acute and chronic effects on hormone levels [1]. Testosterone levels are lowered 1–4 hours after acute administration of opioids and return to normal within 24 hours of stopping the opioid [26, 27]. Opioid endocrinopathy is a term that encompasses the long-term effects of opioids on testosterone, estrogen, luteinizing hormone (LH), gonadotrophin releasing hormone (GnRH), and cortisol [1]. In men, this can lead to sexual dysfunction (decreased libido, erectile dysfunction), depression, and decreased energy [28]. Women may experience amenorrhea, reduced bone density and depression. Several studies have shown an increased risk of fractures in older women on opioids [29]. The effects of opioids on the endocrine system are medication-dependent; for example, data from addiction studies show that individuals receiving buprenorphine have higher testosterone levels and less sexual dysfunction than individuals receiving methadone [30].

Bladder Dysfunction

Urinary retention may occur in 3.8–18.1% of patients receiving opioids in the post-operative period [31]. Proposed mechanisms include decreased detrusor tone and inhibition of the voiding reflex [1].

Cardiac Effects

Opioids may lead to hypotension and bradycardia [32]. Methadone may lead to QT prolongation which can be complicated by Torsade de Pointes [33], which warrants obtaining an EKG to monitor QTc in those patients on methadone; this risk is higher in patients receiving methadone and concomitantly fluxetine, fluconazole, or other CYP3A4 inhibitors [34]. Most other opioids have no effect on cardiac conductivity except for buprenorphine, which has a dose-dependent effect on QTc: transdermal buprenorphine at

low doses of 10 mcg/h have no clinically meaningful effect on QTc, but a higher dose of 40 mcg/h can prolong QTc by 9.2 ms [6].

Respiratory Depression

Although the risk of respiratory depression is low (<1% of patients administered opioids in the postoperative setting), it can be life-threatening [35]. The proposed mechanism is via the inhibitory effect of opioids on the pre-BotC, which contain pacemaker neuronal circuits that generate and synchronize respiratory rhythm, and subsequent respiratory depression [36].

Hyperalgesia

Hyperalgesia refers to increased pain sensitivity, which presents as rising pain despite increasing doses of opioids. Proposed mechanisms include opioid metabolites such as morphine 3-gluceronide (M3G), opioid-induced cell apoptosis of GABA neurons, and NMDA receptor agonism [1, 37]. Clinically, hyperalgesia can lead to inappropriate increases in opioid doses that further exacerbate the pain. It presents as a rapidly developing tolerance to opioid analgesic effect and is often associated with a change in pain pattern to include allodynia and diffuse pain [38].

Other Side Effects

Hydrocodone may cause sensorineural hearing loss in some patients especially at higher doses, and this may not resolve following discontinuation of therapy [1, 39].

Special Opiates

The main problem behind why opioid side effects are difficult to avoid, is that the mu-receptor mediates both the analgesic and most of the undesired side effects. This leads to the inception of several drugs that combine mu-opioid agonist properties and a separate analgesic effect that can have an additive or synergistic analgesic effect thereby allowing decreasing opioid receptor activation [40, 41].

Tapentadol acts via the mu-opioid agonism and inhibition of norepinephrine reuptake. According to some studies, it can provide clinical efficacy close to that of oxycodone but with improved GI tolerability [42]. Another advantage is that it does not have any clinically active metabolites. In a study of patients with knee pain from osteoarthritis, the incidence of GI side effects was 56% for the oxycodone group (20 mg CR), compared to 30% for the tapentadol 100 mg and 49% for the tapentadol 200 mg [43]. Tapentadol administration can lead to serotonin syndrome [6].

Tramadol is another commonly used partial opioid. According to the Cochrane review, the risk of adverse effects with tramadol compared to a placebo was 26% for nausea (compared to 6.9% in the placebo group), 29% for constipation (compared with 6.5% with placebo), and 33% for sedation (compared to 10% in the placebo group) [44]. One of the side effects of tramadol is lowering of the seizure threshold. Tramadol can also lead to serotonin syndrome [6].

Intrathecal morphine is less likely to elicit systemic side effects compared to oral opioid therapy [45]. The proposed mechanism is that intrathecal therapy delivers analgesic medication directly to the dorsal horn of the spinal cord. However, only morphine is FDA approved for intrathecal opioid therapy. Further, IT morphine can be associated with other side effects such as formation of granulomatous masses which may lead to spinal cord compression [46].

Management of Adverse Effects

In general terms, the main ways to manage the side effects of opioids are 1) manage the symptoms of the adverse effect through patient education and lifestyle changes, 2) dose reduction or switching route of administration, 3) opioid rotation [7]. The idea behind opioid rotation is that opioids have subtle differences in their affinities to the mu, kappa, and sigma receptors which may reduce the side effects and the dose required to provide comparable inalagesia due to incomplete cross tolerance [47].

For nausea, symptomatic management includes the use of antipsychotics such as haldol, metoclopramide, serotonin antagonists, and steroids. Metoclopromide is typically first line because its mechanism of action is at the CTZ and has a more favorable side-effect profile [12].

For constipation, symptomatic management includes hydration, fiber intake, stool softeners and laxatives [12]. Lifestyle modifications such as increasing fluid and dietary fiber intake, increasing physical activity, and establishing a toileting routine are important measures to mitigate this common opioid side effect.

For sedation, symptomatic management includes the use of psychostimulants such as methylphenidate [12]. In one study, the use of 10 mg methylphenidate improved drowsiness scores by 35% compared to 8% for the placebo group [48]. For delirium, use of