

Diwan-Staats'

ATLAS OF
**PAIN MEDICINE
PROCEDURES**

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PETER STAATS

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ATLAS OF PAIN MEDICINE PROCEDURES

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This atlas is dedicated to:

My mother Late Raniba Diwan for teaching me the meaning of life

My family Indira, Sneh, Kaushal, and Shira for their love and unconditional support

My grandchildren Jonathon and Belen for bringing joy to our lives

My friends and my mentors who supported me and guided me to the path of knowledge

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And,

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Weill Cornell Medical College and New York Presbyterian Hospital of Cornell University

For being an integral part of my personal and professional success

Sudhir Diwan

*To Mom and Dad. You taught me how to change the world to make it a better place,
one patient at a time, and more globally through theory and research.*

*To my children, Alyssa, Dylan and Rachel. I am so proud of all three of you and the
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*Most of all, to my wife Nancy, Thank you for your understanding and compassion.
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Preface

The field of interventional pain management is a forever evolving field. There are new developments occurring daily with new approaches and new equipment that make therapies safer and more effective.

This book gives clinical pearls on strategies that we use in interventional pain management. It has been designed as an easy-to-use source for most of the interventional pain specialists needs. It is not intended to replace a comprehensive fellowship in pain management. The pros and cons of medications, the psychological approaches effective in pain, as well as the comprehensive use of rehabilitation and complementary approaches are simply not covered. This book, however, does provide the physician with relevant anatomy and should prompt a thoughtful approach to specific pain syndromes and what causes them. Many years ago, patients with pain referred to as having “chronic pain syndrome” or sometimes were maligned with pejorative terms. Patients were called malingerers, assumed to have major psychiatric disorders or were assumed to be drug seeking. While all of these certainly occur, I believe patients with legitimate medical problems were frequently misdiagnosed. This occurred because there was not an adequate training of physicians to diagnose and treat complex pain disorders. To date, many physicians have inadequate training in recognizing complex medical and neurologic disorders, and many syndromes are missed.

In previous decades there were a few procedures that were commonly performed. Epidurals, Trigger points, and major joint injections were common. Complex procedures were rarely performed. Medications were (and still are) a mainstay of a comprehensive pain practice. While we today still use these classes of analgesics, we are now recognizing that the medication approach is not without risks. The use of opiates has increased dramatically over the past twenty years. With this we have seen a dramatic rise in deaths attributed, at least in part to the use of prescription analgesics. It was estimated that in 2012 there were over 16 thousand deaths with a prescription opioid as at least a part of the problem.

Pain management is not just about giving a patient drugs. It is about making an accurate diagnosis, developing a therapeutic plan, and devising a minimally invasive approach when possible to effectively treat or manage the problem. The *Diwan–Staats Atlas* puts together what we know about various pain states, along with the most current information in anatomy and pathophysiology. We concentrate on the most minimally invasive techniques available, thereby enhancing safety. This book is really the “how to” of current interventional pain management; however, it does not address the “when to.” The “when to” involves clinical judgment, careful evaluation, and individual case-specific issues, along with evidence-based medicine and an assessment of the risks, benefits, and alternatives of all interventional procedures. Summarizing all the available clinical trials would have been beyond the scope of a single volume.

There are so many leaders and influential figures that have helped the development of this field. Dr. Bonica, Dr. Stanton Hicks, Dr. Gabor Racz, Dr. Prithvi Raj, and Dr. Lax Manchikanti are a few who have devoted so much of their life to advancing the specialty of interventional pain. On behalf of the millions of pain sufferers and the physicians you have taught, we thank you.

We would like to express our deep appreciation to so many individuals. First, we must thank the section editors, Drs. Lema, Patel, Trescot, Vad, Gharibo, and Shah who have gone above and beyond, reviewing and re-reviewing the chapters. Thank you to our numerous authors who have created such wonderful original works. The synthesis of all of your works has made this volume special.

With all of the talk about evidence-based medicine, and the needs for multiple randomized controlled trials to support reimbursement, and the battles in the halls of Congress, and the battles with insurers, we sincerely hope that this book will help physicians help patients, as safely and effectively as possible. That’s why we all do what we do.

Introduction

EVIDENCE-BASED MEDICINE

Peter S. Staats and Sudhir Diwan

"Doctors are men who give drugs of which they know little, into bodies of which they know less, for diseases of which they know nothing at all." Voltaire 1770s

For thousands of years, however, physicians blithely administered a variety of concoctions intended to treat pain; a few worked, many eventually fell by the wayside; and others were reluctantly abandoned when they failed to stand up to rigorous therapeutic analysis. Thus, although healers throughout antiquity accurately touted the efficacy of opium, now known to contain the potent analgesic morphine, and of willow bark, which is the source for aspirin, dusty tomes also contain scores of therapeutic recommendations that have little merit in the management of pain.

The Skillful Physician, the mainstay of seventeenth-century medicine, unequivocally recommends applying hot goose oil to treat sciatica.

The Concept

Evidence-based medicine, the concept that physicians should use the best available data to guide one's practice, has become the mainstay in modern medicine. Comparative effectiveness research, comparing two accepted strategies to determine which therapies are the most effective, is widely being considered the standard.

The Flaws and Frustrations

While no one can argue that physicians should use the best "available data to guide the practice," the concept is now being misinterpreted and distorted largely by insurers and other carriers to deny appropriate care. Years ago, the same week the media reported the CEO of a major health care insurance company's compensation package of over a billion dollars, one of the authors (PSS) was called to emergently evaluate a patient (with previous back surgery in the ICU) with a lumbosacral radiculopathy with this insurance. The request was specifically for an epidural lysis of adhesions procedure. After a thorough evaluation it was felt to be a reasonable approach, and the procedure was performed successfully. The next day his pain was under control for the first time in weeks, we facilitated discharge, there was great patient and hospital satisfaction and, we succeeded in saving the insurance company money since he was discharged from the hospital. The insurance company never paid for this procedure and claimed that the therapy offered was experimental. This was in spite of four double-blind randomized controlled trials demonstrating the efficacy of this therapy. The denial was appealed which was reviewed by the insurance company's "appeal committee" that included three physicians: a gynecologist, a neurologist, and a general surgeon. None of whom had heard of an epidural lysis of adhesions procedure. Not surprisingly the committee upheld the denial of the insurance carrier, indicating that there was no "evidenced-based medicine" supporting the claim. Of course, this was patently untrue, but does highlight several problems that can occur with evidence-based medicine if they are not judiciously applied.

Problems With Evidence-Based Medicine

- EBM is limited to clinical research only, and does not correlate well to the clinical expertise.
- It presents a "cookbook" approach to practice medicine.
- The clinical evidence should be a source of information, not a replacement of individual clinical expertise.
- Insurance industry uses this concept as a cost-effective (cost-cutting) tool, and ignores patient's values and preferences.
- It promotes a state of mind that is analogous to ivory-tower, whereby the insurers define the care path.
- Continued concern of EBM being hijacked by purchasers and insurance managers to cut costs.

Many physicians have received similar frustrating denials from insurance companies claiming the procedures or medications being offered are experimental. We receive these denials with discography, epidural steroids, therapeutic occipital nerve blocks, radiofrequency ablations of facet joints, spinal cord stimulation to name a few, claiming that each of the above is "experimental." It became clear that the insurers are using the rationale of "no evidence-based medicine" to selectively deny high-cost procedures, or procedures insurers have felt have been abused.

Conflicts With Common Sense

- Quantitative research from randomized controlled trials (RCTs) may not be relevant to all treatments in all situations.
- The EBM is a slow, lengthy, and expensive process that will take years before the evidence is produced and applied to the clinical practice.
- RCTs may restrict under-researched racial minorities and patients with comorbid diseases from practice of EBM.
- RCTs apply to only the group of people that are included in the studies, and do not address the individualized treatment plans based on physicians' personal experience and knowledge.

Historical Perspective on Evidence-Based Practice

- In the 1960s, there were very few double-blind randomized controlled trials demonstrating efficacy of any number of therapies.
- Medical decisions were largely made on the basis of clinical intuition pathophysiology and clinical experience.
- There were few large studies, and the results of large clinical trials were rarely used to modify or change clinical practice paradigms.
- In the 1990s, physicians began to realize that that a higher standard was required. Evidence-based medicine and evidence-based practice were born.

What Is Evidence-Based Medicine?

Evidence-based practice is "the conscientious, explicit and judicious use of current best evidence in making decisions about the care of the individual patient. It means integrating individual clinical expertise with the best available external clinical evidence from systematic research." (Sackett D, 1996)

- Evidence-based medicine and guidelines that use evidence-based medicine are involved in synthesizing the available published data to come up with the most effective approach to care.
- The available data is graded in a hierarchal fashion.
- Large double-blind randomized controlled trials receive the highest grade, followed by prospective studies and retrospective reviews and even case reports and opinions of experts are graded.
- If an approach has a large number of well-designed randomized controlled trials supporting its use, the approach is given a high grade.
- If there are no well-designed trials, and the physician's experience is touted as the only rationale for proceeding with a therapy, a low grade is given.

Source and Synthesis of Evidence

- Basic science studies on and animal research: Very first step to produce evidence.
- Case reports and case series: Reports of treatment of individual cases or case series without control groups, with a little statistical validity.
- Case-control studies: Studies with a specific condition are compared with people without the condition. These studies are less reliable than randomized controlled trials and cohort studies.
- Cohort studies: A group of patients treated with a particular treatment and followed for an extended period, and then compared their outcomes with a similar group that has not been treated with the similar treatment.
- Randomized controlled trials: Carefully planned methodologies to randomize and blind the researcher and the patient to reduce a potential bias while comparing the interventional (treated) and control (untreated) groups. These studies provide the best evidence with high statistical validity.
- Systemic reviews: An extensive literature search is conducted to identify studies with sound methodology focused on a specific treatment or procedure. The studies are reviewed for quality and results are summarized based on predetermined criteria.
- Meta-analysis: It is a large study to mathematically combine results of a number of very valid studies that have used accepted standards of statistical methodology.

Levels of Evidence

United States Preventive Services Task Force (USPSTF) has developed systems to stratify evidence by its quality for ranking evidence about the effectiveness of the treatment:

- Level I: Evidence obtained from at least one properly designed randomized controlled trials
- Level II-1: Evidence obtained from well-designed controlled trials without randomization
- Level II-2: Evidence obtained from well-designed multicenter cohort or case-control analysis
- Level II-3: Evidence obtained from multiple studies with or without intervention including uncontrolled trials
- Level III: Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees

Levels of Recommendations

The risks versus benefits ratio obtained from the evidence available in literature, USPSTF uses following levels of recommendations for clinical service or treatments.

- Level A: Good scientific evidence to suggest substantial benefits outweigh the potential risks
- Level B: Fair scientific evidence to suggest the clinical benefits outweigh the potential risks
- Level C: Fair evidence to suggest clinical benefits, but the ratio of benefits to risks is too close to make recommendations
- Level D: Fair scientific evidence to suggest that risks of clinical service clearly outweigh the potential benefits
- Level I: The scientific evidence is either lacking, or poor quality, or conflicting to assess the risks of clinical service to potential benefits

Problems With Evidence-Based Medicine (EBM)

There are several problems with using evidence-based medicine to guide all care in pain management or the development of guidelines. Frequently studies are funded by industry, either pharmaceutical or medical device companies. Those are the companies with the money to spend on demonstrating the efficacy of large clinical trials. These studies may have potential conflict of interest, but there is no funding otherwise to conduct studies.

- There is a shortage of coherent and consistent scientific studies to produce evidence.
- The insurance companies obtain the evidence to their advantage from nonindexed journals with non-peer-reviewed articles, and ignore the good evidence published in indexed journals.
- The evidence is often reviewed by the physicians who do not have hands-on experience of particular procedures, eg, a neurologist who never performed an epidural steroid injection, writing the guidelines for epidural steroid injections based on evidence.
- The poorly written guidelines produced by the “so-called” experts with vested produce barriers to the practice of high-quality medicine.

Expensive Proposition

Double-blind randomized controlled trials are widely considered the gold standard for study design. The paucity of evidence is largely due to paucity of good studies, and the cost is a big factor.

- New drug applications for the FDA require multiple studies.
- It has been estimated cost close to a billion dollars to get a new drug approved through the FDA.
- Each study costs millions to perform.
- For this reason, many well-designed studies do not come from physicians as sponsors, looking at old drugs or new approaches to pain.

Companies with significant financial resources, that stand to make financial gain if their drug or product is successful, are motivated to fund large-scale clinical trials to demonstrate efficacy of their product. Older inexpensive drugs, that may be off patent, may be just as effective as a new drug but will not be studied in large-scale clinical trials and will be given a low score in an EBM approach.

Different Standards

Limitations for Studies Regarding Interventional Procedures

- Physicians do not have the financial wherewithal to pay for the studies requested by the insurers.
- Few physicians have the time and expertise to apply for federal funding to perform these studies.
- Infrequently performed procedures may be cost effective (ie, thoracic epidurals) but have no medical device company funding the studies. There will be a paucity of data supporting their use.
- For these reasons, many insurers are denying interventional procedures under the guise of “evidence-based medicine.”
- Different standards: They site lack of randomized double-blind controlled trials as a rationale for noncoverage, but allow surgical procedures that have not been subjected to the same rigor as many of the interventional therapies discussed in this book.

Oxford Centre for Evidence-Based Medicine Levels of Evidence (May 2001)

Level	Therapy/ prevention, etiology/harm	Prognosis	Diagnosis	Differential diagnosis/symptom prevalence study	Economic and decision analysis
1a	SR (with homogeneity ^a) of RCTs	SR (with homogeneity ^a) of inception cohort studies; CDR ^b validated in different populations	SR (with homogeneity ^a) of Level 1 diagnostic studies; CDR ^b with 1b studies from different clinical centers	SR (with homogeneity ^a) of prospective cohort studies	SR (with homogeneity ^a) Level 1 economic studies
1b	Individual RCT (with narrow confidence interval ^f)	Individual inception cohort study with > 80% follow-up; CDR ^b validated in a single population	Validating ^d cohort study with good ^e reference standards; or CDR ^b tested within one clinical center	Prospective cohort study with good follow-up ^f	Analysis based on clinically sensible costs or alternatives; systematic review of the evidence; and including multi-way sensitivity analyses
1c	All or none ^g	All or none case series	Absolute SpPins and SnNouts ^f	All or none case series	Absolute better-value or worse-value analyses ^h
2a	SR (with homogeneity ^a) of cohort studies	SR (with homogeneity ^a) of either retrospective cohort studies or untreated control groups in RCTs	SR (with homogeneity ^a) of Level >2 diagnostic studies	SR (with homogeneity ^a) of 2b and better studies	SR (with homogeneity ^a) Level >2 economic studies
2b	Individual cohort study (including low quality RCT; eg, <80% follow-up)	Retrospective cohort study or follow-up of untreated control patients in an RCT; derivation of CDR ^b or validated on split-sample ⁱ only	Exploratory ^d cohort study with good ^e reference standards; CDR ^b after derivation, or validated only on split-sample ⁱ or databases	Retrospective cohort study, or poor follow-up	Analysis based on clinically sensible costs or alternatives; limited review(s) of evidence, or single study and including multi-way sensitivity analyses
2c	"Outcomes" research; ecological studies	"Outcomes" research		Ecological studies	Audit or outcomes research
3a	SR (with homogeneity ^a) of case-control studies		SR (with homogeneity ^a) of 3b and better studies	SR (with homogeneity ^a) of 3b and better studies	SR (with homogeneity ^a) of 3b and better studies
3b	Individual case-control study		Nonconsecutive study; or without consistently applied reference standards	Nonconsecutive cohort study, or very limited population	Analysis based on limited alternatives or costs, poor quality estimates of data including sensitivity analysis incorporating clinically sensible variations
4	Case series (and poor quality cohort and case-control studies ^g)	Case-series (and poor quality prognostic cohort studies ^{***})	Case-control study, poor or nonindependent reference standard	Case series or superseded reference standards	Analysis with no sensitivity analysis
5	Expert opinion without explicit critical appraisal, or based on physiology, bench research, or "first principles"	Expert opinion without explicit critical appraisal, or based on physiology, bench research, or "first principles"	Expert opinion without explicit critical appraisal, or based on physiology, bench research, or "first principles"	Expert opinion without explicit critical appraisal, or based on physiology, bench research, or "first principles"	Expert opinion without explicit critical appraisal based on economic theory or "first principles"

Our perspective is that there has been an explosive growth in our field, associated with abuse. We as a society and the payers, need to establish reasonable reimbursement criteria and follow those with poor outcome, not to blanketly deny care.

Many Intricacies in Doing the Procedures

If one does not do the procedure exactly the same as another, there will be inconsistencies and results will vary. For example, the difficulty in determining the efficacy of epidural steroids will be influenced by the following factors.

- Blind procedures versus fluoroscopically guided procedures.
- Transforaminal versus Interlaminar.
- Cervical epidurals versus thoracic epidurals.
- The quality of pain may vary.
- The severity of the pain may be poorly controlled for.
- Coexisting diseases such as obesity or diabetes may influence the outcome.
- The doses and types of steroids may vary between practitioners.
- The technique may vary on precisely where the needle is placed.
- The use or amount of local anesthetics used may vary greatly.

Level of Skills and Experience

Inexperienced physicians may perform a procedure under fluoro guidance but may not have the same expertise in guiding the needle to the exact position as well-experienced physician who has spent years perfecting this approach. Thus taking one very simple examples one can see that physicians outcomes would be expected to vary greatly. Some physicians routinely do one procedure while others do a series of injections.

Varieties in Indications for Procedures

The indications may vary for a variety of techniques being performed for patients with:

- Herniated disc versus stenosis.
- Radiculopathy versus axial back pain.
- Epidural steroids may be used for CRPS, radiculopathy, or postherpetic neuralgia.
- Difference in rates of traditional insurance versus workman's compensation.

Accordingly many small studies may not represent the exact patient population being studied. While it is important for the physician to remain conversant with the literature, it is important to continually individualize the therapy for that specific case.

Comparative Effectiveness Research

Comparative effectiveness research (CER) is the direct comparison of existing health care interventions to determine:

- Which treatment works best for which patients
- Which treatment poses the greatest benefits and harms
- The core question of CER in which treatment works best, for whom, and under what circumstances

It is more of a pragmatic approach that attempts to compare a variety of reasonable interventions in determining the most appropriate strategy.

Cost-Effectiveness Analysis

Cost-effectiveness analysis (CEA) is a form of economic analysis that compares the relative costs and outcomes (effects) of two or more courses of action. CEA is distinct from cost-benefit analysis, which assigns a monetary value to the measure of effect. CEA is often used in the field of health services, where it may be inappropriate to monetize health effect.

Guideline Development

Guidelines on the appropriate steps in the management of various diseases have become a useful tool for physicians.

- The guidelines synthesize the evidence-based medicine, the well-designed studies that have been done.
- More studies on a particular therapy or drug it is more likely to receive a favorable position in the guideline development.
- Guidelines which attempt to synthesize evidence-based medicine in to clinical paradigms, count the number of evidence-based studies, and make recommendations based on the total number of patients and number of studies in the literature.
- Those with better financial resources may increase the total number of studies that will lead to a pharmaceutical or medical device approach. This type of weighted research will favor more expensive therapies that are frequently funded by pharmaceuticals and medical device companies.
- The guideline development itself may be insidiously influenced by medical device and pharmaceutical companies as they tend to fund those guidelines that support their development.
- Some insurers have begun funding the development of guidelines, and they tend to weigh more heavily noninterventional therapies, in spite of a demonstrated lack of efficacy.

Conclusions

This text is an atlas of interventional pain medicine. We espouse Sackett's original tenets, of using the *best available* evidence, as well as those of Hippocrates to do no harm. We recognize that the practice of medicine takes an individual approach to the management of pain. We do believe that a rationale physician, when faced with limited data, may try therapies that make sense. The text that follows is more of a "how to" approach. The denial of appropriate care by insurers when there is a paucity of data on a specific approach, indicating that there is no evidence-based medicine flies in the face of what evidence-based medicine is about. Evidence-based medicine allows the physician to understand the literature, its pitfalls, and extrapolate based on their clinical experience in determining the most appropriate course of action.

Suggested Reading

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BASIC APPLICATIONS

Fluoroscopy in Interventional Pain Medicine

David M. Schultz

Since their discovery in 1895, x-rays have revolutionized the practice of medicine. By allowing doctors to view the inside of the living body, x-rays have greatly increased our ability to diagnose and treat disease and to precisely deliver targeted therapies. The fluoroscope was the first x-ray machine and has evolved from its humble beginnings into a powerful and sophisticated device that has become the basis for the new field of interventional pain management. Modern fluoroscopes enable the interventional pain practitioner to use continuous, real-time x-ray imaging to guide interventional procedures that target the physical generators of pain with a high degree of precision and safety. Since fluoroscopy is essential for most invasive pain procedures, it is imperative that interventional pain physicians have a firm understanding of the fluoroscope in order to use it safely and effectively in daily practice.

HIGHLIGHTS IN THE HISTORY OF FLUOROSCOPY

- 1895: German physicist Wilhelm Roentgen discovers x-rays and takes the first fluoroscopic image, purportedly of his wife's hand, winning the 1903 Nobel Prize in Physics for his efforts.
- 1896: Thomas Edison invents the first fluoroscope, which is quickly adopted for medical uses.
- 1897: Madame Curie discovers radium, which is then used to illuminate games of chance in New York City.
- 1898: The inappropriate, nonmedical use of fluoroscopy becomes increasingly common.
- 1899: Compensation is awarded in the first medical malpractice suit involving x-ray injury.
- 1900: Radiation injuries become increasingly common, and practitioners become increasingly aware of the dangers of x-ray exposure.
- 1910: After several years of practice, radiology pioneer Dr. Mihran Kassabian suffers severe radiation burns to his hands and ultimately dies of radiation-induced cancer at age 34.
- 1929: The National Council on Radiation Protection and Measurement (NCRP) is created to protect patients, healthcare workers, and the public from the harmful effects of radiation.
- 1994: Patient injuries resulting from excessive use of fluoroscopy during medical procedures prompt the FDA to issue a Public Health Advisory.¹

THE PHYSICS OF X-RAYS

X-rays are a form of ionizing radiation that can be created in the fluoroscope and harnessed for medical imaging. X-rays are produced in the x-ray tube of the fluoroscope, which contains a cathode and metal anode.

- When high-velocity electrons leave the cathode and collide with the metal anode, the kinetic energy contained within the electrons is converted to electromagnetic energy and released in the form of x-rays.
- X-rays are close to light photons on the electromagnetic spectrum but have shorter wavelength and higher energy (Figure 1-1).

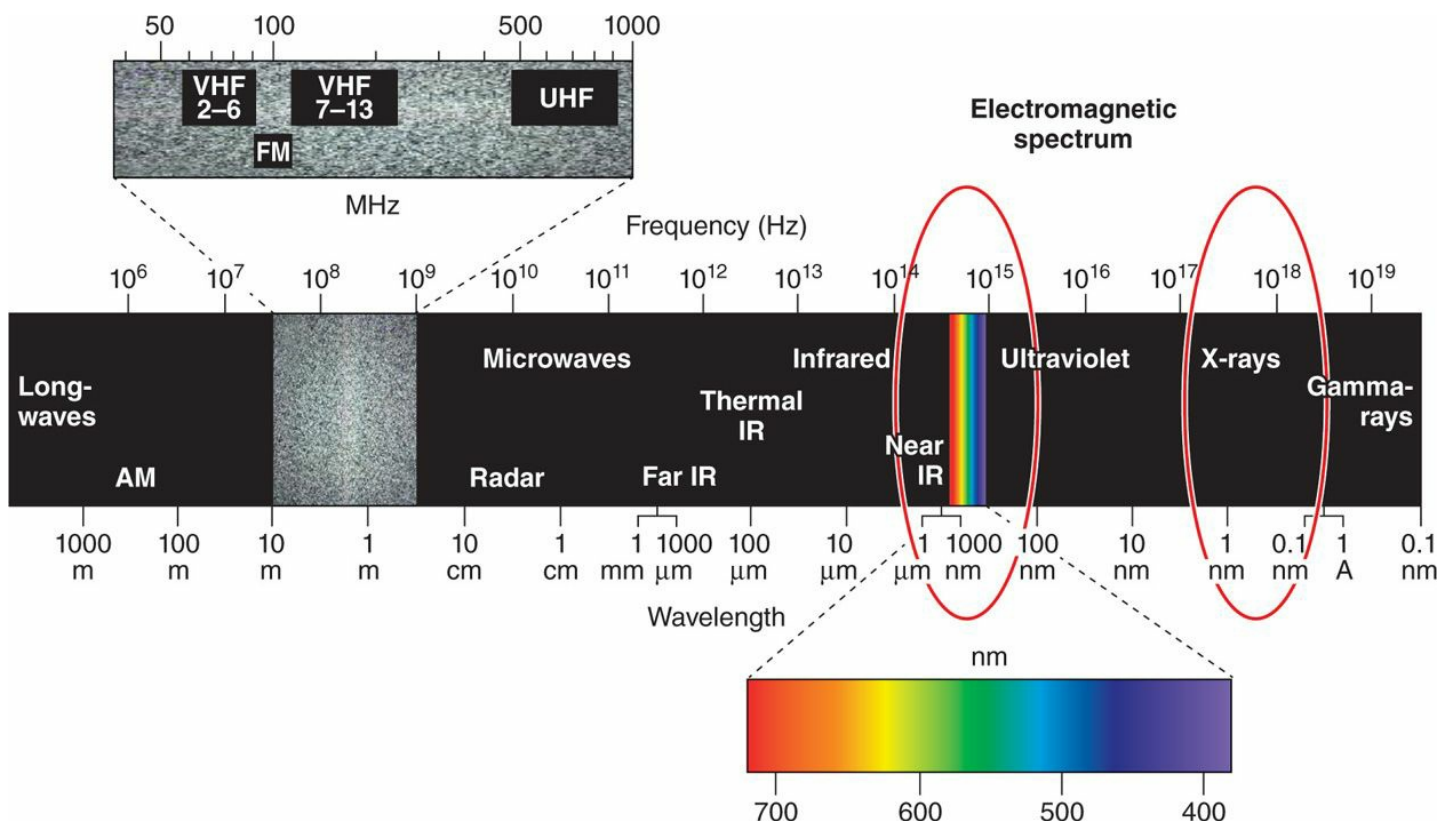


Figure 1-1. X-rays are close to light photons on the electromagnetic spectrum but have shorter wavelength and higher energy.

The x-rays produced by the x-ray tube are directed through body tissues. When these x-rays contact matter, they interact in one of three ways:

1. They are absorbed.
2. They are deflected and scattered.
3. They pass through matter unheeded.

Since x-rays are a form of ionizing radiation, they interact with certain media in ways that allow the human eye to view their presence. In fluoroscopy, the x-rays cause the phosphorous in a fluorescent screen to emit visible light. Modern fluoroscopic systems use zinc-cadmium sulfide as an effective phosphor.

The fluoroscopic image is essentially composed of shadows created as body tissues of various densities preferentially absorb x-rays. As the density of matter increases, x-rays are absorbed or scattered to a greater extent, giving rise to the 5 radiologic densities commonly used to describe radiographs:

1. Air
2. Fat

3. Water (soft tissue)
4. Bone
5. Metal

Air allows most emitted x-rays to penetrate through to the underlying imaging medium. Bone and metal are denser and absorb or deflect x-rays, allowing fewer x-rays to penetrate through to the imaging medium. Consequently, higher-density tissues cast shadows that appear darker on the displayed image because the x-rays contacting the phosphor create light (Figure 1-2). This is in contrast with traditional x-ray imaging, which uses a photographic plate to capture the effects of photons (Figure 1-3). The plate starts out as a white background that is exposed by the x-rays reaching it. The fluoroscopic image is analogous to the photographic negative whereas the developed x-ray film is analogous to the photograph.

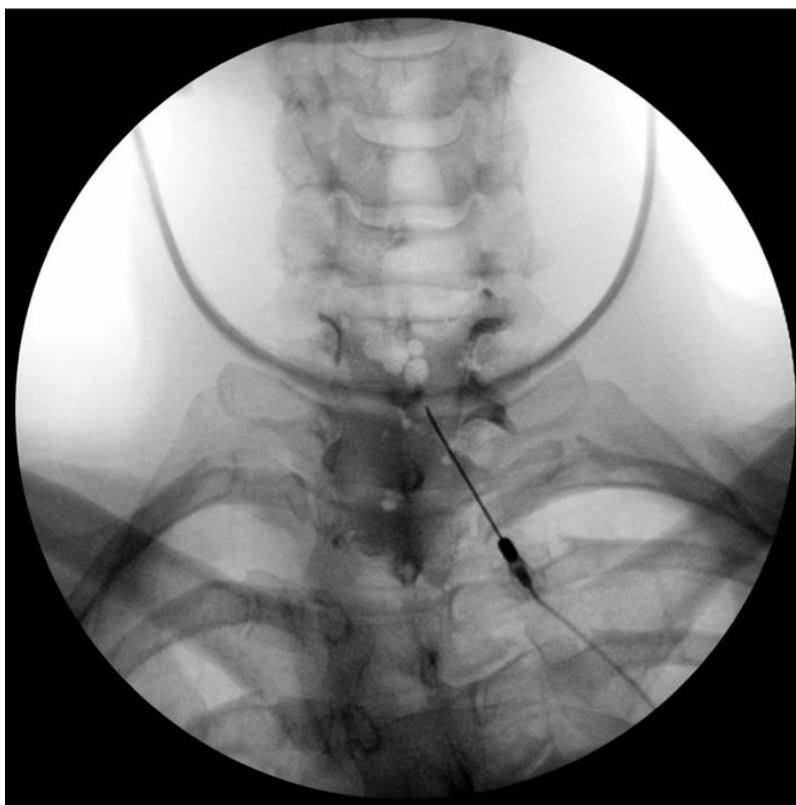


Figure 1-2. Fluoroscopic image with higher density structures appearing darker; note the bubbles of air contained within the injected x-ray contrast medium.



Figure 1-3. Plain chest radiograph with denser tissues appearing lighter. (Reprinted with permission from Fuster V, Walsh RA, Harrington RA: *Hurst's The Heart*, 13th Edition: www.accessmedicine.com © The McGraw-Hill Companies, Inc. All rights reserved.)

THE C-ARM FLUOROSCOPE

The primary function of the fluoroscope is to generate a controllable beam of x-rays that can be directed through tissue and then captured on a viewing medium to form a visible image. Interventional pain physicians commonly use the C-arm fluoroscope because of its maneuverability and compact design (Figure 1-4).

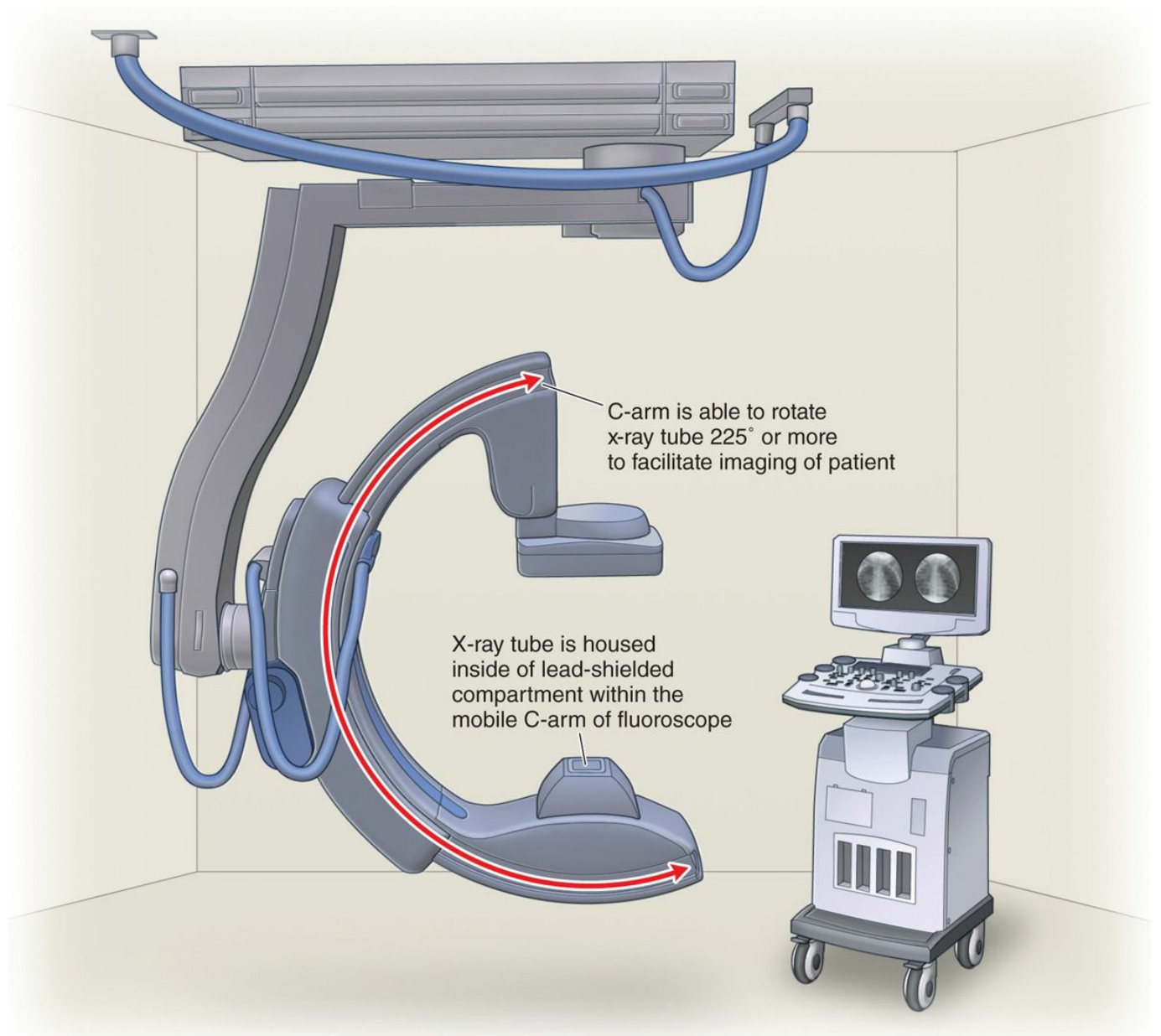


Figure 1-4. Modern fluoroscope with a shielded x-ray tube contained within a movable C-arm.

The main components of a typical mobile C-arm fluoroscope include the x-ray generator, x-ray tube, collimator, image intensifier, optical coupling chain and viewing monitor (Figure 1-5).

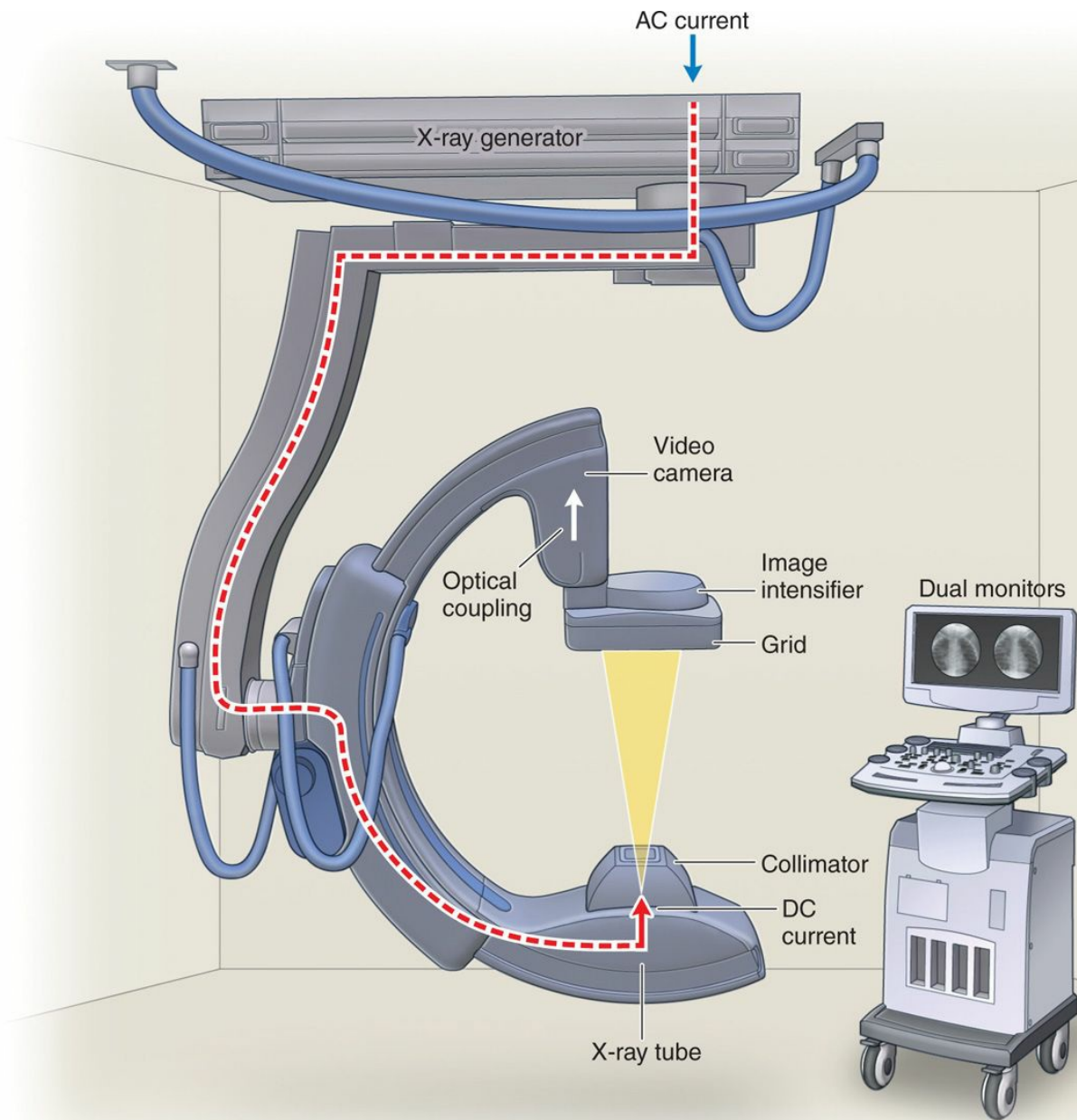


Figure 1-5. Modern fluoroscope with components labeled.

The *x-ray generator* converts alternating current to high voltage direct current, which is delivered to the *x-ray tube*.

- The current determines the *number* of *x-rays* produced by the *x-ray tube* and therefore controls the *density* and *intensity* of the *x-ray beam*.
- The voltage determines the *energy* of the *x-rays* produced and the *penetrating ability* of the *x-ray beam*.
- The current and voltage can be automatically or manually adjusted from the base unit of the fluoroscope (Figure 1-6).

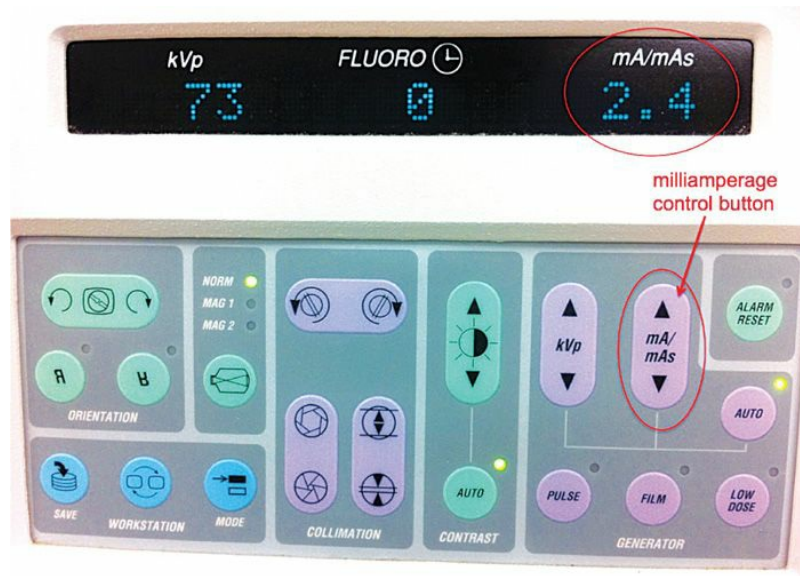


Figure 1-6. The amount of current supplied to the *x-ray tube* is measured in milliamps (mA) and determines the *density* and *intensity* of the *x-ray beam*.

The *x-ray tube* is housed in one end of the C-arm and is balanced by the **image intensifier** at the other end.

- The beam that is released from the x-ray tube diverges as it moves toward the image intensifier.
- The x-ray beam is most concentrated as it exits the x-ray tube at the center point aperture.
- Severe patient injuries occur when body tissue remains in close proximity to the origin of the x-ray beam for prolonged periods.²

Fluoroscopic images are dim and difficult to view without some mechanism to brighten the viewable image. The image intensifier was introduced in 1934 and functions to convert x-rays into light photons, which amplify brightness by 5000 to 20,000-fold.

Collimation allows the fluoroscope operator to reduce the size and shape of the x-ray beam to better conform to the field of view (Figures 1-7 and 1-8). As the fluoroscope moves across areas of varying body tissue density, the collimator automatically adjusts the x-ray beam to conform to the viewing field. The operator can also adjust the collimation window manually to conform to a region of clinical interest (Figure 1-9).

- By reducing the x-ray beam to include only the tissue targeted for viewing, less tissue is irradiated, and patient exposure to radiation is reduced. In addition, there is less scattered radiation exposure to personnel in the room.
- Unattenuated x-rays also cause glare on the image screen resulting in poor image quality. Collimation reduces glare and improves the clarity of the image.

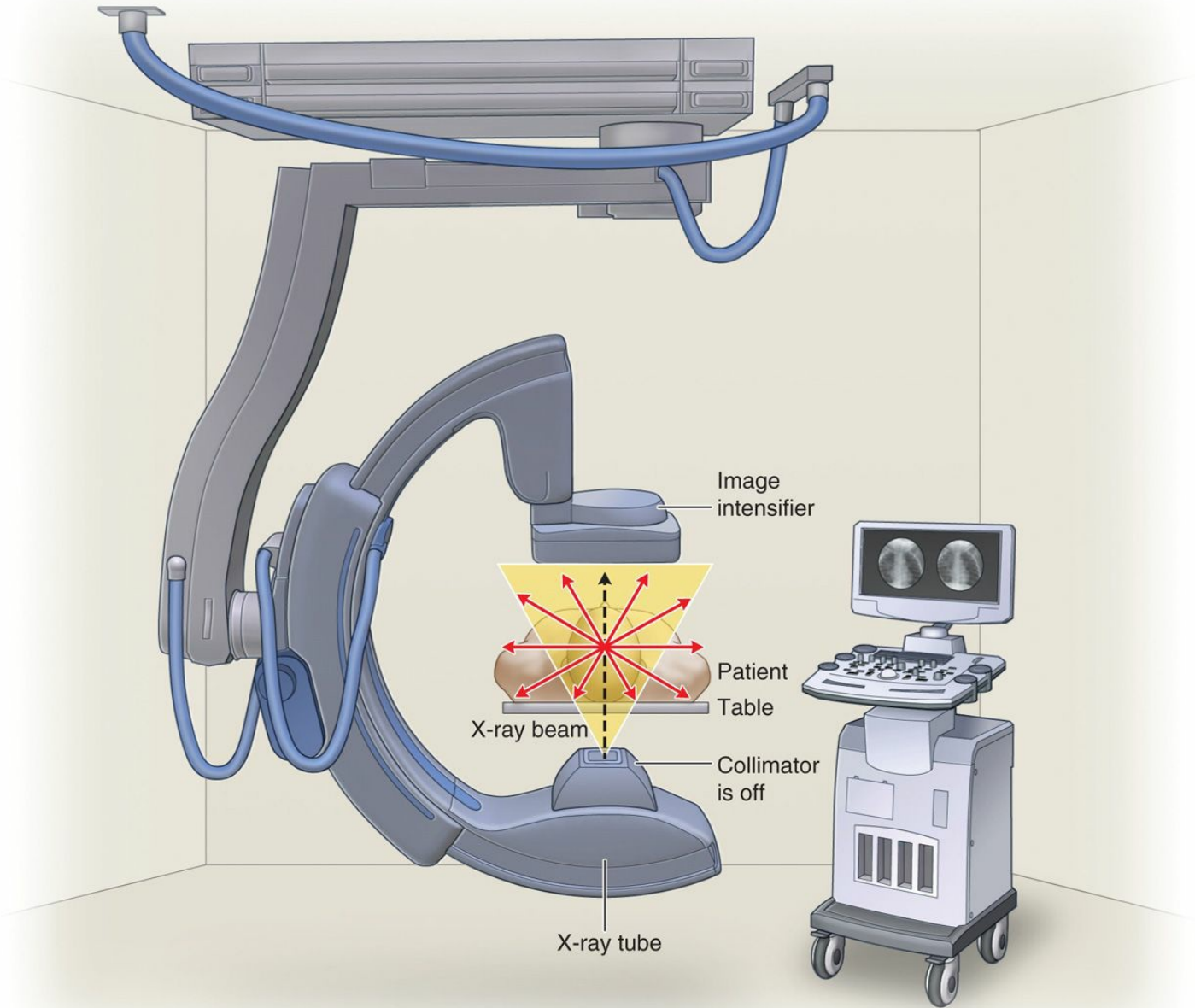


Figure 1-7. Without collimation, the x-ray beam is not optimized to fit the field of view, and there is a large amount of scattered radiation from the patient and table as well as a monitor image that is relatively degraded.

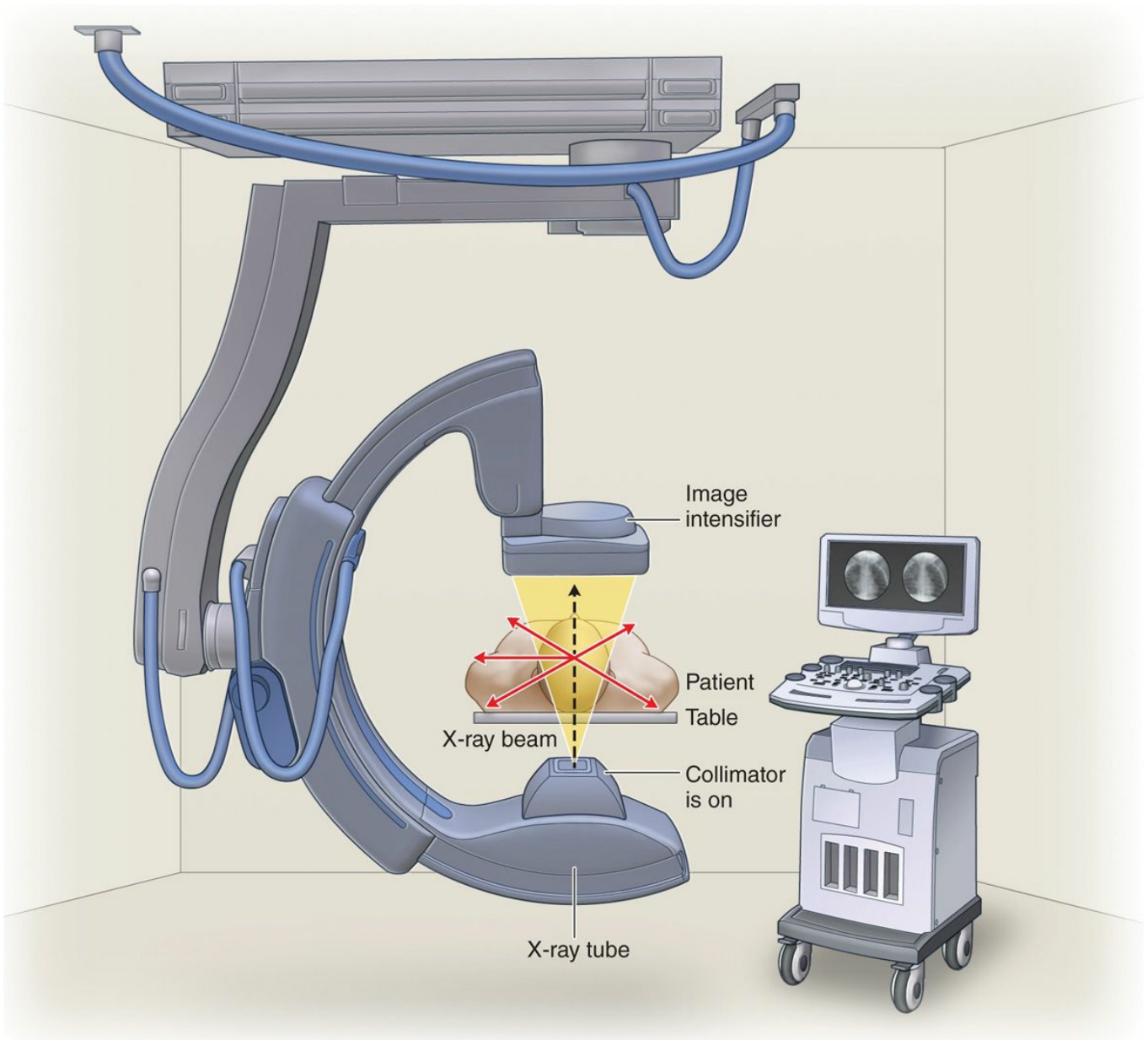


Figure 1-8. By using collimation, the x-ray beam is shaped to better fit the field of view resulting in fewer x-rays leaving the x-ray tube, less scatter radiation, and a clearer image on the monitor.

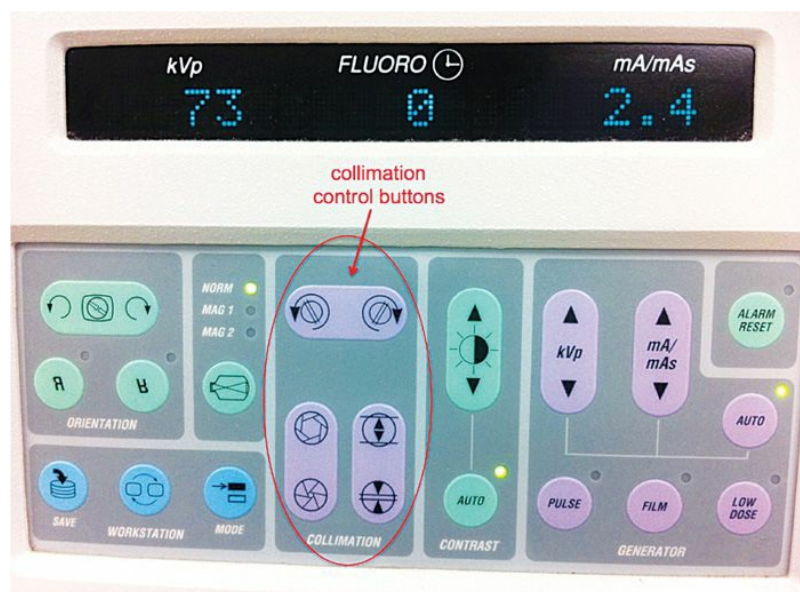


Figure 1-9. Controls for both radial (iris) and rectangular collimation on a typical C-arm fluoroscope.

To process the images that have been brightened by the image intensifier for optimal viewing, modern fluoroscopic systems incorporate optical coupling chains that route the image signal to a video camera. Optical coupling enables the x-ray image to be viewed via closed-circuit television, displaying real-time video imaging of continuous fluoroscopy.

A typical mobile C-arm fluoroscope can also display simultaneous static images on a second television monitor for viewing of the last image in a video sequence. This “last image hold” capability allows the interventionalist to minimize radiation exposure by performing procedures that utilize a series of static images to follow needle placement.

Using digital image conversion technology, analogue video signals are digitized and stored in computer memory. Using less radiation, subsequent digital enhancement of the fluoroscopic image can achieve

image clarity approaching that of x-ray film. Digital images can also be quickly and conveniently distributed via computer networks and stored on computer workstations or archived into various digital storage media for later retrieval.

Since materials of differing density cause x-rays to be absorbed or deflected to varying degrees, fluoroscopy table and pad materials with high or inconsistent density can result in poor image quality.

- Denser materials in table and pad attenuate x-rays, which will result in increased patient radiation exposure and loss of image contrast.
- Materials that are inconsistent in density tend to cast artifactual shadows on the imaging screen.

It is therefore imperative to use only x-ray tables and pads designed to optimize fluoroscopic imaging. Newer composite materials such as carbon fiber in fluoroscopy tables provide adequate strength to support large patients while minimizing x-ray attenuation and distortion. Likewise, thin foam pads overlying the table have minimal effect on x-rays, but large gel supports or irregularly folded pillows may create significant x-ray attenuation, distortion, and artifact. A diving-board table configuration allows for easier imaging of upper body structures during interventional pain procedures.

RADIATION SAFETY

Exposure to ionizing radiation—including x-rays—can result in the formation of free radicals that cause damage to cell structures.

- Chemical chain reactions may trigger changes in cell membrane permeability, resulting in cellular dysfunction.
- Damage to DNA may cause somatic mutations, causing harm to subsequent generations.
- Radiation protection standards are designed to prevent unintended radiation and to maintain exposure for therapeutic purposes “As Low As is Reasonably Achievable” (ALARA).

Dosimetry badges are solid-state radiation detection devices used to measure cumulative radiation dose. For optimal monitoring, two badges are worn, one inside and one outside of a protective lead apron, to determine both overall exposure and the efficacy of the lead apron protection.

- Badges are analyzed on a monthly basis and allow for monitoring of cumulative radiation exposure.
- Current occupational exposure recommendations set the upper effective dose equivalent of 50 mSv/y (5 rem/y) and a cumulative dose not to exceed 10 mSv (1 rem) times the age of the worker. Thus, lifetime exposure for a 50-year-old radiation worker would be 500 mSv (50 rem).

Modern x-rays are completed within milliseconds, and typical radiation exposure is a small fraction of what it was 100 years ago; however, prolonged patient exposures to x-rays may occur as increasingly complex procedures are performed using continuous fluoroscopy.

More than 50 reports of patient injury from prolonged exposure to x-rays during fluoroscopic procedures occurred in 1994 alone, resulting in the health advisory issued by the Food and Drug Administration.¹

- Several reports of serious patient injuries from radiation during fluoroscopy have been recently published.^{3,4}
- Recognition of patient injury from fluoroscopy is often delayed, since the effects of excessive radiation exposure are usually not immediately apparent.
- Fluoroscopy injuries documented in the past 20 years have included skin burns serious enough to require skin grafting.
- Since reporting of fluoroscopy injury is not mandatory, the actual extent of this problem is unknown.

Occupational radiation exposure can be reduced to as low as is reasonably achievable through adherence to 3 basic principles:

- Reduce exposure time.
- Increase the distance from the radiation source.
- Shield yourself and your patient from direct and scattered radiation.

The longer one is exposed to a radiation field, the greater the total radiation dose. Thus, limiting time of exposure is a simple, common-sense method for reducing risk.

- With modern fluoroscopic systems, a short burst of radiation used with “last image hold” capability allows the operator to identify needle position with minimal x-ray exposure time.
- This technique allows the interventionalist to take a fluoroscopic “snapshot” of the field, hold the static image on the monitor, move the needle a small distance toward the target, and then obtain another brief fluoroscopic image to determine the next needle position.
- A recent study found the average time required for needle placement during various interventional pain procedures was 7.7 seconds, which is quite low compared to other dosimetry-measured radiation exposure times in other medical specialties using fluoroscopy.⁵

Based on the inverse square law, the amount of radiation exposure is proportional to the inverse square of the distance from the source.

- Therefore, the amount of radiation exposure declines exponentially as the operator moves away from the source.
- With fluoroscopy, distances of 6 ft or more from the x-ray tube, and from scatter radiation coming off the patient and table, result in minimal radiation exposure.

Lead aprons are mandatory, and thyroid shields are recommended, as standard garb within the procedure room during fluoroscopy (Figure 1-10).

- Lead shielding can be tailored to body contours and made reasonably comfortable while providing an effective barrier to radiation exposure especially to the thyroid and pelvis.
- A wide variety of lead glass screens can be placed between the operator and the x-ray source and/or patient in order to reduce direct and scatter radiation exposure, respectively.
- The interventional procedure room can be configured with leaded glass screens that are attached to ceiling mounts or used with rolling frames on the floor to fit a particular space.
- Leaded glass lenses offer an effective barrier to eye exposure and can be configured with optical correction; however, they may be heavy and uncomfortable. Regular glass lenses also afford some protection and other alternative materials for eye protection are becoming available (Figure 1-10).

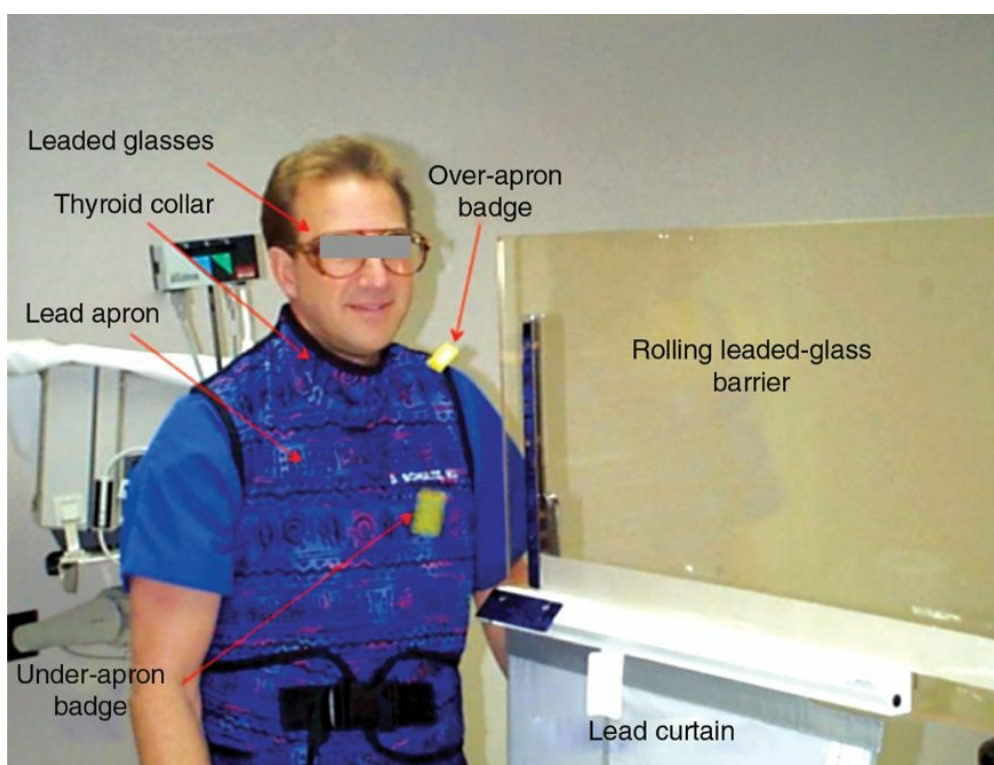


Figure 1-10. Radiation protection with lead apron, glasses, and screen.

Some experts have advocated the use of leaded gloves in order to reduce hand exposure to x-rays during fluoroscopic procedures.

- With lead gloves, there is less chance of hand exposure to scattered x-rays.
- However, the increased density of lead gloves placed within the x-ray field will cause the fluoroscope to increase output as it tries to penetrate the high-density lead.
- Therefore, leaded gloves within the field of view of the monitor will cause an automatic increase in direct and scattered radiation.
- Lead gloves are also expensive and may decrease the tactile sensation, hindering safe and accurate needle placement.
- Keeping hands completely out of the beam is advisable with or without lead gloves.

SUMMARY

The fluoroscope has revolutionized the treatment of chronic pain. For optimal safe and effective use, the pain specialist physician should have an in-depth understanding of fluoroscopy and the fluoroscope to accurately diagnose and treat the physical generators of pain. Skill with the fluoroscope combined with needle placement skills and an understanding of the anatomy and pathophysiology of chronic pain will allow the interventional pain specialist to help patients with chronic pain more effectively than ever before possible.

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Computed Tomography Guidance in Pain Management

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INTRODUCTION

- Computed tomography (CT) creates an image of the body by reconstructing image slices from a series of x-ray projections acquired as the patient is moved through the center of the CT scanner. The CT scanner is able to measure the attenuation of the x-ray beam by the various tissues along each projection. The spatial localization of these tissues is then determined using mathematical algorithms.
- The CT image is then displayed as a matrix of x-ray attenuation values using a reference scale (Hounsfield units [HU]) relative to water; water is assigned a value of 0 HU on all scanners. On this scale, air measures approximately -1000 HU and dense cortical bone approximately +1000 HU.
- A CT image can be displayed as different shades of grey by appropriately choosing the display parameters.
- All current CT scanners offer multi-detector technology (multiple CT slices can be obtained in one rotation of the gantry) and enable isotropic acquisition (ie, spatial resolution is equal in x, y, and z planes) with volumetric multi-planar image reconstruction.

ADVANTAGES OF CT GUIDANCE FOR INTERVENTIONAL PROCEDURES

Anatomical Detail

- Soft tissue structures such as nerve roots and bony constraints including severe scoliosis or large osteophytes are accurately defined (Figure 2-1). Particularly useful for nerve root or epidural injections in patients with advanced degenerative disease or previous surgery.
- Important neurovascular structures are visualized in real time (eg, avoidance of the vertebral artery in cervical nerve root blocks).
- Allows precise needle localization for very small targets.
- Avoids inadvertent transgression of nontarget tissue compartments (Figure 2-2).

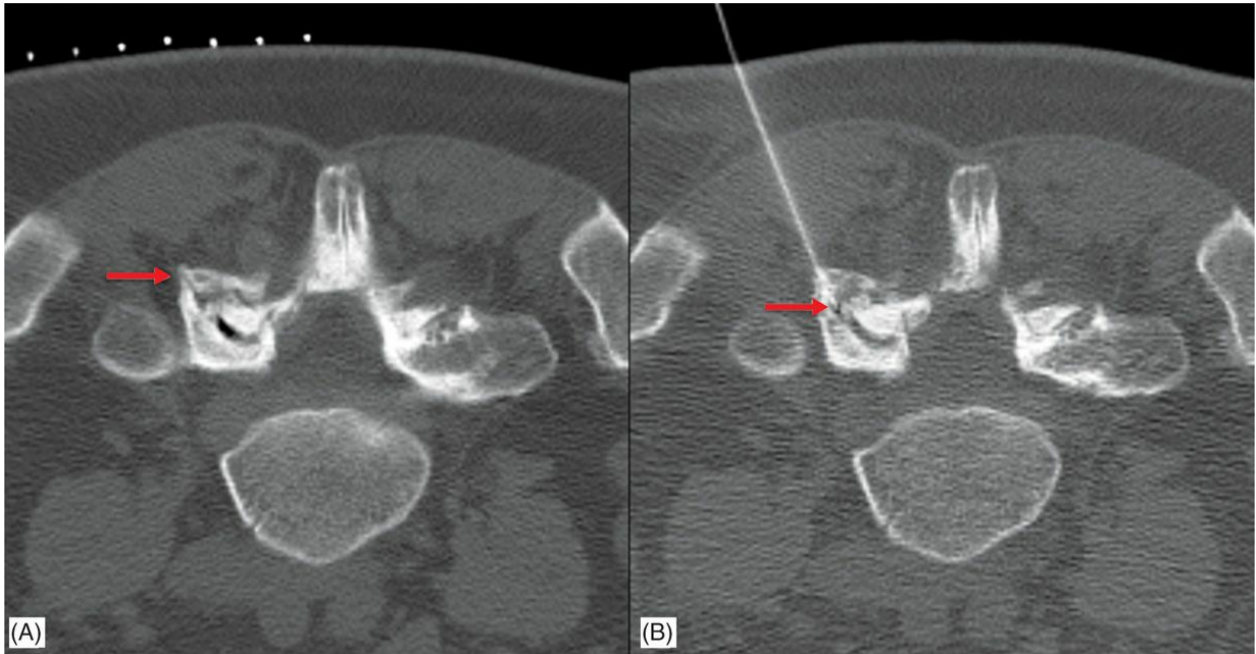


Figure 2-1. CT-guided facet joint injection. (A) Axial prone CT clearly identifies large facet joint osteophytes (arrow) that would make intra-articular needle position difficult to achieve under fluoroscopic guidance. (B) CT guidance facilitates accurate targeting of the narrowed articular space, and intra-articular position (arrow) is achieved.

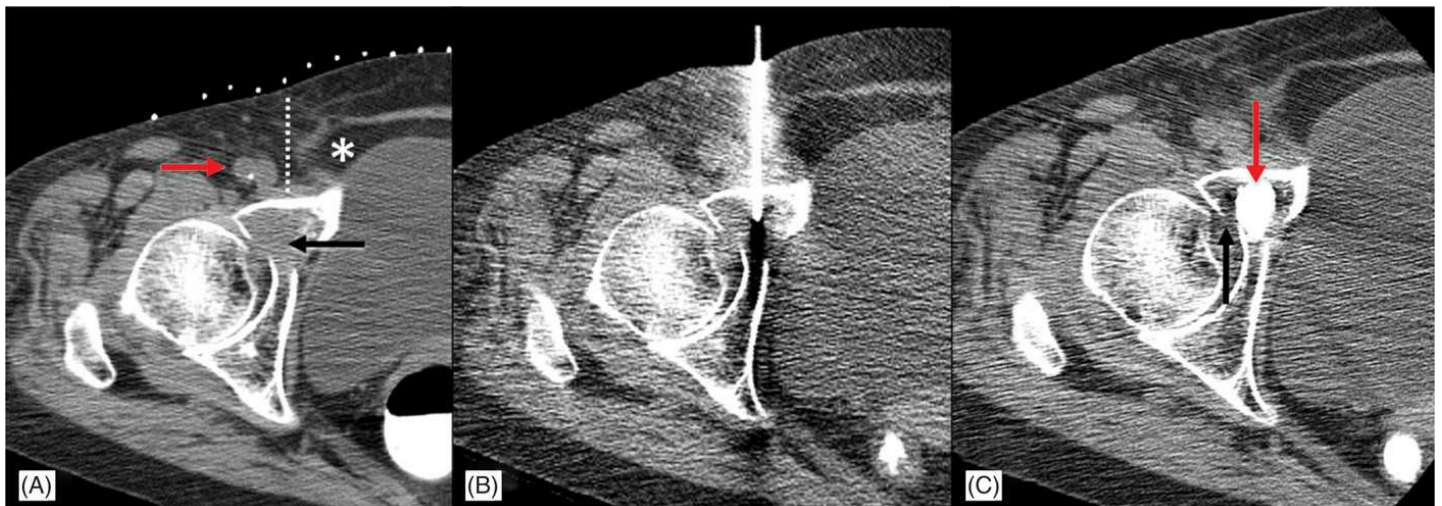


Figure 2-2. CT-guided acetabuloplasty for metastasis. (A) Axial CT clearly identifies soft tissue mass (black arrow) in anterior column of acetabulum, with narrow needle window (dotted line) between common femoral vessels (red arrow) and intra-abdominal compartment (star). (B) CT guidance allows accurate needle placement without injury to neurovascular bundle nor transgression of nontarget compartments. (C) In spite of the focal areas of cortical breach in the acetabular cortex (black arrow), careful injection of Polymethylmethacrylate (PMMA; red arrow) under CT guidance allows delivery without intra-articular extravasation.

Needle Placement

- Unlike fluoroscopy, which is hindered by tissue overlap, multi-planar reformats allow three dimensional trajectory planning.

- Direct visualization allows accurate needle placement with respect to the target nervous structure without use of contrast media.
- If required, the expected spread of injectate can be determined by injection of a small amount of contrast media (Figure 2-3). This is useful for epidural injections where inadvertent intrathecal needle tip position is clearly recognized by injection of contrast media.¹



Figure 2-3. CT-guided celiac plexus blockade. Axial prone CT clearly identifies needle position adjacent to the aorta during bilateral transcureal approach. Injection of a small amount of contrast reveals expected spread of final injectate.

DISADVANTAGES OF CT GUIDANCE

- Generally more time consuming than fluoroscopic approach.
- May have greater radiation dose to patient and practitioner compared to fluoroscopy depending on techniques used.
- Requires further expertise—an understanding of CT imaging, normal CT anatomy, and pathology.
- Less accessible modality, typically located in radiology departments.
- Requires further trained personnel—CT technologists.

PREOPERATIVE CONSIDERATIONS

- Patient positioning
 - For ideal needle trajectory
 - The simplest needle trajectory to achieve accurately is perpendicular to the floor—take advantage of oblique prone positioning if possible (Figure 2-4).
 - Ideally, the entire needle trajectory should lie in one axial CT image—this can be facilitated by angling the CT machine gantry (Figures 2-5 and 2-6).
 - Note that positioning in the lateral decubitus or oblique prone position alters the position of the diaphragm, which can facilitate retroperitoneal needle access without transgressing the pleural space.

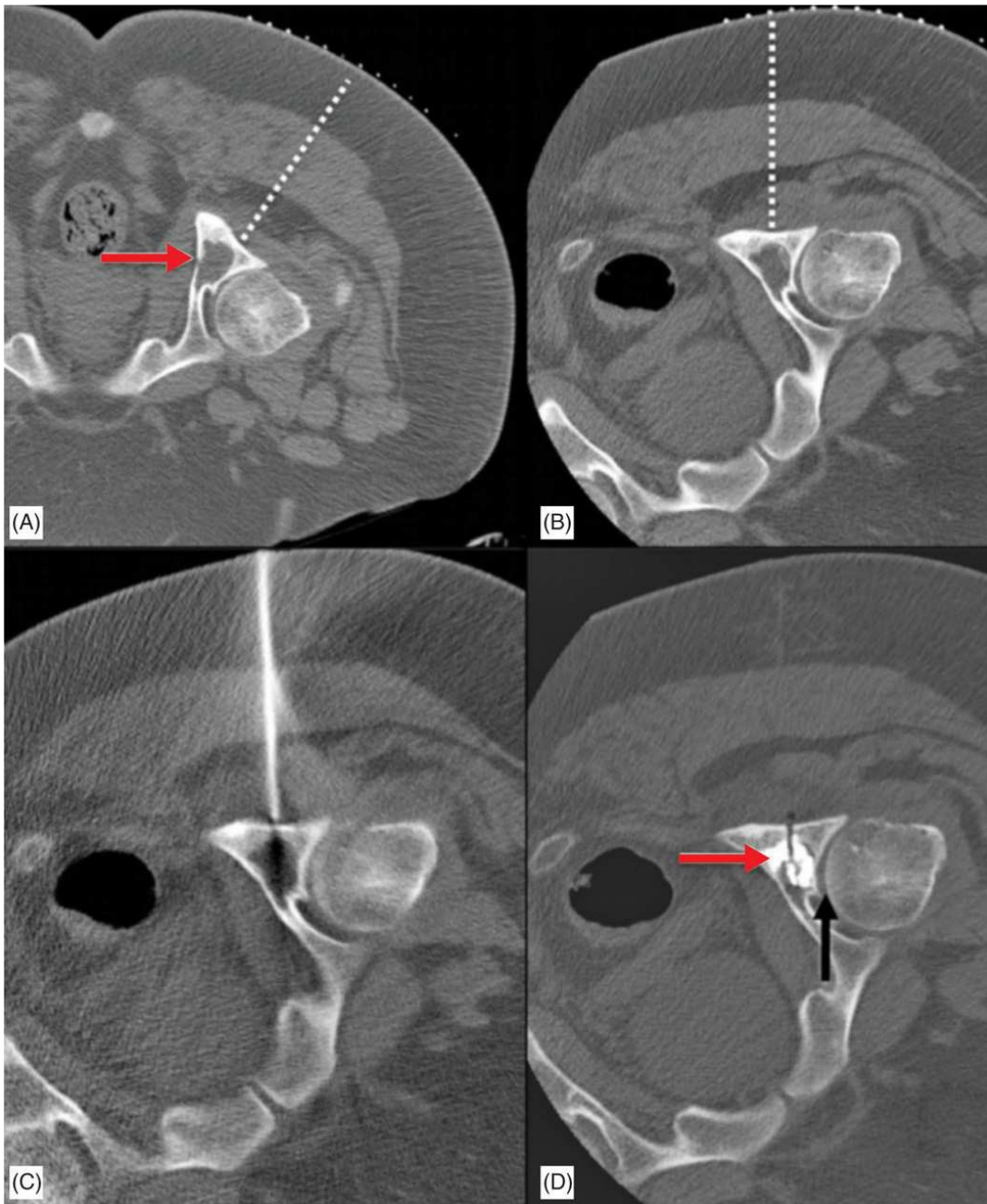


Figure 2-4. Oblique prone positioning to facilitate easier needle placement during acetabuloplasty. (A) Axial prone CT during planning reveals lucent mass in the posterior column of the acetabulum. With prone positioning, an oblique needle trajectory (dotted line) is required. (B) With oblique prone imaging a needle trajectory perpendicular to the floor (dotted line) is obtained, which is easier and less time consuming to achieve. (C) Imaging with 11-gauge needle in place, prior to cortical entry. (D) Postprocedure CT after PMMA injection (red arrow) and removal of needle, with no leakage into the hip joint (black arrow).

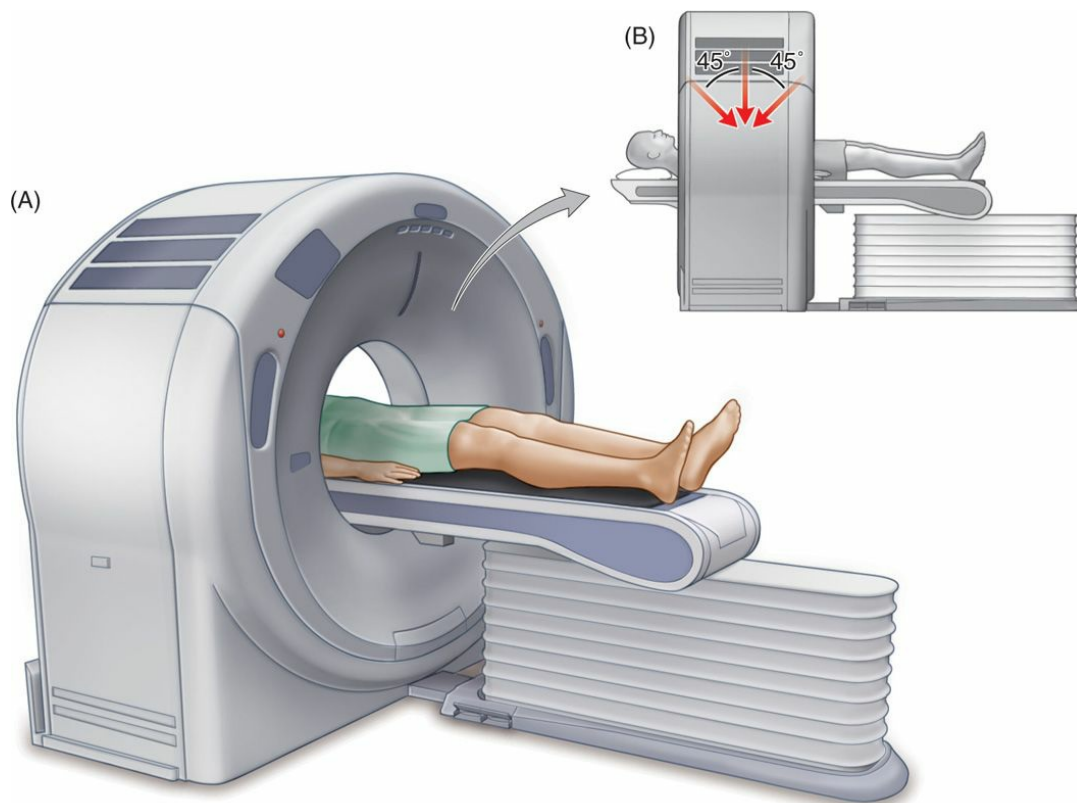


Figure 2-5. The angled gantry approach. (A) The traditional CT gantry position is perpendicular to the CT table. (B) Angling the CT gantry along the line of an angled needle trajectory allows the entire needle trajectory to remain along a single CT slice.

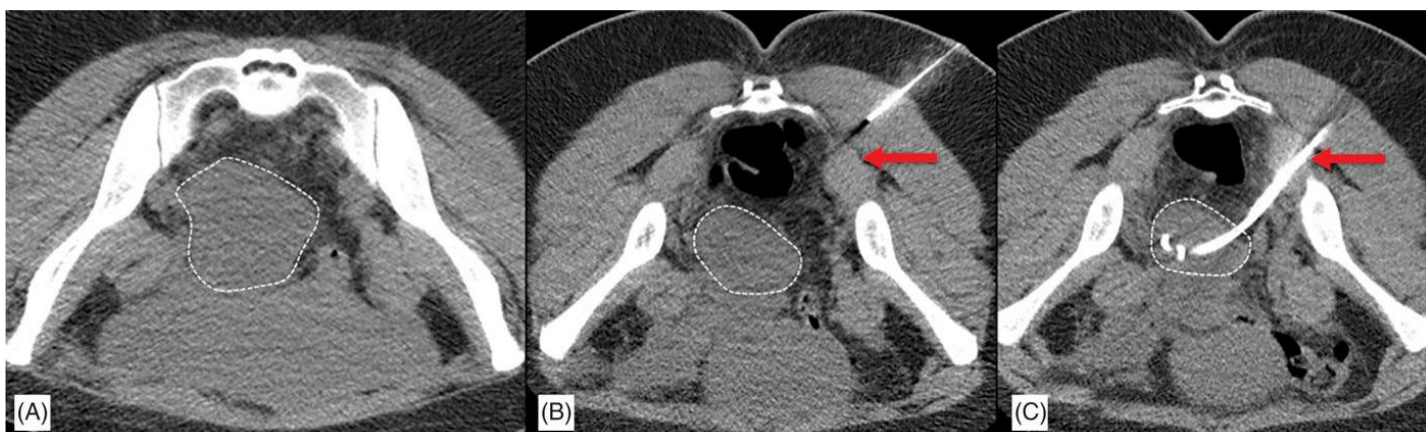


Figure 2-6. CT-guided pelvic collection drainage using angled gantry approach. (A) Axial CT clearly identifies pelvic collection (dotted lines) but without clear needle access. (B) Tilting the CT gantry and repeat imaging identify a safe angled direct needle trajectory. (C) Pigtail drain tube successfully placed into pelvic collection.

- To maximize patient comfort
 - Maximizing patient comfort prior to commencing the procedure minimizes patient motion during needle placement.
 - The prone position is well tolerated with pillows under the chest, hips, and ankles.
 - Further pillows, wedges, or towels may be necessary to achieve a comfortable oblique prone position.
- Needle entry planning
 - Once the patient is positioned, a skin grid marker is placed over the target entry site.
 - An initial radiographic CT scout image is acquired to delineate the superior and inferior extent of the planning CT scan.
 - An initial planning CT scan is performed to define the needle entry site, using the skin grid markers (Figure 2-7).
 - The trajectory is planned, taking into account anatomical limitations.
 - The needle entry site is marked on the patient's skin, the skin grid is removed, the site is prepped with antiseptic solution, and the patient is draped appropriately.
 - If available, a monitor in the CT room should have the needle trajectory available as a reference image to facilitate needle placement.

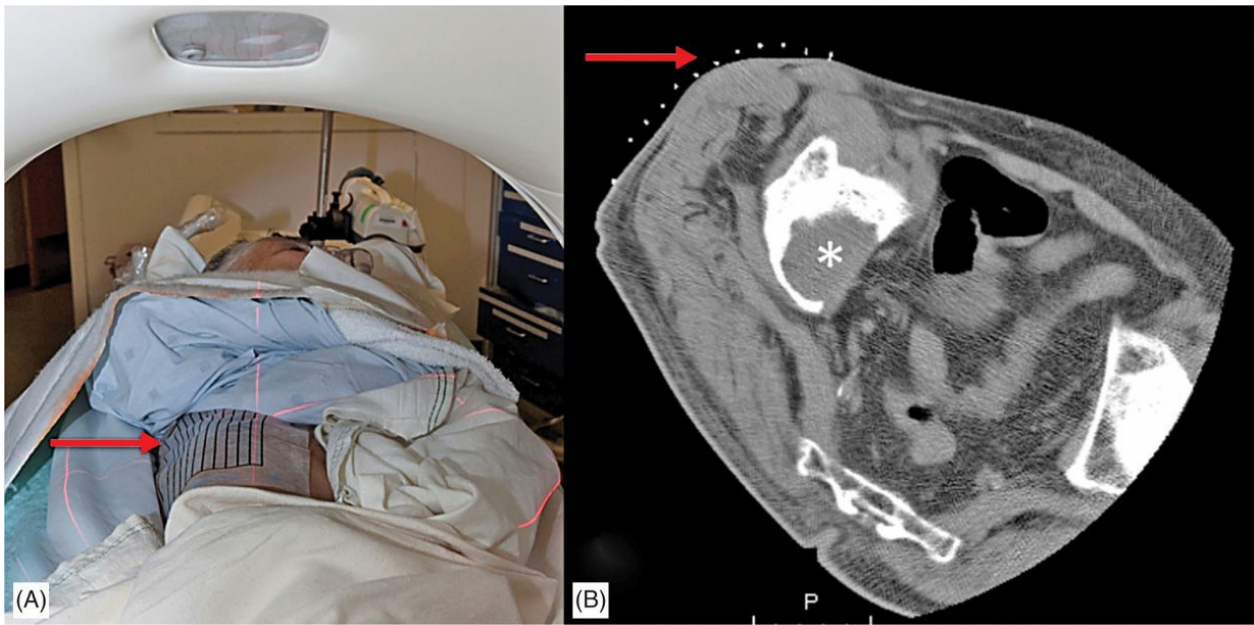


Figure 2-7. Use of skin grid to mark skin entry position. (A) Photograph of patient positioned prone oblique on CT table, with skin grid placed (arrow), and laser light used to mark entry position. (B) Corresponding CT image with skin grid markers (arrow) to guide needle trajectory into acetabular mass (star).

INTRAOPERATIVE TECHNICAL STEPS

- Local anesthetic is injected at the skin entry marker site.
- It may be helpful to leave the local anesthetic needle in place along the planned needle trajectory for subsequent confirmation by CT scanning.
- Infiltrate local anesthetic along the planned needle trajectory.
 - A 22G spinal needle can be used to infiltrate deeply and into the periosteum if entering a bony target.
- As the definitive needle is placed, the needle position and trajectory should be verified with intermittent CT imaging.
 - Intermittent CT imaging needs to define the entire needle course and needle tip.
 - The needle tip can be verified by the identification of the bevel on the needle tip or the presence of a black shadowing artifact. Ensure adjacent CT images above and below are reviewed (Figures 2-8 and 2-9).
 - If using an angled approach in the superior-inferior direction, more frequent CT imaging is recommended.

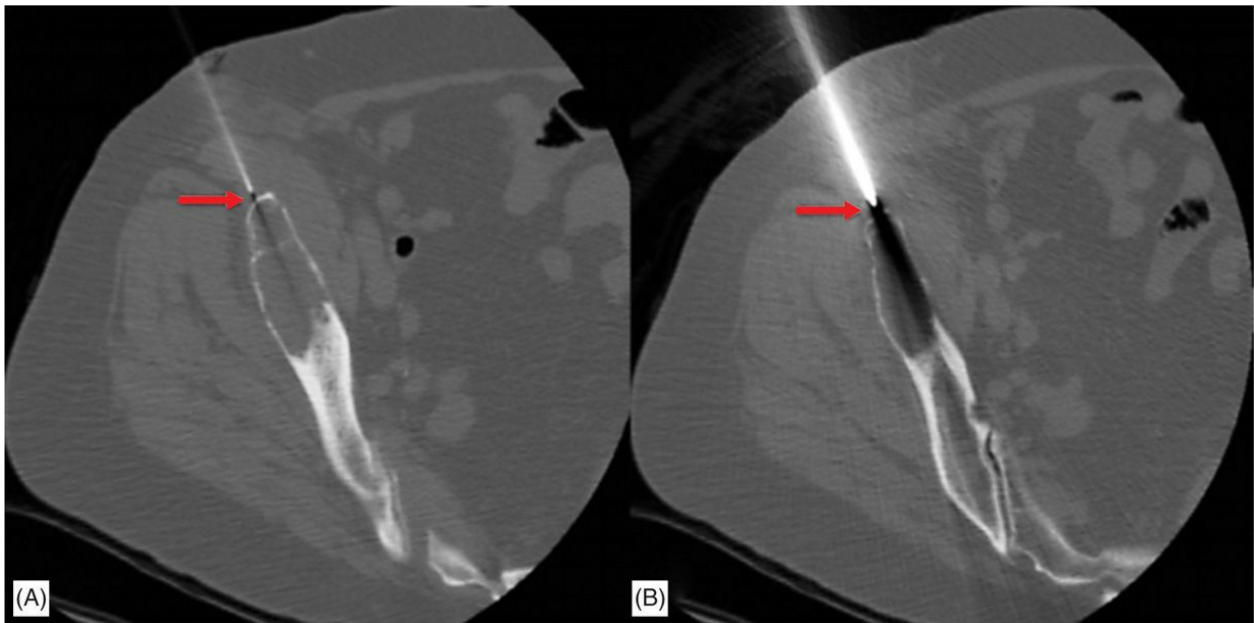


Figure 2-8. Demonstration of needle tip. (A) Axial CT during localization of local anesthetic needle reveals shadowing artifact arising from the tip, confirming identification of the needle tip. (B) With placement of the larger 11-gauge needle, a larger shadowing should be expected. The identification of the bevel of the needle tip is the most accurate method to localize the needle tip.

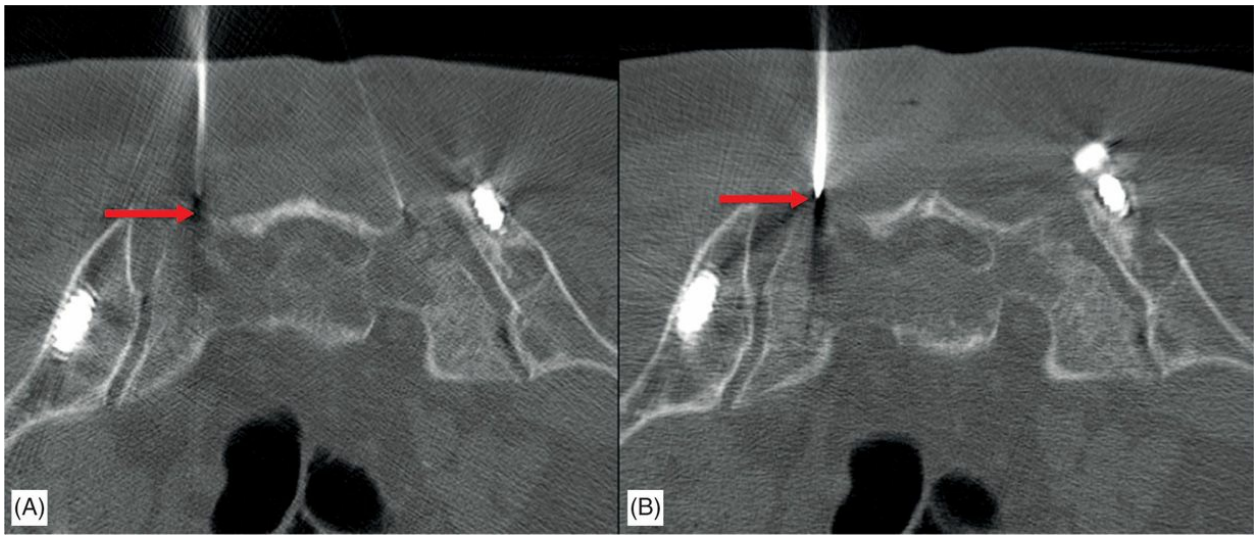


Figure 2-9. Demonstration of needle tip during sacroplasty. (A) Axial CT during localization reveals minor shadowing artifact arising from near the tip, however less than expected for a 13-gauge needle. (B) Imaging 2.5 mm cranial identifies further shadowing artifact as well as the diamond tip bevel confirming exact needle tip position.

- Once the target location is reached, diluted contrast media can be injected to assess intended spread of planned injectate.
- Final postprocedure CT should be performed after needle is removed.
- Use of CT fluoroscopy.
 - CT fluoroscopy is a technique in which the operator remains in the CT room while imaging is acquired, displayed on a monitor, and then used to guide needle placement.
 - Requires additional hardware and software—a display monitor in the CT room, a foot pedal to initiate scanning and control console to initiate table movement (Figure 2-10).
 - Best used when the entire needle trajectory lies in one axial slice and minimal needle manipulations are expected. Deviation from the needle trajectory often requires multiple images to be acquired to achieve correction.
 - Due to radiation exposure, the operator must wear a lead apron and thyroid shield. Lead eye protection is recommended.
 - The typical radiation dose rate in CT fluoroscopy is approximately 7 times lower than the dose rate with conventional diagnostic CT parameters, but it can be up to 60 times higher than conventional fluoroscopy depending on dose settings.²



Figure 2-10. Photograph of patient draped and positioned in preparation for CT fluoroscopy, with in-room monitor, controlling joystick (black arrow) and foot pedal (white arrow).

- This can lead to large radiation doses to patient and operator if not used appropriately. Furthermore, radiation dose is concentrated on a focal area of skin and can result in a large skin radiation dose for the patient.
- However, when used appropriately (low tube current and minimal exposure time), it can result in reduced patient radiation dose and reduced procedural time compared to conventional CT guidance.³
- For selected procedures such as epidural injections and lumbar nerve root blocks, this method can result in radiation dose levels and procedural times similar to conventional fluoroscopic guidance.^{1,4}
- There are two modes of CT fluoroscopic imaging:
 - Quick check imaging
 - The operator presses a pedal to acquire CT images.
 - Typically 3 images are displayed on a screen, with a central image at the expected needle location, and an image above and below.
 - Lower patient and operator radiation dose than continuous imaging.²
 - Continuous imaging
 - CT scanner can acquire continuous imaging (~10 frames per second) during needle manipulation to reproduce live nature of imaging with conventional fluoroscopy.
 - Requires nonmetallic needle holders to ensure that operator's hands are not in gantry. This is less tactile method for needle placement.
 - Results in a high patient skin and operator radiation dose.
 - If using this mode, there should be an inbuilt preset time limit for CT exposure to avoid excessive radiation dose.
 - May be of benefit in targets within particularly mobile organs such as the lung or liver.

CLINICAL PEARLS

- Prior to any case, review the mechanics of the CT gantry, and ensure that all necessary equipment is available.
- For obese patients, ensure the patient is within the maximal CT table weight restrictions and can fit in to the CT gantry.
- If possible, once needle trajectory is planned and local anesthetic is infiltrated, manipulate the needle during the remainder of the procedure while the patient remains in the CT gantry—this reduces the chance of patient motion with table movement, and reduces procedure time.
- Use the laser guiding light in the CT gantry as frequently as possible.
 - If the laser light bisects the needle hub, the needle trajectory will be in the plane of the CT image.
 - If the needle hub lies above the plane of the laser guiding light, the needle tip is pointing in the opposite direction and can be adjusted without repeat imaging.
- If the patient needs to be moved into and out of the CT gantry, use of a pedal or sterile cover over the CT controls can allow the operator to move the CT table immediately and independently of the CT technician.
- If there is no safe direct access to the target in the axial plane, consider tilting the CT gantry to obtain oblique axial imaging—this may facilitate a safe angled pathway in which the entire needle trajectory can be visualized.
- Injection of normal saline or 5% dextrose can allow creation of a needle trajectory pathway in between compartments, eg, facilitating access to the celiac plexus by enlarging the retroperitoneal space or displacing adjacent tissues.
- If there is a CT contrast allergy, depending on the target location, a small amount of air can be effectively used as a contrast medium, eg, in confirming epidural needle tip position.¹
- Radiation reduction.
 - Any reduction in radiation to the patient also reduces radiation dose to the operator and to assisting staff members.
 - Acquire images only when necessary to assess needle position and trajectory.
 - Step as far away from the CT gantry during image acquisition as possible. Exit the room if not using CT fluoroscopy.
 - If using CT fluoroscopy.
 - Use the quick check method.
 - A lower tube current during imaging can reduce radiation dose while providing adequate trajectory information without loss of anatomical resolution.²
 - Place the foot pedal further away from the gantry to reduce dose (radiation intensity is inversely proportional to the square of the distance from the source).⁴
 - A lead drape over the patient adjacent to the scan plane can reduce scattered dose to the operator's hands.⁵

Suggested Reading

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