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PRACTICE GUIDELINE FOR THE PERFORMANCE OF DIAGNOSTIC INFUSION VENOGRAPHY

PREAMBLE

These guidelines are an educational tool designed to assist practitioners in providing appropriate radiologic care for patients. They are not inflexible rules or requirements of practice and are not intended, nor should they be used, to establish a legal standard of care. For these reasons and those set forth below, the American College of Radiology cautions against the use of these guidelines in litigation in which the clinical decisions of a practitioner are called into question.

The ultimate judgment regarding the propriety of any specific procedure or course of action must be made by the physician or medical physicist in light of all the circumstances presented. Thus, an approach that differs from the guidelines, standing alone, does not necessarily imply that the approach was below the standard of care. To the contrary, a conscientious practitioner may responsibly adopt a course of action different from that set forth in the guidelines when, in the reasonable judgment of the practitioner, such course of action is indicated by the condition of the patient, limitations on available resources, or advances in knowledge or technology subsequent to publication of the guidelines. However, a practitioner who employs an approach substantially different from these guidelines is advised to document in the patient record information sufficient to explain the approach taken.

The practice of medicine involves not only the science, but also the art of dealing with the prevention, diagnosis, alleviation, and treatment of disease. The variety and complexity of human conditions make it impossible to always reach the most appropriate diagnosis or to predict with certainty a particular response to treatment. Therefore, it should be recognized that adherence to these guidelines will not assure an accurate diagnosis or a successful outcome. All that should be expected is that the practitioner will follow a reasonable course of action based on current knowledge, available resources, and the needs of the patient to deliver effective and safe medical care. The sole purpose of these guidelines is to assist practitioners in achieving this objective.

I. INTRODUCTION

This guideline was developed and written by the Society for Interventional Radiology (SIR) in collaboration with the American College of Radiology (ACR).

Diagnostic infusion venography is defined as the radiographic study of an extremity with iodinated contrast injection through peripheral intravenous access, often at the level of the hand or the foot. The term does not imply a specific method or rate of contrast injection. Such a study will often visualize the venous system to the level of the superior or the inferior vena cava. However, the term diagnostic infusion venography does not include central or selective venography through an angiographic catheter.

Diagnostic infusion venography is an established, safe, and accurate method when used as indicated and is considered the diagnostic standard by which the accuracy of other venous imaging modalities should be judged.

However, alternative methods of studying the venous system such as duplex ultrasound, CT venography, and MR venography may be preferable in specific clinical situations. In particular, duplex ultrasound has largely replaced diagnostic infusion venography of the lower extremity since the sensitivity and specificity of duplex ultrasound above the knee is adequate for the initiation of treatment for deep venous thrombosis (DVT) [1-9]. The use of diagnostic infusion venography may be preferred, specifically for the diagnosis of below-knee and upper extremity DVT and in patients who have had joint replacement [10-13]. Diagnostic infusion venography, however, has a small but definite risk of complications [14-21].

Diagnostic infusion venography should be performed only for a valid medical reason (e.g., see Section II below) and with the minimum radiation dose necessary to achieve an optimal study. While venography is an invasive test with defined risks, it is a valuable and informative procedure performed routinely in the evaluation of disorders of the venous system. The information obtained by diagnostic infusion venography, combined with other clinical and noninvasive imaging findings, can be used to plan or evaluate results of treatment.

This guideline can be used in institution-wide quality-improvement programs to assess the practice of venography. The most important processes of care are (1) patient selection, preparation, and education, (2) performing and interpreting the procedure, and (3) monitoring the patient. The outcome measures for these processes are indications, success rates, and complication rates. Outcome measures are assigned threshold levels.

II. INDICATIONS AND CONTRAINDICATIONS

Indications for diagnostic infusion venography include, but are not limited to:

1. Diagnosis of DVT in a patient:
   a. With a nondiagnostic duplex exam or for whom a duplex exam is not technically feasible.
   b. Suspected of having infrapopliteal disease.
   c. With a symptomatic extremity status after joint replacement.
   d. With a high clinical suspicion for DVT but with a negative duplex exam.
   e. When duplex ultrasound is not available.

2. Evaluation of valvular insufficiency prior to stripping or ligation of superficial varicose veins.

3. Venous mapping prior to or following a surgical or interventional procedure.

4. Evaluation for venous stenosis or venous hypertension.

5. Evaluation for venous malformations.

6. Preoperative evaluation for tumor involvement or encasement.

The threshold for these indications is 95 percent. When fewer than 95 percent of procedures are for these indications, the department should review the process of patient selection.

There are no absolute contraindications to diagnostic infusion venography. Relative contraindications include, but are not limited to:

1. Evidence of active cellulitis of the extremity to be imaged.

2. Iodinated contrast allergy.

3. Renal insufficiency in patients who are not on dialysis, particularly those with diabetes or congestive heart failure (CHF).

All imaging facilities should have policies and procedures to reasonably attempt to identify pregnant patients prior to the performance of any diagnostic examination involving ionizing radiation. If the patient is known to be pregnant, the potential radiation risks to the fetus and clinical benefits of the procedure should be considered before proceeding with the study. 1995, 2005 (Res. 1a)

III. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

A. Physician

Diagnostic infusion venography examinations must be performed under the supervision of and interpreted by a physician who has the following qualifications:

1. Certification in Radiology or Diagnostic Radiology by the American Board of Radiology (ABR), the American Osteopathic Board of Radiology, the Royal College of Physicians and Surgeons of Canada, or Le College des Medecins du Quebec.

or

2. Completion of an Accreditation Council for Graduate Medical Education (ACGME) approved residency program or an American Osteopathic Association (AOA) approved residency program and a minimum of 3 months training in fluoroscopy and performance of at least 10 extremity venograms.

or

3. In the absence of appropriate ACGME approved residency training as outlined in Section III.A.2 above or postgraduate training that included comparable instruction and experience in diagnostic venography, the physician must have experience and demonstrated competency as primary operator in diagnostic venography under the supervision of an on-site qualified physician, during which a minimum of 10 extremity venograms were performed with documented success and complication rates that meet the threshold criteria listed in Section VIII.

and

4. Substantiation in writing by the director of interventional radiology or the chief of the department of radiology of the institution that the physician is familiar with all of the following:

    a. Indications and contraindications for the procedure.
    b. Preprocedural assessment of the patient.
    c. Fluoroscopic and radiographic equipment, and other electronic imaging systems.
    d. Principles of radiation protection, the hazards of radiation exposure both to patients and radiologic personnel, and monitoring requirements.
    e. Pharmacology of contrast agents and recognition and treatment of adverse reactions to them.
    f. Technical aspects of performing the procedure, including appropriate injection rates and volumes of contrast media, and filming sequences.
    g. Anatomy, physiology, and pathophysiology of peripheral venous vasculature.
    h. Interpretation of diagnostic venography.
    i. Postprocedural patient management, especially recognition and initial management of complications.

Maintenance of Competence

Physicians must perform a sufficient number of venographic procedures to maintain their skills, with acceptable success and complication rates as outlined in this guideline. Continued competence should depend on participation in a quality improvement program that monitors these rates.

The physician's continuing education should be in accordance with the ACR Practice Guideline for Continuing Medical Education (CME).

B. Qualified Medical Physicist

A Qualified Medical Physicist is an individual who is competent to practice independently in one or more of the subfields in medical physics. The American College of Radiology considers certification and continuing education in the appropriate subfield(s) to demonstrate that an individual is competent to practice in one or more of the subfields in medical physics and to be a Qualified Medical Physicist. The ACR recommends that the individual be certified in the appropriate subfield(s) by the American Board of Radiology (ABR) or for MRI, by the American Board of Medical Physics (ABMP) in magnetic resonance imaging physics.

The appropriate subfields of medical physics for this guideline are Radiological Physics and Diagnostic Radiological Physics.

The continuing education of a Qualified Medical Physicist should be in accordance with the ACR Practice Guideline for Continuing Medical Education (CME). 2006 (Res. 16g)

C. Radiologist Assistant

A radiologist assistant is an advanced level radiographer who is certified and registered as a radiologist assistant by the American Registry of Radiologic Technologists (ARRT) after having successfully completed an advanced academic program encompassing an ACR/ASRT (American Society of Radiologic Technologists) radiologist assistant curriculum and a radiologist-directed clinical preceptorship. Under radiologist supervision, the radiologist assistant may perform patient assessment, patient management and selected examinations as delineated in the Joint Policy Statement of the ACR and the ASRT titled "Radiologist Assistant: Roles and Responsibilities" and as allowed by state law. The radiologist assistant transmits to the supervising radiologists those observations that have a bearing on diagnosis. Performance of diagnostic interpretations remains outside the scope of practice of the radiologist assistant. 2006 (Res. 34)

D. Radiologic Technologist

1. The technologist, together with the physician and nursing personnel, should have responsibility for patient comfort and safety. The technologist should be able to prepare and position[1] the

[1]The American College of Radiology approves of the practice of certified and/or licensed radiologic technologists performing fluoroscopy only as a positioning or localizing procedure and then only if monitored by a supervising physician who is personally and immediately available, and the positioning or localizing procedure must have prior written approval by the

patient for the venographic procedure. The technologist should obtain the imaging data in a manner prescribed by the supervising physician. The technologist should also perform the regular quality control testing of the equipment under supervision of the physicist.

2. The technologist should be certified by the American Registry of Radiologic Technologists (ARRT) or have an unrestricted state license with documented training and experience in diagnostic venography procedure**s**.

IV. SPECIFICATIONS OF THE EXAMINATION

There are several technical requirements that are necessary to ensure safe and successful diagnostic infusion venograms. These include adequate radiographic imaging equipment, institutional facilities, and physiologic monitoring equipment.

A. Venography Equipment and Facilities

The following are considered the minimal equipment requirements for performing diagnostic infusion venography. In planning facilities for diagnostic infusion venography, equipment and facilities more advanced than those listed below may be desired to produce higher-quality studies with reduced risk and time of study. In general, the facility should include at a minimum:

1. A radiography suite that is large enough to allow easy transfer of the patient from the bed to the table and to accomodate the procedure table, monitoring equipment, and other hardware such as intravenous pumps, respirators, anesthesia equipment, and oxygen tanks. Ideally, there should be adequate space for circulation of technical staff in the room without interfering with the contrast injection.

2. For lower extremity venography, a tilt table fluoroscopy unit is desirable.

B. Resuscitation Equipment

There should be ready access to emergency resuscitation equipment and drugs, to include the following: an emergency defibrillator, an oxygen supply and appropriate tubing and delivery systems, suction equipment, tubes for endotracheal intubation, laryngoscope, ventilation bag-mask-valve apparatus, and central venous line sets. Drugs for treating cardiopulmonary arrest, contrast reaction, vasovagal reactions, narcotic or benzodiazepine overdose, bradycardia, and ventricular arrhythmias should also be readily available.

C. Support Personnel

Radiologic technologists properly trained in the use of the diagnostic imaging equipment should assist in performing and imaging the procedure. They should be able to demonstrate appropriate knowledge of patient positioning, venographic image recording, adjunctive supplies, and the location of resuscitation equipment. Technologists should be trained in basic cardiopulmonary resuscitation and in the function of the resuscitation equipment.

D. Patient Care

The written or electronic request for a venography examination should provide sufficient information to demonstrate the medical necessity of the examination and allow for the proper performance and interpretation of the examination.

Documentation that satisfies medical necessity includes 1) signs and symptoms and/or 2) relevant history (including known diagnoses). The provision of additional information regarding the specific reason for the examination or a provisional diagnosis would be helpful and may at times be needed to allow for the proper performance and interpretation of the examination.

The request for the examination must be originated by a physician or other appropriately licensed health care provider. The accompanying clinical information should be provided by a physician or other appropriately licensed health care provider familiar with the patient's clinical problem or question and consistent with the state scope of practice requirements. 2006 (Res. 35)

1. Preprocedure care

   The physician performing the procedure must have knowledge of the following:

   a. Clinically significant history including the indications for the procedure.
   b. Clinically significant physical examination including an awareness of clinical or medical conditions that may necessitate specific care.
   c. Possible alternative methods, such as ultrasound, MR or CT to obtain the desired diagnostic information or therapeutic result.

Informed consent must be in compliance with all state laws and applicable ACR Practice Guidelines and Technical Standards. See the ACR Practice Guideline on Informed Consent for Image-Guided Procedures.

medical director of the radiology department/service and there be written authority, policy and procedures for designating radiologic technologists who perform such procedures.1987, 1997 (Res. 1-E)

2. Procedural care
   a. Adherence to the JCAHO Universal Protocol for Preventing Wrong Site, Wrong Procedure, Wrong Person Surgery™ is required for procedures in non-operating room settings including bedside procedures. "Time out" must be conducted in the location where the procedure will be done, just before starting the procedure and must:
      - Involve the entire operative team.
      - Use active communication.
      - Be briefly documented, such as in a checklist, and
      - At the least, include:
        - Correct patient identity.
        - Correct side and site.
        - Agreement on the procedure to be done.
        - Correct patient position.
        - Availability of correct implants and any special equipment or special requirements.

      The organization should have processes and systems in place for reconciling differences in staff responses during the "time out."

   b. During the use of fluoroscopy, the physician should have knowledge of exposure factors including kVp, mA, magnification factor, and dose rate, and consider additional parameters such as collimation, field of view, and last image hold.
   c. Nursing personnel, technologists, and those directly involved in the care of patients undergoing venography should have protocols for use in standardizing care. These should include, but are not limited to, the following:
      i. Equipment needed for the procedure.
      ii. Patient monitoring.

      Protocols should be reviewed and updated periodically.

V. DOCUMENTATION

Documentation of a complete venogram procedure will vary according to the indication for the examination, as outlined in Section II. At a minimum, for any indication, the operator should document and archive a sufficient number of full contrast images of the anatomic region being studied to answer the clinical question that prompted the examination.

Each operator should have full knowledge of the pathophysiology of venous diseases and should tailor the examination appropriately to provide optimal diagnostic information while attempting to minimize the patient's exposure to iodinated contrast and ionizing radiation.

Reporting should be in accordance with the Practice Guideline for the Reporting and Archiving of Interventional Radiology Procedures.

VI. RADIATION SAFETY IN IMAGING

Radiologists, radiologic technologists, and all supervising physicians have a responsibility to minimize radiation dose to individual patients, to staff, and to society as a whole, while maintaining the necessary diagnostic image quality. This is the concept "As Low As Reasonably Achievable (ALARA)."

Facilities, in consultation with the medical physicist, should have in place and should adhere to policies and procedures, in accordance with ALARA, to vary examination protocols to take into account patient body habitus, such as height and/or weight, body mass index or lateral width. The dose reduction devices that are available on imaging equipment should be active or manual techniques should be used to moderate the exposure while maintaining the necessary diagnostic image quality. Patient radiation doses should be periodically measured by a medical physicist in accordance with the appropriate ACR Technical Standard. 2006 (Res. 17)

VII. QUALITY CONTROL AND IMPROVEMENT, SAFETY, INFECTION CONTROL, AND PATIENT EDUCATION CONCERNS

Policies and procedures related to quality, patient education, infection control, and safety should be developed and implemented in accordance with the ACR Policy on Quality Control and Improvement, Safety, Infection Control, and Patient Education Concerns appearing elsewhere in the ACR Practice Guidelines and Technical Standards book.

These data should be utilized in conjunction with the thresholds described in Section VII below to assess procedural efficacy and complication rates and to trigger institutional review when these thresholds are exceeded.

VIII. QUALITY IMPROVEMENT

These guidelines are written to be used in quality improvement (QI) programs to assess diagnostic venography. The most important processes of care are patient selection, and performance of the exam. The major outcome measures for diagnostic venography include diagnosis of pathology and complication rates. Outcome measures are assigned threshold levels.

While practicing physicians should strive to achieve perfect outcomes (e.g., 100% success, 0% complications), in practice all physicians will fall short of this ideal to a

variable extent. Thus, in addition to QI case reviews customarily conducted after individual procedural failures or complications, outcome measure thresholds should be used to assess diagnostic venography in ongoing QI programs. For the purpose of these guidelines, a threshold is a specific level of an indicator which, when reached or crossed, should prompt a review of departmental policies and procedures. Procedure thresholds or overall thresholds refer to a group of outcome measures for a procedure, e.g., major complications for diagnostic venography. Individual complications may also be associated with complication-specific thresholds, e.g., fever or hemorrhage. When outcome measures such as success rates or indications fall below a minimum threshold, or when complication rates exceed a maximum threshold, a departmental review should be performed to determine causes and to implement changes, if necessary. Thresholds may vary from those listed here; for example, patient referral patterns and selection factors may dictate a different threshold value for a particular indicator at a particular institution. Thus, setting universal thresholds is very difficult, and each department is urged to alter the thresholds as needed to higher or lower values, to meet its own quality improvement program needs.

Complications can be stratified on the basis of outcome. Major complications may result in admission to a hospital for therapy (for outpatient procedures), an unplanned increase in the level of care, prolonged hospitalization, permanent adverse sequelae, or death. Minor complications result in no sequelae; they may require nominal therapy or a short hospital stay for observation (generally overnight). See Appendix A. The complication rates and thresholds in Table 2 below refer to major complications.

Measures of Success

Technical Success – technical success describes the successful placement of appropriate IV access, the use of the appropriate contrast, the acquisition of acceptable images of diagnostic quality and the communication of the findings to the referring physician.

Success Rates – published rates for individual types of complications are highly dependent on patient selection and are based on series comprising several hundred patients, which is a volume larger than most individual practitioners are likely to treat. Therefore, we recommend that complication-specific thresholds usually should be set higher than the complication-specific reported rates listed below. It is also recognized that a single complication can cause a rate to cross above a complication-specific threshold when the complication occurs in a small volume of patients, e.g., early in a quality improvement program. In this situation, the overall procedure threshold is more appropriate for use in a QI program.

In Tables 1 and 2, all values were supported by the weight of literature evidence and panel consensus.

Table 1 – Successful Rates for Infusion Venography [1,2,7, 22-24]

	Reported Rates	Suggested Threshold
Success Rates	84%-100%	95%

Table 2 – Major Complications of Diagnostic Infusion Venography [14-21]

	Reported Rates	Suggested Threshold
Death	<1%	<1%
Bronchospasm	<1%	<1%
Cardiovascular collapse	<1%	<1%
DVT with ionic contrast	2.6-10%	<3%
DVT with nonionic contrast	0 -9%	<3%
Contrast-media-induced nephrotoxicity	0-0.15%	<2%
Skin necrosis	0.5%	0.5%

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Appendix A

Society of Interventional Radiology
Standards of Practice Committee
Classification of Complications by Outcome

Minor Complications

A. No therapy, no consequence.
B. Nominal therapy, no consequence; includes overnight admission for observation only.

Major Complications

C. Require therapy, minor hospitalization (<48 hours).
D. Require major therapy, unplanned increase in level of care, prolonged hospitalization (>48 hours).
E. Permanent adverse sequelae.
F. Death.