Quality Improvement Guidelines for Diagnostic Infusion Venography

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Abbreviations:  DVT = deep venous thrombosis, QI = quality improvement

PREAMBLE

The membership of the Society of Interventional Radiology (SIR) Standards of Practice Committee represents experts in a broad spectrum of interventional procedures from both the private and academic sectors of medicine. Generally, Standards of Practice Committee Members dedicate the vast majority of their professional time to performing interventional procedures; as such, they represent a valid, broad expert constituency of the subject matter under consideration for standards production.

METHODOLOGY

SIR produces its Standards of Practice documents with use of the following process: Standards documents of relevance and timeliness are conceptualized by the Standards of Practice Committee Members. A recognized expert is identified to serve as the principal author for the standard. Additional authors may be assigned depending on the magnitude of the project.

An in-depth literature search is performed with use of electronic medical literature databases. Then, a critical review of peer-reviewed articles is performed with regards to the study methodology, results, and conclusions. The qualitative weight of these articles is assembled into an evidence table, which is used to write the document such that it contains evidence-based data with respect to content, rates, and thresholds.

When the evidence of literature is weak, conflicting, or contradictory, consensus for the parameter is reached by a minimum of 12 Standards of Practice Committee Members with use of a Modified Delphi Consensus Method (see Appendix 2). For purposes of these documents, consensus is defined as 80% Delphi participant agreement on a value or parameter.

The draft document is critically reviewed by the Standards of Practice Committee Members in either a telephone conference call or face-to-face meeting. The finalized draft from the Committee is sent to the SIR membership for further input/criticism during a 30-day comment period. These comments are discussed by the Standards of Practice Committee and appropriate revisions made to create the finished standards document. Before its publication, the document is endorsed by the SIR Executive Council.

Diagnostic infusion venography, particularly of the lower extremity, has been largely replaced by duplex ultrasound (US) (1–4). The sensitivity and specificity of duplex US above the knee are more than adequate for the initiation of treatment for deep venous thrombosis (DVT) (5–9). The use of diagnostic infusion venography has increased, specifically for the diagnosis of below-knee and upper extremity DVT and in patients who have undergone joint replacement (10–13). Diagnostic infusion venography is an established, safe, and accurate method of evaluating deep venous clot and is considered the diagnostic standard by which the accuracy of other venous imaging modalities should be judged. However, diagnostic infusion venography has a small but definite risk of complications (14–21).

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

Although 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. Therefore, in addition to QI case reviews customarily conducted after individual procedural failures or complications, outcome measure thresholds should be used to assess diagnostic venography efficacy 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” reference 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. Therefore, 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 QI program needs.

Complications can be stratified on the basis of outcome. Major complications 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 1). The complication rates and thresholds below refer to major complications, unless otherwise noted.

**INDICATIONS**

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

1. Diagnosis of DVT in a patient: With a limited duplex examination,
   Suspected of having infrapopliteal disease,
   With a symptomatic extremity after joint replacement, or
   With a high clinical suspicion for DVT but with negative duplex examination results;
2. Evaluation for suspected DVT or venous mapping;
3. Evaluation of valvular insufficiency before stripping or ligation of superficial varicose veins;
4. Preoperative venous mapping before venous harvest to be used as a potential arterial graft, dialysis access, or venous access planning;
5. Evaluation for venous stenosis or venous hypertension;
6. Evaluation for venous malformations;
7. Preoperative evaluation for tumor involvement or encasement; and
8. Targeting for central venous catheter placement.

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

**Contraindications**

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

1. Evidence of an active cellulitis of the extremity to be imaged;
2. Contrast allergy; or
3. Renal insufficiency, particularly in patients with diabetes or congestive heart failure.

**Measures of Success**

Technical success describes the successful creation of appropriate intravenous access, the use of the appropriate contrast material, 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 be set at twice the complication-specific rates listed in this article. 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 QI 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**

<table>
<thead>
<tr>
<th>Successful Performance of Infusion Venography (1,2,7,22–24)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reported Rates (%)</td>
</tr>
<tr>
<td>---------------------</td>
</tr>
<tr>
<td>84–100</td>
</tr>
</tbody>
</table>

**Acknowledgments**: Dr. Daniel Brown authored the first draft of this document and served as topic leader during the subsequent revisions of the draft. Dr. John F. Cardella is chair of the SIR Standards of Practice Committee. Dr. Curtis A. Lewis is Councilor of the SIR Standards Division. All other authors are listed alphabetically. Other members of the Standards of Practice Committee and SIR who participated in the development of this clinical practice guideline are (listed alphabetically): Neil J. Freeman, MD; Jeffrey D. Georgia, MD; Scott C. Goodwin, MD; Clement J. Grassi, MD; Ziv Haskal, MD; Michael T. Jones, MD; Patrick C. Malloy, MD; Louis G. Martin, MD; Timothy C. McCowan, MD; James K. McGraw, MD; Steven G. Meraney, MD; Theodore R. Mirra, MD; Kenneth D. Murphy, MD; Calvin D. Neithamer, Jr., MD; Anne Roberts, MD;
Table 2
Complications of Infusion Venography

<table>
<thead>
<tr>
<th>Complication</th>
<th>Reported Rates (%)</th>
<th>Suggested Threshold (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Death</td>
<td>&lt;1</td>
<td>&lt;1</td>
</tr>
<tr>
<td>Bronchospasm</td>
<td>&lt;1</td>
<td>&lt;1</td>
</tr>
<tr>
<td>Cardiovascular collapse</td>
<td>&lt;1</td>
<td>&lt;1</td>
</tr>
<tr>
<td>DVT with ionic contrast material</td>
<td>2.6–10</td>
<td>&lt;3</td>
</tr>
<tr>
<td>DVT with nonionic contrast material</td>
<td>0–9</td>
<td>&lt;3</td>
</tr>
<tr>
<td>Skin necrosis</td>
<td>0.5</td>
<td>0.5</td>
</tr>
</tbody>
</table>

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APPENDIX 1: SIR STANDARDS OF PRACTICE COMMITTEE
CLASSIFICATION OF COMPLICATIONS BY OUTCOME

Minor Complications

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

Major Complications

C. Require therapy, minor hospitalization (<48 h),
D. Require major therapy, unplanned increase in level of care, prolonged hospitalization (>48 h),
E. Have permanent adverse sequelae,
F. Result in death.

APPENDIX 2: METHODOLOGY

Reported complication-specific rates in some cases reflect the aggregate of major and minor complications. Thresholds are derived from critical evaluation of the literature, evaluation of empirical data from Standards of Practice Committee member practices, and, when available, the SIR HI-IQ® system national database.

Consensus on statements in this document was obtained utilizing a modified Delphi technique (25,26).

Technical documents specifying the exact consensus and literature review methodologies as well as the institutional affiliations and professional credentials of the authors of this document are available upon request from SIR, 10201 Lee Highway, Suite 500, Fairfax, VA 22030.

References

The clinical practice guidelines of the Society of Interventional Radiology attempt to define practice principles that generally should assist in producing high-quality medical care. These guidelines are voluntary and are not rules. A physician may deviate from these guidelines, as necessitated by the individual patient and available resources. These practice guidelines should not be deemed inclusive of all proper methods of care or exclusive of other methods of care that are reasonably directed toward the same result. Other sources of information may be used in conjunction with these principles to produce a process leading to high-quality medical care. The ultimate judgment regarding the conduct of any specific procedure or course of management must be made by the physician, who should consider all circumstances relevant to the individual clinical situation. Adherence to the SIR Quality Improvement Program will not assure a successful outcome in every situation. It is prudent to document the rationale for any deviation from the suggested practice guidelines in the department policies and procedure manual or in the patient’s medical record.