Quality Improvement Guidelines for Percutaneous Transcatheter Embolization

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PERCUTANEOUS transcatheter embolization is a safe and effective method of vascular occlusion. Therapeutic embolization has been successfully applied in virtually every vascular territory to arrest hemorrhage, to occlude congenital and acquired vascular abnormalities, to palliate neoplasms, and to ablate tissue. With accumulated experience and the advent of microcatheter delivery systems, low-osmolality contrast material, high-resolution digital imaging, and roadmaping, percutaneous transcatheter embolization has become the therapeutic technique of choice in the treatment of many of these vascular abnormalities.

Participation by the radiologist in patient follow-up is an integral part of percutaneous transcatheter embolization and will increase the success rate of the procedure. Close follow-up, with monitoring and management of the patient after the embolization procedure is appropriate for the radiologist.

These guidelines are written to be used in quality improvement programs to assess percutaneous transcatheter embolization procedures. The most important processes of care are patient selection, performing the procedure, and monitoring the patient. The outcome measures or indicators for these processes are indications, success rates, and complication rates. Outcome measures are assigned threshold levels.

DEFINITIONS

Percutaneous transcatheter embolization is defined as the intravascular deposition of particulate, liquid, or mechanical agents, or autologous blood clot to produce intentional vessel occlusion. Embolic vascular occlusion may be performed at any level from large arteries or veins to the capillary beds, and it may be temporary or permanent in nature.

Percutaneous transcatheter embolization may be undertaken with curative or palliative intent. Embolization may be performed as a staged procedure, particularly in cases of complex or multiple lesions.

Successful embolization results in devascularization of a focal lesion or intentional reduction or cessation of blood flow to a target vascular bed or an entire organ. Technical success reflects immediate results and is typically evaluated with completion angiography. Clinical success reflects results in the 30 days immediately following the embolization procedure and is typically assessed by close patient follow-up. Complete clinical success is defined as the resolution of signs or symptoms that prompted the embolization procedure. Partial clinical success is defined as significant improvement of signs or symptoms after the procedure, with a positive impact on the clinical course of the patient and/or the subsequent need for reintervention (eg, the presence of blood-tinged sputum after bronchial artery embolization for massive hemoptysis) (1). Palliative embolization is considered successful if there is diminished symptomatology after the procedure (eg, decreased transfusion requirements following embolization of a pelvic malignancy).

The target area is defined as the focal lesion, vessel, vascular territory, or organ to be devascularized. Target ischemia is defined as symptoms resulting from devascularization within the immediate vascular distribution of the target (eg, the development of duodenal stenosis after gastroduodenal artery embolization for upper gastrointestinal bleeding) (2). Nontarget embolization is defined as unintentional deposition of embolic material distant from the target area (eg, colonic or spinal infarction during renal embolization) (3,4).

This document addresses quality improvement guidelines for embolization in the bronchial, pulmonary, celiac, superior and inferior mesenteric, renal, and hypogastric arterial territories. Varicocele embolization is discussed as well. Specific procedures that will not be discussed include hepatic embolization/chemoembolization for neoplasm and embolization of gastroesophageal varices. Hepatic che-
Table 1

<table>
<thead>
<tr>
<th>Success Rates*</th>
<th>Reported Rates (%)</th>
<th>Threshold (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Bronchial Arteries</strong> (1,4,4,5,23,54,55,75,76)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Initial success</td>
<td>70-100</td>
<td>85</td>
</tr>
<tr>
<td>1-year success</td>
<td>64-82</td>
<td>70</td>
</tr>
<tr>
<td>*Aspergillosis and malignancy clinical success</td>
<td>58-67</td>
<td>60</td>
</tr>
<tr>
<td>Cystic fibrosis</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Clinical success</td>
<td>95</td>
<td>85</td>
</tr>
<tr>
<td>9-month success</td>
<td>64-68</td>
<td>65</td>
</tr>
<tr>
<td><strong>Pulmonary Arteries</strong> (21,45)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Initial success</td>
<td>96</td>
<td>90</td>
</tr>
<tr>
<td><strong>Renal Arteries</strong> (18,51,57,59,71)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Organ infarction</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nonneoplastic</td>
<td>64-100</td>
<td>90</td>
</tr>
<tr>
<td>Malignant</td>
<td>64-100</td>
<td>75</td>
</tr>
<tr>
<td>Preoperative</td>
<td>79</td>
<td>75</td>
</tr>
<tr>
<td>Selective</td>
<td>82-100</td>
<td>90</td>
</tr>
<tr>
<td><strong>Hypogastric/Lumbar</strong> (13,14,39,40,51,77)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Obstetric/Gynecologic (benign and malignant)</td>
<td>88-100</td>
<td>95</td>
</tr>
<tr>
<td>Clinical success rates in patients with malignancy</td>
<td>60</td>
<td>40</td>
</tr>
<tr>
<td>Trauma</td>
<td>93-95</td>
<td>90</td>
</tr>
<tr>
<td>Overall</td>
<td>88-100</td>
<td>95</td>
</tr>
<tr>
<td><strong>Gastrointestinal</strong> (2,9,24-27,29,30,31)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Upper gastrointestinal bleeding</td>
<td>62-100</td>
<td>75</td>
</tr>
<tr>
<td>Focal gastrointestinal (Mallory-Weiss, gastric ulcer)</td>
<td>71-100</td>
<td>90</td>
</tr>
<tr>
<td>Hemorrhagic gastritis (vasopressin is usually primary therapy)</td>
<td>25-78</td>
<td>70</td>
</tr>
<tr>
<td>Duodenal ulcer (benign)</td>
<td>72-100</td>
<td></td>
</tr>
<tr>
<td>Technical success</td>
<td></td>
<td>90</td>
</tr>
<tr>
<td>Clinical success</td>
<td></td>
<td>60</td>
</tr>
<tr>
<td>Small bowel and colonic bleeding*†</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Pancreatic</strong> (7,17)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>100</td>
<td>90</td>
</tr>
<tr>
<td><strong>Spleen</strong> (35,62,70,78-81) (trauma and hypersplenism)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>87-100</td>
<td>95</td>
</tr>
<tr>
<td><strong>Varicocele</strong> (64-68)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Success</td>
<td>83-96</td>
<td>90</td>
</tr>
<tr>
<td>Recurrence (after 6 weeks)</td>
<td>7-16</td>
<td>16</td>
</tr>
<tr>
<td><strong>Overall Suggested Technical Success Rate</strong></td>
<td>95</td>
<td></td>
</tr>
<tr>
<td><strong>Overall Suggested Clinical Success Rate</strong></td>
<td>85</td>
<td></td>
</tr>
</tbody>
</table>

* Variations in reporting within the literature reviewed made it difficult to differentiate between technical and clinical success rates. Except where noted, these rates are expected to be similar to each other.
† Several small studies report clinical success; to our knowledge, no large series has been published.

moembolization generally carries a different set of indications and higher complication rates. Insufficient data are available on transjugular embolization of esophageal varices.

While practicing physicians should strive to achieve perfect outcomes (eg, 100% success, 0% complications), in practice all physicians will fall short of this ideal to a variable extent. Therefore, indicator thresholds may be used to assess the efficacy of ongoing quality improvement programs. For the purpose of these guidelines, a threshold is a specific level of an indicator that should prompt a review. "Procedure thresholds" or "overall thresholds" reference a group of indicators for a procedure (eg, major complications of percutaneous transcatheter embolization). Individual complications may also be associated with complication-specific thresholds. When measures such as indications or success rates fall below a (minimum) threshold, or when complication rates exceed a (maximum) threshold, a 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 quality improvement 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) (Appendix A). The complication rates and thresholds below refer to major complications.

**INDICATIONS**

1. Occlusion of congenital or acquired vascular abnormalities, (eg, aneurysm, pseudoaneurysm, arteriovenous fistula, arteriovenous malformation and hemangioma) (5-22).
2. Treatment of acute or recurrent hemorrhage (eg, hemoptysis, gastrointestinal bleeding, post-traumatic and iatrogenic hemorrhage, and hemorrhagic neoplasms) (1,9,13,14,22-56).
3. Devascularization of neoplasms for palliation or to reduce operative blood loss (7,8,18,22,33,40,57-60).
4. Ablation of nonneoplastic tissue that produces adverse health effects to the patient (eg, hypersplenism, refractory renovascular hypertension, proteinuria, urine leak, varicocele, pelvic congestion syndrome, priapism, and abdominal pregnancy) (13,14,18,20,36,61-72).
5. Flow redistribution to protect normal tissue (eg, gastroduodenal artery embolization in hepatic artery chemoembolization or proximal superior gluteal artery embolization in therapy for pelvic hemorrhage) (33,73).

The threshold for these indications is 95%. When fewer than 95% of procedures are for these indications, the
Patients with hemodynamic instability, multiorgan failure, malignancies, coagulopathy, renal failure, and infection will have higher complication rates (11,22,33). Infectious complications can be minimized by antibiotic prophylaxis in splenic embolization and in cases in which bacterial contamination is likely (eg, colon, open trauma, and some hepatic embolizations) (22,27,62,70,74,82). Complications related to the angiographic procedure will not be discussed here. The reader is referred to the Diagnostic Angiography Standard published by Spies et al (83).

The embolization procedure should always be documented by completion angiography. Incomplete embolization may leave the patient exposed to the risks that the procedure was intended to alleviate (6). In addition, in some preoperative cases incomplete embolization may increase the risk of operative hemorrhage (57). Incomplete embolization also has been reported to cause hemolysis (84). Specific major complications for percutaneous transcatheter embolization (1–4,7–9,13,14,16–22,24,30–34,38–43,49–55,57,58,62,64–68,70,71,73–77,85–89) are listed in Table 2.

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 number larger than most individual practitioners are likely to treat. 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 (eg, early in a quality improvement program). In this situation, the overall procedure threshold is more appropriate for use in a quality-improvement program.

**SUCCESS RATES**

Success rates for percutaneous transcatheter embolization are listed in Table 1, along with recommended threshold values.

**COMPPLICATION**

Complication rates are dependent on operator experience, vascular territory, the specific lesion addressed, and on the clinical condition of the patient.

### Table 2: Major Complication Rates and Suggested Thresholds for Percutaneous Transcatheter Embolization

<table>
<thead>
<tr>
<th>Complication</th>
<th>Rate (%)</th>
<th>Suggested Threshold (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sepsis</td>
<td>&lt;1</td>
<td>1</td>
</tr>
<tr>
<td>Abscess</td>
<td>0.3–4.8</td>
<td>1</td>
</tr>
<tr>
<td>Target ischemia</td>
<td>0.4–8</td>
<td>4</td>
</tr>
<tr>
<td>Nontarget embolization</td>
<td>0.6–5.5</td>
<td>2.5</td>
</tr>
<tr>
<td>Hemorrhage</td>
<td>&lt;1</td>
<td>&lt;1</td>
</tr>
<tr>
<td>Spinal infarction</td>
<td>0.3–0.9</td>
<td>&lt;1</td>
</tr>
<tr>
<td>Death (procedure-related)</td>
<td>0.9–2</td>
<td>1</td>
</tr>
<tr>
<td>Overall major complications</td>
<td>0.6–12</td>
<td>6</td>
</tr>
</tbody>
</table>

**Partial Complication—Splenic Embolization**

(62,70,78–81)

<table>
<thead>
<tr>
<th>Complication</th>
<th>Rate (%)</th>
<th>Suggested Threshold (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abscess/sepsis</td>
<td>0–5</td>
<td>5</td>
</tr>
<tr>
<td>Pneumonia</td>
<td>5–12</td>
<td>8</td>
</tr>
<tr>
<td>Pleural effusion</td>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td>Death (procedure-related)</td>
<td>0–1.7</td>
<td>2</td>
</tr>
<tr>
<td>Overall major complications</td>
<td>8–22</td>
<td>15</td>
</tr>
</tbody>
</table>

References


APPENDIX A

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.
APPENDIX B

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 members, and, when available, the SIR HI-IQ™ System national database.

Consensus on statements in this document was obtained utilizing a modified Delphi technique (90,91).

ADDENDUM

Dr. Alain Drooz authored the first draft of this document and served as topic leader during the subsequent revisions of the draft. Dr. Curtis A. Lewis is chairman of the SIR Standards of Practice Committee. Dr. Curtis Bakal, 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 John E. Aruny, MD, Raymond E. Bertino, MD, Dana R. Burke, MD, John F. Cardella, MD, Paramjit S. Chopra, MD, Philip S. Cook, MD, Martin Crain, MD, Donald F. Denny, Jr, MD, Elizabeth A. Drucker, MD, JD, Gregg M. Gaylord, MD, Murray G. Gordon, MD, Ziv J. Haskal, MD, Terence A.S. Matalon, MD, Timothy C. McCowan, MD, Steven G. Meranze, MD, Albert A. Nemcek, Jr, MD, Steven B. Oglevie, MD, Kenneth S. Rholl, MD, James B. Spies, MD, Patricia E. Thorpe, MD, Richard B. Towbin, MD, Daniel J. Wunder, MD, and Robert L. Vogelzang, MD.

*Technical documents specifying the exact consensus and literature review methodologies are available upon request from the Society of Interventional Radiology, 10201 Lee Highway Suite 500, Fairfax, VA 22030.