

Quality Improvement Guidelines for Percutaneous Transcatheter Embolization

Society of Interventional Radiology
Standards of Practice Committee



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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.

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,

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METHODOLOGY

SIR produces its Standards of Practice documents using 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 dependent upon the magnitude of the project.

An in-depth literature search is performed using electronic medical literature databases. Then a critical review of peer-reviewed articles is performed with regard 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 using a Modified Delphi Consensus Method ([Appendix B](#), reference 1). 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 Revisions Subcommittee members of the Standards of Practice Committee, either by telephone conference calling 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 Subcommittee, and appropriate revisions made to create the finished standards document. Prior to its publication the document is endorsed by the SIR Executive Council.

INTRODUCTION

This guideline is a revision of the quality improvement document initially developed by the SIR for percutaneous transcatheter embolization (1).

Percutaneous transcatheter embolization is a widely practiced method of therapeutic vascular occlusion that has been successfully applied in virtually every vascular territory to arrest hemorrhage, occlude congenital and acquired vascular abnormalities, palliate neoplasms, and infarct tissue. With accumulated experience and the progression in the design of embolization agents and devices, embolization is the treatment of choice for many vascular abnormalities.

This document addresses quality improvement guidelines for embolization in the bronchial, celiac, superior and inferior mesenteric, renal, hypogastric, and extremity arterial territories. Pulmonary artery embolization, preoperative portal vein embolization, and gonadal vein embolization are discussed as well. Specific procedures that will not be discussed include intracranial embolizations, hepatic artery embolization/chemoemboliza-

tion for neoplasm, and embolization of gastroesophageal or splenorenal varices. Transcatheter delivery of therapeutic agents, such as chemoembolization of the liver, generally carries a different set of indications and contraindications (2). Similarly, the management of the portal venous hypertension represents a unique and evolving subset of embolization which is best discussed in the context of portosystemic shunt placement (3).

Interventional radiologists must be actively involved in patient consultation and case selection. For this reason, interventional radiologists must be aware of the relevant treatment options, which is beyond the scope of this document. Close follow-up, with monitoring and management of the patient after the embolization procedure, is an integral component of a safe and effective practice of embolotherapy.

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

DEFINITION

Percutaneous transcatheter embolization is defined as the intravascular deposition of a device or agent (solid or liquid) to produce intentional vessel occlusion. Embolic vascular occlusion may be performed at any level from large arteries or veins to capillary beds, and it may be temporary or permanent in nature.

Percutaneous transcatheter embolization may be undertaken with curative or palliative intent. Depending on the indication the degree of embolization may require partial or complete occlusion of the vascular territory. Indications for embolization encompass a wide range of clinical situations from control of hemorrhage to tumor devascularization. The embolization may be a procedure in and of itself or a component of an intervention for regional drug, gene, radiation, or other biologic therapy. Embolization may be per-

formed as a staged procedure, particularly in cases of complex or multiple lesions. Embolization results in varying degrees of reduction or cessation of blood flow of a focal lesion or an entire target organ.

Technical success reflects immediate angiographic results and is typically evaluated with completion angiography.

Clinical success reflects some measured results within 30 days of embolization and is typically assessed by clinical or imaging follow-up or both.

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 or the subsequent need for reintervention (eg, minimal blood-tinged sputum after a successful embolization for massive hemoptysis) (4).

Palliative embolization is considered successful if there is improvement in symptoms after the procedure (eg, decreased transfusion requirements following embolization of a pelvic malignancy).

Target area is defined as the focal lesion, vessel, vascular territory, or organ to be devascularized.

Target ischemia is defined as the clinical effects, intended or not, 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) (5).

Nontarget embolization is defined as unintentional deposition of embolic material separate from the target area (eg, colonic or spinal infarction during renal embolization) (6,7).

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 A.](#)) The complication rates and thresholds below refer to *major*

complications unless otherwise specified.

INDICATIONS AND CONTRAINDICATIONS

The indications for transarterial embolization can be grouped into several broad categories.

1. Occlusion of congenital or acquired aneurysm, pseudoaneurysm, vascular malformation, or other vascular abnormalities that have potential to cause adverse health effects (8–25).
2. Treatment of acute or recurrent hemorrhage (eg, hemoptysis, gastrointestinal bleeding, posttraumatic and iatrogenic hemorrhage, and hemorrhagic neoplasms) (4,12,16,17,25–59). This may include the placement of a covered stent to occlude flow in a pathologic segment of vessel or to slow flow in a branch that is feeding a site of hemorrhage or fistula (60).
3. Devascularization of benign tumors or malignancies for palliation (eg, reduce pain, slow tumor growth, or prevent hemorrhage) or to reduce operative blood loss (10,11,21,25,36,43,61–64). Common applications are vascular hepatic malignancies, renal angiomyolipoma, renal cell carcinoma, pelvic malignancies, and bone tumors.
4. Devascularization of nonneoplastic tissue that produces adverse health effects to the patient (eg, hypersplenism, uterine fibroids, refractory renovascular hypertension, untreatable urine leak, proteinuria in end-stage kidney disease, varicocele, pelvic congestion syndrome, priapism, and ectopic pregnancy) (16,17,21,23,39,65–76).
5. Flow redistribution to protect normal tissue (eg, gastroduodenal artery and right gastric artery embolization in hepatic artery chemoembolization and radioembolization or proximal superior gluteal artery coil embolization during particle embolization of the anterior division of the internal iliac artery for tumor devascularization) (36,77) or to facilitate subsequent other treatments (eg, right portal vein embolization to induce left lobe hypertrophy prior to surgical resection) (78,79).

6. Endoleak management including direct sac puncture or collateral vessel embolization for type II endoleaks (80–85). There is insufficient evidence to assess the intraoperative embolization of the inferior mesenteric artery or aneurysm sac (86) or the management of other endoleaks (eg, type I) using embolization techniques (87). Thoracic endograft intervention also needs further evidence to form a standard (88).

An important part of quality improvement for embolization should be assessment of whether procedures are performed for one of these indications. There are no published thresholds for embolization indications. The authors suggest a threshold for these indications of 95%. When fewer than 95% of procedures meet these indications, the department will review the process of patient selection.

In addition to these on-indication thresholds, a process should be set up to review the appropriateness of individual procedure indications. For example, a splenic pseudoaneurysm is an accepted indication for embolization, but embolization of a stable 1-cm fusiform splenic true aneurysm may not be an appropriate indication (89). Similarly, embolization of a 6-cm renal angiomyolipoma that has hemorrhaged is appropriate, but treatment of a 2-cm asymptomatic angiomyolipoma may not be necessary (90).

Coagulopathy, sepsis, and renal insufficiency are relative contraindications to percutaneous transcatheter embolization. Appropriate efforts should be made to correct or improve these conditions prior to the procedure. Lack of safe or appropriate access to the target is another contraindication to treatment. Stable catheter position may not be achieved in a minority of patients. In other patients, a vascular communication may exist between the target and an adjacent vital structure (eg, spinal arteries arising from bronchial or arteriovenous shunting to lungs when using particle embolization). This has been viewed as an absolute contraindication by some authors and as a relative contraindication by others (4,45,55,57,58,91).

All imaging facilities should have policies and procedures to attempt reasonably to identify pregnant pa-

Table 1
Success Rates for Percutaneous Transcatheter Embolization

	Reported Success Rates (%)	Suggested Threshold (%)
Bronchial arteries (3,47,55–58,92,93)		
Initial success (all indications)	70–100	85
1-y success (all indications)	64–82	70
Aspergillosis and malignancy clinical success*	58–67	60
Cystic fibrosis*		
Clinical success	95	85
9-mo success	64–68	65
Pulmonary artery arteriovenous malformation (24,48)	96	90
Renal arteries (21,54,61,63,75)		
Nonneoplastic	64–100	90
Malignant	64–100	75
Preoperative	79–100	90
Selective	82–100	90
Hypogastric/lumbar (16,17,42,43,54,94,95)		
Obstetric/gynecologic (benign and malignant)	88–100	95
Clinical success rates in patients with malignancy	60	40
Trauma	93–95	90
Overall	88–100	95
Endoleak (type II) (80–85)		
Technical success	92–100	90
Clinical success	40–100	85
Gastrointestinal (5,12,27–30,31,33,34)		
Upper gastrointestinal bleeding	62–100	75
Focal gastroesophageal (Mallory-Weiss, gastric ulcer)	71–100	90
Hemorrhagic gastritis (vasopressin or embolization)	25–78	70
Duodenal ulcer (benign)	72–100	
Technical success		90
Clinical success		60
Lower gastrointestinal bleeding (95,96)	95	90
Pancreatic (10,20)	100	90
Splenic (38,66,74,97–100) (trauma and hypersplenism)	87–100	95
Portal vein embolization (78,79,101,102)		
Technical success	99–100	95
Adequate left lobe hypertrophy for surgery	85–86	85
Varicocele (68–72)		
Success	83–96	90
Recurrence (after 6 wk)	7–16	16
Overall suggested technical success rate		95
Overall suggested clinical success rate		85
Pelvic congestion syndrome (103–105)		
Success	100	95
Clinical success	83	83

* Technical and clinical success rates were separately reported in the literature. Except where noted, these rates are expected to be similar to each other.

tients prior to the performance of any examination involving ionizing radiation. If the patient is known to be pregnant, the potential radiation risk to the fetus and clinical benefits of the procedure should be considered before proceeding with the study (1995, 2005—ACR Resolution 1a).

QUALITY IMPROVEMENT

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. Thus, indicator thresholds may be used to

assess the efficacy of ongoing quality improvement programs. For the purposes 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). 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. For example, if the incidence of nontarget embolization is one measure of the quality of percutaneous transcatheter embolization, then values in excess of the defined threshold should trigger a review of policies and procedures within the department to determine the causes and to implement changes to lower the incidence for the complication. 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.*

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 patients who have undergone percutaneous transcatheter embolization, is appropriate for the radiologist.

Success Rates and Thresholds

Technical and some clinical success rates for percutaneous transcatheter embolization are listed in **Table 1**, along with recommended threshold values.

Complication Rates and Thresholds

Complication rates are dependent on operator experience, vascular territory, the specific lesion addressed, and the clinical condition of the patient. Patients with hemodynamic instability, multiorgan failure, malignancies,

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

	Rate (%)	Suggested Threshold (%)
Complications—general		
Sepsis	1	1
Abscess	0.3–4.8	1
Target ischemia	0.4–8	4
Nontarget embolization	0.6–5.5	2.5
Hemorrhage	1	1
Spinal infarction	0.3–0.9	1
Procedure-related mortality	0.9–2	1
Overall major complications	0.6–12	6
Complications—splenic embolization (66,74,97–100)		
Abscess/sepsis	0–5	5
Pneumonia	5–12	8
Pleural effusion	4	4
Procedure-related mortality	0–1.7	2
Overall major complications	8–22	15
Complications—portal vein embolization (78,79,101,102)		
Abscess or septic necrosis	< 1	1
Cholangitis	< 1	1
Main or left portal vein occlusion	< 1	1
Pneumothorax	< 1	1
Portal hypertension	< 1	1
Subcapsular hematoma	< 1	1
Procedure-related mortality	0	1
Overall major complications	0–6.4	6
Overall morbidity	2.2–12.8	10

coagulopathy, renal failure, and infection will have higher complication rates (14,25,36). Infectious complications can be minimized by antibiotic prophylaxis in cases in which bacterial contamination is likely (eg, colon, open trauma, and some hepatic embolizations) (25,30,66,74,91,106). Infectious complications with partial splenic embolization were implied to be reduced by an antiobiotic regimen of broad-spectrum antibiotic prophylaxis before and for 5 days after treatment in the study by Spigos et al (74) in 1980 where a series of 13 patients had no infections compared with historical series. Splenic embolization complications are related to the extent of embolization, with 70% reduction considered a threshold for more serious complications (107,108). Otherwise, complications related to the angiographic procedure technique are not discussed here. The reader is referred to the Diagnostic Angiography Standard published by Spies et al (109). The embolization procedure may be followed by completion angiography. Incomplete embolization may leave

the patient exposed to the risks that the procedure was intended to alleviate (9). In addition, in some preoperative cases incomplete embolization may increase the risk of operative hemorrhage (61). Incomplete embolization also has been reported to cause hemolysis (110). Specific major complications for percutaneous transcatheter embolization (4–7,10,12,16,17,19–25,27,33–37,41–46,52–58,61,62,66,68–72,74,75,91–94,111–115) are listed in **Table 2**. Truncal embolization procedures are associated with higher skin entry radiation doses (116). The principles of ALARA should be applied.

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 larger volume than most individual practitioners are likely to treat. Generally, the complication-specific thresholds should be set higher than the complication-specific reported rates listed above. It is also recognized that a single complication can cause a rate to cross above a com-

plication-specific threshold when the complication occurs within a small patient series (eg, early in a quality improvement program). In this situation, an overall procedural threshold is more appropriate for use in a quality improvement program. In Table 2, all values are supported by the weight of literature evidence and panel consensus.

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

APPENDIX B: CONSENSUS 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 empiric data from Standards of Practice Committee members' practices, and, when available, the SIR HI-IQ System national database.

Consensus on statements in this document was obtained utilizing a modified Delphi technique (1,2).

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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 towards 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.