

Quality Improvement Guidelines for Percutaneous Nephrostomy

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J Vasc Interv Radiol 2003; 14:S277-S281

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 conceptu-

This article first appeared in J Vasc Interv Radiol 2001; 12:1247-1251.

A complete list of the members of the SIR Standards of Practice Committee is given at the end of this article. From the Department of Radiology (P.R.), University of Pennsylvania Medical Center, Philadelphia, Pennsylvania; SUNY-Syracuse Health Science Center (J.F.C.), Syracuse, New York; Department of Radiology (C.J.G.), Brigham and Women's Hospital, Boston, Massachusetts; Department of Radiology (A.C.R.), University of California San Diego Medical Center/Thornton Hospital, La Jolla, California; Department of Radiology (D.S.), Reading Hospital & Medical Center, Reading, Pennsylvania; Leesburg Regional Medical Center (M.S.S.), Leesburg, Florida; and Manuel Maloof Imaging Center (C.A.L.) Emory University School of Medicine, Atlanta, Georgia. Address correspondence to SIR, 10201 Lee Hwy, Suite 500, Fairfax, VA 22030.

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DOI: 10.1097/01.RVI.0000094598.83406.b4

alized by the Standards of Practice Committee members. A recognized expert is identified to serve as the principal author for the document. 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 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 with use of a Modified Delphi Consensus Method (see Appendix 2). For the purpose 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 are made to create the finished standards document. Before its publication, the document is endorsed by the SIR Executive Council.

Percutaneous nephrostomy is a

well-established therapy for urinary drainage in patients with supravescical urinary tract obstruction and for urinary diversion in patients with urinary fistulas, leaks, or hemorrhagic cystitis (1-7). The procedure is also performed to gain access to the urinary tract for percutaneous stone removal and other endoscopic procedures. The collecting system can be localized by cross-sectional techniques such as ultrasonography (US) or computed tomography (CT). Fluoroscopic localization is useful if a radiopaque stone or contrast-opacified collecting system can serve as a target.

These guidelines are written for use in a quality improvement program that monitors percutaneous nephrostomies. This document is not intended to include antegrade pyelography. In the construction of this standard, a literature search was performed with use of MEDLINE methodology and an evidence table was constructed, which is available for review from the SIR office.

The most important processes of care are (a) patient selection, (b) performance of the procedure, and (c) patient monitoring. The outcome measures or indicators for these processes are indications, success rates, and complication rates. Outcome measures are assigned threshold levels.

DEFINITIONS

Percutaneous Nephrostomy: Image-guided placement of a catheter into the renal collecting system.

Successful Percutaneous Nephrostomy: Placement of a catheter of sufficient size to provide adequate drain-

age of the collecting system or allow successful tract dilation so that the planned interventional procedure can be successfully completed through the nephrostomy tract.

Endoscopic Procedure: Procedure performed through the nephrostomy tract under direct visualization, with use of rigid or flexible nephroscopes or ureteroscopes, usually in conjunction with a urologist. Flexible endoscopes require a 12–16-F tract, whereas rigid nephroscopes require a 24–30-F tract. Incision of a strictured ureteropelvic junction (endopyelotomy) and resection or fulguration of upper tract transitional cell carcinomas are some examples of such procedures.

Percutaneous Nephrostolithotomy: Removal of calculi from the kidney or proximal ureter through a percutaneous tract that is dilated to sufficient size to allow placement of a rigid nephroscope so that large stones can be fragmented under direct vision (with ultrasonic, electrohydraulic or laser lithotripsy) before removal. Smaller stones may be amenable to extraction without fragmentation. The targeted stones should be successfully removed through the percutaneous access tract. The placement of multiple nephrostomy tracts and the use of flexible instruments is often necessary for complete removal of stone material (8–11).

Although 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. 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; see Appendix 1). The complication rates and thresholds herein refer to *major* complications.

INDICATIONS

1. Urinary tract obstruction caused by intrinsic or extrinsic ureteral obstruction related to stones, malignancies, or iatrogenic causes. Urinary obstruction may be the indication for as many as 87% of nephrostomies at some institutions (1,2,6,12). Urinary obstruction may come to light because of azotemia, urinary sepsis, or it may be an incidental discovery on imaging studies (13–19).
2. Pyonephrosis or infected hydronephrosis (20–23). Patients with these conditions are at high risk for Gram-negative sepsis, and urinary drainage is of paramount importance. Patients present with fever, flank pain, and evidence of urinary tract obstruction on imaging studies. Urinary tract stones are the source of obstruction in more than 50% of cases.
3. Urinary leakage or fistulas. Percutaneous nephrostomy may need to be combined with ureteral occlusion for complete urinary diversion.
4. Access for other interventional procedures in the urinary tract and for endoscopic procedures:
 - a. Removal of selected renal or ureteral calculi. At medical centers that specialize in the treatment of urinary stone disease, as many as 50% of new nephrostomies

may be for the percutaneous therapy of stones (5,8–11).

- b. Ureteral stent placement when the retrograde approach is unsuccessful or not feasible.
 - c. To deliver medications or chemotherapy into the collecting system, as for treatment of fungus balls, bacillus Calmette-Guérin vaccine instillation for upper tract transitional cell carcinomas, or chemolysis for dissolution of renal or ureteral calculi.
 - d. Foreign body retrieval; eg, fractured or proximally migrated ureteral stents.
5. Urinary diversion for hemorrhagic cystitis (4).

The indications for percutaneous nephrostomy in renal transplants is largely the same as in native kidneys (24,25). Occasionally, percutaneous nephrostomy drainage may be performed as a therapeutic trial to differentiate renal failure caused by urinary obstruction from that related to rejection.

Percutaneous nephrostomy can be performed on an outpatient basis in selected patients (3,18,19). Patients who live alone or in whom the risk of complications is high, such as in those with staghorn calculi, uncorrected hypertension, or a coagulopathy, are best treated in an inpatient setting so they can be appropriately monitored (3,18,19).

In patients with severe uncorrected metabolic imbalance such as hyperkalemia or metabolic acidosis, correction of these imbalances may be necessary before the percutaneous nephrostomy to decrease the risk of complications such as arrhythmias or cardioplegia related to the profound electrolyte abnormality.

The indications for percutaneous nephrostomy can therefore be broadly categorized into the following groups: obstruction with infection, obstruction without infection, stone disease, prelude to endoscopic/interventional procedures, delivery of medications/chemotherapy, urinary leaks, and urinary diversion for hemorrhagic cystitis. The threshold for these indications is 95%. When fewer than 95% of procedures are performed for one of these indications, the department will review the process of patient selection.

Table 1
Technical Success Rates (%) for Percutaneous Nephrostomy

| Clinical Scenario | Reported Success Rate | Threshold |
|--|-----------------------|-----------|
| Obstructed dilated system without stones | 98 | 95 |
| Obstructed system in renal transplant | 98 | 95 |
| Nondilated collecting system (with or without stones) | 85 | 80 |
| Complex stone disease, staghorn calculi | 85 | 85 |
| Stones successfully removed, patient rendered stone-free with combination therapy with extracorporeal shock wave lithotripsy | 75 | 50 |

Table 2
Thresholds (%) for Major Complications of Percutaneous Nephrostomy

| Complication | Reported Rate | Threshold |
|---|---------------|-----------|
| Septic shock (fever, chills with hypotension, requiring major increase in level of care) (6,12,47) | 1-3 | 4 |
| Septic shock (20-22) (in setting of pyonephrosis) | 7-9 | 10 |
| Hemorrhage (requiring transfusion) | | |
| PCN alone (6,7,24,47) | 1-4 | 4 |
| With PCNL (35,37) | 12-14 | 15 |
| Vascular injury (2,49) (requiring embolization or nephrectomy) | 0.1-1 | 1 |
| Bowel transgression (44) | 0.2 | <1 |
| Pleural Complications (pneumothorax, empyema, hydrothorax, hemothorax) | | |
| PCN alone (2,6) | 0.1-0.2 | <1 |
| With PCNL or endopyelotomy (40,41) (intercostal puncture for upper pole access for endoscopic procedures) | 8.7-12 | 15 |
| Individual Threshold | | |
| Complications that result in unexpected transfer to an intensive care unit, emergency surgery or delayed discharge from the hospital (6,24) | 4-7 | 5 |

Note.—PCN = percutaneous nephrostomy; PCNL = percutaneous nephrolithotomy.

RELATIVE CONTRAINDICATIONS TO PERCUTANEOUS NEPHROSTOMY

1. Uncorrectable severe coagulopathy (eg, patients with liver or multisystem failure).
2. Terminal illness; imminent death.

SUCCESS

A percutaneous nephrostomy catheter can be successfully placed in 98%–99% of patients (1,6,7,26). The success rate is lower in patients with nondilated collecting systems, complex stone disease, or staghorn calculi. The technical success rate may vary de-

pending on the clinical scenario, as shown in **Table 1**.

Overall, the ability to render a patient stone-free is dependent on factors beyond the placement of an optimal percutaneous nephrostomy tract. Variables such as the composition of the stones, whether the stone is a staghorn calculus or a solitary renal calculus, the anatomy of the patient, whether multiple access tracks are placed, whether flexible instruments are used, and whether extracorporeal shock wave lithotripsy is combined with the percutaneous methods for complete removal of stone material (7–11) all contribute to the stone-free rate. The success of other endoscopic procedures is similarly affected by factors

other than the creation of an optimal nephrostomy tract.

Complications

When minor and major complications are considered together, they occur in approximately 10% of patients (1–3,5–11,27–51). The specific complications and their thresholds are given herein. The departmental thresholds apply to all complications that occur in the department. The individual thresholds apply to all complications that each practitioner encounters. For the purposes of this document, the thresholds in **Table 2** are for major complications only.

Published rates for individual types of complications are highly dependent on patient selection and are, in some cases, based on series comprising several hundred patients, which is a volume 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 **Table 2**, all values were supported by the weight of literature evidence and panel consensus.

Acknowledgments: Dr. Parvati Ramchandani 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): John E. Aruny, MD; Patricia E. Cole, PhD, MD; Neil J. Freeman, MD; Jeffrey D. Georgia, MD; Scott C. Goodwin, 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. Meranze, MD; Theodore R. Mirra, MD; Kenneth D. Murphy, MD; Calvin D. Neithamer, Jr., MD; Steven B. Oglevie, MD; Reed A. Omary, MD; Nilesh H. Patel, MD; Orestes Sanchez, MD; Mark I. Silverstein, MD; Harjit Singh, MD; Harry R. Smouse, MD; Timothy L. Swan, MD; Patricia E. Thorpe, MD; Richard B. Towbin, MD; Anthony C. Venbrux, MD; and Daniel J. Wunder, MD.

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, or
- 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 with use of a modified Delphi technique (52,53).

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.

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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 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.