

QUALITY IMPROVEMENT GUIDELINES FOR PERCUTANEOUS NEPHROSTOMIES

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Introduction

Percutaneous nephrostomy is a well-established therapy for urinary drainage in patients with supraventricular urinary tract obstruction and for urinary diversion in patients with urinary fistulas, leaks, **traumatic/iatrogenic ureteral dissection**, or hemorrhagic cystitis¹⁻⁸. The procedure is also performed to gain access to the urinary tract for percutaneous stone removal and other endoscopic procedures⁹. Access to the renal collecting system is obtained using fluoroscopy alone, or in combination with ultrasound (US) or computer tomographic guidance (CT)¹⁰. Fluoroscopic guidance 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 programme that monitors percutaneous nephrostomies. It does not include antegrade pyelography or percutaneous antegrade ureteral stent placement. In the construction of this standard, a literature search was performed with the use of the MEDLINE methodology and an evidence table was constructed, which is available for review from both SIR and **CIRSE Offices**.

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 drainage of the collecting system or to 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 visualisation, with the 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 carcinoma 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, electro-hydraulic, or laser lithotripsy) before removal. Smaller stones may be amenable to extraction without fragmentation. The targeted stones should be successfully removed through the percutaneous tract. The placement of multiple nephrostomy tracts and the use of flexible instruments are often necessary for complete removal of stone material¹¹⁻¹⁴.

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, indicator thresholds may be used to assess the efficacy of ongoing quality improvement programmes. 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.

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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 programme 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 hospitalisation, 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^{1,2,6,15,16}. Urinary obstruction may cause symptoms because of azotemia, urinary sepsis, or it may be an incidental discovery on imaging studies¹⁷⁻²³. Malignant disease is the commonest cause in many series and some patients present emergently with sepsis, or with acute renal failure²⁴⁻²⁷.
2. Pyonephrosis or infected hydronephrosis²⁸⁻³². Patients with these conditions are at high risk for Gram-negative sepsis and urinary drainage is of paramount importance. Presenting symptoms include 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 diversion⁸.
4. Access for other interventional procedures in the urinary tract and for endoscopic procedures:
 - a) Removal of selected renal or ureteral calculi. At medical centres that specialise in the treatment of urinary stone disease, as many as 50% of new nephrostomies may be for the percutaneous therapy of stones^{5,11-14}.
 - 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 the treatment of fungus balls, bacillus Calmette-Guerin vaccine instillation for upper tract transitional cell carcinomas, or chemolysis for dissolution of renal or ureteral calculi.
 - d) Foreign body retrieval; e.g. fractured or proximally migrated ureteral stents.
5. Urinary diversion for hemorrhagic cystitis⁴.

The indications for percutaneous nephrostomy in renal transplants is largely the same as in native kidney³³⁻³⁵. 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 on selected patients^{3,22,23,36}. Patients who live alone, or who are at high risk of complications, such as those with infection, staghorn calculi, a solitary kidney with renal failure, uncorrected hypertension, or coagulopathy, are best treated in an inpatient setting so they can be appropriately monitored.

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For 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. It is recommended that the patients have normal pre-procedure coagulation and platelet count [international normalised ratio (INR) < 1.3 and > 80000/dl respectively]. Although some institutions routinely check the coagulation profile prior to the intervention³⁷⁻³⁹, others rely on questioning the patient regarding bleeding diathesis, known liver disease, renal failure, and anticoagulant use^{10,22}. Fresh frozen plasma infusion corrects the abnormalities of INR, whilst platelet counts less than 50000/dl should be corrected by means of platelet transfusion⁴⁰⁻⁴².

The value of antibiotic prophylaxis has not been demonstrated in randomised clinical trials. Nevertheless, most authors recommend antibiotic prophylaxis prior to percutaneous nephrostomy^{10,37,38,43-48}. Patients at low-risk of infection are given one single intravenous dose of 1g of cefazolin IV, or 1g of ceftriaxone IV prior to the intervention. These patients are monitored after the intervention and no additional antibiotics are given if no signs of infection develop¹⁰. High-risk patients (such as patients with advanced age, diabetes, indwelling catheter, ureteointestinal conduit, and bacteriuria) should prophylactically receive ceftriaxone 1g every 8 hours intravenously, or 1g /sulbactame every 6 hours intravenously with 80 mg gentamycin every 8 hours intravenously^{10,37,38}. Urine cultures are obtained at the time of the intervention. Antibiotics are given for 48 hours after the procedure and subsequently adjusted according to the results of the urine culture. Antibiotics are given for 5-7 days. Special attention will be given to patients who are at risk of endocarditis.

The indications for percutaneous nephrostomy can therefore be broadly categorised 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.

Relative Contraindications to Percutaneous Nephrostomy

1. Uncorrectable severe coagulopathy (e.g. 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^{1,6,7,39,49-52}. The success rate is lower in patients with non-dilated collecting systems, complex stone disease, or staghorn calculi. The technical success rate may vary depending 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 tracts 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^{7,11-14} all contribute to stone-free rate. The success of other endoscopic procedures is similarly affected by factors other than the creation of an optimal nephrostomy tract.

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Complications

Major complications occur in less than 10% of the patients^{1-3,5-7,11-14,16,24-27,32,35-37,40-62,64-69}. Haemorrhage or vascular injury occurs in 1-4%, while septic shock in 1-9%. The minor complications rate range from 6.8% to 23%^{6,26,49}, while tube related problems like dislodgement or occlusion range from 0.9% to 36%^{6,11,25,49}.

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 recognised 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 programme.

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

APPENDIX 1 - SIR Standards of Practice Committee Classification of Complications by Outcome

Minor Complications

1. No therapy, no consequence
2. Nominal therapy, no consequence; includes overnight admission for observation only

Major Complications

3. Require therapy, minor hospitalisation (<48h)
4. Require major therapy, unplanned increase in level of care, prolonged hospitalisation (>48h)
5. Have permanent adverse sequelae
6. 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 the use of a modified Delphi technique⁷¹.

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, and CIRSE Office, Bellerivestrasse 42, CH-8008 Zurich.

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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
Non-dilated 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 shockwave lithotripsy	75	50

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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) ^{6,10,15,16,27,32, 35, 37, 49, 65}	1-3	4
Septic shock ²⁸⁻³⁰ (in setting of pyonephrosis)	7-9	10
Hemorrhage (requiring transfusion)	1-4	4
PCN alone ^{6,7,11,27,33,37,49,65}	12-14	15
With PCNL ^{48,54}		
Vascular injury ^{2,67} (requiring embolisation or nephrectomy)	0.1-1	1
Bowel transgression ⁶¹	0.2	<1
Pleural Complications (pneumothorax, empyema, hydrothorax, hemothorax)	0.1-0.2	<1
PCN alone ^{2,6}	8.7-12	15
With PCNL or endopyelotomy ^{57,58} (intercostals puncture for upper pole access for endoscopic procedures)		
Individual threshold		
Complications that result in unexpected transfer to an intensive care unit, emergency surgery or delayed discharge from the hospital ^{6,33}	4-7	5

Note- PCN=percutaneous nephrostomy; PCNL=percutaneous nephrolithotomy