

Suggested Guidelines for Performing Procedures in Patients with Chronic Kidney Disease in Outpatient Centers

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ABSTRACT

Maintenance of hemodialysis vascular access is increasingly performed on an outpatient basis by physicians trained in interventional techniques. The adoption of guidelines by national

reputable organizations will help identify patients eligible for such outpatient treatments and help optimize the safety and efficacy of their procedures in the outpatient setting.

A goal of these types of outpatient centers is to promote improved outcomes for patients' dialysis vascular access. The recent emergence of Outpatient Vascular Access Centers (OVACs) that specialize in the treatment of hemodialysis access has led to improved outcomes for patients with chronic kidney disease (CKD) (1,2). In the United States, the majority of interventional procedures to maintain optimal dialysis access are currently performed in OVACs. Hospitals and ambulatory surgical centers (ASCs) have comprehensive policy and procedure guidelines that govern their facilities. It is therefore timely and appropriate to establish appropriate guidelines that promote safety and efficacy in the OVAC setting.

Patient Selection

Patients on hemodialysis are at an increased risk of cardiovascular complications and mortality (1). Therefore, it is crucial to be aware of a patient's status prior to the start of a procedure and exclude those considered clinically unstable. The history and physical examination are among the most important steps a physician can take to ensure appropriate patient selection for an outpatient procedure (2). Clinical contraindications for outpatient procedures include ventilator dependence, sepsis, coma, arteriovenous access infection, and known or suspected tuberculosis or any other airborne disease. The American Society of Anesthesiologists provides a Physical Status Classification System that is useful in assessing patient status (3).

The expected duration and complexity of the procedure will also factor into the decision process. Preproce-

dural laboratory studies are not routinely performed in the majority of OVACs. Many OVACs will cancel the outpatient procedure if the patient has gone more than 5 days without an adequate dialysis treatment. Patients with CKD are prone to hyperkalemia, but presently, there is insufficient published clinical data to predict potassium levels at which a procedure should be canceled (4). Similarly, patients with CKD frequently have abnormal coagulation profiles. A recent review suggests that large bore dialysis catheters can be safely placed with platelet counts between 25,000 and 50,000/dl and an INR between 1.5 and 2 (5). Individual clinical judgment is recommended regarding preprocedural laboratory work, as there are insufficient clinical data to determine its requirement. Review of the risks and benefits of a procedure for individuals can certainly help guide the decision-making process regarding the appropriateness of the procedure in the outpatient setting.

Patient Visit Protocol

Patient Identification

Upon entrance into the OVAC, each patient's name should be registered and the indication for the procedure confirmed. Patients should receive a physical identifier (e.g., a color-coded bracelet) with information such as patient name, date of birth, and any allergies (e.g., to contrast media, anesthetics, anticoagulants).

Informed Consent

Written informed consent must be required prior to any invasive procedure and for administration of any analgesic or sedative medications (moderate sedation).

Preprocedural Assessment and Verification

Adoption of the universal protocol of The Joint Commission (6) or similar standards is recommended (7).

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The patient's active vascular access and any previous accesses should be assessed. A complete medical and surgical history and medication list must be obtained and updated at each visit.

Medical Imaging and Archiving

Medical image archiving should be performed in accordance with regional health laws. Pertinent images acquired from any study/examination performed must be archived daily to a PACS system, CD, DVD, or other format for long-term storage. At least one landmarked image from each digital subtraction run must be saved, and all saved images must be of the highest quality utilizing the image manipulation software on the fluoroscope [e.g., mask adjustment (pixel shift), landmarking, contrast, and brightness].

Infection Control

Standard precautions must be observed for all patients. Patients with known or suspected communicable disease are screened and scheduled appropriately. All staff should be familiar with infection prevention and control policies and procedures (8) developed by the organization. The implementation of an employee health program should be considered. Terminal cleaning of procedure rooms based on the guidelines of a reputable organization such as the Center for Disease Control and Prevention (CDC), Association of periOperative Registered Nurses (AORN), or Association for Professionals in Infection Control and Epidemiology, Inc. (APIC) should be incorporated into the infection control policies and procedures.

Medication Management

Medication management standards vary by regulating and accrediting body; an OVAC should implement the appropriate standards based on their licensing or accreditation status.

Sedation/Analgesia

A procedure-specific history and physical should be performed and documented. The physician should then determine an anesthesia plan based on these criteria and discussed with the patient. Administration of propofol or greater than moderate sedation should only be performed by an anesthesiologist. Patients should fast for 8 hours prior to the procedure and should not ingest liquids for 4 hours prior to the procedure. Extra precautions should be taken in cases of urgent procedures on patients who have not engaged in such preprocedural fasting.

Contrast Agents

Referral to an inpatient setting should be considered for patients with a known anaphylactic reaction to contrast media. Carbon dioxide may be considered as a substitute contrast agent in select cases.

Time Out

The adoption of a standard similar to the Joint Commissions' Universal Protocol (6) or the New York State Surgical and Invasive Procedure Protocol (7) should be considered to review the right patient, right procedure, right side, significant past patient history of reactions, and allergies in an OVAC setting to enhance patient safety.

Recovery

A postanesthesia care unit should be available with appropriate monitoring during recovery, including pulse oximetry (9). Postsedation scoring mechanisms, such as the Aldrete scoring system (10), can be adopted for use in the recovery phase and utilized as part of an OVAC's discharge criteria to assist in determining patients' readiness for discharge (11). The same scoring mechanism should be utilized in the presedation phase, so that comparisons can be made between baseline status and postoperative measurements.

Facility

The American Institute of Architects guidelines should be followed when designing an OVAC especially if there are future plans to become a state-licensed facility or an ambulatory surgical center (12). In addition, state-specific guidelines must be incorporated into such plans. Safety and security risks should be identified and action taken to minimize these risks. The OVAC should have adequate space, lighting, and infrastructure for the procedures performed.

Smoking

Must be prohibited.

Security

Access to the office, as well as access to and from areas identified as security sensitive must be controlled.

Hazardous Materials

Hazardous materials should be appropriately stored and discarded, and risks related to the handling of such materials must be minimized. Personal protective equipment must be used and appropriate precautions followed to minimize exposure to hazardous materials.

Fire Safety

Potential for harm from fire, smoke, and other products of combustion must be minimized. Free and unobstructed access to all exits must be maintained. The organization should have a written fire response plan, with specific roles of the staff designated. Fire drills should be conducted on a quarterly basis and critiqued for efficiency. Duct detectors, heat detectors, manual fire alarm boxes, smoke detectors, and electromechanical releasing devices (hold fire-rated doors open until power

is interrupted by a fire alarm condition or remote release switch) should be tested as per the local fire code. Fire extinguishers should be inspected monthly.

Electricity

The installation of an uninterrupted power source should be considered in case of power failure (6,13).

Equipment

Equipment for the safe transfer and care of patients through the OVAC should be present, functional, and maintained in accordance with regional health regulations. This should include at minimum a wheelchair, stretcher, and an imaging table. The facility should contain a code cart, which includes emergency drugs, airway management equipment (ambu bag, oral airways), a defibrillator, at least one full E cylinder oxygen tank, and a suction machine. Ventilators are not required within the facility.

The organization should have a systematic approach to the selection and acquisition of medical equipment. The practice should monitor and report all incidents in which medical equipment is directly or indirectly attributed to the death, serious injury, or serious illness of any individual. The practice should identify procedures to follow when medical equipment fails, including emergency clinical interventions, and backup equipment. Life-support and non-life-support equipment should be inspected and tested on a regular basis. All sterilizers should be tested regularly (6).

Radiation Safety

The facility must have a Radiation Safety Officer and a radiation safety manual, which includes radiation safety policies and procedures specific to local, state, and federal regulations.

Radiation Exposure

- The organization must take measures to ensure that personnel radiation exposure is as low as reasonably achievable (ALARA).
- All employees in a procedure room must wear lead aprons, thyroid collars, and radiation badges while the fluoroscope is in operation, and only personnel involved with the procedure should be present during fluoroscopy.

Employee Safety Training and Compliance

- A Radiation Safety Officer should be appointed to oversee regulation and policy compliance and implementation of ALARA regulations for patients and personnel.

Patient Safety

- Appropriate shielding should be used on all examinations except where it will interfere with

the diagnostic information. Devices for shielding should include: adequate collimations, gonadal shield, lead aprons, and lead blockers.

- Fluoroscopy duration should be minimized and pulse fluoroscopy should be set at the lowest pulse rate setting that will still allow adequate imaging.

Radiation Quality Assurance

- Routine testing of radiographic units must be carried out, in accordance with state regulations.
- Quality assurance meetings should include the review of radiation safety at least annually. The quality assurance information to be reviewed includes, but is not limited to, the radiation safety manual and current radiation safety report (6).

Staff Training and Credentialing

All staff should maintain current Basic Life Support certification. All procedural staff should maintain current Advanced Cardiac Life Support (ACLS) certification (14).

Radiologic Technologists

Radiologic technologists must be certified by the American Registry of Radiologic Technologists and a current, active RT license in the state of practice, if required. Experience in interventional medicine and surgical scrub technology is recommended.

Nurses

Nurses must hold a current, active RN license in the state of practice. Experience in critical care, interventional medicine, emergency medicine, and/or hemodialysis is desirable. Proficiency in ECG interpretation and moderate sedation, and the ability to function independently with minimal supervision are required.

Physicians

Physician credentials should be reviewed by a committee of the physician's peers within his or her own medical specialty. Credentialing regulations should not include provisions that are unfair, unreasonable, or inappropriate, such as requirements for hospital privileges in situations where they are unattainable. Due process must be provided to ensure fairness in all considerations of credentialing and in any cases involving revocation of credentialing. Peer review should be performed on an ongoing basis.

Criteria used in the credentialing process may include certification by a national medical specialty board recognized by the American Board of Medical Specialties. Appropriate specialties include nephrology, radiology, and surgery, with additional training in percutaneous vascular access procedures (15).

Emergency Procedures

Emergency Management

A written emergency management plan should be maintained for all emergencies including, but not limited to, floods, power failures, fires, patient codes, staff injuries, community rioting, biological disasters, etc. This plan should detail protocols for coordination of communications, the designation of resources and assets, information on safety and security, and patient clinical and support activities. Code blue drills, like fire drills, could be considered.

Transfer to a Hospital

Emergency transfer protocols should be written, reviewed, and practiced to ensure all staff is familiar with their roles. A formal hospital transfer agreement between the OVAC and hospital may be required in some states.

Performance Improvement

Complications

Complications should be reported in accordance with guidelines developed after consulting with professional organizations that specialize in performing the procedures that your OVAC will perform such as the American Society of Diagnostic and Interventional Nephrologists (ASDIN) (16) or the Society of Interventional Radiologists (SIR) (17) as this format allows standardization of event grading and reporting in vascular access procedures.

Patient Follow-Up

All patients should be contacted postdischarge to obtain information regarding their postprocedural status. Postdischarge adverse events should be documented and reviewed by the physician as well as reviewed in the quality assurance process.

Quality Assurance

Records and statistics regarding the following should be collected:

- the number of procedures of each type performed at the OVAC
- procedural outcomes
- infection rates
- hospital transfer rate
- instances of postprocedure pain
- instances of postprocedure bleeding from the access site
- other relevant information, such as hazard vulnerability analysis, housekeeping competence, patient satisfaction

These data should be aggregated and analyzed at designated intervals. Procedure outcomes should be evaluated on a regular basis and appropriate changes made to procedure and follow-up protocols to provide continuous quality improvement (CQI) (18).

Adverse Events

Reportable adverse events are state specific. The OVAC should have a written policy detailing when and how events must be reported internally, as well as to the local department of health and/or any accrediting body. Trackable events are not necessarily limited to those mandated by the state.

Summary

OVACs have become the site of choice of dialysis vascular access care in the United States, and this access care has a direct impact on the morbidity and mortality of patients with CKD. These guidelines are designed to promote safety and efficacy of dialysis access interventions in patients with CKD in an outpatient setting.

References

1. Muntner P, He J, Hamm L, Loria C, Whelton PK: Renal insufficiency and subsequent death resulting from cardiovascular disease in the United States. *J Am Soc Nephrol* 13:745–753, 2002
2. Horton JB, Reece EM, Broughton G II, Janis JE, Thornton JF, Rohrich RJ: Patient safety in the office-based setting. *Plast Reconstr Surg* 117:61e–80e, 2006
3. American Society of Anesthesiologists: ASA Physical Status Classification System. Available at <http://www.asahq.org/clinical/physicalstatus.htm>, accessed April 20, 2010
4. Haas B, Chittams JL, Trerotola SO: Large-bore tunneled central venous catheter insertion in patients with coagulopathy. *J Vasc Interv Radiol* 21:212–217, 2010
5. Saad TF, Radcliff K, Pottenburgh K, Davis N, Cicone J, Findley-Christian G: iSTAT Blood Potassium Measurement in Outpatient Access Center: Impact on Patient Management. *Semin Dial* 22:218A, 2009
6. The Joint Commission: *Comprehensive Accreditation Manual for Ambulatory Care*. Illinois: Commission Resources, 2009
7. State of New York Department of Health—Office of Health Systems Management Division of Primary and Acute Care Services. New York State Surgical and Invasive Procedure Protocol for Hospitals, Diagnostic and Treatment Centers, Ambulatory Surgery Centers, and Individual Practitioners. Available at http://www.health.state.ny.us/professionals/protocols_and_guidelines/surgical_and_invasive_procedure/docs/protocol.pdf, accessed April 7, 2010
8. Centers for Disease Control and Prevention: Infection Control in Healthcare Settings. Available at <http://www.cdc.gov/ncidod/dhqp/>, accessed April 21, 2010
9. Apfelbaum JL, Klock PA Jr: Clarification of anesthesia standards and guidelines. *Aesthet Surg J* 21:573–575, 2001
10. Aldrete JA, Kroulik D: A postanesthetic recovery score. *Anesth Analg* 49:924–934, 1970
11. Kost M: *Moderate Sedation/Analgesia: Core Competencies for Practice*, 2nd ed. St Louis, MO: Saunders, 2004
12. A.I.A.: *Guidelines for the Design and Construction of Health Care Facilities*, 2006 ed. Washington, D.C.: AIA, 2006
13. Procedural Standards and Checklist for Accreditation of Ambulatory Facilities. Available at <http://www.aaaaf.org/pub/AAAASF%20Procedural%20Standards%20Version%201%20FINAL.pdf>, accessed April 20, 2010
14. Rohrich RJ, Parker TH 3rd, Broughton G II, Garza R, Leblanc D: The importance of advanced cardiac life support certification in office-based surgery. *Plast Reconstr Surg* 121:93e–101e, 2008
15. American Society of Diagnostic and Interventional Nephrology: Application for ASDIN Certification: Hemodialysis Vascular Access Procedures. Available at <http://www.asdin.org/associations/9795/files/HVA%20Application%20111009.pdf>, accessed April 7, 2010
16. Vesely TM, Beathard G, Ash S, Hoggard J, Schon D; ASDIN Clinical Practice Committee: Classification of complications associated with hemodialysis vascular access procedures. A position statement from the American Society of Diagnostic and Interventional Nephrology. *J Vasc Access* 9:12–19, 2008
17. Sacks D, McClenny TE, Cardella JF, Lewis CA: Society of Interventional Radiology Clinical Practice Guidelines. *J Vasc Interv Radiol* 14.9:S199–S202, 2003
18. Walters BAJ, Pennell P, Bosch JP: Quality Assurance and Continuous Quality Improvement Programs for Vascular Access Care. *Contrib Nephrol* 142:323–349, 2004