Quality Improvement Guidelines for Vascular Access and Closure Device Use

Rahul A. Sheth, MD, T. Gregory Walker, MD, Wael E. Saad, MD, Sean R. Dariushnia, MD, Suvranu Ganguli, MD, Mark J. Hogan, MD, Eric J. Hohenwalter, MD, Sanjeeva P. Kalva, MD, Dheeraj K. Rajan, MD, LeAnn S. Stokes, MD, Darryl A. Zuckerman, MD, and Boris Nikolic, MD, MBA, for the Society of Interventional Radiology Standards of Practice Committee

ABBREVIATIONS

CLIP = Closure in Percutaneous Procedures [trial], FDA = Food and Drug Administration, PCI = percutaneous coronary intervention, VCD = vascular closure device

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, 3975 Fair Ridge Dr., Suite 400 N., Fairfax, VA 22033.

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 depending on the magnitude of the project.

An in-depth literature search is performed by 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. With regard to this document, the authors performed a review of the literature through manual and MEDLINE keyword searches of relevant journals between 1990 and July 2013.

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 by using a Modified Delphi Consensus Method (**Appendix A**). 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 Standards of Practice Committee members 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 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.

INTRODUCTION

Since the introduction of the Seldinger technique for obtaining percutaneous transarterial access, the challenge of achieving postprocedural hemostasis has been traditionally addressed with manual compression. Manual compression usually requires sustained partially occlusive pressure over the arterial access site for approximately 15–20 minutes, followed by 4–6 hours of patient immobilization. Although this method successfully achieves hemostasis in the majority of cases, there are drawbacks. These include patient discomfort associated with the applied groin pressure and the subsequent restricted ambulation. This patient discomfort can lead to noncompliance, potentially resulting in significant bleeding. Manual compression may not be as effective in obese patients or those with coagulopathy. In addition, as increasingly complex transarterial interventions frequently use devices that require larger sheath sizes, the risk of hematoma formation and/or other arterial access-related complications following manual compression has increased (1).

In cardiovascular interventions, the advent of multiagent anticoagulation and antiplatelet regimens, as well as the increased arterial

From the Division of Vascular Imaging and Intervention, Department of Radiology (R.A.S., T.G.W., S.G.), Massachusetts General Hospital, 55 Fruit St., Gray 290, Boston, MA 02114; Department of Radiology (W.E.S.), University of Michigan Medical Center, Ann Arbor, Michigan; Department of Interventional Radiology and Image-guided Medicine (S.R.D.), Emory University, Atlanta, Georgia; Section of Vascular and Interventional Radiology; Department of Radiology (M.J.H.), Nationwide Children's Hospital, The Ohio State University, Columbus, Ohio; Department of Radiology (E.J.H.), Medical College of Wisconsin, Froedtert Memorial Lutheran Hospital, Milwaukee, Wisconsin; Department of Radiology (S.P.K.), University of Texas Southwestern Medical Center, Dallas, Texas; Department of Medical Imaging (D.K.R.), University of Toronto, University Health Network, Toronto, Ontario, Canada; Department of Radiology and Radiological Sciences (L.S.S.), Vanderbilt University Medical Center, Nashville, Tennessee; Mallinckrodt Institute of Radiology (D.A.Z.), Washington University School of Medicine, St. Louis, Missouri; and Department of Radiology (B.N.), Stratton Medical Center, Albany, New York. Received August 7, 2013; final revision received August 15, 2013; accepted August 16, 2013. **Address correspondence to** T.G.W., SIR, 3975 Fair Ridge Dr., Suite 400 N., Fairfax, VA 22033; E-mail: tgwalker@partners.org

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sheath dwell times, has increased the risk of noncoronary complications. For example, although complication rates for diagnostic cardiac catheterization procedures are typically less than 1%, those for routine percutaneous coronary interventions (PCIs) range from 1% to 3%. This difference can be ascribed to a combination of increased sheath size (6 F or 7 F versus 5 F), increased patient-related risk factors, and the concomitant use of anticoagulant and antiplatelet agents (2). Bleeding complications not only increase costs but are also associated with poor prognosis, as well as increased short- and long-term mortality rates in coronary interventions (3).

The ability to achieve satisfactory hemostasis after transarterial interventions while maximizing patient satisfaction, minimizing complications, and decreasing postprocedural monitoring time is highly desirable. Consequently, multiple innovative strategies for reducing time to hemostasis and decreasing the duration of the requisite immobilization have been developed since the mid-1990s. One such innovation involves the use of specialized devices to aid in accomplishing these objectives. These devices, known collectively as vascular closure devices (VCDs), operate through a variety of mechanisms and are commonly used in clinical practice today. Although potential benefits of VCDs over manual compression include reduction of bleeding complications, hemostasis, and earlier time to ambulation, the use of these devices has also resulted in a variety of previously unencountered complications such as nontargeted deployment, intravascular embolization of closure device components, arterial thrombosis, and infection of closure material.

VCDs have undergone several iterations of research and development, and the clinical use for these devices continues to grow, with the global market for VCDs projected to reach nearly $1 billion in 2013. However, to date, there are limited published guidelines regarding the safe and appropriate use of these devices, particularly for interventional radiology procedures.

This statement is a summary of clinically available VCDs and an overview of the current data regarding their indications, contraindications, efficacy, and complications. This includes a review of available clinical trials related to individual devices as well as metaanalyses of VCD use compared with manual compression. Although use of VCDs in nonfemoral arterial access sites has been reported, the present document focuses on their use following femoral arteriotomy. The document concludes with guidelines, which are written to be used in quality improvement programs to assess the safe and appropriate use of VCDs. The most important processes of care are (i) patient selection, (ii) performing the procedure, and (iii) 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

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. 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 pseudoaneurysm is one measure of the quality of VCD placement, 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 of 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. 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 B**). The complication rates and thresholds here refer to major complications. However, it is important to realize that the definitions of major and minor complications are not universal, and that there may be variations in the definitions of these terms among the trials referenced in this document.

Manual Compression

The most commonly used technique for achieving hemostasis following percutaneous arterial access and the current "gold standard." The technique requires an operator to maintain controlled pressure over the access artery, centered over the estimated position of the arterial entry site following removal of the vascular sheath or catheter. Initially, near-occlusive pressure is maintained and is gradually reduced over approximately 15–20 minutes, although the actual required duration of compression may vary depending on a multitude of factors, including arteriotomy size. If bleeding occurs upon cessation of compression, near-occlusive pressure is reapplied and the process is repeated.

Vascular Closure Device

A VCD is a medical device designed to achieve hemostasis following percutaneous arterial access. An ideal VCD would exhibit numerous characteristics, principal among which would be the ability to safely achieve complete hemostasis and closure of the arteriotomy, independent of the size of the defect in the arterial wall, patient related risk factors, or anticoagulation status. The device should be easy to use, with successful deployment every time and a complication rate that is less than or, at most, equal to that of manual compression. The device should be easily directed to the arteriotomy site to minimize nontarget deployment. Upon deployment, the device should pose no risk for downstream embolization of material or occlusion of the target artery. Also, as patients may require repeat interventions, the device should cause no significant periarterial inflammatory changes that would prevent repeat arterial access. Additional desirable features include nonimmunogenic and bioabsorbable implanted components and low cost. No currently available closure device satisfies all of these criteria. However, each possesses unique advantages and disadvantages based on the mechanism of action.

TYPES OF VCDs

VCDs can be broadly categorized as active closure devices, compression assist devices, or topical hemostasis devices (**Table 1**) (1,3–37). Active devices use a variety of methods to directly close the arteriotomy site; examples include collagen-based products, suture-based products, and products that use staples or clips. Compression assist devices include mechanical clamps designed to provide sustained, targeted pressure at the arteriotomy. Topical hemostasis devices consist of procoagulant pads or water-soluble sealants that serve as an adjunct to manual compression.

ACTIVE CLOSURE DEVICES

Mechanical Plug Devices

One type of mechanical plug device is the collagen plug-based device. These VCDs function by delivering bovine collagen to the arteriotomy site, which serves to promote closure of the arterial defect in two ways. First, the increased availability of collagen augments the body's natural ability to form a clot. The natural healing mechanism at the site of