



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

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, Froedter 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

None of the authors have identified a conflict of interest.

© SIR, 2013

J Vasc Interv Radiol 2013; XX:■■■-■■■

<http://dx.doi.org/10.1016/j.jvir.2013.08.011>

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

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

Table 1. Summary of VCDs and Clinical Data (1,3–37)

Type/Device/Study, Year	Quality of Clinical Data	No. of Pts.	Complication Rate (vs Manual)
Active closure devices			
Angio-Seal			
Kussmaul et al, 1995 (11)	Multiple RCTs (11–16)	435	Bleeding 7% (vs 15%)*, arterial injury 3% (vs 2%)*
Kapadia et al, 2001 (14)		280	Major complications 0.5%
Applegate et al, 2002 (15)		4,525	Major complications 1.1% (vs 1.8%)*
Chevalier et al, 2003 (12)		612	Major and minor complications 5.9% (vs 18%) [†]
Mynx			
Scheinert et al, 2007 (18)	One prospective nonrandomized study, retrospective studies, case reports (18–21)	190	Major complications 0.5%
Fields et al, 2010 (20)		135	Intravascular sealant 18%, pseudoaneurysm formation 11% (retrospective study)
ExoSeal			
Wong et al, 2009 (3)	Randomized prospective trial and retrospective study (3,22)	401	Major complications 0% (vs 0%)
Perclose			
Gerckens et al, 1999 (17)	Multiple RCTs (1,12,17,23–30)	600	Major complications 1.3% (vs 2.7%)*
Baim et al, 2000 (23)		515	Major complications 2.4% (vs 1.1%)*
Fram et al, 2001 (28)		1,097	Major complications 2.2%
Balzer et al, 2001 (30)		930	Major and minor complications 7%
Rickli et al, 2002 (26)		193	Major complications 0% (vs 0%)
StarClose			
Hermiller et al, 2006 (32)	RCT and case reports (10,31–33)	596	Major complications 1.1% (vs 1.1%)
Compression assist devices			
Axera			
Fortes et al, 2013 (4)	Retrospective trial	94	Major complications 0%, minor complications 3%
Boomerang/Catalyst			
Doyle et al, 2007 (34)	Prospective nonrandomized trial	96	Major complications 0%
External/topical hemostasis devices			
Syvek patch			
Nader et al, 2002 (5)	Randomized prospective trial	1,000	Major complications 0.1%
Clo-Sur			
Nguyen et al, 2007 (6)	Prospective trial	184	Major bleeding 0% (vs 0% for no pad)
Chito-Seal			
Nguyen et al, 2007 (6)	Prospective trial	184	Major bleeding 0% (vs 0% for no pad)
D-Stat Dry			
Hallak et al, 2007 (7)	Randomized prospective trials (7–9)	376	Major complication 0.5% (vs 1.1%) [†]
FemoStop			
Sridhar et al, 1996 (35)	Randomized prospective trials (35–37)	101	Major and minor complications 2.4% (vs 22.4%)

Definitions of major complication varies between trials but generally includes adverse events that require surgical or nonsurgical intervention, blood transfusion, or antibiotics or that result in limb ischemia or permanent nerve injury. Minor complications included prolongation of bleeding requiring manual compression or hematomas < 5 cm or those that did not require further intervention. RCT = randomized controlled trial.

*No statistically significantly difference between device use and manual compression.

[†]Statistically significant difference between device use and manual compression.

arterial puncture is driven by the exposure of clotting factors in the blood to collagen and smooth muscle cells in the walls of the artery, which in turn triggers a clotting cascade resulting in platelet aggregation, activation, and clot formation. Second, the physical expansion of the device's collagen plug following deployment causes a mechanical barrier that seals the artery and tissue tract. The collagen plug is then completely degraded by phagocytes by 4 weeks in an animal model (1). The principal advantage of this VCD design is the dual mode of action

of promoting clot formation and providing a mechanical seal. However, a significant drawback of collagen-based devices are the potential risks attendant to immediate repeat puncture, which include infection and dislodgment of the hemostatic plug resulting in distal embolization. Moreover, the inflammatory response incited by the collagen plug has been implicated as a cause for scarred groin. Some data exist to suggest that these concerns may be overstated (38). Examples of collagen-based VCDs are the VasoSeal (Datascope,

Montvale, New Jersey) and Angio-Seal (St. Jude Medical, St. Paul, Minnesota) devices.

Non-collagen-based mechanical plug devices are similar in concept to collagen-based devices, as a bioabsorbable plug is delivered to the external aspect of the arteriotomy. The lack of collagen incites a minimal inflammatory response and does not directly promote coagulation. The plugs employed in these devices function via a mechanical sealant effect on the arteriotomy. Given the biologically inert composition of these plugs, theoretical advantages include decreased post-procedural discomfort as well as minimization of tissue scarring that could impede reaccess. The Mynx (AccessClosure, Mountain View, California) and ExoSeal (Cordis, Bridgewater, New Jersey) devices are examples of VCDs that use noncollagen plugs.

VasoSeal. VasoSeal was one of the first commercially available VCDs, receiving Food and Drug Administration (FDA) approval for clinical use in 1995. Although no longer marketed or used to any significant clinical extent, this device is included for historical completeness and because outcomes data with the use of this device are included in several metaanalyses and retrospective studies. The device deployed a bovine collagen plug at the arteriotomy site and left no residual intravascular component. Early prospective randomized trials demonstrated that VasoSeal device use yielded significant reductions in hemostasis times following diagnostic and therapeutic coronary angiography (39). However, the VasoSeal device was associated with an increased risk of vascular complications relative to manual compression, primarily following diagnostic cardiac catheterization (40,41). Given the mounting evidence of the device's risk profile, the VasoSeal device is not used in clinical practice today.

Angio-Seal. The Angio-Seal device was first approved in 1996. An intraarterial component is integral to the Angio-Seal device, in contrast to the VasoSeal device. During deployment, a T-shaped anchor is delivered through a customized sheath into the arterial lumen and is then securely apposed against the intraluminal arterial wall to seal the puncture site. An extravascular collagen plug is subsequently compressed against the arteriotomy by an absorbable suture. Hemostasis is therefore achieved by mechanical compression of the arteriotomy between the intravascular anchor and the extravascular collagen plug, as well as by the promotion of the hemostatic cascade by the collagen plug. The anchor, plug, and suture are absorbed by 30 days.

Mynx. The Mynx device, approved in 2007, works through the existing procedural sheath and requires no sheath exchange or subcutaneous tract dilation. A temporary intraarterial balloon is advanced through the procedural sheath and pulled back against the arterial wall, and a water-soluble polyethylene glycol sealant plug is then delivered through the procedural sheath along the tissue tract. When it has been delivered, the material rapidly absorbs blood and expands, effectively creating a mechanical seal and a scaffold to which platelets may adhere and initiate clot formation. The plug is fully resorbed by 30 days. As no intraarterial anchor is used, the risk of distal embolization is diminished, the risk of stricture or occlusion is theoretically reduced, and immediate repeat puncture can be performed. A short duration of manual pressure is still recommended with the use of this device.

The most recent model of the Mynx closure device is termed MynxGrip and contains a modified formulation of the sealant plug. Composed of a new configuration of polyethylene glycol, the MynxGrip sealant is marketed to improve adherence of the plug to the arterial wall as well as swell by 300%–400% of its original size upon absorption of blood and fluid.

ExoSeal. The ExoSeal device uses a bioabsorbable extravascular polyglycolic acid plug that is deployed by the device atop the femo-

ral arteriotomy site. Hemostasis is therefore achieved by mechanically occluding the arteriotomy without activating the coagulation cascade, analogous to the closure method of the Mynx device. Unlike the Mynx device, the ExoSeal device incorporates a unique visually guided deployment system and does not rely on tactile feedback or a temporary intraarterial balloon tamponade.

Duett. The Duett device (Vascular Solutions, Minneapolis, Minnesota) is a mechanical plug-based VCD that employs an intravascular balloon catheter to occlude the arteriotomy intraluminally (1). A mixture of thrombin and collagen are then injected into the tissues overlying the arteriotomy to promote hemostasis. The balloon is then deflated and retracted, leaving behind no intravascular component. The Duett device is not used in clinical practice today and is only included for historical completeness.

Active Arteriotomy Approximation Devices

Active arteriotomy approximation devices achieve a limited form of surgical closure. In an open surgical arterial closure, sutures are placed at approximately 1-mm intervals around the arteriotomy; in this class of VCDs, however, only one or two sutures or a nitinol clip are placed, and therefore the suture density of a surgical arterial closure is not replicated (1). Nevertheless, these devices are popular because of their ability to cause complete apposition of the walls of the arteriotomy defect. This theoretically obviates subsequent manual compression or the administration of procoagulant material as with the Angio-Seal device. As such, the concerns regarding immediate repeat puncture or inflammation from the implanted material resulting in patient discomfort or scarred groin do not apply to the use of these devices. There are two major active arteriotomy subgroups, based on the device mechanism of action: suture-based devices, of which the Perclose family of devices is the prototype, and nitinol clip-based devices, such as the StarClose device.

Perclose. The Perclose device was the first FDA-approved suture-based VCD, receiving approval in 1997. The device has undergone several revisions designed to facilitate ease of use and accommodate larger sheath sizes. The preponderance of clinical data for this group of devices revolves around the Techstar 6-F model (Abbott Laboratories, North Chicago, Illinois) and ProStar 8-F model (Abbott Laboratories). The most recent model of this device, the Proglide, features a pretied knot as well as a suture composed of polypropylene monofilament, which allows for easier knot advancement; a distal suture-cutting mechanism adds to the device's ease of use. These devices can successfully ensure hemostasis following the use of larger-caliber sheaths, and currently available devices are indicated after the use of devices or sheaths up to 10 F in caliber. The practice of "preclosure," in which sutures are placed before the initial dilation of the arteriotomy, extends the applicability of VCD use to even larger sheath sizes without the need for a surgical approach; the data regarding this technique will be discussed separately.

The SuperStitch device (Sutura, Fountain Valley, California) uses a similar mechanism of action (42) but has fewer clinical data regarding its safety and efficacy relative to other suture-based VCDs. However, this device has the distinct advantages of being deployable through an existing procedural sheath as well as accommodating larger arteriotomies, as large as 12 F (43). This device is no longer on the market and is included for historical completeness.

StarClose. The StarClose device (Abbott Laboratories) is the prototypical clip-based VCD. This device applies a 4-mm flexible nitinol clip to create a completely circumferential extravascular approximation of an arteriotomy and accommodates 5-F or 6-F sheaths. Before clip deployment, small flexible wings are extended from the device and positioned along the undersurface of the arterial wall to confirm the correct positioning of the clip. Activation of the StarClose device results in the nitinol clip grasping the adventitia of the

artery with small tines to pull the edges of the arteriotomy together, simulating a purse-string suture. As with the suture material used in the Perclose device, the nitinol clip of the StarClose device is essentially biologically inert and does not incite an inflammatory response. As the clip is extraluminal, StarClose device is designed to minimize the risk of deforming the arterial lumen. One unique limitation is the local susceptibility artifact created by the metallic clip during magnetic resonance imaging that may limit the image quality of adjacent structures.

Compression Assist Devices

Passive arteriotomy approximation devices are a class of VCDs that assist in coapting the walls of the arteriotomy without the use of retained sutures or clips. As such, they possess several theoretical advantages versus other techniques, including a reduced infection risk and a negligible embolization/arterial occlusion risk given the lack of implanted material. One drawback to this class of devices is the ancillary need for manual compression despite the use of a VCD, albeit for a reduced duration of time.

Axera. The Axera device (Arstasis, Redwood City, California) is unique compared with other VCDs in terms of its mechanism of augmenting hemostasis. This device relies on no additional sealant, procoagulant, or suture material, instead capitalizing on the improved apposition of an arteriotomy afforded by the use of a very shallow needle trajectory during arterial access. The Axera device is used at the initiation of the arterial access to convert a standard arterial puncture into a low-angle one, (approximately 5°), through which the arteriotomy is subsequently dilated to accommodate the procedural access sheath. The improved arterial overlap allows for more rapid hemostasis as well as intrinsic tract compression as a result of the radially oriented pressure of blood flow within the lumen; in essence, the latter effectively results in “autotamponade” of the arteriotomy. Manual compression is still necessary after the sheath is removed. No retained material is left in the patient, and therefore the attendant risks of embolization or infection are not a concern for this VCD (4).

Boomerang and Catalyst. The Boomerang system (Cardiva, Mountain View, California), which was approved for use in 2004, consists of an 18-gauge wire with a nitinol braided mesh disc that is inserted through the procedural sheath at the end of the procedure (43). Upon deployment, a low-profile conformable disc is expanded at the intraarterial end of the wire. As the working sheath is removed and gentle traction is applied to the wire tether, targeted internal compression by the intravascular nitinol disc is generated at the arteriotomy site. The device tether is fixed in place externally, and the patient is kept in the supine position for 30 minutes. After this time, the device is removed in its entirety, with no residual retained component, and light manual compression is then provided for 5–7 minutes (44). The device can be used for 5–7-F arteriotomies.

The Boomerang device has been succeeded by the Catalyst family of devices (Cardiva). The Catalyst II device is a modification of the Boomerang system that incorporates a biocompatible coating to assist in hemostasis. A further device modification, Catalyst III, is coated with protamine sulfate for use in patients undergoing heparinization.

External/Topical Hemostasis Devices

The passive closure devices class of VCDs includes procoagulant patches or pads and clamps for assisted compression. These devices are intended to accelerate hemostasis or apply targeted compression to reduce the duration or diminish the physical burden of manual compression, respectively. No material is implanted with these devices, and manual compression is required if these devices are used alone. However, they can also be used supplementally following the use of another VCD. Clinical data regarding the efficacy and safety of these devices varies, but is limited overall.

The Syvek patch (Marine Polymer Technologies, Danvers, Massachusetts) is a topical pad composed of poly-N-acetyl glucosamine that is FDA-approved for hemostasis in patients following femoral access

procedures with anticoagulation. The patch is placed over the dermatome, and manual compression is applied over the patch (1,45). In a study of 1,000 consecutive patients undergoing diagnostic or interventional cardiac procedures with sheaths ranging from 4 F to 12 F (5), the Syvek patch was applied during manual compression and resulted in hemostasis with minimal complications.

The Chito-Seal (Abbott Laboratories) and Clo-Sur devices (Medtronic Vascular, Santa Rosa, California) are other proprietary hemostatic patches. These were compared with manual compression alone following PCIs in a single trial (6), which demonstrated a statistically significant, though small, decrease in time to hemostasis with the use of the pads during manual compression compared with manual compression alone. There was no overall difference in time to ambulation.

The D-Stat Dry pad (Vascular Solutions, Minneapolis, Minnesota) was compared with manual compression alone in a randomized trial of 376 patients (7) and was found to result in a statistically significant, but slight, decrease in time to ambulation. However, no difference in time to discharge was found with this device (7,8), and higher rates of major and minor vascular complications were identified compared with the use of Angio-Seal or StarClose devices in one trial (9).

The FemoStop device (RADI Medical Systems, Wilmington, Massachusetts) is a mechanical compression device that has been used in the control arms of clinical trials of other VCDs. The device consists of a rigid plastic frame and a pneumatic dome that is inflated over the arteriotomy; the dome is fixed by a belt that is wrapped around the patient's hips. The dome is pressurized via a hand pump and kept in place for approximately 15 minutes. Randomized trials and single institution studies comparing the FemoStop device versus manual compression showed similar or decreased rates of complications with the use of the device (2).

The Safeguard device (Maquet Cardiovascular–Datascope, Fairfield, New Jersey) is a single-use disposable external compression assist device that has a polyurethane window and pneumatic bladder that is inflated over the arteriotomy and secured in place via a sterile adhesive backing. The Safeguard device has a clear window that facilitates visualization of the access site without removal or manipulation of the device during its use, which is typically of 15 minutes duration.

INDICATIONS

Limitations of Currently Available Trial Data Regarding VCD Use

Primary data regarding the effectiveness and complication rates associated with the use of VCDs are mostly derived from the cardiovascular literature. Unfortunately, these data give an incomplete picture of the appropriate clinical use of VCDs for numerous reasons. Most clinical trials of VCDs range in patient enrollment from 100 to 650 patients and compare VCDs with manual compression as the gold standard. The majority are single-institution investigations that include patients who have few to no risk factors for increased vascular complications during cardiovascular procedures. Examples of such risk factors include age greater than or equal to 70 years, female sex, a body surface area less than 1.6 m², renal failure, calcified femoral arterial atherosclerosis, and the use of glycoprotein IIb/IIIa inhibitors (10). Most trials involved low- to moderate-risk procedures and enrolled patients who underwent diagnostic coronary angiography or routine PCI. Patients with multiple risk factors, including those with known peripheral arterial disease or coagulopathy, and those who underwent high-risk procedures, such as emergent PCI, lengthy multivessel angioplasty, or stent implantation were excluded for the most part, as were those who underwent procedures that involved sheath sizes of 8 F or greater. Given their enrollment size, these clinical trials were often underpowered to detect uncommon complications of VCDs. Outcome analyses may not have been blinded. Finally, standard definitions as to what constitutes a major vascular complication or an effective outcome of VCD use were not employed. These limitations pose a significant hurdle to the legitimacy of extrapolating these trial data to procedures that are performed in patients at higher risk.

Device-specific Trial Data Regarding VCDs

Angio-Seal. Some of the largest prospective randomized trials of VCDs have been conducted with Angio-Seal devices. Kussmaul et al (11) showed a significant decrease in time to hemostasis following the use of Angio-Seal devices, with 76% of patients in the Angio-Seal arm showing hemostasis within 1 minute. Any complication, including bleeding or hematoma, was less common in the Angio-Seal arm than in the manual compression control arm. Although anticoagulation with heparin increased the complication rate in the control arm, there was no effect on time to hemostasis or complications in the device arm. These findings were corroborated in a subsequent randomized trial (12). The improved mean time to hemostasis is unaffected by factors such as anticoagulation status (11,13,14) or use of larger sheaths (13,15). Length of hospital stay has been reported to be shorter with the use of the Angio-Seal device (13,14), and rates of postprocedural hematoma formation have been reported to be lower (16).

Complication rates with the use of the Angio-Seal device range in the literature from 0.8% to 3.6% (11,13,46–50), values that were significantly increased compared with manual compression in only one study (50). The most commonly occurring complication was arterial occlusion of the femoral artery at the puncture site (47), possibly caused by arterial luminal narrowing or foreign body reaction caused by the intra-arterial anchor. The rate of occlusion for the Angio-Seal device is comparable to those of other VCDs, including non-collagen-based devices (13,15,17,49). As the Angio-Seal device relies on a bioabsorbable intravascular anchor, distal embolization of this retained component is a potential risk. Indeed, case reports of migration and distal arterial occlusion of the anchor and suture complex have been reported (51).

Mynx. In a prospective single-arm trial of 190 consecutive patients undergoing diagnostic or interventional cardiac procedures (18), the use of the Mynx device resulted in a mean time to hemostasis of 1.3 minutes; time to ambulation was 2.6 hours. No major device-related complication was identified (18).

Data regarding the safety profile of the Mynx device are varied. Case reports have been published detailing distal embolization of sealant material, resulting in lower-limb ischemic symptoms and requiring surgical excision (19). Fields et al (20) reported on 26 patients who underwent Mynx closure following neurointerventional diagnostic or therapeutic procedures and subsequently were evaluated with diagnostic femoral angiography for indications unrelated to the VCD use; median time to follow-up imaging was 6 days. Of these patients, 18% were found to have an intravascular filling defect at the initial arteriotomy site, one of which was confirmed surgically to represent intravascular sealant (20). Moreover, three patients were found to have pseudoaneurysms, two of which were treated with thrombin injection. Although this high complication rate is alarming, it is interesting to note that all patients were asymptomatic. A possible reason for intraarterial deployment is poor contact between the temporary intraarterial balloon and the arterial wall when the sealant is released. In a more recent retrospective analysis of 31 patients who underwent neurointerventional procedures followed by repeat femoral angiography within a median time of 5.5 days (21), no intraluminal filling defects were identified. It is unclear how to reconcile the widely discordant findings between these two trials (20,21), although one can speculate that variables such as operator experience and patient risk factors including obesity and arterial calcifications may play a role.

ExoSeal. Ensure's Vascular Closure Device Speeds Hemostasis Trial (3) was a nonblinded multicenter trial of 401 patients randomized to undergo ExoSeal or manual compression following diagnostic or interventional cardiovascular procedures through 6-F sheaths. Mean time to hemostasis was significantly shorter in the device arm (4.4 min versus 20.1 min), as was the time to ambulation (2.5 h vs 6.2 h). No major complications were identified in the trial. It is important to note that exclusion criteria for this trial were extensive, as patients with femoral arterial disease, moderate calcifications at the site of sheath

insertion, or recent femoral artery access were not enrolled. The ability of the device to achieve hemostasis in arteriotomies greater than 6 F was not evaluated. In a retrospective study, Boschewitz et al (22) evaluated 682 ExoSeal device deployments and found a 95.5% success rate for achieving hemostasis. The rate of minor complications was 1.17%, and no major complications were reported.

Perclose. Rates of hemostasis provided by Perclose devices alone have been reported as ranging from 85.7%–99% (1). The overall time to hemostasis is reduced with Perclose device use, requiring approximately 6.4–20 minutes (17,23). The anticoagulation status of the patient does not significantly affect the time to hemostasis (1). Likewise, the time to ambulation is significantly improved with the use of Perclose devices (13,17,23–27). For example, in a 600-patient randomized trial comparing Perclose device use with manual compression (17), the time to hemostasis following VCD use was 7.8 minutes, compared with 13.2 minutes in the manual compression arm; similarly, the time to ambulation in the device arm was 4.5 hours, compared with 17.8 hours in the manual compression arm. No statistically significant increase in the number of vascular complications was found following Perclose device use compared with manual compression, and, in fact, vascular complications were less common in the device group for patients undergoing diagnostic cardiac procedures. In a trial of 1,097 consecutive patients in whom a Perclose device was applied by experienced operators following cardiac procedures (28), the overall complication rate was 3.4%, with hematoma formation greater than 4 cm occurring in 2.1% of cases, and with the need for vascular surgical repair of the arteriotomy following the use of the Perclose device in 0.6% of cases.

The major disadvantage most frequently cited for the Perclose device is the relative complexity of operating the device. Published deployment success rates range from 89% to 100% (1), with conversion to manual or mechanical compression required in 4%–14% of patients (1). Concern has also been raised regarding the risk of infection as a result of the indwelling suture component; Fram et al (28) reported an infection rate of 0.4% in their patient series, but the rate has been reported as high as 1.6% (1), compared with 0% with manual compression (29). Suture-based devices have the theoretical risk of causing deformity and/or stenosis of the artery. However, this risk has not been corroborated in the available clinical data, with follow-up angiography or ultrasound demonstrating no significant stenosis or deformation following Perclose device use (30). The presence of peripheral vascular disease is considered a relative contraindication, as mural calcifications may prevent the proper deployment of the sutures; however, there are data to suggest that the Perclose device may be used safely and effectively in patients with arterial calcifications as well (30).

StarClose. The Closure in Percutaneous Procedures (CLIP) trial (10,31,32) compared the safety and efficacy of the StarClose device with that of manual compression. This was a randomized prospective trial of 596 patients, of whom 208 underwent diagnostic coronary angiography and 275 underwent PCI. In the diagnostic subset, mean time to hemostasis was 1.5 minutes and mean time to ambulation was 163 minutes in the device arm, compared with 15.5 minutes and 269 minutes, respectively, in the manual compression arm. No major complications were noted in either arm following diagnostic procedures. In the interventional arm, the mean time to hemostasis was 8 minutes, compared with 29 minutes with standard compression; notably, there was no statistically significant improvement in mean time to ambulation with the StarClose device compared with manual compression, with mean times of 411 minutes in the device group and 466 minutes in the manual compression group. The major complication rate (1.1%) was identical for both arms of the interventional subset, and there was a trend toward fewer minor complications in the device arm. A follow-up US examination at 30 days was performed on 96 trial subjects to evaluate for short-term complications. No hematoma, pseudoaneurysm, or arteriovenous fistula was noted in the StarClose arm; there was also no evidence of arterial stenosis or occlusion in these patients.

Case reports of clip embolization from misplacement during device activation have been described (33), though this complication was not encountered in the CLIP trial (10,31,32). There were no instances of infection associated with the indwelling clip noted in the CLIP trial. One important drawback is the rate of device failure, which was 11% in the PCI subset of the CLIP trial (10). Additionally, robust data regarding safe repeat puncture of the ipsilateral groin within 90 days following StarClose device use are not available.

Johnson et al (52) queried the FDA and Manufacturer and User Facility Device Experience databases for occurrences of complications following StarClose device use from July 2009 to October 2010. They identified 1,118 complications related to this device's use during the specified time period. Many of these complications were related to improper deployment and functioning of the device. For example, inability to complete the deployment sequence constituted 24% of the complications, and inability to remove the deployment device represented 20%. These findings are remarkable considering that they differ significantly in frequency and character compared with published clinical trials.

Compression Assist Devices. Few published data are available regarding the Axera device. In a retrospective study, Fortes et al (4) evaluated the use of the Axera device in 84 patients. They found that the median time to hemostasis with the use of this device was 4 minutes of manual compression, with a minor complication rate of 3%.

The Boomerang device has been studied in a limited number of clinical trials. In a study of 96 patients undergoing diagnostic cardiac catheterization (34), the deployment success rate for Boomerang was 99%. Time to ambulation following the use of a Boomerang device was 2–4 hours, with a mean time of 82 minutes. The authors noted that this device was used successfully in a limited number of patients with arterial calcifications, as well as in patients with arteriotomies that were not in the common femoral artery or profunda femoris artery; the trial was not powered to assess use in these circumstances rigorously (34).

Meta-analyses and Registry Data of VCDs

Given the dearth of available large randomized controlled trials, an important source of data on the safety and efficacy of VCDs is from metaanalyses and registry data mining. Overall, these data appear to confirm the efficacy of VCDs but do not provide concrete evidence of an improved safety profile relative to manual compression. They also do not provide a comparative analysis of the merits of individual VCDs.

Data from the American College of Cardiology–National Cardiovascular Data Registry, which incorporated information from 59 institutions, were analyzed by Tavris et al (53,54). More than 160,000 VCD deployments, which predominantly involved the use of suture-mediated and collagen-mediated devices, were performed during diagnostic and interventional cardiac procedures and were included in the registry data. The authors found that, as a result of lower rates of bleeding and pseudoaneurysm formation, there was an overall decreased risk of vascular complications in diagnostic procedures in which a VCD was used. The exception was those cases in which a VasoSeal device was used, as there was a higher complication rate associated with this device compared with manual compression (odds ratio, 2.38). However, given the retrospective nature of this study, limitations such as reporting bias and recall bias are important considerations.

Several metaanalyses of VCDs have been conducted. Koreny et al (55) aggregated data from 4,000 patients across 30 randomized trials comparing VCD use versus manual compression. They concluded that time to hemostasis with the use of VCDs was decreased by 17 minutes. However, the authors noted that there was a high degree of heterogeneity in the results of the included trials, many of which were of poor methodologic quality. Likewise, Biancari et al (56) compared data across 31 prospective trials totaling more than 7,500 patients who were randomized to receive VCD closure or manual compression following

diagnostic coronary angiography or other transarterial procedures. In this metaanalysis as well, there was a very statistically significant decrease in time to hemostasis with VCDs.

Nikolsky et al (40) pooled data from 37,066 patients to compare the relative safety of VCDs versus manual compression and found manual compression to be marginally safer than VCD use. There was a trend toward improved safety with the use of VCDs following diagnostic cardiac catheterization procedures, with the exception of the VasoSeal device. Similarly, Vaitkus et al (41) aggregated data from 16 randomized trials and found that use of Angio-Seal and Perclose devices was marginally safer than manual compression, whereas there was an increased risk of vascular complications relative to manual compression when a VasoSeal device was used.

Evidence of VCD Use in Interventional Radiology

The majority of available data on the safe and effective use of VCDs has been acquired through trials designed to investigate VCD use following low-risk diagnostic or interventional cardiac procedures. However, patients undergoing interventional radiology procedures may benefit from VCD use, and there is a growing body of literature investigating the use of VCDs during interventional radiology procedures.

Anticoagulation following peripheral arterial angioplasty and/or stent placement can lead to prolonged sheath dwell times, with associated discomfort that could be reduced or resolved via use of a VCD. Likewise, the larger-sized sheaths used in many interventional radiology procedures require longer manual compression and immobilization times, both of which could be improved with the use of a VCD. In patients undergoing peripheral vascular intervention, Balzer et al (30) showed that Perclose device use resulted in rapid hemostasis and early ambulation in the majority of patients, with complication rates comparable to those in other patient populations. Additionally, although there is a relative contraindication to the use of the Angio-Seal device in patients with peripheral vascular disease, two trials (57,58) have demonstrated no significant differences in complication rates between the use of this device and manual compression, but a significant improvement in time to hemostasis.

StarClose device use in the interventional radiology setting has been investigated to a limited extent. Imam et al (59) studied 200 consecutive patients who underwent diagnostic (12%) or therapeutic (88%) procedures followed by arteriotomy closure by StarClose device. The therapeutic procedures performed were primarily suprainguinal angioplasty (20%), infrainguinal angioplasty (58%), and iliac stent placement (8%), and were performed through 6-F sheaths, with the exception of two procedures that required 7-F sheaths. Although parameters such as time to hemostasis or time to ambulation were not reported, the authors note that “immediate” hemostasis was achieved in 96% of patients. The operators in the trial also enjoyed a greater device success rate than those of the CLIP study (10,31,32), with a failure rate of only 4%. No complications related to StarClose closure of 7-F arteriotomies were noted in the two patients in this trial (59).

One metaanalysis and one data registry regarding the use of VCDs in interventional radiologic procedures have been published. Das et al (60) reviewed 34 studies in which four VCDs (Angio-Seal, StarClose, Perclose, and Duett) were used in a variety of interventional radiologic procedures that included uterine artery embolization, transhepatic chemoembolization, and various neurointerventional procedures. Procedures requiring nonfemoral access or sheaths larger than 8 F were excluded. In a pooled analysis of all VCDs, there was a nonsignificant decrease in complications noted with device use versus manual compression. Reekers et al (61) developed a Cardiovascular and Interventional Radiological Society of Europe registry of VCDs in 2009 that collected data from 28 centers across 10 European countries, with a total enrollment of 1,107 patients. All VCDs included in the study consisted of an intraarterial anchor and collagen plug (Angio-Seal). Device deployment was successful in 97.2% of cases, with failures

rarely attributed to vascular calcification. The complication rate was 2.4%, of which half were considered serious.

Evidence Regarding “Preclosure” Technique

The preclosure technique is an application for VCDs as a means of securing nonsurgical closure of very large arteriotomies, created during procedures such as aortic endograft, percutaneous cardiac valve, or left ventricular assist device placement. These procedures may require the use of arterial sheaths or devices ranging from 12 to 24 F in size. In the preclosure technique, one or more VCDs are deployed before the initial dilation of the arteriotomy. Potential benefits of the preclosure technique include the avoidance of a surgical cutdown (surgical arterial exposure and arteriotomy), with the resultant improved patient comfort and decreased wound complications such as infection, femoral neuropathy, and those arising from lymphatic disruption (62–65).

The most commonly used VCDs for this technique are the suture-mediated devices, particularly the ProStar device, which deploys two sutures. The ProStar VCD received CE Mark approval in 2009 to treat punctures from sheaths up to 24 F (62). Other devices, including the Mynx, have also been applied in this setting (63). It is important to note that the use of VCDs in the preclosure setting constitutes an off-label use.

A metaanalysis of ProStar-mediated closures of femoral arteriotomies greater than 10 F (62) found technical success rates for VCD closure (defined as the acquisition of adequate hemostasis without requiring surgical cutdown) ranging from 64.4% to 100%, with a weighted average of 91%. This metaanalysis included data from randomized controlled trials, nonrandomized controlled trials, observational studies, case series, and case reports; however, of the 20 trials, only one was a randomized controlled trial, and only seven compared the use of a ProStar device versus surgical cutdown. Other studies have likewise found an equivalently high technical success rate with VCD-mediated closure compared with an open surgical approach, with similar short-term and long-term complication rates, but decreased hospital length of stay with VCD use (66).

Lee et al (64,65) performed a retrospective single-institution study evaluating preclosure in patients undergoing endovascular aortic aneurysm repair and compared them with a contemporaneous cohort of patients who underwent surgical cutdown for vascular access; the selection for VCD versus cutdown was determined by operator preference. All patients in this series were followed for at least 6 months. The success rate in the VCD group was 94%. Failures usually required open surgical arteriotomy repair; risk factors for failure included obesity, device malfunction, severe arterial calcifications, or nonideal puncture sites. Early complication rates for the VCD group and cutdown group were statistically similar.

Comparison of Efficacy and Complications between VCDs

Few studies have compared the relative efficacy and complication rates between different types of VCDs. As highlighted by registry data mining and metaanalyses, differences may be subtle and may require large trials to elicit statistically significant differences (10,13,40,41,54,55,67). There is presently insufficient evidence to suggest that deployment success rates, time to hemostasis, time to ambulation, or major complication rates are significantly different among VCDs, with the exception of the VasoSeal device, which demonstrated increased rates of vascular complications (14,15).

VCD Use in Locations Other than the Common Femoral Artery

Although the vast majority of available data on VCDs apply to their use in femoral arteriotomies, there are published reports of their successful implementation for other vascular access sites. In a retrospective study of 238 patients who underwent closure with Angio-Seal

devices following brachial arterial access, Lupattelli et al (68) described a high rate of hemostasis in a carefully selected patient population. Similarly, other studies have revealed a high deployment rate and low complication rate with Angio-Seal device use in brachial access sites (69). A case of Boomerang device-assisted compression device use following brachial artery access has also been reported (70). A successful Mynx device closure of an inadvertent subclavian arterial catheterization has been reported (71). Given that the preponderance of data regarding VCD is relevant to only femoral artery access, the present document does not make specific recommendations regarding VCD use at nonfemoral arterial access sites.

Cost-effectiveness of VCD Use

Several studies have suggested that VCD use is superior to manual compression in terms of efficacy and cost as a result of the decreased periprocedural physician time as well as a possible decreased duration of hospital stay (1,72,73). For example, Rickli et al (26) evaluated the cost-effectiveness of VCD use versus manual compression in a cohort of patients undergoing elective cardiac catheterization. Patients who underwent closure by a suture-mediated device were allowed to ambulate within 4 hours, whereas patients who underwent manual compression were restricted to bedrest until the following day. A cost analysis, which included cost of the VCD as well as personnel costs, procedural costs, and infrastructure costs, concluded that overall expenses were reduced with the use of VCDs. However, the topic of cost-effectiveness for VCDs is complicated, and any cost/benefit analysis must take into consideration all the ramifications of VCD use, including the cost of managing complications as well as of follow-up imaging; neither of these was fully examined in this trial (26), partly given its sample size. Conclusive evidence for health care savings through the use of VCDs relative to manual compression has yet to be demonstrated.

VCD Use in Children

It is not uncommon for pediatric interventional procedures to require placement of access sheaths or intravascular devices sized 8 F or greater. The use of VCDs in children has been documented (74); however, there are insufficient data available on which to base recommendations regarding VCD use in this population.

VCD Use in Access Sites Involving Synthetic Material

There are no relevant clinical data regarding the use of VCD closure devices in arteriotomies that involve punctures through stents or synthetic graft material. In fact, access in this manner was an exclusion criterion for some clinical trials. Given that the safety of this practice cannot be evaluated, the present document does not endorse the use of VCDs in this setting.

THRESHOLDS

Appropriate indications for the use of VCDs include promoting hemostasis, improving patient comfort, and decreasing the duration of bedrest following femoral arteriotomy. We recommend a proper deployment success rate threshold of 90% and a successful hemostasis success rate threshold of 90%.

COMPLICATIONS

VCD use and manual compression are associated with several well known complications, including arterial thrombosis, hematoma, sustained bleeding, and formation of pseudoaneurysms or arteriovenous fistulas. The use of VCDs also introduces a new subset of possible complications, including distal embolization of device material, deployment failure, and infection.

In the past two decades, reported complication rates for VCDs have been trending downward; whereas published rates were as high at

Table 2. Guidelines for Acceptable Major Access Site-related Complication Rates for Manual Compression and VCD Use

Treatment	Major Complications (%)	
	Reported	Acceptable
Manual compression	0–3	3
VCD use	0–7	3

Complications in patients for whom VCDs are used should be no more frequent than in patients for whom manual compression is employed.

6% in the 1990s, more recent trials have reported rates of approximately 2% (10), on par with the complication rates that are associated with manual compression (Table 2). This phenomenon may be attributed to several factors, including improved patient selection, less potent anticoagulation regimens, device design improvements, improved VCD placement techniques, and operator experience (10,44). The routine performance of femoral angiography to exclude VCD use in patients with suboptimal arterial access sites represents one such example of improved technique that has led to fewer complications. Some data exist suggesting that VCD use is associated with complication rates lower than that of manual compression (75–77). However, this conclusion is not universally shared by all clinical trials comparing VCDs versus manual compression. For example, McDonald et al (78) reviewed the Premier Perspective database for vascular access complication rates in patients undergoing carotid stent placement between 2006 and 2011. In a sample size of 12,287 patients, approximately half of whom underwent VCD deployment, they found a minimally decreased risk of minor complications and no improvement in major complications with VCD use compared with manual compression.

Given the unique complication profile for VCDs, in some institutions, the use of these devices is regarded as an independent procedure. As such, at the conclusion of the principal procedure, the patient's arterial access site is prepared again, and clean sterile drapes are applied, to minimize the risk of infection from an indwelling component of the VCD. Before the initiation of the principal procedure, separate informed consent for the use of a VCD is obtained. Antibiotic agents may be administered prophylactically before routine closure device use as well. Although infections associated with the use of VCDs have been reported (79), there is no evidence to support the practice of routine prophylactic antibiotic agent administration. In some circumstances (eg, intraarterial catheter-directed thrombolysis), an arterial access sheath is left indwelling for a prolonged time period. In such cases, a stronger consideration may be made for prophylactic antibiotic agent administration, although, again, there is no supporting evidence.

Contraindications to Closure Device Use

Many of the patient-related risk factors associated with manual compression-related complications also impact VCD use. These include age older than 65 years, female sex, diabetes, hypertension, recent catheterization, peripheral vascular disease, and anticoagulation. Obesity is also an important independent risk factor for complications following VCD use (80).

Access site location is an important consideration and should be evaluated before VCD use. Most VCDs are contraindicated for use in suboptimally positioned arteriotomies such as those involving the superficial femoral or profunda femoral artery, those located at the common femoral arterial bifurcation or above the inferior epigastric artery and/or inguinal ligament, or ones in which multiple punctures were required. For this reason, it is recommended that femoral angiography always be performed before VCD deployment to evaluate the anatomy of the arterial puncture. Pertinent findings include the presence of heavy arterial calcifications, small arterial caliber, vessel tortuosity, and the location of the arteriotomy. Ipsilateral repeat puncture of an artery within 30 days of VCD use is contraindicated in certain devices, including the Angio-Seal

device; some authors have suggested the safety of immediate repeat puncture if it is performed 1 cm proximal to the original access site (10). Angio-Seal devices should not be used in patients who may undergo surgical cutdown, as this may lead to disengagement of the absorbable suture and embolization of the intraarterial anchor.

There is a lack of data for the use of VCD in several clinical settings. These include the use of VCDs involving a vascular stent or graft, or those in which an ipsilateral venous sheath is also present. Most manufacturers also warn that there is a lack of data for the safe use of VCDs in patients receiving anticoagulant agents, including antiplatelet drugs, glycoprotein IIb/IIIa inhibitors, and thrombolytic drugs; however, the interventional cardiology literature generally indicates no increased risk of complications in this patient population (44). A notable exception was published by Dangas et al (81), who found a higher rate of complications including hematoma formation, hematocrit decrease, and need for surgical repair following VCD use compared with manual compression in patients undergoing PCI. It is important to note that, in this retrospective, nonrandomized study (81), VCD use was left to the operator's discretion, and only 8% of these patients underwent VCD deployment. Moreover, the use of antiplatelet drugs by patients in the VCD group or the manual compression group was not reported.

CONCLUSIONS AND RECOMMENDATIONS

Quality of Available Data

- Currently available data are heavily weighted toward cardiovascular procedures, low-risk procedures, and procedures in patients at low to moderate risk.
- The relevance of the available data to interventional radiologic procedures is limited, as interventional radiology patients may be at higher risk, and the procedures may use different techniques and devices and larger sheaths.
- There are some data on the utility of VCDs in interventional radiology.
- There are no clinical safety data regarding the use of VCDs in arteriotomies through stent or graft material.

Conclusions from Available Data

- Deployment success rates for VCDs, independent of mechanism, are very high.
- The use of VCDs, independent of mechanism, result in shorter time to hemostasis and decreased time to ambulation.
- VCDs, independent of mechanism, are generally safe, with complication rates not significantly greater than that of manual compression, with the VasoSeal device representing a notable exception.
- There are insufficient data to support comparative analysis of the relative efficacy and safety of different types of VCDs.
- Although the preclosure technique represents an innovative and potentially beneficial approach to the treatment of large arteriotomies, there is at present a paucity of data to establish its noninferiority or superiority to traditional surgical approaches.

Recommendations

- Further study of the safety and efficacy of VCDs in patients undergoing interventional radiologic procedures is needed.
- Femoral angiography should be considered before deployment of a VCD.
- The use of VCDs may be considered a safe method to reduce time to hemostasis and duration of bedrest following transarterial intervention. The potential benefits of these devices should be balanced by a careful evaluation of patient-related risk factors, vascular anatomy, body habitus, and bleeding risk. The appropriate duration of bedrest and manual compression following VCD

use vary among different devices, and the individual manufacturer's recommendations should be followed.

- D. Institutional complication rates for VCDs should be, at minimum, equivalent to the complication rates of manual compression (Table 2).
- E. VCDs should not be used for the explicit goal of reducing vascular complications.
- F. There is insufficient evidence to support the routine use of VCDs in arterial grafts or stents.
- G. There is insufficient evidence to support the routine use of VCDs for the explicit purpose of health care cost reduction.
- H. Some institutions regard the use of VCDs as an independent procedure, requiring separate informed consent, repeat preparation of the sterile field, and/or use of prophylactic antibiotic agents. This document neither endorses nor discourages such practices, though discussing the unique risks and benefits of VCDs with patients before the initiation of any procedure in which such devices may be used is recommended.

ACKNOWLEDGMENTS

Rahul A. Sheth, MD, and T. Gregory Walker, MD, authored the first draft of this document and served as topic leaders during the subsequent revisions of the draft. Wael E. Saad, MD, is chair of the SIR Standards of Practice Committee. Boris Nikolic, MD, MBA, 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 as follows: John "Fritz" Angle, MD, Ganesh Annamalai, MD, Ronald S. Arellano, MD, Sriharsha Athreya MBBS, MS, FRCS, FRCR, Mark Otto Baerlocher, MD, Stephen Balter, PhD, Kevin M. Baskin, MD, Daniel B. Brown, MD, Drew M. Caplin, MD, Timothy W.I. Clark, MD, MSc, Jon C. Davidson, MD, B. Janne d'Othee, MD, MPH, Eduardo P. Eyheremendy, MD, S. Nahum Goldberg, MD, Maxim Itkin, MD, Arshad Ahmed Khan, MD, Hyun S. Kim, MD, Venkataramu Krishnamurthy, MD, Christy E. Lee, MSN, APRN-BC, CRN, Ashish Mahajan, MD, Patrick C. Malloy, MD, Gloria M. Salazar, MD, J. Kevin McGraw, MD, Donald L. Miller, MD, Philip M. Meyers, MD, Robert B. Osnis, MD, Charles A. Owens, MD, Darren Postoak, MD, Uei Pua, MD, Anne C. Roberts, MD, Steven C. Rose, MD, Nael Saad, MD, Tarun Sabharwal, MD, Marc R. Sapoval, MD, PhD, Cindy Kaiser Saiter, NP, Marc S. Schwartzberg, MD, Samir S. Shah, MD, Nasir H. Siddiqi, MD, Tony P. Smith, MD, Constantinos T. Sofocleous, MD, PhD, James R. Stone, MD, PhD, Rajeev Suri, MD, Timothy L. Swan, MD, Raymond H. Thornton, MD Patricia E. Thorpe, MD, Richard Towbin, MD, Aradhana Venkatesan, MD, Joan C. Wojak, MD, Curtis A. Lewis, MD, MBA, JD, and David Sacks, MD.

REFERENCES

1. Hoffer EK, Bloch RD. Percutaneous arterial closure devices. *J Vasc Interv Radiol* 2003; 14:865–885.
2. Patel MR, Jneid H, Derdeyn CP, et al. Arteriotomy closure devices for cardiovascular procedures: a scientific statement from the American Heart Association. *Circulation* 2010; 122:1882–1893.
3. Wong SC, Bachinsky W, Cambier P, et al. A randomized comparison of a novel bioabsorbable vascular closure device versus manual compression in the achievement of hemostasis after percutaneous femoral procedures: the ECLIPSE (Ensure's Vascular Closure Device Speeds Hemostasis Trial). *JACC Cardiovasc Interv* 2009; 2:785–793.
4. Fortes MC, Jindal G, Polifka AJ, et al. Low-angle vascular access for neurovascular procedures using the Arstasis AXERA access device. *J Vasc Interv Radiol* 2013; 24:693–697.
5. Nader RG, Garcia JC, Drushal K, Pesek T. Clinical evaluation of SyvekPatch in patients undergoing interventional, EPS and diagnostic cardiac catheterization procedures. *J Invas Cardiol* 2002; 14:305–307.
6. Nguyen N, Hasan S, Caufield L, Ling FS, Narins CR. Randomized controlled trial of topical hemostasis pad use for achieving vascular hemostasis following percutaneous coronary intervention. *Cathet Cardiovasc Interv* 2007; 69:801–807.
7. Hallak OK, Cubeddu RJ, Griffith RA, Reyes BJ. The use of the D-STAT dry bandage for the control of vascular access site bleeding: a multicenter experience in 376 patients. *Cardiovasc Intervent Radiol* 2007; 30:593–600.
8. Applegate RJ, Sacrinty MT, Kutcher MA, et al. Propensity score analysis of vascular complications after diagnostic cardiac catheterization and percutaneous coronary intervention using thrombin hemostatic patch-facilitated manual compression. *J Invas Cardiol* 2007; 19:164–170.
9. Rastan A, Sixt S, Schwarzwälder U, et al. VIPER-2: a prospective, randomized single-center comparison of 2 different closure devices with a hemostatic wound dressing for closure of femoral artery access sites. *J Endovasc Ther* 2008; 15:83–90.
10. Dauerman HL, Applegate RJ, Cohen DJ. Vascular closure devices: the second decade. *J Am Coll Cardiol* 2007; 50:1617–1626.
11. Kussmaul WG, Buchbinder M, Whitlow PL, et al. Rapid arterial hemostasis and decreased access site complications after cardiac catheterization and angioplasty: results of a randomized trial of a novel hemostatic device. *J Am Coll Cardiol* 1995; 25:1685–1692.
12. Chevalier B, Lancelin B, Koning R, et al. Effect of a closure device on complication rates in high-local-risk patients: results of a randomized multicenter trial. *Cathet Cardiovasc Interv* 2003; 58:285–291.
13. Duffin DC, Muhlestein JB, Allison SB, et al. Femoral arterial puncture management after percutaneous coronary procedures: a comparison of clinical outcomes and patient satisfaction between manual compression and two different vascular closure devices. *J Invas Cardiol* 2001; 13:354–362.
14. Kapadia SR, Raymond R, Knopf W, et al. The 6Fr Angio-Seal arterial closure device: results from a multimember prospective registry. *Am J Cardiol* 2001; 87:789–791, A8.
15. Applegate RJ, Grabarczyk MA, Little WC, et al. Vascular closure devices in patients treated with anticoagulation and IIb/IIIa receptor inhibitors during percutaneous revascularization. *J Am Coll Cardiol* 2002; 40:78–83.
16. Cremonesi A, Castriota F, Tarantino F, et al. Femoral arterial hemostasis using the angio-seal system after coronary and vascular percutaneous angioplasty and stenting. *J Invas Cardiol* 1998; 10:464–469.
17. Gerckens U, Cattelaens N, Lampe EG, Grube E. Management of arterial puncture site after catheterization procedures: evaluating a suture-mediated closure device. *Am J Cardiol* 1999; 83:1658–1663.
18. Scheinert D, Sievert H, Turco MA, et al. The safety and efficacy of an extravascular, water-soluble sealant for vascular closure: initial clinical results for Mynx. *Cathet Cardiovasc Interv* 2007; 70:627–633.
19. Islam MA, George AK, Norris M. Popliteal artery embolization with the Mynx closure device. *Cathet Cardiovasc Interv* 2010; 75:35–37.
20. Fields JD, Liu KC, Lee DS, et al. Femoral artery complications associated with the Mynx closure device. *AJNR Am J Neuroradiol* 2010; 31:1737–1740.
21. Fargen KM, Velat GJ, Lawson MF, et al. Occurrence of angiographic femoral artery complications after vascular closure with Mynx and AngioSeal. *J Neurointerv Surg* 2013; 5:161–164.
22. Boschewitz JM, Andersson M, Naehle CP, et al. Retrospective evaluation of safety and effectiveness of the EXOSEAL vascular closure device for single vascular closure and closure after repeat puncture in diagnostic and interventional radiology: single-center experience. *J Vasc Interv Radiol* 2013; 24:698–702.
23. Baim DS, Knopf WD, Hinohara T, et al. Suture-mediated closure of the femoral access site after cardiac catheterization: results of the suture to ambulate and discharge (STAND I and STAND II) trials. *Am J Cardiol* 2000; 85:864–869.
24. Noguchi T, Miyazaki S, Yasuda S, et al. A randomised controlled trial of Prostar Plus for haemostasis in patients after coronary angioplasty. *Eur J Vasc Endovasc Surg* 2000; 19:451–455.
25. Wetter DR, Rickli H, Smekal von A, Amann FW. Early sheath removal after coronary artery interventions with use of a suture-mediated closure device: clinical outcome and results of Doppler US evaluation. *J Vasc Interv Radiol* 2000; 11:1033–1037.
26. Rickli H, Unterweger M, Sütsch G, et al. Comparison of costs and safety of a suture-mediated closure device with conventional manual compression after coronary artery interventions. *Cathet Cardiovasc Interv* 2002; 57:297–302.
27. Nasu K, Tsuchikane E, Sumitsuiji S, PARADISE Investigators. Clinical effectiveness of the Prostar XL suture-mediated percutaneous vascular

- closure device following PCI: results of the Perclose AceleRated Ambulation and DISChargE (PARADISE) Trial. *J Invas Cardiol* 2003; 15: 251–256.
28. Fram DB, Giri S, Jamil G, et al. Suture closure of the femoral arteriotomy following invasive cardiac procedures: a detailed analysis of efficacy, complications, and the impact of early ambulation in 1,200 consecutive, unselected cases. *Cathet Cardiovasc Interv* 2001; 53: 163–173.
 29. Smith TP, Cruz CP, Moursi MM, Eidt JF. Infectious complications resulting from use of hemostatic puncture closure devices. *Am J Surg* 2001; 182:658–662.
 30. Balzer JO, Scheinert D, Diebold T, et al. Postinterventional transcatheter suture of femoral artery access sites in patients with peripheral arterial occlusive disease: a study of 930 patients. *Cathet Cardiovasc Interv* 2001; 53:174–181.
 31. Hermiller J, Simonton C, Hinohara T, et al. Clinical experience with a circumferential clip-based vascular closure device in diagnostic catheterization. *J Invas Cardiol* 2005; 17:504–510.
 32. Hermiller JB, Simonton C, Hinohara T, et al. The StarClose Vascular Closure System: interventional results from the CLIP study. *Cathet Cardiovasc Interv* 2006; 68:677–683.
 33. Stock U, Flach P, Gross M, et al. Intravascular misplacement of an extravascular closure system: StarClose. *J Interv Cardiol* 2006; 19: 170–172.
 34. Doyle BJ, Godfrey MJ, Lennon RJ, et al. Initial experience with the Cardiva Boomerang vascular closure device in diagnostic catheterization. *Cathet Cardiovasc Interv* 2007; 69:203–208.
 35. Sridhar K, Fischman D, Goldberg S, et al. Peripheral vascular complications after intracoronary stent placement: prevention by use of a pneumatic vascular compression device. *Cathet Cardiovasc Diagn* 1996; 39:224–229.
 36. Jaspers L, Benit E. Immediate sheath removal after PCI using a FemoStop is feasible and safe. Results of a registry. *Acta Cardiol* 2003; 58:535–537.
 37. Walker SB, Cleary S, Higgins M. Comparison of the FemoStop device and manual pressure in reducing groin puncture site complications following coronary angioplasty and coronary stent placement. *Int J Nurs Pract* 2001; 7:366–375.
 38. Applegate RJ, Rankin KM, Little WC, Kahl FR, Kutcher MA. Restick following initial AngioSeal use. *Cathet Cardiovasc Interv* 2003; 58: 181–184.
 39. Hoch von F, Neumann FJ, Theiss W, Kastrati A, Schömig A. Efficacy and safety of collagen implants for haemostasis of the vascular access site after coronary balloon angioplasty and coronary stent implantation. A randomized study. *Eur Heart J* 1995; 16:640–646.
 40. Nikolsky E, Mehran R, Halkin A, et al. Vascular complications associated with arteriotomy closure devices in patients undergoing percutaneous coronary procedures: a meta-analysis. *J Am Coll Cardiol* 2004; 44: 1200–1209.
 41. Vaitkus PT. A meta-analysis of percutaneous vascular closure devices after diagnostic catheterization and percutaneous coronary intervention. *J Invas Cardiol* 2004; 16:243–246.
 42. Eggebrecht H, Naber C, Woertgen U, et al. Percutaneous suture-mediated closure of femoral access sites deployed through the procedure sheath: initial clinical experience with a novel vascular closure device. *Cathet Cardiovasc Interv* 2003; 58:313–321.
 43. Bechara CF, Annambhotla S, Lin PH. Access site management with vascular closure devices for percutaneous transarterial procedures. *J Vasc Surg* 2010; 52:1682–1696.
 44. Hon LQ, Ganeshan A, Thomas SM, et al. An overview of vascular closure devices: what every radiologist should know. *Eur J Radiol* 2010; 73:181–190.
 45. Hirsch JA, Reddy SA, Capasso WE, Linfante I. Non-invasive hemostatic closure devices: “patches and pads”. *Tech Vasc Interv Radiol* 2003; 6: 92–95.
 46. Amin FR, Yousufuddin M, Stables R, et al. Femoral haemostasis after transcatheter therapeutic intervention: a prospective randomised study of the angio-seal device vs. the Femostop device. *Int J Cardiol* 2000; 76: 235–240.
 47. Eidt JF, Habibipour S, Saucedo JF, et al. Surgical complications from hemostatic puncture closure devices. *Am J Surg* 1999; 178:511–516.
 48. Ward SR, Casale P, Raymond R, Kussmaul WG, Simpfordorfer C. Efficacy and safety of a hemostatic puncture closure device with early ambulation after coronary angiography. *Angio-Seal Investigators. Am J Cardiol* 1998; 81:569–572.
 49. Cura FA, Kapadia SR, L’Allier PL, et al. Safety of femoral closure devices after percutaneous coronary interventions in the era of glycoprotein IIb/IIIa platelet blockade. *Am J Cardiol* 2000; 86:780–782, A9.
 50. Carey D, Martin JR, Moore CA, Valentine MC, Nygaard TW. Complications of femoral artery closure devices. *Cathet Cardiovasc Interv* 2001; 52:3–7.
 51. Adusumilli S, Mah J, Richardson A. Acute leg ischemia secondary to embolization of an Angio-Seal device. *Diagn Interv Radiol* 2011; 17: 98–100.
 52. Johnson DT, Durack JC, Fidelman N, Kerlan RK, Laberge JM. Distribution of reported StarClose SE vascular closure device complications in the manufacturer and user facility device experience database. *J Vasc Interv Radiol* 2013; 24:1051–1056.
 53. Tavis DR, Gallaresi BA, Lin B, et al. Risk of local adverse events following cardiac catheterization by hemostasis device use and gender. *J Invas Cardiol* 2004; 16:459–464.
 54. Tavis DR, Dey S, Albrecht-Gallaresi B, et al. Risk of local adverse events following cardiac catheterization by hemostasis device use - phase II. *J Invas Cardiol* 2005; 17:644–650.
 55. Koreny M, Riedmüller E, Nikfardjam M, Siostrzonek P, Müllner M. Arterial puncture closing devices compared with standard manual compression after cardiac catheterization: systematic review and meta-analysis. *JAMA* 2004; 291:350–357.
 56. Biancari F, D’Andrea V, Di Marco C, et al. Meta-analysis of randomized trials on the efficacy of vascular closure devices after diagnostic angiography and angioplasty. *Am Heart J* 2010; 159:518–531.
 57. Beyer-Enke SA, Söldner J, Zeitler E. Immediate sealing of arterial puncture site following femoropopliteal angioplasty: a prospective randomized trial. *Cardiovasc Intervent Radiol* 1996; 19:406–410.
 58. Upponi SS, Ganeshan AG, Warakaulle DR, et al. AngioSeal versus manual compression for haemostasis following peripheral vascular diagnostic and interventional procedures—a randomized controlled trial. *Eur J Radiol* 2007; 61:332–334.
 59. Imam A, Carter RMS, Phillips-Hughes J, Boardman P, Uberoi R. StarClose vascular closure device: prospective study on 222 deployments in an interventional radiology practice. *Cardiovasc Intervent Radiol* 2007; 30: 738–742.
 60. Das R, Ahmed K, Athanasiou T, Morgan RA, Belli AM. Arterial closure devices versus manual compression for femoral haemostasis in interventional radiological procedures: a systematic review and meta-analysis. *Cardiovasc Intervent Radiol* 2011; 34:723–738.
 61. Reekers JA, Müller-Hülsbeck S, Libicher M, et al. CIRSE vascular closure device registry. *Cardiovasc Intervent Radiol* 2011; 34:50–53.
 62. Haulon S, Hassen Khodja R, Proudfoot CW, Samuels E. A systematic literature review of the efficacy and safety of the Prostar XL device for the closure of large femoral arterial access sites in patients undergoing percutaneous endovascular aortic procedures. *Eur J Vasc Endovasc Surg* 2011; 41:201–213.
 63. Korngold EC, Inglessis I, Garasic JM. A novel technique for 14 French arteriotomy closure after percutaneous aortic valvuloplasty using two Mynx closure devices. *J Interv Cardiol* 2009; 22:179–183.
 64. Lee WA, Brown MP, Nelson PR, Huber TS, Seeger JM. Midterm outcomes of femoral arteries after percutaneous endovascular aortic repair using the preclose technique. *J Vasc Surg* 2008; 47:919–923.
 65. Lee WA, Brown MP, Nelson PR, Huber TS. Total percutaneous access for endovascular aortic aneurysm repair (“Preclose” technique). *J Vasc Surg* 2007; 45:1095–1101.
 66. Jean-Baptiste E, Hassen Khodja R, Haudebourg P, et al. Percutaneous closure devices for endovascular repair of infrarenal abdominal aortic aneurysms: a prospective, non-randomized comparative study. *Eur J Vasc Endovasc Surg* 2008; 35:422–428.
 67. Ratnam LA, Raja J, Munneke GJ, Morgan RA, Belli AM. Prospective nonrandomized trial of manual compression and Angio-Seal and Starclose arterial closure devices in common femoral punctures. *Cardiovasc Intervent Radiol* 2007; 30:182–188.
 68. Lupattelli T, Clerissi J, Clerici G, et al. The efficacy and safety of closure of brachial access using the AngioSeal closure device: experience with 161 interventions in diabetic patients with critical limb ischemia. *J Vasc Surg* 2008; 47:782–788.
 69. Belenky A, Aranovich D, Greif F, et al. Use of a collagen-based device for closure of low brachial artery punctures. *Cardiovasc Intervent Radiol* 2007; 30:273–275.
 70. Cirillo P, Petrillo G, D’Ascoli GL, Piscione F, Chiariello M. Successful use of the Cardiva Boomerang™ vascular closure device to close a

- brachial artery puncture site after emergency PTCA. *Heart Vessels* 2010; 25:565–568.
71. Yap FY, Alaraj AM, Gaba RC. Inadvertent subclavian arteriotomy closure using the Mynx vascular closure device. *J Vasc Interv Radiol* 2012; 23:1253–1255.
 72. Carere RG, Webb JG, Miyagishima R, et al. Groin complications associated with collagen plug closure of femoral arterial puncture sites in anticoagulated patients. *Cathet Cardiovasc Diagn* 1998; 43:124–129.
 73. Slaughter PM, Chetty R, Flintoft VF, et al. A single center randomized trial assessing use of a vascular hemostasis device vs. conventional manual compression following PTCA: what are the potential resource savings? *Cathet Cardiovasc Diagn* 1995; 34:210–214.
 74. Ozawa A, Chaturvedi R, Lee KJ, Benson L. Femoral vein hemostasis in children using a suture-mediated closure device. *J Interv Cardiol* 2007; 20:164–167.
 75. Sanborn TA, Ebrahimi R, Manoukian SV, et al. Impact of femoral vascular closure devices and antithrombotic therapy on access site bleeding in acute coronary syndromes: The Acute Catheterization and Urgent Intervention Triage Strategy (ACUITY) trial. *Circ Cardiovasc Interv* 2010; 3:57–62.
 76. Smilowitz NR, Kirtane AJ, Guiry M, et al. Practices and complications of vascular closure devices and manual compression in patients undergoing elective transfemoral coronary procedures. *Am J Cardiol* 2012; 110:177–182.
 77. Arora N, Matheny ME, Sepke C, Resnic FS. A propensity analysis of the risk of vascular complications after cardiac catheterization procedures with the use of vascular closure devices. *Am Heart J* 2007; 153:606–611.
 78. McDonald JS, Kallmes DF, Lanzino G, Cloft HJ. Percutaneous closure devices do not reduce the risk of major access site complications in patients undergoing elective carotid stent placement. *J Vasc Interv Radiol* 2013; 24:1057–1062.
 79. Sohail MR, Khan AH, Holmes DR, et al. Infectious complications of percutaneous vascular closure devices. *Mayo Clin Proc* 2005; 80:1011–1015.
 80. Minko P, Katoh M, Gräber S, Buecker A. Obesity: an independent risk factor for insufficient hemostasis using the AngioSeal vascular closure device after antegrade puncture. *Cardiovasc Intervent Radiol* 2012; 35:775–778.
 81. Dangas G, Mehran R, Kokolis S, et al. Vascular complications after percutaneous coronary interventions following hemostasis with manual compression versus arteriotomy closure devices. *J Am Coll Cardiol* 2001; 38:638–641.

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

APPENDIX B: 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 (≤ 23 h) for observation only.

Major Complications

- C. Require therapy, minor hospitalization (≥ 24 h but < 48 h)
- D. Require major therapy, unplanned increase in level of care, prolonged hospitalization (> 48 h).
- E. Cause permanent adverse sequelae
- F. Result in death.

SIR DISCLAIMER

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.