AHA Scientific Statement

Arteriotomy Closure Devices for Cardiovascular Procedures
A Scientific Statement From the American Heart Association

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Arterial puncture and sheath insertion by use of the modified Seldinger technique has become the standard method by which invasive cardiovascular procedures are performed.[1] With improvement in techniques and devices, a significant number of patients with atherosclerotic disease are undergoing invasive vascular procedures. Approximately 7 million invasive cardiovascular procedures are performed worldwide each year, and this number is expected to increase with the aging of the population. The vast majority of these procedures are performed with femoral arterial access. Because the number of cardiovascular procedures performed via the femoral artery approach continues to increase, effective arterial hemostasis techniques are essential to high-quality patient care. In fact, vascular access complications, reported to be as high as 6% in some series, remain the leading cause of morbidity after a cardiac catheterization procedure.[2]

Manual compression has been considered the traditional technique to achieve closure of the arteriotomy site, requiring close observation and immobilization for success. Arteriotomy closure devices (ACDs) were introduced in 1995 to decrease vascular complications and reduce the time to hemostasis and ambulation. Subsequently, several generations of passive and active ACDs have been introduced that incorporate suture, collagen plug, nitinol clip, and other mechanisms to achieve hemostasis. According to a new Life Science Intelligence report entitled "2008 Global Vascular Closure Device Markets: US, Europe, Rest of World," the global market for vascular closure devices will reach nearly $1 billion in 2013.[3] Despite this widespread use of both passive and active ACDs, there are incomplete data on their safety and efficacy. Additionally, there are few published recommendations regarding the indications for the use of these devices, their comparative effectiveness versus manual compression, and the end points of clinical interest for patients undergoing vascular closure.

Therefore, the present scientific statement provides an overview of vascular access and patient risk for vascular complications, the available evidence for ACDs, recommendations for their use based on the available evidence, and the trials and end points needed to inform future clinical practice.

Choice of Site and Arterial Access

To perform both diagnostic and interventional percutaneous cardiovascular procedures, arterial access is usually obtained at the common femoral or radial artery. There has been significant recent interest in the use of the transradial approach for cardiac catheterization and endovascular interventions in the United States, a practice that is standard in many other countries. A recent meta-analysis has reported a significant reduction in bleeding complications with the use of the transradial approach.[4] These patients do not have ACDs deployed and likely have a reduction in bleeding, in part because of the relative ease of radial site compression and possibly the use of smaller-caliber devices with the radial approach. Although randomized data exist linking access site and vascular complications, the majority of procedures are performed from locations that are based on the operator's
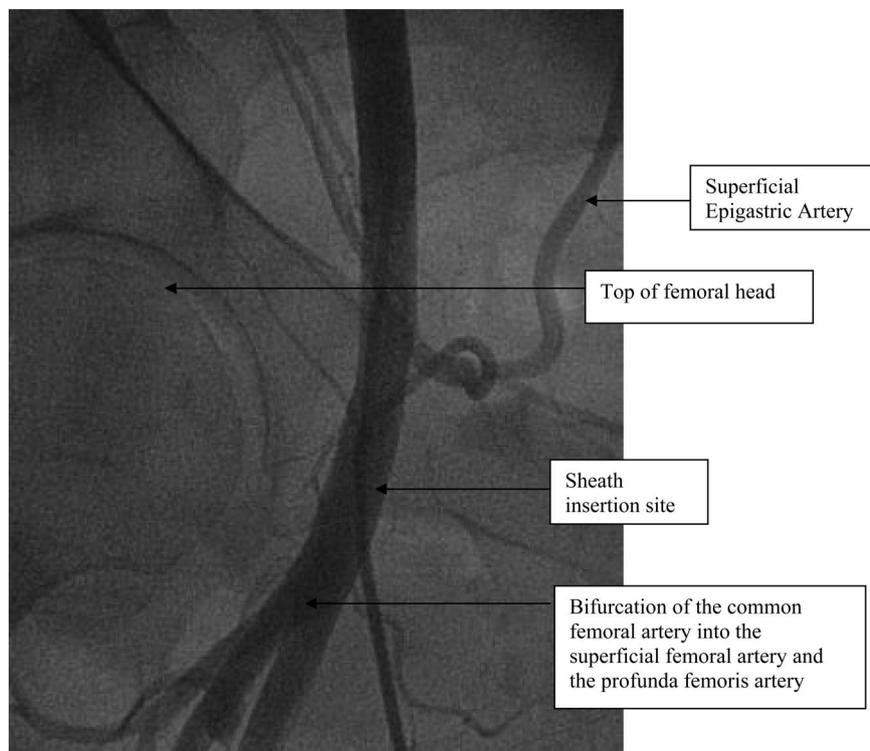
(*Circulation*. 2010;122:00-00.)

Figure. Femoral angiogram.

experience and comfort level.[5] Of note, a recent review of the American College of Cardiology's National Cardiovascular Data Registry (ACC-NCDR) found that fewer than 2% of all cardiac catheterization procedures are performed from the radial site,[6] which indicates that the common femoral artery remains the most common arterial access site for invasive cardiovascular procedures in the United States.

Proper techniques regarding identification, puncture, and location of sheath insertion into the common femoral artery are important predictors for the occurrence of access-site complications.[7] Most studies of ACDs excluded patients with sheath insertion at arterial sites deemed unsuitable, either "too low" (below the bifurcation of the common femoral into the profunda femoris and superficial femoral artery) or "too high" (above the superior ramus of the pubis and thus noncompressible; Figure).[7] In clinical practice, the arterial puncture site is usually verified by use of a femoral angiogram. Therefore, the importance of operator experience and meticulous technique cannot be overemphasized.

Femoral Access Complications With Manual Compression

Although complications of vascular access are an inevitable part of the practice of interventional cardiology, patients' morbidity and mortality can be minimized by anticipation of these potential complications, as well as by their prompt diagnosis and management. In 1 series, diagnostic cardiac catheterization was associated with an overall 3.4% rate of serious vascular complications.[8] The rate of noncoronary vascular complications after interventional catheter-based procedures varies from 2% to 6% (Table 1).[11] Vascular complications increase with the complexity of the procedure and with the intensity of anticoagulation and antiplatelet

therapy (Table 2). A meta-analysis of more than 35 000 patients identified an overall vascular complication rate of 3.3% for femoral artery access with manual compression for hemostasis.[13] A multicenter registry of more than 18 000 patients undergoing percutaneous coronary intervention (PCI) also reported a 3% vascular complication rate. The strongest multivariate predictors of vascular complications during PCIs were age ≥70 years, female sex, body surface area <1.6 m², renal failure or creatinine >2 mg/dL, emergent procedures, and the periprocedural use of glycoprotein IIb/IIIa inhibitors.[12]

In an attempt to reduce some of these potential complications, ACDs have been developed as adjuncts or alternatives to manual compression for hemostasis. The other potential benefits of ACDs include improved patient comfort and satisfaction, faster hemostasis, shorter time to ambulation, and shorter duration of observation. However, ACDs also introduce the possibility of unique vascular complications that require highly specialized clinical care. Severe groin infections have been described that

Table 1.   Femoral Access Complication Rates[9]

Complication Type	Rate, %
Diagnostic cardiac catheterization (SCA&I Registry 1990)*: vascular complications	0.40
Interventional coronary procedures	
Femoral-access hematoma (>6 cm)	5–23
Retroperitoneal hematoma	0.15–0.44
Pseudoaneurysm	0.5–6.3
Arteriovenous fistulae	0.2–2.1
Infection	<0.1

SCA&I indicates Society for Cardiac Angiography and Interventions.
*Pepine et al.[10]

Table 2. Predictors of Increased Vascular Complications During PCIs[12]

Increasing age
Among women
In smaller individuals
History of CABG, congestive heart failure, a bleeding disorder (hemophilia, thrombocytopenia, or disseminated intravascular coagulation), stroke, PAD, diabetes, chronic obstructive pulmonary disease, renal failure or a creatinine ≥2 mg/dL, liver failure, immunosuppression
Higher patient acuity (procedural priority and indication)
Greater number of diseased coronary vessels
Higher lesion complexity
Multilesion interventions were associated with a higher incidence of vascular complications
Use of an intra-aortic balloon pump (before or during the procedure)
Preprocedure use of thienopyridines
Anti-GP IIb/ IIIa agents

CABG indicates coronary artery bypass graft; PAD, peripheral artery disease; and GP, glycoprotein.

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often present with unusual manifestations and time frames. Embolization of devices and collagen material requires rapid recognition and urgent therapy. Although low in frequency, the severity of these events relative to the indications for the use of ACDs must be considered in each individual case. Therefore, to understand the evidence and clinical utility of ACDs, patients' risk for vascular complications and clinical indications for deployment must be defined clearly. The writing group proposed the following categories of risk for vascular complications when generating evidence for future development of ACDs.

Patient Risk for Vascular Complications

Low Risk: Diagnostic Angiographic Procedures (<1% Complication Rate)

Patients undergoing diagnostic cardiac catheterization and/or peripheral angiography without intervention should be considered at low risk for vascular complications. As noted, patient characteristics associated with fewer vascular complications include male sex, younger age, normal renal function, and increased body size. These procedures are often elective and characterized by the use of a smaller sheath size (5F), shorter overall procedural time, and little or no concomitant anticoagulation. The expected rate of all vascular complications in this group undergoing diagnostic-only procedures has been reported to be <1%, with registry data noting the rate to be near 0.4% to 0.7%.[14] Given this low event rate in patients undergoing diagnostic-only procedures, large sample sizes are required to determine the noninferiority or superiority of ACD technology for reducing vascular complications in this group. Traditionally, other end points such as time to ambulation and cost-effectiveness have been used by studies in this group of patients, without clear documentation of the certainty concerning the safety findings.

Moderate Risk: Routine Percutaneous Intervention (1% to 3% Complication Rate)

Patient populations undergoing routine percutaneous coronary or peripheral intervention with their associated anticoagulation regimens should be considered at moderate risk for developing vascular complications. These patients with moderate risk are likely to be older, are more often female, and may have evidence of renal dysfunction. The procedure is generally notable for increased sheath sizes (6F to 7F), procedure time that may be prolonged compared with diagnostic procedures, and the use of adjunctive anticoagulants and antithrombotic regimens.[15] Recent clinical trial and registry data would suggest the rate of significant vascular complications in patients undergoing percutaneous intervention ranges between 1% and 3%.[16,17] Standardized definitions for major vascular complications have not been applied routinely across studies evaluating ACDs.

High Risk (>3% Complication Rate)

Patient-specific features and/or certain clinical indications can help identify the group considered at high risk for vascular complications. Patients at the highest risk for vascular complications include but are not limited to those with known peripheral arterial disease, advanced age, female sex, liver disease, coagulopathy, immunosuppression, status after valve replacement, and renal dysfunction. High-risk clinical indications include emergent procedures such as primary percutaneous intervention for acute myocardial infarction, prolonged multivessel intervention, or procedures that require larger sheath sizes (eg, $\geq8F$). The major vascular complication rate in these patients was observed in clinical trials[18] and registries[12,19] to be $\geq3\%$.

Additionally, an emerging clinical indication for ACDs is their preclosure use during endovascular procedures with very large sheath insertion (ie, 12F to 15F) for percutaneous ventricular assist devices, such as TandemHeart and Impella,[20] and >20F for endovascular valve procedures, such as aortic repair.[21,22] The majority of these initial descriptions involve the use of 2 to 3 suture-mediated ACDs deployed at the start of the procedure with closure at the end. Use of this "preclose" technique has also been described for large sheath insertion associated with endovascular abdominal aortic aneurysm repair.[23] Recently, multiple device deployment of extravascular water-soluble sealant with the Mynx device (AccessClosure, Inc, Mountain View, Calif) for large sheath closure has also been reported.[24] The use of ACDs with these large sheaths requires careful evaluation, because the anticipated vascular complication rates are likely much higher in this patient cohort both with device use and with standard management.

Hence, there is a significant gradient in the risk for vascular complications based on both patient risk factors and procedural factors. Ideally, the clinical indication and population risk should be identified clearly in clinical studies so that future practice may be informed directly. This clinical risk with routine care must then be compared with the risk of deployment of the proposed ACD in prospective clinical trials with agreed-on clinical end points.

Table 3.   Arteriotomy Closure Devices

	Mechanism	Clinical Trial Data	Evidence Limitations	References
Active ACDs				
AngioSeal	Collagen plug	Multiple RCTs and observational studies	Underpowered for rare vascular events	25–28
Perclose	Suture	Multiple RCTs and observational studies	Underpowered for rare vascular events	29–35
StarClose	Extravascular clip	Randomized trial	Lacking evaluation in broad range of patients	17,36–38
Passive-closure devices				
FemoStop	Mechanical compression	Largest RCT N=212, no benefit	Mostly observational, few RCTs	39–42
Boomerang	Assisted compression	Single-arm cohort studies	No PCI patients, no controls	43
SafeGuard	Compression patch	Observational reports	No comparisons	
Mynx	Water-soluble sealant	Single-arm study	No control group	44
Clo-Sur PAD	Procoagulant patch	RCT with manual compression	Limited patient types/indications	45
Syvek NT patch	Procoagulant patch	Observational study	No control group	46
D-Stat	Hemostatic patch	RCT vs manual RCT vs AngioSeal/Perclose	Mostly diagnostic patients, observational data with PCI, RCT vs active closure	47–49
Chito-Seal	Procoagulant patch	RCT with manual compression	Limited patient types/indications	48

RCTs indicates randomized controlled trials.

Closure Devices

In general, ACDs can be categorized as either passive-closure devices (including devices that help with compression, such as clamps/tamping devices, assisted or enhanced coagulation, and sealants) or active-closure devices (including immediate closure with suture devices, clips, and collagen plug devices; Table 3). These ACDs may have a gradient of risk for vascular complications based on their respective mechanisms of action. Although small studies have identified differing rates of vascular complications for specific devices, there are no definitive data across a wide spectrum of patients.

The existing evidence in the literature emanates largely from small and moderate-sized clinical trials (100 to 650 patients) that compared ACDs with manual compression, which has historically been considered the "gold standard." Many of these studies were single-center trials that enrolled predominantly low- and medium-risk patients. These studies were likely underpowered to detect differences in the rates of infrequent vascular complications. Other studies lacked defined allocation concealment, blinded outcome assessment, or intention-to-treat analyses. Finally, standardized definitions of what constitutes a vascular complication or an effective outcome of ACDs are lacking. To overcome the limitations of the existing medical literature on ACDs, invasive cardiologists have increasingly resorted to data from large registries and meta-analyses, which are outlined below. When possible, the clinical indications or population risk will be identified from the clinical studies. This review of relevant recent literature is used to provide a basis for recommendations and future studies of ACDs.

Evidence From the Medical Literature on ACDs

Randomized Clinical Studies in Active-Closure Devices

Collagen-Mediated Devices

The Vasoseal device (Datascope Corp, Montvale, NJ) was one of the first ACDs developed. It was originally studied in a cohort of 100 patients undergoing diagnostic or interventional catheterization procedures and randomized to the device or to conventional pressure dressing.[50] Use of the Vasoseal resulted in a shorter compression time (4 versus 42 minutes, P<0.001) and faster ambulation (6 versus 22 hours, P<0.001) and demonstrated a trend toward a reduction in bleeding rates.[50–52] The efficacy of the Vasoseal was subsequently confirmed in other randomized studies,[53,54] although other trials showed small increases in access-site complications or failed to demonstrate superiority over mechanical compression during PCI.[52,55,56] This device is no longer marketed because of findings from subsequent observational studies.

Angio-Seal (St Jude Medical, St Paul, Minn) is among the most widely used ACDs. One of its earliest and largest randomized studies was a multicenter trial of 435 patients undergoing cardiac catheterization and angioplasty procedures who were randomized (1:1) to the device or to manual compression.[25] Angio-Seal achieved faster hemostasis (2.5 versus 15.3 minutes, P<0.0001) and lower rates of bleeding, hematoma, or any complication.[25] A more contemporary randomized study was conducted by Chevalier and colleagues,[26] who enrolled 612 moderate- to high-risk patients undergoing PCI and demonstrated faster hemostasis (5 versus 52 minutes, P<0.001) and reduced bed-rest time (438 versus 952 minutes; P<0.001) and complication rates (6% versus 18%, P<0.001) with Angio-Seal.[26] Although these effects of Angio-Seal were confirmed by others,[27] some studies still favored mechanical compression with the FemoStop device (Radi Medical Systems, Inc, Wilmington, Mass) over Angio-Seal.[28]

Suture-Mediated Devices

Perclose (Abbott Vascular, Abbott Park, Ill) is the prototype of a suture-mediated ACD. One of its early studies, conducted by Gerckens et al,[29] randomized 600 patients to the device or to manual compression and demonstrated faster hemostasis (8 versus 13 minutes, P<0.0001) and ambulation

(5 versus 18 hours, $P<0.0001$) with Perclose use. In this particular study, Perclose was associated with rates of vascular complications comparable to those observed with manual compression in all patient populations but with lower rates in patients undergoing diagnostic procedures.[29] The safety and efficacy of Perclose were subsequently supported by the results of other randomized studies.[30–35]

Clip/Staple-Mediated Devices

The StarClose Vascular Closure System (Abbott Vascular) is the prototype of clip-mediated ACDs and uses a flexible nitinol clip to complete a circumferential, extravascular arteriotomy closing. Its pivotal study was the CLip closure In Percutaneous procedures (CLIP) study, a prospective, randomized (2:1) multicenter trial that compared its safety and efficacy with that of manual compression. A total of 596 subjects were enrolled, of whom 208 underwent diagnostic angiography only. In the latter population subset, no differences in the rates of major and minor vascular complications were observed between the 2 strategies.[36] StarClose also reduced the mean time to hemostasis (15.5 versus 1.5 minutes, $P<0.001$) and time to ambulation (269 to 163 minutes, $P<0.001$) and was deployed successfully in 94% of patients.[36] The CLIP study findings were subsequently confirmed in the interventional population subset (n=275), in which no differences in the rates of major vascular complications or infections and a trend toward a lower rate of minor complications were observed with StarClose.[17] An ultrasound substudy from CLIP confirmed these findings with the StarClose as well.[37] Both StarClose and Angio-Seal were recently found in a randomized trial of patients undergoing diagnostic and interventional procedures to have similar rates of hemostasis (69%), with some increased bruising with Angio-Seal.[38]

Evidence for Passive-Closure Devices

Passive-closure devices include devices such as clamps for assisted compression and newer technologies, such as assisted coagulant patches and sealants. Clinical studies examining these devices are also limited.

The FemoStop femoral compression system (RADI Medical Systems) has been studied primarily as part of the control arm for clinical studies on hemostasis after endovascular procedures.[28] Single-center observational studies[39,40] and a small randomized study[41] found similar or reduced rates of vascular complications with FemoStop compared with manual pressure in patients undergoing interventional procedures. In contrast, a recent randomized study of 212 patients found FemoStop use to have a higher rate of vascular complications than manual compression.[42]

The Boomerang assisted-compression system (Cardiva Medical, Inc, Mountain View, Calif) has been studied in 96 consecutive patients undergoing diagnostic cardiac catheterization, with successful deployment in 99% of patients without any major complications in the study cohort.[43] The D-Stat dry patch (Vascular Solutions, Minneapolis, Minn) was compared with manual compression in a multicenter randomized trial of 376 patients undergoing diagnostic or peripheral angiography.[47] Although time to ambulation was slightly shorter (392 versus

415 minutes, $P=0.02$), there were no differences in time to discharge or vascular complications. In a large, single-center observational study, a retrospective analysis found the D-Stat patch with facilitated manual compression to be associated with earlier time to ambulation and similar vascular complication rates as standard manual compression.[48] However, in a randomized trial (n=852) comparing D-Stat with Angio-Seal and Perclose in patients undergoing diagnostic or interventional procedures, the D-Stat was associated with a statistically higher rate of vascular complications than the active-closure devices (7.1% versus 1.9%, $P<0.0001$).[49]

Other patch and sealant systems have even fewer available data. The Mynx water-soluble sealant system was studied in a multicenter single-arm study of 190 consecutive patients undergoing diagnostic and interventional procedures (5F to 7F).[44] The device was found to have a major complication rate of 0.5% in this low- to intermediate-risk population. A randomized study using the procoagulant pads Chito-Seal (Abbott Vascular Devices) and the Clo-Sur (Medtronic Vascular, Santa Rosa, Calif) compared with manual compression for patients undergoing PCI found only a slightly reduced time to hemostasis with procoagulant pad use without an effect on overall bed-rest time or vascular complications.[45] The Syvek Patch (Marine Polymer Technologies, Inc, Danvers, Mass) has been examined in a single-center study of 1000 consecutive patients undergoing diagnostic and interventional catheterization and electrophysiological procedures, with minimal clinical complications.[46]

Overall, the evidence for passive-closure devices varies significantly across device types, with the majority of studies characterized as observational studies or small randomized controlled trials in limited-risk populations.

Registry Data

Given the limitations and somewhat conflicting safety data of the randomized studies, physicians have resorted to large registries and databases to confirm the efficacy and safety of ACDs and test them against manual compression and each other. Chamberlin and colleagues[57] compared Vasoseal, Perclose, and mechanical compression with FemoStop in a cohort of 185 patients undergoing PCI with periprocedural abciximab. In that small analysis, Vasoseal and Perclose showed comparable safety to FemoStop but achieved significantly lower initial rates of successful hemostasis (79% and 86% versus 100%, respectively).[57] Another retrospective, nonrandomized study of 827 ACDs (245 Angio-Seal and 582 suture-based) after PCI showed similar success and low and comparable vascular complication rates between the devices.[58] A larger retrospective analysis compared outcomes of 5892 uses of manual compression with 516 ACD uses (mostly Angio-Seal, n=371, and Techstar [suture-based], n=101) after diagnostic and PCI procedures.[18] This single-center experience demonstrated that the use of ACDs was associated with significantly more hematomas, a greater hematocrit drop, and a greater need for vascular surgical repair at the access site.[18] However, after multivariable analysis, age, body surface area, and sex, but not the use of ACDs, were independent predictors of vascular complications.[18] Duffin et al[59] compared Perclose and Angio-Seal with manual compression in 1500 patients and found Angio-Seal

Table 4.   Summary of the Major Meta-Analyses and Systematic Reviews for ACDs

Study	n	Device Types	End Points	Major Outcomes
Koreny et al[11]	4000	ACD (AngioSeal, Vasoseal, Duett, Perclose/Techstar/Prostar) vs manual compression	Efficacy plus vascular complications	Nonsignificant trends toward increased hematoma, bleeding, arteriovenous fistula, and pseudoaneurysm formation with ACDs Faster hemostasis with ACDs (mean difference 17 min, range 14–19 min)
Nikolsky et al[13]	37 066	ACD (AngioSeal, Vasoseal, Perclose) vs manual compression	Vascular complications	Overall OR for vascular complications 1.34, 95% CI 1.01–1.79 (ACDs vs manual compression) No differences in vascular complications between AngioSeal, Perclose, and manual compression Higher vascular complication rates with Vasoseal (OR 2.27, 95% CI 1.35–3.80 vs manual compression)
Vaitkus et al[61]	5045	ACD (AngioSeal, Vasoseal, Duett, Perclose) vs manual compression	Vascular complications	Significant reduction in overall rate of vascular complications with ACDs (OR 0.89, 95% CI 0.86–0.91) Increased risk of vascular complications with Vasoseal (OR 1.18; 95% CI 1.16–1.20)

use to be associated with faster hemostasis and ambulation than Perclose. Perclose use, on the other hand, was associated with more access-site complications than Angio-Seal and manual compression.[59] Another registry[19] of patients undergoing PCI with abciximab compared outcomes of 524 patients closed with Angio-Seal, 2177 patients with Perclose, and 1824 patients with manual compression. Hemostasis success was higher with Angio-Seal than with Perclose (97% versus 94%, $P<0.05$), no intergroup differences in vascular complications were observed, and overall complications were reduced among patients with successful ACD applications versus manual compression (1.5% versus 2.5%, $P<0.05$).[19] A smaller study[60] examined outcomes after unsuccessful deployment of ACDs in 285 consecutive patients undergoing PCI with glycoprotein IIb/IIIa inhibitor therapy. Manual compression was used in 123 patients, whereas Perclose and Angio-Seal were used in 123 and 39 patients, respectively. Angio-Seal was the only independent predictor for deployment failure and vascular complications, in contrast to manual compression and Perclose, which appeared to be safe and effective.[60]

The largest registry of data from the ACC-NCDR[8] compared the relative risks associated with the use of ACDs versus manual compression. This database included a total of 166 680 ACD uses during diagnostic and interventional cardiac procedures in 214 sites, of which 25 495 were suture-mediated ACDs, 28 160 were collagen-mediated ACDs, and the rest were manual compression. Tavris et al[8] demonstrated that the use of ACDs was associated with a lower risk of vascular complications in men than in women and after diagnostic versus PCI procedures. On multivariable analysis, ACD use was associated with lower risk of any vascular complication (adjusted odds ratio [OR] 0.83, 95% confidence interval [CI] 0.75 to 0.91). This was driven predominantly by lower rates of bleeding and pseudoaneurysm formation and was seen exclusively with diagnostic procedures.[8] Unfortunately, this analysis from ACC-NCDR did not capture access-site–related infections or neurological injury and was based solely on site-reported complications, which may be subject to underreporting and potential recall bias.

Overall, the nonrandomized observational registry data appeared to confirm the efficacy of ACDs but provided no definitive evidence as to their safety vis-à-vis manual compression nor of their safety and efficacy relative to each other.

Meta-Analyses and Systematic Reviews

Three meta-analyses have been published (Table 4). Koreny et al[11] pooled data from 30 randomized trials (including data published in abstract form) that enrolled 4000 patients to assess the efficacy and safety of ACDs compared with manual compression. Overall time to hemostasis was decreased by a mean of 17 minutes with ACDs; however, there were nonsignificant trends toward increased hematomas, bleeding, arteriovenous fistulas, and pseudoaneurysms with ACDs.[11] No significant interactions between the ACD or procedure type and outcomes were observed.[11]

Nikolsky and colleagues[13] examined the safety of ACDs versus manual compression in another meta-analysis of 30 studies that enrolled 37 066 patients. This meta-analysis favored mechanical compression over ACDs (OR 1.34, 95% CI 1.01 to 1.79) with respect to the overall rate of vascular complications; however, unlike what was observed with PCIs, there was a nonsignificant trend that favored ACDs over mechanical compression in patients undergoing diagnostic procedures. Importantly, when the analyses were stratified according to ACD type, significant heterogeneity was observed (Figure). Angio-Seal and Perclose devices were comparable to mechanical compression after diagnostic and interventional procedures; the Vasoseal, on the other hand, was associated with increased vascular complications compared with manual compression (OR 2.27, 95% CI 1.35 to 3.80), an effect observed predominantly in PCI patients (OR 2.52, 95% CI 1.36 to 4.65).

The third meta-analysis was conducted by Vaitkus et al,[61] who pooled data from 16 prospective randomized clinical trials that enrolled 5084 patients and demonstrated an overall reduction in vascular complications associated with ACD use (OR 0.89, 95% CI 0.86 to 0.91), especially with the Angio-Seal and Perclose devices. Vasoseal use, on the other hand, was associated with a significantly higher risk of vascular complications, although significant heterogeneity was observed among the Vasoseal studies. When the analysis was limited to PCI procedures only, a significant reduction in vascular complications was associated with Angio-Seal (OR 0.51, 95% CI 0.45 to 0.58), a

Table 5.   Applying Classification of Recommendations and Level of Evidence

	SIZE OF TREATMENT EFFECT →			
	CLASS I *Benefit >>> Risk* Procedure/Treatment **SHOULD** be performed/administered	**CLASS IIa** *Benefit >> Risk* *Additional studies with focused objectives needed* **IT IS REASONABLE** to perform procedure/administer treatment	**CLASS IIb** *Benefit ≥ Risk* *Additional studies with broad objectives needed; additional registry data would be helpful* Procedure/Treatment **MAY BE CONSIDERED**	**CLASS III** *Risk ≥ Benefit* Procedure/Treatment should **NOT** be performed/administered **SINCE IT IS NOT HELPFUL AND MAY BE HARMFUL**
LEVEL A Multiple populations evaluated* Data derived from multiple randomized clinical trials or meta-analyses	■ Recommendation that procedure or treatment is useful/effective ■ Sufficient evidence from multiple randomized trials or meta-analyses	■ Recommendation in favor of treatment or procedure being useful/effective ■ Some conflicting evidence from multiple randomized trials or meta-analyses	■ Recommendation's usefulness/efficacy less well established ■ Greater conflicting evidence from multiple randomized trials or meta-analyses	■ Recommendation that procedure or treatment is not useful/effective and may be harmful ■ Sufficient evidence from multiple randomized trials or meta-analyses
LEVEL B Limited populations evaluated* Data derived from a single randomized trial or nonrandomized studies	■ Recommendation that procedure or treatment is useful/effective ■ Evidence from single randomized trial or nonrandomized studies	■ Recommendation in favor of treatment or procedure being useful/effective ■ Some conflicting evidence from single randomized trial or nonrandomized studies	■ Recommendation's usefulness/efficacy less well established ■ Greater conflicting evidence from single randomized trial or nonrandomized studies	■ Recommendation that procedure or treatment is not useful/effective and may be harmful ■ Evidence from single randomized trial or nonrandomized studies
LEVEL C Very limited populations evaluated* Only consensus opinion of experts, case studies, or standard of care	■ Recommendation that procedure or treatment is useful/effective ■ Only expert opinion, case studies, or standard of care	■ Recommendation in favor of treatment or procedure being useful/effective ■ Only diverging expert opinion, case studies, or standard of care	■ Recommendation's usefulness/efficacy less well established ■ Only diverging expert opinion, case studies, or standard of care	■ Recommendation that procedure or treatment is not useful/effective and may be harmful ■ Only expert opinion, case studies, or standard of care
Suggested phrases for writing recommendations†	should is recommended is indicated is useful/effective/beneficial	is reasonable can be useful/effective/beneficial is probably recommended or indicated	may/might be considered may/might be reasonable usefulness/effectiveness is unknown/unclear/uncertain or not well established	is not recommended is not indicated should not is not useful/effective/beneficial may be harmful

ESTIMATE OF CERTAINTY (PRECISION) OF TREATMENT EFFECT

*Data available from clinical trials or registries about the usefulness/efficacy in different subpopulations, such as sex, age, history of diabetes, history of prior myocardial infarction, history of heart failure, and prior aspirin use. A recommendation with Level of Evidence B or C does not imply that the recommendation is weak. Many important clinical questions addressed in the guidelines do not lend themselves to clinical trials. Even though randomized trials are not available, there may be a very clear clinical consensus that a particular test or therapy is useful or effective.

†In 2003, the ACCF/AHA Task Force on Practice Guidelines developed a list of suggested phrases to use when writing recommendations. All guideline recommendations have been written in full sentences that express a complete thought, such that a recommendation, even if separated and presented apart from the rest of the document (including headings above sets of recommendations), would still convey the full intent of the recommendation. It is hoped that this will increase readers' comprehension of the guidelines and will allow queries at the individual recommendation level.

neutral effect with Perclose (OR 1.0, 95% CI 0.13 to 7.48), and an increased risk with Vasoseal (OR 1.18, 95% CI 1.16 to 1.20).

Overall, the results of the observational registry data and meta-analysis highlight the fact that devices may have different effects, and these clinical effects may not be easily identified in the small randomized trials conducted in populations that may be at lower risk than those in clinical use.

Recommendations Regarding ACD Use

The available literature is limited and characterized by small studies in select populations that are often underpowered to detect meaningful differences in clinical rates of vascular complications. The available evidence allows the following conclusions to be made regarding the consideration and deployment of arteriotomy closure devices. The writing group recommends the following (Table 5):

1. Patients considered for deployment of ACDs at the femoral artery site should undergo a femoral angiogram with identification of sheath-insertion site and other features (atherosclerosis, calcification, etc) to ensure anatomic suitability for their use (Class I; Level of Evidence C).
2. Facilities with standard manual compression regimens should aim to achieve the reported low vascular complication rates (<1%) in patients undergoing uncomplicated 5F diagnostic angiography (Class I; Level of Evidence C).
3. Use of ACDs is reasonable after invasive cardiovascular procedures performed via the femoral artery to achieve faster hemostasis, shorter duration of bed rest, and possibly improved patient comfort. The use of these devices should be weighed against the risk of increased complications in certain patient subsets and also take into account body habitus, location of arteriotomy, size

and condition of the parent vessel, sheath size, and presence or absence of systemic disease in the patient (Class IIa – Level of Evidence B). This recommendation is based on a meta-analysis and several small-scale trials; however, in these studies, there are trends toward higher rates of complications.

4. ACDs should not be used routinely for the specific purpose of reducing vascular complications in patients undergoing invasive cardiovascular procedures via the femoral artery approach (Class III, Level of Evidence B). This recommendation is based on the aggregate of 3 meta-analyses, registry data, and moderate-sized randomized controlled trials of suboptimal quality. There is significant heterogeneity among the reported effects of the different devices deployed. The writing committee did not believe there was sufficient evidence to warrant a separate recommendation at this time for specific ACDs or for active- versus passive-closure devices.

5. Data on complications encountered during or after deployment of ACDs should be collected systematically either as part of local quality efforts or national registries (such as the ACC-NCDR) and systematically reported to the Food and Drug Administration (Class I, Level of Evidence C).

Limitations of the Current Evidence in the Medical Literature

The recommendations above highlight the limitations of the available evidence, namely, variable and conflicting data for specific ACD use for many common clinical indications and scenarios. Important understudied indications for ACD use include moderate- and high-risk patients such as those undergoing acute myocardial infarction intervention, patients undergoing endovascular procedures for peripheral vascular disease, and patients undergoing neurovascular interventions with concomitant standard anticoagulation regimens. Additionally, few data are available regarding the recognition of unique ACD complications and their management. Furthermore, the safety and timing of repeated vascular access at a site previously closed with an ACD has not been evaluated systematically.

Despite the need for large, definitive, and well-designed comparative trials, such studies are difficult to conduct. The rapidly evolving ACDs are moving targets. Newer-generation ACDs are lower profile, have a simpler design, may be easier to use,[62] and appear to have fewer complications than their older-generation counterparts.[63] Manual compression has also been enhanced by the use of external patches with prothrombotic coatings,[46,48] through assisted compression with mechanical clamps and other advances. Adjunctive pharmacological therapy has also evolved rapidly, with weight-adjusted heparin, direct thrombin inhibitors, and triple-antiplatelet therapy being widely adopted during PCIs. New techniques and strategies have emerged as well, starting with the use of lower sheath size (6F and 5F), same-day discharge after PCI,[64] and the increased use of radial artery access. The aforementioned factors appear to rapidly change the landscape of ACDs and require updated, adequately powered, and well-designed clinical trials.

End Points for Studies With ACDs

The issue of appropriate end points for studies of ACDs continues to be controversial and poorly defined. Numerous

end points have been used in the various studies, including vascular complications; time to hemostasis, ambulation, or discharge; device success; cost-effectiveness; and many combinations of the above end points. Only a few studies have been randomized controlled trials between devices or versus manual compression. Additionally, the types and duration of manual compression varied markedly and were poorly defined. Furthermore, the nature of such studies prevents them from being truly blinded studies. Most have used investigator-reported complications to determine study end points, which compromises the objective adjudication of outcomes. Many studies have not incorporated follow-up clinical or ultrasound examinations. In addition, patients enrolled in these studies had differing anticoagulation regimens, with variable activated clotting time protocols, and had differing arterial sheath sizes, which makes comparisons between studies and devices even more problematic.

Three sources (a meta-analysis,[13] the CLIP study,[36] and the ACC-NCDR[8]) provide examples of potential end points for studies with arteriotomy closure. In a recent meta-analysis of vascular complications associated with ACDs, the end point of "major vascular complications" included pseudoaneurysm that required treatment, arteriovenous fistula, retroperitoneal hematoma (that caused hemodynamic compromise, specific intervention, prolonged hospitalization, or death), femoral artery thrombosis, surgical vascular repair, access-site infection that necessitated treatment, and blood transfusion.[36] Study end points of the recent CLIP study of the StarClose system included vascular injury that required surgical or interventional repair, new ipsilateral lower-extremity ischemia that required revascularization, access-site–related nerve injury that required intervention, access-site bleeding that required transfusion, and access-site infection that required intravenous antibiotics. Relevant data on vascular and bleeding complications collected by the ACC-NCDR include bleeding at the percutaneous entry site, retroperitoneal bleeding, access-site occlusion, peripheral embolization, pseudoaneurysm, and arteriovenous fistula (http://www.accncdr.com/WebNCDR/ELEMENTS.ASPX).

Acceptable vascular complication end points for clinical trials ideally should be developed in conjunction with the Food and Drug Administration before study initiation. Although simply adopting the end points currently collected by the very large ACC-NCDR database is operationally attractive, this large registry at present does not include 2 end points essential for the evaluation of new ACDs (access-site infection and access-site–related neurological injury). A sample of clinically relevant end points that incorporate many data points from the ACC-NCDR database is presented in Table 6.

In clinical trials, the end points (such as those proposed in Table 6) should be carefully defined and should be as objective as possible. Investigators blinded to treatment should independently adjudicate vascular complications. Studies that incorporate time to hemostasis and times to ambulation and discharge should have those times recorded systematically beginning at the end of the procedure, so that differences in these times can be captured and compared accurately. Economic analyses should take into account the cost of the entire episode of care, including nursing time, the cost of the device, and the costs of any complication-related treatments. Consideration should be given

Table 6.   Proposed Criteria for Assessment of Vascular Complications Related to Use of Vascular Closure Devices

Access-site–related bleeding requiring intervention (additional device or manual compression, cessation of anticoagulant agents, transfusion, vasopressor agents, or percutaneous/surgical intervention)

Vascular injury including

   Pseudoaneurysm

   AV fistula

   Lower-extremity ischemia (including peripheral embolization) or vascular occlusion requiring percutaneous/surgical intervention

Access-site–related neurological injury requiring neurological consultation or intervention

Access-site–related infection requiring antibiotics or surgical intervention

AV indicates arteriovenous.

to substudies in which some randomized patients undergo ultrasound examination.

Studies ideally should match the end points evaluated with the patient risk. For example, patients undergoing diagnostic angiography with ≤5F catheters should be expected to be at low risk (<1%) for vascular complications. In fact, recent reports have found the rate of any vascular complication in such patients who are ambulated 1 hour after sheath removal to be 3.3%, with the rate of major complications approaching 0.1%.[65] Therefore, ACDs are unlikely to significantly reduce vascular complications in such a population, and demonstration of true noninferiority will require many thousands of patients. In a moderate-risk population (patients undergoing uncomplicated PCI with standard anticoagulation therapy), ACDs should be evaluated for clinical outcomes and cost-effectiveness, time to ambulation, and patient satisfaction. The safety evaluation of vascular complications in this population should be appropriately powered at a minimum to examine the noninferiority of the ACD compared with manual compression. Alternatively, studies in patients at moderate to high risk for vascular complications should be powered to detect superiority with regard to clinical complications resulting from attempts at hemostasis. If all the proposed end points presented in Table 6 are used, then event rates will likely allow reasonably sized studies.

To best assess the efficacy of ACDs, it is preferable that future studies be prospective, randomized trials. As much as possible, "all-comers" should be enrolled in such studies, and the routine use of femoral angiography to dictate the most appropriate approach should be encouraged in these trials. A variety of clinical indications for cardiovascular intervention should be included. It also may be appropriate to study the clinical and angiographic characteristics that impart worse outcomes after ACD use. Additionally, the best use (and most appropriate dosing) of pharmacological adjuncts that prevent thrombosis and

may abet bleeding complications when used in association with ACDs should be analyzed in a formal study.

Recommendations for Future Studies of ACDs

To develop evidence that can directly inform clinical practice and lead to guideline recommendations for use, the writing group recommends the following standard for future studies evaluating ACDs:

1. Clear identification of the anticipated risk of vascular complications for patients being studied, specifically divided into low-risk (<1%), moderate-risk (1% to 3%), and high-risk (>3%) groups. This will allow assessment of the power of the studies to identify clinically meaningful differences.
2. Use of standard clinical end points for vascular complications (note that these end points should be independently and blindly adjudicated during the conduct of the trial).
3. Collection of data on all vascular complications in all ACD studies, with study primary end points commensurate with patient risk. Cost-effectiveness, hemostasis, and time-to-ambulation measures may be appropriate for studies in patients/clinical indications that are low risk for complications, provided that safety is maintained. Alternatively, patients at moderate to high risk for vascular complications should undergo studies with ACD use that evaluate clinical complications and end points.

It is the opinion of the writing group that randomized studies that meet the above criteria should be accepted as clinical evidence for device efficacy and lead to clinical use of tested devices. Until such clear demonstration of benefit is achieved, use of ACDs remains dependent on the treating physician's assessment of individual patient risk/benefit analysis.

Conclusions

Cardiovascular procedures offer the potential to improve patient outcomes and are increasing in frequency as new devices are developed and vascular territories are approached. Currently, ACDs have the potential to improve patient comfort. Novel devices and methods for achieving hemostasis are under investigation. However, the available evidence is limited to specific patient populations, often studied in nonrandomized fashion, without methodological follow-up and standardized clinical outcomes. This limits the widespread routine use of these devices in clinical practice. The goal of future research should be to examine these ACDs using adequately powered randomized studies in relevant populations with varying risk and to evaluate clinically relevant outcomes in a blinded fashion.

Disclosures

Writing Group Disclosures

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  *Modest.

  †Significant.

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Arteriotomy Closure Devices for Cardiovascular Procedures. A Scientific Statement From the American Heart Association

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Correction

In the article by Patel et al, "Closure Devices for Cardiovascular Procedures: A Scientific Statement From the American Heart Association," which published ahead of print on October 4, 2010, several corrections are needed.

1. On page 1, the Council on Cardiovascular Surgery and Anesthesia and the Stroke Council were inadvertently omitted from the author list. The council credits section of the author list should read:
    > . . .on behalf of the American Heart Association Diagnostic and Interventional Cardiac Catheterization Committee of the Council on Clinical Cardiology, Council on Cardiovascular Radiology and Intervention, Council on Peripheral Vascular Disease, Council on Cardiovascular Surgery and Anesthesia, and Stroke Council

2. On page 1, the citation information in the third paragraph of the footnotes should read:
    > Patel MR, Jneid H, Derdeyn CP, Klein LW, Levine GN, Lookstein RA, White CJ, Yeghiazarians Y, Rosenfield K; on behalf of the American Heart Association Diagnostic and Interventional Cardiac Catheterization Committee of the Council on Clinical Cardiology, Council on Cardiovascular Radiology and Intervention, Council on Peripheral Vascular Disease, Council on Cardiovascular Surgery and Anesthesia, and Stroke Council. Arteriotomy closure devices for cardiovascular procedures: a scientific statement from the American Heart Association. *Circulation*. 2010;122:●●●–●●●.