

The Two Sides of Vascular Access and Closure

Part 1: Debating the pros and cons of manual compression versus vascular closure devices.

BY ZOLTAN G. TURI, MD

Although vascular closure devices (VCDs) have been available for only a decade and a half, the percutaneous approach to vascular access has been in use for more than half a century. Despite several hundred million access procedures and many millions of VCD closures, the evidence base remains remarkably thin. Relatively few clinical trials in this arena could be described as high quality. As a result, there remain many unresolved issues. As a new feature to the annual closure update, I am going to try to address some of the controversies as a debate between two opposing viewpoints. I have selected five issues for debate, with the first being the subject of this installment:

1. Manual compression (MC) versus VCDs;
2. Radial versus femoral access;
3. Active versus passive closure;
4. Fluoroscopy, ultrasound, and angiography versus traditional landmark-guided access;
5. Miscellany: manual compression versus compression devices; topical patches versus MC; nurse/technician versus physician closure.

Each side of every controversy in the list has strong advocates and opponents. I will try to give both the pro and con arguments for each, as well as try to carry the arguments for both sides in a fashion similar to the cat in George Orwell's *Animal Farm* (who voted both sides of every issue). However, after dividing each controversy into its components, I will weigh in with an opinion and at the end provide a final verdict. An important caveat: the evidence base is very thin, and despite my preference for an objective and relatively inarguable conclusion, it is not necessarily possible. Hence, this is a best effort, which in some cases will not be good enough to result in more

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than a tie. Of necessity, my choices reveal my best interpretation of the evidence base, but invariably, some biases will be incorporated as well. Also, I do consultation for a variety of companies in the vascular access and closure arena, although I hope you will find my opinions suitably curmudgeonly and not favoring either side.

MANUAL COMPRESSION VERSUS VASCULAR CLOSURE DEVICES

The debate chosen for this issue of *Cardiac Interventions Today* is perhaps the most controversial on our list. The components I have chosen for this comparison are success rates, time to hemostasis (TTH), time to ambulation (TTA), patient comfort, complications, and cost. There are several confounding issues, including the differences in the performance of various closure techniques after diagnostic or interventional cases. In addition, the VCDs are quite heterogeneous in their mechanisms, and some have features that overlap with those of MC. I have chosen not to incorporate a discussion of mechanical compression devices versus MC—that will be covered in another installment.

The overall use of VCDs has grown significantly, despite continuing ambiguity about their utility com-

pared with MC. Much of the decision making by hospitals and individual physicians remains empiric; hence, I have chosen this controversy to start off this series. In the sections that follow, I will argue in favor of MC or VCDs, in many cases using the pulpit to argue against, rather than for, one side or the other.

SUCCESS RATES

Manual Compression

The gold standard for successful hemostasis remains plain old manual compression (POMC); it does, after all, have a 60-year track record. In most studies, MC is 100% successful,¹ and it achieves this enviable statistic without the technology, cost, or complications associated with VCDs (see discussion that follows regarding each of these elements). MC requires no additional time in the catheterization lab when performed in a holding area or at bedside and can be performed by an experienced technician or nurse. It is difficult to beat the track record of MC for success or simplicity (Figure 1).

Vascular Closure Devices

The 100% success rates claimed for MC are definition dependent, but success rates are close to 100% for VCDs as well when used after diagnostic catheterizations. The latter is still the primary setting for VCD use in the United States. In the interventional setting, some VCDs have evidence for success rates in the mid or even high 90% range.² These success rates are achieved while the patient is still in the catheterization lab—an advantage over having an inexperienced or undersupervised first-year fellow pulling the sheaths at 9:00 PM. Moreover, interventionists want the positive feedback and control of taking care of closure right there in the lab.

The Verdict

Both MC and VCD success rates are contaminated by definition issues; the definition of success is highly variable across studies. Thus, “device success” may be achievement of hemostasis with a device alone, or a device plus manual compression for a fixed duration of time, or other combinations of parameters, sometimes including freedom from complications. “Procedure success” may have a more generous definition: hemostasis achieved without major complications, sometimes regardless of compression time or even crossover to another VCD. A discussion of success rates comparing devices will follow in a separate installment of this series. When success is defined in its simplest form, such as “absence of pulsatile blood,” MC is 100% successful. However, “all bleeding eventually stops,” so MC success definitions



Figure 1. Although it is difficult to compete with MC in simplicity and overall success rate, the tradeoffs can be substantial. The technique above has been in continuous use for 56 years. Note that the sheath is being pulled in a nonsterile environment, a common although not desirable practice.

are potentially meaningless unless TTH is a parameter of success for both VCDs as well as MC, which is frequently not the case. The exact duration for MC is not defined in most protocols, nor are the techniques, the latter being more dependent on “know how” passed down through a half century than any rigorous animal or human testing. At the same time, a close look at VCD success rates reveals a nuance of the vascular closure literature; adjunctive MC is used when there is still bleeding after device deployment and, depending on definitions, VCDs may get credit for procedure success when it was really POMC that closed the vessel. Primary (or device) success rates, when using specific definitions such as absence of pulsatile blood flow or oozing without adjunctive compression, have been significantly lower (85%–95%) for a number of VCDs.³ Several issues need to be considered in deciding whether MC or VCD wins this category, and it may seem a little unfair—after all, MC is only performed when patients are no longer anticoagulated, whereas VCDs are used while patients are still fully anticoagulated. This is an uneven comparison that inherently favors MC. *The winner: manual compression.*

TIME TO HEMOSTASIS

Manual Compression

Yes, MC does take longer, and VCDs shorten the TTH

dramatically, particularly in the interventional setting. But how important is the difference in reality? A diagnostic catheterization typically requires a 10- to 15-minute hold, sometimes longer. Although the VCD proponents will argue MC has longer TTH, this may be less significant than it seems. First, VCD preparation and deployment take at least a few minutes. Second, many VCDs require adjunctive compression (I hold for a few minutes even when there is no bleeding or oozing after VCD deployment regardless of device type). Third, some additional steps required for VCD use, such as cineangiography to confirm suitable location of puncture, femoral artery size, and absence of disease, add several more minutes to the procedure. (Although we have advocated angiography of all femoral artery puncture sites regardless of VCD use, regrettably this does not yet constitute standard of care.) When one considers the additional cost and potential for complications of VCD use, a few minutes saved on TTH after diagnostic catheterization do not seem very compelling. With interventional cases, MC itself does not take that much longer once the activated clotting time (ACT) has normalized, assuming that the sheath size is 5 or 6 F.

Vascular Closure Devices

This is where VCDs truly excel. Although it is true that in unanticoagulated patients after diagnostic catheterization TTH differences may be less than meet the eye, the primary disadvantage of MC in interventional cases is the delay until ACTs have returned to normal. Depending on the agent used for anticoagulation (particularly unfractionated heparin rather than bivalirudin), several hours may be required for the ACT to reach an appropriate threshold so that the sheath pull can begin. The duration of MC is typically longer after interventional cases, especially if a larger sheath is used, but the fact that VCDs are deployed on the catheterization table instead of hours later is the most impressive determinant of the dramatically reduced TTH. So the real TTH, the time between end of the procedure and hemostasis, not between sheath pull and hemostasis, dramatically favors VCDs.

The Verdict

Inherently, TTH is a soft endpoint. Some studies inadvertently bias results against MC because of "multiple looks." Multiple looks, that is, letting up on MC early and often to assess for TTH, will interfere with a proper clot forming at the arteriotomy site and will delay TTH, a confounding factor in a number of MC versus VCD studies, in my opinion. Another issue with study design is that in many

cases, the first attempt to perform MC is defined by protocol rather than the exact time that the anticoagulation environment might be suitable. A classic example was the STAND trial (I and II), in which the 50th percentile for TTH was 4 hours, with a median of almost 7 hours for interventional cases.⁴ Finally, the operators in these studies are inherently unblinded, so there is substantial room for inadvertent investigator bias to creep in. Despite such problems with study design, this decision is fairly straightforward. *The winner: vascular closure devices.*

TIME TO AMBULATION

Manual Compression

Although MC typically requires a longer period of bed rest, in diagnostic cases, especially when small sheaths are used, patients have been ambulated very early.⁵ At the same time, most VCD users are reluctant to have their patients ambulate as early as the Instructions for Use (IFU) may allow. Regardless of closure technique, the use of conscious sedation limits the TTA such that the ability to ambulate very early after VCDs may be pointless. With regard to interventional cases, patients are currently kept overnight in most hospitals in the United States, so the benefits of early ambulation are blunted.

Vascular Closure Devices

VCDs shine in this arena. The literature describes everything from immediate ambulation to 1 to 2 hours,⁶ with 1-hour ambulation supported by some series. Early ambulation has several benefits. Long MC times and longer bed rest predispose to the occasional venous thrombosis and add considerably to patient discomfort, especially those with back problems. Earlier ambulation also adds efficiencies to patient management, as reflected in the cost discussion later in this debate.

The Verdict

In fully anticoagulated patients, the prolonged bed rest required to allow the anticoagulation to wear off, pull the sheaths with MC, and then wait until the patient can be ambulated safely is a significant drawback of MC. TTA is uniformly shorter with VCD use, most strikingly after interventions. *The winner: vascular closure devices.*

PATIENT COMFORT

Manual Compression

If done by gentle hands, MC can be relatively painless.

Most of the hold period can be done at relatively low pressure. In contrast, VCD deployments can occasionally be painful. Patients sometimes describe the tug of an anchor, the firing of a clip, or the deployment of a suture as the most painful part of the case.

Vascular Closure Devices

Despite what the MC proponents claim, having someone push down on your femoral artery at suprasystemic pressure hurts, and MC does not stop bleeding unless suprasystemic pressure is applied, at least for a few minutes. The biggest converts to VCD use are patients who have had MC in the past. The evidence for better patient tolerance of VCDs than MC has been consistent in the literature,¹ not just for the actual deployment and hemostasis portion, but because of the more limited time of bed rest.

The Verdict

The proponents of MC cite occasional complaints of pain with three devices that are, not coincidentally, active closure devices. Arguably, some passive closure devices, because they do not involve as much manipulation of the artery, may have less associated discomfort but have their own potential drawbacks (active vs passive closure will be part of a separate installment in this series in *Cardiac Interventions Today*). A little extra local anesthetic after a long case (when presumably it has worn off) will go a long way to address any discomfort as will being gentle while tugging on VCD anchors or sutures during deployment. Use of longer-acting local anesthetics (such as bupivacaine) or anesthetics with epinephrine (which have the additional benefit of decreasing any periclosure oozing) will also address this issue. Lying flat in bed for all those extra hours after MC is the real discomfort that patients notice. *The winner: vascular closure devices.*

COMPLICATIONS

Manual Compression

MC has, for the most part, been shown to have fewer or, at worst, similar complication rates as VCDs. For the interested reader, a foray into the US FDA MAUDE (United States Food and Drug Administration Manufacturer and User Facility Device Experience) database (<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/search.CFM>) will reveal a large number of significant complications associated with VCDs. Because many—probably most—complications are not reported to the FDA, this represents a tip of the iceberg. Excess complica-

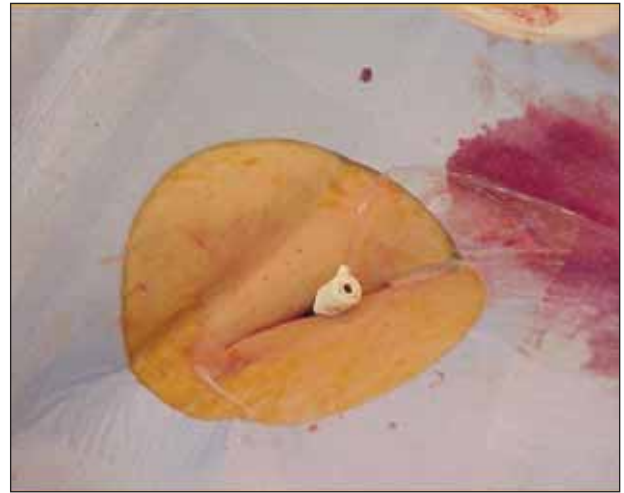


Figure 2. The decision on MC or VCD use is complex and, in the absence of a vigorous evidence base, laboratory and physician practices vary widely. This patient turned out to be a poor candidate for device use (the puncture, right at the inguinal crease, was into the profunda femoris), a fact that could be gleaned only by routine use of femoral angiography, a technique that has been recommended extensively in this series of articles but unfortunately not performed routinely by most laboratories. Note that this patient has two creases, quite common in obese patients.

tions associated with VCDs have been described in a number of series, as well as several meta-analyses. Some of the nonrandomized studies that suggested lower complication rates with VCDs than with MC were skewed by selection criteria that assigned VCDs to patients with uncomplicated femoral punctures and MC to patients who were deemed unsuitable for VCD use for reasons that predisposed to bad outcomes. Certain complications, such as infections, retroperitoneal hemorrhage, and vascular occlusion are, by general consensus as well as a reasonable evidence base, less likely to occur when MC is used. Here the question to be asked is: "Is the risk of those complications, even in a small percentage of patients, worth the shorter TTH, TTA, comfort, or convenience associated with VCDs?"

Vascular Closure Devices

Although the FDA MAUDE database does indeed shed light on VCD complications, there is no FDA database on MC. Some of the complications reflect the use of VCDs in sick patients or in violation of IFUs, and the narratives are not always compelling that the devices caused the complications that are listed (causality rather than association). Although some studies have

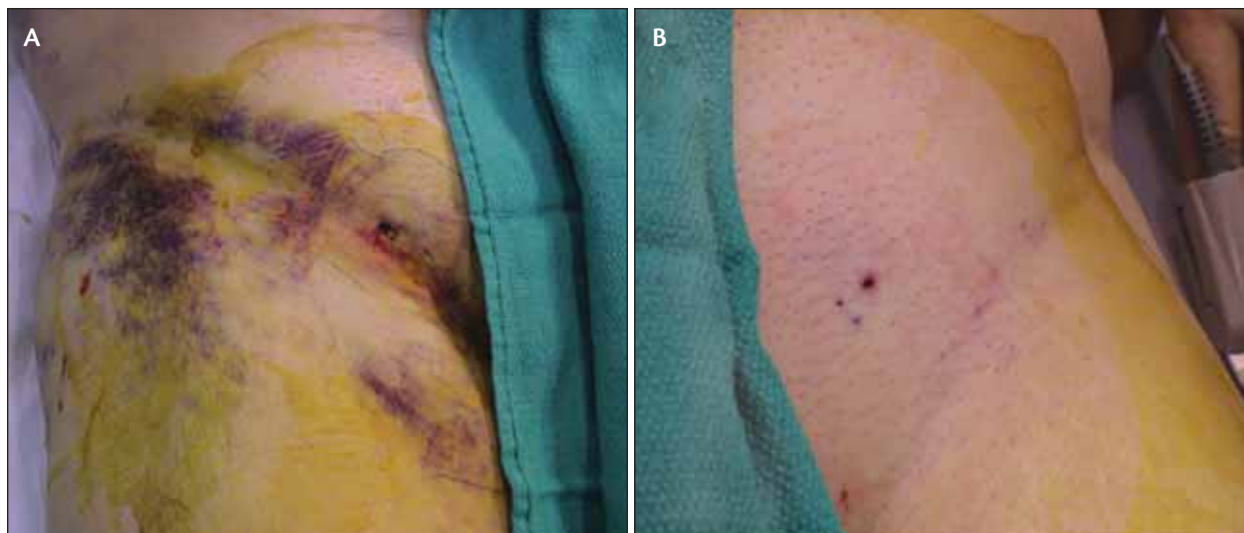


Figure 3. Two femoral punctures and closures in the same patient, one with manual compression and one with a VCD, one after diagnostic catheterization and one after coronary intervention. Figure 3A was taken after diagnostic catheterization that utilized MC, and Figure 3B was taken immediately after intervention and VCD use. The difference in results was not due to the closure technique but rather the access technique. The operator performing the diagnostic catheterization used none of the techniques advocated in this series and limited himself to his primary landmark, the inguinal crease. The operator doing the intervention used fluoroscopic-guided access. The puncture on the left (A) was at the inguinal crease, which in this patient was far below the femoral head. The puncture on the right (B) appears unusually high, but fluoroscopy-guided entry was in fact ideal: into the common femoral artery below the center of the femoral head.

described excess complications with VCDs, these have occasionally incorporated operator learning curves and selection bias issues. Most of those studies are old, with outdated device platforms and less than optimal methods (eg, large sheaths, overanticoagulation, poor access techniques, lack of femoral angiography) (Figure 2). With good operator practices (access as well as closure), several more recent propensity analyses have suggested parity⁷ or actual superiority⁸ in outcomes with VCDs over MC. Interventional cardiologists routinely adopt technologies such as VCDs that improve patient comfort and convenience if parity can be shown in overall outcomes.

The Verdict

Of the controversies to be discussed in this series, comparison of complications between MC and VCDs has drawn, by far, the most attention. There are a number of meta-analyses,⁹⁻¹¹ as well as several single-site propensity analysis studies,^{7,8} that shed light on this issue. The meta-analyses suffer from the weak study designs of the trials that they analyzed and generally incorporated studies from the earliest VCD era, which included outdated platforms, learning curves of all types, highly variable endpoint definitions, and a host of undesirable clinical trial fea-

tures. The propensity analyses are admirable single-site studies and, although the results appear relatively compelling, they may not be applicable across a broader range of institutions. The single sites in those two studies use particularly compulsive vascular access and closure methodologies that have not been adopted by most physicians or hospitals (Figure 3). The meta-analyses varied in their conclusions (Figure 4), but generally MC resulted in fewer or similar complications, with the exception of a device that is no longer marketed (VasoSeal). The propensity analysis by Arora and colleagues⁸ is the first compelling large-scale study to show superiority of VCDs. However, their institution (the Brigham and Women's Hospital) uses a particularly comprehensive algorithm for vascular access and closure (incorporating elements recommended over a number of years in this magazine and its sister publication, *Endovascular Today*), which unfortunately has not yet been incorporated by most hospitals; thus, the applicability of their data to general cardiac catheterization laboratory practice elsewhere may be questionable. Regardless, that study shows that it is possible to achieve very low complication rates with VCDs.

Importantly, certain complications attributable to VCDs are additive—that is, they occur over and

above whatever complications might occur if MC were used. This applies in particular to two adverse events: infection and retroperitoneal hemorrhage. Infection after VCD use is particularly disturbing; although it occurs in < 0.5% of cases, it has a 6% associated mortality.¹² In contrast, infection after MC is truly rare. VCDs (with the exception of the Cardiva Catalyst [Cardiva Medical, Inc., Sunnyvale, CA] and topical patches) leave a foreign body in the tissue track, potentially acting as a wick to the surface of the skin. The area is inherently bacteria rich, and blood in the tissue tract or soaked into the device enhances the potential for infection. Retroperitoneal hemorrhage is exacerbated by VCDs for several reasons.¹³ First, they are deployed while the patient is still anticoagulated. Removing a small sheath after a high stick in an unanticoagulated patient is relatively benign. In contrast, in a fully anticoagulated patient, it may be fatal if the VCD does not deploy properly. Second, apposition of the plug, clip, knot, sealant, etc., against the arterial wall may be made impossible by layers of muscle, cartilage, etc., between the skin and the artery when access is high, as the artery dives away from the surface. Although at least one study has called this association into question, I believe it continues to apply. Some other complications, including vascular obstruction (by foreign body or a thrombosing agent in the blood vessel), dissection or occlusion, and neural entrapment, are all potentially additive to complications associated with MC. Conversely, long MC has its own additive complications, most particularly those associated with prolonged stasis of blood in the femoral vein, with anecdotal reports of deep vein thrombosis and pulmonary embolism. I believe there is an inherent liability in leaving a sheath in place waiting for anticoagulation to wear off. By the time the patient is ready to have the sheath pulled, the operator performing the case may not be present, and the circumstances may be under far less control than in the cardiac catheterization lab. The margin is thinning, but in my opinion, *the winner: manual compression.*

COST

Manual Compression

MC is cheap. No \$200 (or greater) device is required. The early ambulation argument for VCDs does not hold water, at least after interventions, if the patient is staying overnight anyway. Although there have been some claims for lower costs associated with VCD use, a care-

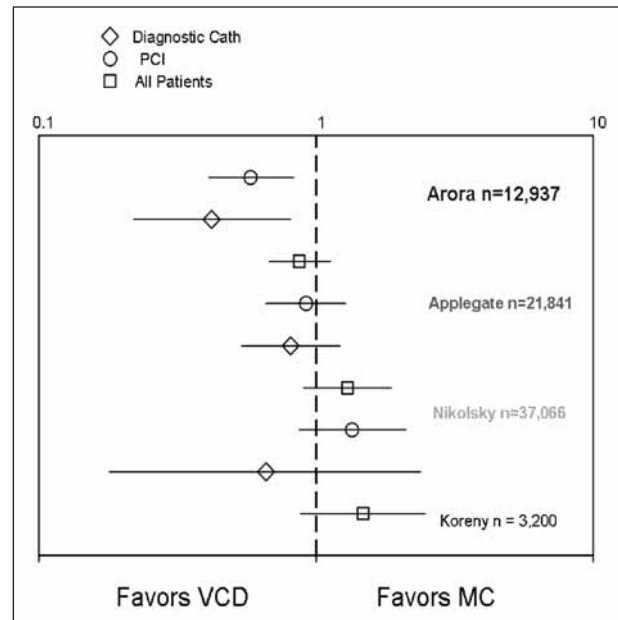


Figure 4. Two meta-analyses and two propensity analyses comparing MC and VCDs. The most recent study is at the top, whereas the oldest data are at the bottom. The Koreny⁹ study incorporated data from the early 1990s on, as did Nikolsky.¹⁰ In contrast, Applegate⁷ examined patients from 1998 to 2003, whereas Arora⁸ studied patients between 2002 to 2005. Note that the overall results have moved steadily to the left in favor of VCD use. During this period, there were major changes in device platforms, substantial decreases in sheath sizes and anticoagulation levels, and incorporation, by the hospitals participating in the Arora and Applegate propensity analyses, of many of the access and closure techniques advocated in this series in *Endovascular Today* and *Cardiac Interventions Today* during the past 7 years.

ful reading of the most cited study to date shows that this is in part predicated on a lower complication rate with VCDs; the latter has proven illusive to demonstrate in most institutions.¹⁴

Vascular Closure Devices

That minimum \$200 cost is a loss leader. In diagnostic cases, earlier ambulation means fewer nursing and other hospital stay costs. MC is not free either; it ties up a staff member or fellow and a bed for a nontrivial amount of time. Late sheath pulls in particular may involve bringing a staff member back into the hospital. If an institution has access and closure practices good enough to actually have lower complication rates with VCDs, the shorter length of stay and avoidance of the numerous costs associated with complications may result in ultimate cost savings despite the initial outlay.¹⁴

The Verdict

The issue remains unsettled, with proponents in both directions. MC remains the dominant closure technique in the United States and more so outside of the United States because of this issue in particular. In many countries, the cost of labor involved in MC and the hospital costs associated with longer TTA are dwarfed by the initial outlay for the VCD. In the United States, this is, in my opinion, a toss-up. The moral of the article by Resnic and colleagues¹⁴ is not just that VCD use can be associated with lower cost—although I have no doubt that in the authors' institution it does—but rather that every institution should adopt better access and closure methodologies. If and when that happens, VCDs can and will deliver net cost savings. *The winner: manual compression.*

OVERALL

MC remains the mainstay for vascular closure in the vast majority of procedures done around the world and in 60% to 70% of cases in the United States. VCD use has been inhibited primarily by cost and complications issues. There is little question that comfort and convenience favor VCD use. As existing platforms have been refined and new technologies have appeared, the scale has tilted steadily but not overwhelmingly in favor of VCD use. Cost, in particular, has not declined significantly. There remains a concern that, in the absence of a compelling evidence base, we will eventually look back at VCDs and wonder why we accepted the complications that are additive. Still, as a clinician, I do vote with my personal practice, which includes VCDs in almost all interventional cases when the risks are reasonable. This practice engenders gratitude of patients and the catheterization lab staff, the former because of comfort and the latter because of more time spent with their families. I define reasonable-risk patients as those without major disease in the common femoral artery, without unusual infection risk, and with puncture into the common femoral well away from the inguinal ligament. In interventional cases, this practice is driven not by early discharge considerations but by the desire to control the closure process and not have it take place at a remote site and without my direct supervision. I look at a sheath in place leaving the catheterization lab as a clinical liability. I close a somewhat lower percentage of my routine diagnostic cases, although the comfort and early ambulation issues are compelling. As an additional front in the battle to improve access and closure results, I do a moderate number of radial cases, but I will discuss more on that in another installment. So, despite

breaking the considerations down into varying components, the ultimate vote here reflects these biases and remains a very close call overall. *The winner: vascular closure devices.*

Please contact me with any suggestions for the next installments in this series in terms of format, number and types of references, and whether or not you find this approach helpful overall. ■

Zoltan G. Turi, MD, is Director of the Cooper Vascular Center and Professor of Medicine at Robert Wood Johnson Medical School in Camden, New Jersey. He has disclosed that he receives research grants support from Abbott Vascular, Johnson & Johnson, and St. Jude Medical, has performed consultation for Arstasis, St. Jude and Johnson & Johnson, and has received lecturing honoraria from Abbott Vascular and St. Jude Medical. Dr. Turi may be reached at (856) 342-3488; turi-zoltan@cooperhealth.edu

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