though femoral artery angiography mended techniques for device deployment. For example, even Balzer et al. (6) appears to level off at approximately 350 cases. Contrast, the learning curve for one Perclose device as published by to fewer than 150 cases per year, spread over multiple operators. In The 516 deployments constitute only 8% of their cases, and amounts

demonstrate contraindications to device deployment were unknown to the operators in what is likely a high percentage of the cases. Also, because at least 13% and probably more of these femoral sticks were not in the common femoral artery (regardless of the operators being “very experienced with arterial puncture”), any number of the pseudoaneurysms and retroperitoneal bleeds could have been due to misplacement of the femoral puncture (7). In the manual compression group, such sins were much more easily masked when sheath pulling took place at an activated clotting time (ACT) <150 s.

Fourth, prior published data have demonstrated that level of anticoagulation, sheath size, physician learning curves, location of puncture site, vessel size and presence of local atherosclerotic disease all influence outcomes of vascular closure. The investigators have demonstrated a mismatch in anticoagulation (ACT 277 vs. <150 s) and learning curves (experienced manual compression technicians versus inexperienced closure device users). They do not have the data regarding location of puncture site, atherosclerotic disease or vessel size, and have failed to inform us regarding sheath sizes other than that ≥10F sheath pulls were excluded. The latter also raises the issue of possibly inappropriate use of closure devices for larger than approved sheath sizes.

Fifth, Dangas and colleagues draw conclusions comparing two sealing methods in a retrospective fashion using statistical methods designed with the assumption that samples were selected at random (8). Thus, the p values are misleading, adding to the problems of this observational study with uncontrolled (retrospective) data acquisition, and ad hoc group assignment. These groups are likely to have varied in ways the investigators did not notice or choose to ignore, and these differences, rather than the treatment modalities, may account for the potentially different outcomes. Further, such studies can be subject to bias in completeness and quality of information recorded in the hospital charts; the investigators reading such charts often must use considerable judgment in assessing the data present. Sizing hematomas, for example, can be difficult even in prospective studies and can be quite subjective even with the most sophisticated measuring tools.

The study by Dangas et al. demonstrates that relatively novice users of vascular closure devices, probably frequently not following manufacturers’ recommendations, and deploying these devices in fully anticoagulated patients, had a higher complication rate than full-time employees trained to do manual compression who were pulling sheaths when the ACT was <150 s. Perhaps the only truly useful conclusion one could draw from the study (1) is that operators should be well into their learning curve, should perform an angiogram on the femoral artery before device deployment and otherwise follow the recommended protocols before deployment in fully anticoagulated patients. Although we use these devices after percutaneous intervention in nearly 100% of our cases, we believe that any recommendation should await the results of prospective randomized studies applying uniform definitions of complications and uniform measurement of end points.

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Complications of Vascular Closure Devices—Not Yet Evidence Based

The interesting publication by Dangas et al. (1) claims to compare arteriotomy closure devices with manual compression after percutaneous coronary intervention. Unfortunately, this is a comparison only in the fashion that can be ascribed to a retrospective trial with mismatched procedural variables and operator experience, ad hoc recruitment, and broadly applied statistical techniques. The conclusion that closure devices are associated with a higher rate of vascular complications could not possibly be ascertained from this study. In fairness to the investigators, the segment of the interventional cardiology literature to which they have contributed is largely a collection of testimonials and historical comparisons (2).

Unfortunately, there is a striking paucity of properly conducted controlled clinical trials in this arena.

Our problems with this study (1) are multiple, some of which were outlined in the accompanying editorial by Tavris et al. (3). First, the investigators claim that “no large report exists on the ‘real world’ application” of these devices. Multiple studies have reported far larger experiences, at least as “real world” as the investigators’ (4–6).

Second, Dangas et al., highly experienced and with an international reputation in interventional cardiology, are largely novices at vascular closure, having apparently declined to adopt them in routine use. They include experience with only 6 VasoSeals, 32 Duettts, and 6 Prostars; the majority of cases used AngioSeals and Techstars. The 516 deployments constitute only 8% of their cases, and amounts to fewer than 150 cases per year, spread over multiple operators. In contrast, the learning curve for one Perclose device as published by Balzer et al. (6) appears to level off at approximately 350 cases.

Third, the individual operators may not have used the recommended techniques for device deployment. For example, even though femoral artery angiography “was recommended before arteriotomy closure device application,” it was used only “in the majority of cases” (we are not told the actual number). This is clearly a disadvantage and probably inappropriate handling of the devices, as numerous factors that predict outcome and might

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REPLY

We read with interest the letter of Schnyder and Turi, and are not surprised that our study reporting increased complications associated with arteriotomy closure devices (ACD) has engendered such a strong and obviously heartfelt response. When a negative study is generated and subsequently published in the pursuit of academic honesty and patient well-being (our overriding motivation), one must regretfully anticipate one-sided and dogmatic reactions from patients with possible academic, professional or commercial interests at stake. Unfortunately, Schnyder and Turi have seemingly lost the “forest for the trees” in their apparent zeal to promote this subspecialty. We shall attempt to respond point by point to their critique.

The first generation ACDs were approved in the U.S. on the basis of relatively small randomized trials designed to demonstrate shorter times to hemostasis compared with manual compression in patients undergoing diagnostic and interventional procedures. None of these trials were powered to show differences in complication rates. Yet notwithstanding differing patient composition, device sizes and complication definitions, all four studies showed trends toward increased vascular complications with the ACD, despite their application in the tightly controlled environment of a clinical trial (Table 1).

We therefore examined our experience with closure devices in patients undergoing percutaneous coronary intervention (PCI) at the Washington Hospital Center, one of the busiest interventional hospitals in the country, confirming significant increases in hematoma formation, large declines in hematocrit, and need for vascular surgical repair with ACDs (1). Contrary to Schnyder and Turi’s contention, this was not a “retrospective trial” subject to “bias in completeness and quality of information recorded in the hospital chart”; all data were prospectively collected by dedicated research nurses, all field definitions were prespecified, and all adverse events adjudicated. These quality measures far outstrip that of the usual registry based either on retrospective chart review, or physician recollection or documentation.

Schnyder and Turi are correct though in pointing out potential hidden physician prejudices; the operators in the present study were “biased” to tend to use these devices in ideal patients, explaining why procedure duration was less in patients receiving ACDs, and in whom less debulking and more stand-alone angioplasty were performed, requiring smaller sheaths (2). Nonetheless, complications were still increased with closure devices despite these predispositions favoring the ACD group. We further acknowledge that the increased activated clotting time (ACT) levels at the time of closure device insertion likely favored more bleeding in the ACD group (1). However, the ability to withdraw sheaths in the catheter laboratory in the fully anticoagulated patient, rather than waiting 4 to 6 h for sheath extraction in the in-patient telemetry unit prior to manual compression, is a purported advantage of ACDs and the standard way these devices are utilized. Certainly, Schnyder and Turi are not suggesting ACT normalization is required before using a closure device, which would obviate much of the device’s clinical desirability.

Schnyder and Turi criticize the physicians involved in this study as being “largely novices at vascular closure, having apparently failed to adopt them in routine use.” The great majority of the closure procedures were performed by four senior physicians, who collectively have performed >25,000 PCI procedures and many more diagnostic angiograms. They note, however, that only ~150 ACD procedures were being done per year in the study by these physicians; this is true if only “interventional” procedures are considered—the same four operators performed approximately two- to threefold this many closure procedures annually on diagnostic patients. Furthermore, the physicians involved have been participating investigators in most of the premarket approval ACD clinical trials. Thus, while we do not profess to possess the expertise of Schnyder and Turi, the volume and experience with ACDs represented in the present report certainly would more than match the real-world qualifications of most centers experienced in both traditional and novel methods of arteriotomy closure.

Schnyder and Turi also repeatedly note that not all patients in our study had a preclosure femoral angiogram. Though we did not collect this data, we believe >90% of patients did undergo such examination, a frequency that is likely greater than at most hospitals using ACDs in the “real world.” Indeed, one reason why more patients did not receive closure devices in our study was the low threshold in place to exclude patients upon the identification of disease or calcification at the access site, an excessively low puncture, or small vessel diameter. Furthermore, femoral angiography was not performed in the manual compression group, and cases unsuitable for closure devices on the basis of the angiogram were also included in the manual compression group, both factors that would favor the ACD group. Finally, to our knowledge, no prior study (whether real-world or controlled trial) has ever reported the actual frequency with which the recommended femoral angiogram was in fact performed.

Schnyder and Turi state that “multiple studies have reported far larger experiences” (2–4), taking issue with our statement that large postapproval studies with these devices were lacking. At the time of submission for publication, our analysis of 6,408 interventional procedures was indeed the only large experience with >500 ACDs investigating femoral access complications after PCI; the three referenced single-center studies were published afterward. Regardless, these subsequent experiences largely support our findings.