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Q We are reviewing our policy and procedures on arterial and venous sheath removal after percutaneous coronary intervention (PCI). What is the proper activated clotting time (ACT) at which to remove a femoral sheath after PCI? What are the best "protocols" for sheath removal?

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The number of PCIs continues to increase each year. Balloons, stents, and drug-eluting stents have proven effective in treating plaque blockages in coronary vessels. Although the rate of ischemic complications continues to diminish after PCI, bleeding complications are still common.

The most bleeding associated with PCI occurs at the femoral artery access site.¹ Recent research has shown that bleeding complications are more serious than previously thought, and it is important that clinicians make all efforts to reduce bleeding after PCI.² Reaching hemostasis after sheath removal is a critical step in patient recovery.

Proper sheath removal protocols and policies can significantly reduce access site bleeding. However, surprisingly, sheath removal protocols differ from hospital to hospital. In fact, orders can differ from physician to physician within the same hospital. It may be impossible to determine the "best" protocol for sheath removal on the basis of a literature search.³ There are little rigorous data on the subject and no significant trial that provides evidence for a standard technique.

There are many choices in closure methods and differing anticoagulation therapies, which may contribute to some of the disparity in protocols. Treatment with antithrombin and antiplatelet agents puts patients at risk of bleeding complications, and patients have often received multiple drug therapies before arrival to the catheterization laboratory. Nurses are required to carefully assess the

risk of bleeding on the basis of the type of anticoagulant drugs administered. When plug-type or suture-mediated closure devices are used, sheaths are generally removed immediately at the end of the PCI procedure, regardless of the patient's coagulation status. The advantage of these devices is 2-fold: immediate closure of the access site and the potential for early ambulation. Although closure devices allow for immediate hemostasis, they are not associated with decreased access site complications.⁴ A downside to closure devices is their cost, adding several hundred dollars to the hospital bill.

Most centers still rely on the standard compression method of arterial closure, using either manual or mechanical compression, or a combination. Many clinicians consider manual compression the gold standard in sheath removal. In the absence of strong evidence-based data, clinicians have devised strategies that work within their institution for safe sheath removal, leading to differing protocols, techniques, and great disparity among institutions, as well as the unanswered question, What is the proper ACT for sheath removal after PCI?

Activated Clotting Time

Patients who undergo PCI receive an antithrombin agent (unfractionated heparin or bivalirudin) and antiplatelet therapies (aspirin, clopidogrel, glycoprotein IIb/IIIa) to prevent thrombosis during and after the procedure, and/or to treat thrombosis causing angina. These

agents serve to prevent clot formation. Before the femoral sheath can be removed, the patient must have some ability to form a clot at the arterial puncture site to prevent a serious bleeding complication or prolonged compression of the artery. Thus, the anticoagulant “effect” of the anticoagulant agents (not the antiplatelets) must be diminished for the patient to be ready for sheath removal. The literature supports the fact that earlier sheath removal reduces bleeding and improves patient comfort.⁵ The difficulty has been in determining when the ability to clot has returned to a level at which sheath removal is safe. To date, clinicians have erred on the conservative side, preferring to wait until certain of hemostasis rather than risk removing the sheath too soon. Yet this may cause unnecessary prolonged sheath

dwelling time, which is known to increase access site bleeding.⁶

How Early Is Too Early?

The quick answer is that it depends on which antithrombin is used during the procedure. In patients receiving unfractionated heparin, an external measure is used to determine clotting ability and, generally, sheaths are removed 4 to 6 hours after PCI. When bivalirudin is used as the base anticoagulant in PCI, sheaths are removed 2 hours after the drug is discontinued. A closer look at the mechanism of action of these 2 drugs explains this difference.

Heparin is an indirect thrombin inhibitor, and requires the presence of the cofactor antithrombin to be effective. Heparin’s action is nonspecific and nonlinear, and each patient responds differently to a dose of

heparin. Unlike most drugs, it is impossible to determine timing of peak effect of heparin, or when plasma levels of heparin are diminished and the drug has “worn off.” Clinicians have dealt with this unpredictability by using an external measure of the patient’s ability to form a clot, generally by using point-of-care ACT. It is critical to understand that the reason ACT testing is done is because of the unpredictable nature of heparin.

Although the ACT test provides a gross measure of coagulation status, it is not an easy solution to determining sheath removal readiness. Perhaps most problematic is the fact that the ACT is not standardized—the absolute numbers are dependent on a number of variables, including the type of instrument, sample factors such as whether

venous or arterial blood is used, the operator's technique, and how the instrument is calibrated.

There are several types of ACT machines on the market. Each works differently, but in general they measure how long it takes a sample of blood to form a clot. Because of variability among machines, results can not be extrapolated from one system to another. For example, readings on the Hemocron (ITC, Edison, NJ) will range 30% higher than the same sample tested on the Hemotec (Medtronic, Minneapolis, Minn) device.⁷

In addition, hospitals differ in the ACT level they consider safe for sheath removal with heparin. Protocols for sheath removal require reaching ACT levels anywhere from 150 to 200 seconds—a tremendous variation—resulting in up to 2 hours or more difference in sheath dwell times. Yet

most hospitals have not done testing to determine whether their ACT “threshold” accurately correlates to access site complications. Most clinicians cannot determine how or why a specific ACT reading was chosen for their particular protocol. Furthermore, the ACT is not a quantitative measure, and the ACT responds to different anticoagulants differently. Because the ACT was developed as an estimation of anticoagulation during procedures with higher levels of anticoagulants, ACTs can get “hung up,” that is, the ACT inaccurately plateaus above the recommended protocol for sheath removal.⁸ When an ACT device does not give a true reading of the patient's ability to clot, it causes an unnecessary delay in sheath removal. If the ACT plateaus, clinicians should be instructed to retest using a different instrument.

Finally, there is no scientific study that even supports the use of ACT in assessing patient readiness for sheath removal. Although Bowers and Ferguson⁷ suggest ACT be used to assess patient readiness for sheath removal, they do not provide data or protocols. One of the few studies⁸ looking at heparin levels and ACT measurement concludes that ACT should not be used for determining sheath removal as ACT tests lose their reliability below 225 seconds. The activated partial thromboplastin time (aPTT) test—although not standardized either—would be somewhat better than the ACT because the low levels of anticoagulation at sheath removal are more within the range of this clotting test. As with the ACT, there are no studies determining the appropriate aPTT level for sheath

removal, and most centers do not have access to a point-of-care aPTT test. However, there is little alternative to these imperfect clotting tests when heparin is used, as some objective measure of coagulation status must be used to show the patient can clot before sheath removal.

Bivalirudin is a newer drug used as a replacement for heparin in PCI. Trials have shown bivalirudin to be more effective than heparin, and as effective as heparin with glycoprotein IIb/IIIa in treating unstable angina patients undergoing a coronary intervention. Bivalirudin has 2 other great advantages over heparin. First, it causes significantly less bleeding, particularly at the access site, and second, sheaths can be removed sooner without the need for ACT testing.⁹ Bivalirudin is a direct thrombin inhibitor, with linear dose

response and little interpatient variability.¹⁰ It is administered as a bolus at the start of the PCI procedure, and maintained with an infusion. Most physicians discontinue bivalirudin at the end of the procedure, although the package insert calls for continuation 4 hours after procedure.¹¹

Because of the reliable pharmacology of bivalirudin, it is possible to determine when the drug has plasma levels that are low enough to safely

remove the femoral sheath without requiring ACT testing.¹²

The half-life of bivalirudin is 25 minutes in patients with normal renal function, and slightly longer

in patients with renal disease (Table 1).^{11,13} A look at the pharmacokinetic curve shows that once the drug is discontinued, it takes approximately 2 half-lives for drug levels to fall to a nontherapeutic level.¹³ Thus, sheaths can be removed in most patients 2 hours after bivalirudin has been discontinued. It is not necessary to monitor the coaguability of the patient's blood with an ACT test as bivalirudin levels fall quickly and

Table 1 Bivalirudin pharmacokinetics

Renal function, GFR, mL/min	Clearance, mL/min/kg	Half-life, min
Normal, 90	3.4	25
Mild renal impairment, 60-89	3.4	22
Moderate renal impairment, 30-59	2.7	34
Severe renal impairment, 10-29	2.8	57
Dialysis-dependent patients	1.0	210

Abbreviation: GFR, glomerular filtration rate.

reliably after the drug is discontinued. The half-life is prolonged in patients with renal failure (creatinine clearance < 0.17 mL/s [10 mL/min]) and who receive renal dialysis, and sheaths should not be removed in 2 hours in these patients. The great advantage to using bivalirudin is that sheaths are removed approximately 2 to 4 hours sooner than in patients who have received heparin, and reliance of the ACT test is unnecessary. Many centers have a separate protocol for sheath removal in bivalirudin patients that calls for sheath removal 2 hours after the bivalirudin has been stopped without requiring ACT testing, and an ACT-based sheath removal protocol in heparin patients.¹¹

Sheath Removal and Bleeding

It is prudent to remove the femoral sheath as soon as possible. While the

sheath is in place, patients must remain in bed, with their leg still, and the head of the bed elevated 30°. This position is extremely difficult for some patients, and is a source of great discomfort to most. Patients who are bedridden and who have not reached hemostasis have a high level of acuity, and require significant staff resources to care for them. Time of first ambulation is almost always predicated on sheath removal time, and once a patient has reached hemostasis and is ambulatory, the level of care required is significantly reduced. Perhaps most importantly, early sheath removal is associated with lower rates of bleeding. True rates of bleeding after PCI are often underreported, despite the fact that bleeding is one of the most frequent complications of PCI.²

Bleeding remains a significant postprocedural complication.²

Often, the nursing staff reports and manages bleeding complications, and nurses are so effective at managing bleeding that physicians do not always appreciate the significance of postprocedural bleeding complications. Only recently has literature appeared to describe the consequence and true rates of bleeding after PCI. These published reports should cause all clinicians to work diligently at reducing bleeding. In a retrospective study of 10 974 PCI patients, Kinnaird et al² reported bleeding to be a significant predictor for in-hospital mortality, as well as other adverse cardiac events. Surprisingly, patients in this study who had a bleeding event had greater mortality even 1 year after hospitalization. Also, Kinnaird et al reported high rates of thrombolysis in myocardial infarction (TIMI) major (5.4%) and

TIMI minor (12.7%) bleeding events, with most of the bleeding (60%) presenting as a hematoma. Both are significant clinical events that increase morbidity and length of stay. This study also reported a high transfusion rate of 5.4%. Slater et al¹⁴ confirmed the relationship between bleeding and mortality in a study of 6613 PCI patients, finding that patients who had a hematoma requiring transfusion had a 3.5 times greater risk of mortality. Even minor bleeding and small hematomas cause an increase in length of hospitalization.¹⁵ Finally, hematomas are significant complications to patients, regardless of their size. In addition to causing pain and discomfort, hematomas delay a patient's return to complete mobility for several weeks. Although this may be inconsequential for nurses and physicians, it is something patients will remember negatively about their hospital stay and recovery period at home.

How Long Is Too Long?

Data show that delayed sheath removal is dangerous. In the REPLACE-2 trial¹⁵ of more than 6000 PCI patients, the study protocol called for sheaths to be removed when ACT was <175 seconds. Sheath dwell time of 7 hours or greater was a statistically significant predictor of a protocol major bleeding event, but dwell time of 5 hours was not a predictor.¹⁶ Previously, the SANDBAG substudy of the IMPACT-II trial⁵ also found that patients who had femoral sheaths removed <7.1 hours after insertion had a lower rate of access site bleeding (5.4%) compared with patients who had sheaths removed up to 16.8 hours (6.4%).⁵ These data strongly suggest that sheaths should

be removed before 7 hours after insertion, and the REPLACE-2 data suggest most patients can probably have sheaths removed within 5 hours of insertion (sheath dwell time was measured from sheath insert until sheath removal).¹⁵

Another study, the National Angiomax Sheath Removal Survey (NASS; unpublished data, The Medicines Company, Parsippany, NJ), documented sheath removal, ambulation, times, and bleeding outcomes in 505 patients receiving bivalirudin. The study was a prospective, multi-center, observational survey and included 320 patients who did not receive closure devices. Sheath removal was performed in accordance with institutional practice. This study found a strong correlation between sheath removal times and bleeding complications that further supports the concept of a window of opportunity for sheath removal. The NASS survey data showed a reduction in access site bleeding in patients receiving bivalirudin when sheaths were removed within 2 to 4 hours of

insertion. A sheath dwell time of >4 hours showed an increase in complications in this set of patients taking bivalirudin (Table 2).

Conclusion

Protocols for sheath removal vary from hospital to hospital. There are little rigorous data on the "best" method of sheath removal. Yet sheath removal is arguably the most critical step toward patient recovery after PCI. Current thinking is to use caution when determining patient readiness for sheath removal by taking continual ACT measurements and waiting until certain that the patient's clotting mechanism is functioning. Data challenging that cautious approach suggest that although early sheath removal may cause complications, sheaths left in too long can also cause serious complications.

Timing of sheath removal is more complex than waiting for an ACT level to reach the protocol-stated level. There is a window of optimal timing to sheath removal. In bivalirudin patients, a simple 2-hour sheath

Table 2 Results from the National Angiomax Sheath Removal Survey for nonclosure device patients (unpublished data, The Medicines Company, 2004)

Characteristic	2 hours (n=61)	2.1-2.9 hours, (n=63)	3.1-3.9 hours, (n=69)	4 hours, (n=127)
Sheath removal time in minutes, mean±SD	89±29	152±18	209±17.5	405±241
ACT* at sheath removal, mean±SD	246±75	151±51	126±64	113±67
Access site complications, %	6.5	3.2	4.3	7.9
No. of patients with transfusion (%)	1 (1.6)	0	0	3 (2.4)
Access site complications				
No. of patients with a hematoma >5 cm (%)	1 (1.6)	0	1 (1.4)	6 (4.7)
No. of patients with pseudoaneurysm (%)	0	0	2 (2.9)	0
No. of patients with oozing requiring intervention (%)	2 (3.3)	2 (3.2)	0	1 (0.8)

Abbreviation: ACT, activated clotting time.
*Reported in seconds.

removal protocol (except in dialysis-dependent patients) helps avoid missing the window of opportunity. The window is more complicated to determine in heparin patients, but even in this group the data advocate for faster sheath removal than is presently practiced in many institutions.

Sheath dwell time is clearly associated with access site complications, and perhaps some of the caution that causes sheaths to stay in longer is actually detrimental to our patients. This is a critical issue that needs more study and attention.

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