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Trends in Vascular Complications After Diagnostic Cardiac Catheterization and Percutaneous Coronary Intervention Via the Femoral Artery, 1998 to 2007

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Objectives This study sought to evaluate trends in vascular complications after diagnostic cardiac catheterization (CATH) and percutaneous coronary intervention (PCI) from the femoral artery from 1998 to 2007.

Background Vascular complications have been recognized as an important factor in morbidity after CATH and PCI. Whether strategies to reduce vascular complications performed from the femoral artery in the past decade have improved the safety of these procedures, however, is uncertain.

Methods A total of 35,016 consecutive diagnostic cardiac catheterization (n = 20,777) and percutaneous coronary intervention procedures (n = 14,239) performed via a femoral access at a single site (Wake Forest University Baptist Medical Center) between 1998 and 2007 were evaluated. Annual rates of vascular complications were evaluated. Covariate effects on the risk of vascular complications were evaluated by logistic regression and risk-adjusted trend analysis.

Results Overall, the incidence of any vascular complication decreased significantly for CATH, 1.7% versus 0.2%, and PCI, 3.1% versus 1.0%, from 1998 to 2007, both $p < 0.001$ for trend. Favorable trends in procedural covariates affecting vascular complications were mainly responsible for the decrease in the incidence of vascular complications, including fewer closure device failures and use of smaller sheath sizes.

Conclusions In this large, single-center, contemporary observational study, the safety of CATH and PCI performed from the femoral artery improved significantly from 1998 to 2007. Reductions in the prevalence of adverse procedural factors contributed to the decrease in the incidence of vascular complications, suggesting that strategies to reduce vascular complications can be effective in improving the safety of these procedures. (J Am Coll Cardiol Intv 2008;1:317–26) © 2008 by the American College of Cardiology Foundation

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Recent studies have identified bleeding after diagnostic cardiac catheterization (CATH) and percutaneous coronary intervention (PCI) procedures (1–4), particularly retroperitoneal bleeding (5,6), as a significant source of morbidity and mortality after these procedures. Although not all of the bleeding can be directly attributed to complications at the procedure access site, access site complications remain a significant factor in post-procedural bleeding (7–9). Although medical and PCI treatments have been modified to minimize access site bleeding from anticoagulant and antiplatelet therapies (8,10), their use as pre-procedural treatment has increased substantially in the past decade, which could increase the risk of vascular complications. At the same time, strategies aimed at reducing femoral artery access site complications, such as use of fluoroscopy to guide femoral artery access (11), utilization of vascular closure devices (VCDs), and use of smaller sheath sizes, have been introduced into practice. Whether the awareness of the importance of access site complications on overall procedural outcomes (12–14), or utilization of VCDs (15,16) and smaller sheath sizes (12,17,18), or changes in medical and PCI practice (8,10) have had an effect on the incidence of vascular complications in the past decade is not clear. Accordingly, we assessed trends in the incidence of vascular complications after CATH and PCI procedures performed from the femoral artery from 1998 to 2007. We also evaluated trends in patient and procedural covariates that may have affected the risk of developing a vascular complication from these procedures.

Abbreviations and Acronyms

CATH = diagnostic cardiac catheterization
GP = glycoprotein
MC = manual compression
PCI = percutaneous coronary intervention
VCD = vascular closure device

Methods

All patients at our institution undergoing percutaneous CATH and PCI were evaluated for this study, which was approved by the Institutional Review Board. A total of 23,157 patients underwent 35,016 procedures from January 1998 to March 2007. Choice of the access site was at the discretion of the physician performing the case. Preference was for femoral artery access, with radial and brachial access obtained when femoral access could not be obtained; 22,846 patients underwent 34,556 procedures using the femoral approach, 79 patients underwent 105 procedures from the radial artery, and 232 patients underwent 355 procedures from the brachial approach, and form the basis for this study. Data from some of these patients have been included in a prior publication (19).

For patients undergoing procedures via femoral artery access, CATH patients received unfractionated heparin after sheath insertion at the discretion of the cardiologist performing the procedure. For patients undergoing procedures via radial or brachial access, 3,000 to 5,000 units of heparin were given immediately after sheath insertion. Anticoagulation after sheath insertion for PCI patients was obtained using unfractionated heparin with a target activated clotting time of 200 to 250 s if used in conjunction with glycoprotein (GP) IIb/IIIa inhibitors, or 250 to 300s otherwise (10), or bivalirudin per standard protocol (8). Patients in the study received GP IIb/IIIa receptor inhibition also according to usual protocol with abciximab or eptifibatide (20). Post-PCI patients were treated with aspirin (81 to 325 mg/day) and clopidogrel (300 or 600 mg as a loading dose followed by 75 mg/day) if stents were placed.

Access site management. The method of arterial access management was chosen by the cardiologist performing the procedure. Manual compression was obtained by physicians performing the procedure, or trained catheter laboratory and nursing unit personnel. The VCD placement was performed by physicians trained in their use. Brachial artery sheaths were removed immediately after the procedure, and hemostasis was obtained by manual compression. Radial artery sheaths also were removed immediately after the procedure with hemostasis obtained using Hemoband compression (Hemoband Corp., Portland, Oregon). The VCDs were placed only after a femoral arteriogram was performed via the arterial sheath. Patients did not undergo arterial closure with a VCD if: 1) the arteriotomy site was below the femoral bifurcation; 2) the common femoral artery was <5 mm in diameter; 3) extensive calcification or plaque formation was present in the common femoral artery; or 4) extensive scar tissue was present at the access site. Closure was performed using a variety of VCDs at the discretion of the cardiologist performing the procedure including Angioseal (St. Jude Medical, St. Paul, Minnesota), Vasoseal (Datascope Corp., Mahwah, New Jersey), Quikseal (Sub-Q Inc., San Clemente, California), Duett (Vascular Solutions, Minneapolis, Minnesota), and Perclose and Starclose (Abbott Vascular, Redwood City, California) (20). All sheaths were removed soon after the procedure as outlined below. In patients in whom arterial closure was not performed in the laboratory, the sheath was pulled when the activated clotting time was $\leq$180 s in patients who received heparin or $\geq$2 h after the infusion of bivalirudin was completed. Use of a topical thrombin hemostatic patch (D-STAT Dry, Vascular Solutions) to facilitate manual compression was introduced in April 2004 and used on all subsequent manual compressions (21). Ambulation was initiated 2 h after the VCD was placed or D-STAT was used, and 6 h after manual compression alone.

Access site evaluation was routinely done after the procedure and before discharge. The nurse caring for the patient examined the access site for possible vascular complications and recorded the findings in the nurses' notes. The physicians caring for the patient also examined the