Peripheral Vascular Complications After Conventional and Complex Percutaneous Coronary Interventional Procedures

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To determine whether complex cardiovascular interventional procedures (including coronary stent implantation, directional atherectomy, aortic valvuloplasty, and the use of an intraaortic balloon pump or cardiopulmonary bypass support) are associated with an increased likelihood of vascular access site complications, 2,400 consecutive cardiac catheterization procedures were prospectively screened over a 12-month study period. Complications occurred in 35 patients after 39 procedures (1.6%) and included the need for vascular surgical repair (17 patients), blood transfusion (28 patients) and systemic antibiotic therapy (7 patients). The incidence of complications after 1,519 diagnostic studies was 0.6%, after 698 conventional coronary balloon angioplasties 2.6%, and after 183 complex interventions 6.0% ($p < 0.0001$); 43% of the complications occurred after procedures of >2 hours' duration and 14% occurred in patients in whom arterial sheaths remained in situ for >24 hours. Detailed demographic and procedural characteristics were compared between the 35 patients with vascular complications and 150 patients randomly drawn from a computerized database of the uncomplicated procedures performed during the screening period. By univariate analysis with correction for multiple comparisons, variables predicting the likelihood of vascular complications included: periprocedural use of heparin ($p < 0.001$) or fibrinolytic therapy ($p < 0.001$), arterial sheath size ≥8Fr ($p < 0.001$), patient age ≥65 years ($p = 0.01$), and the presence of peripheral vascular disease ($p = 0.03$).

The results of this study suggest that the overall incidence of access site complications is low but increases with the use of complex cardiovascular interventional procedures. Further refinements in the caliber of the new devices, vigilant monitoring of adjunctive anticoagulant therapy, and careful patient selection may reduce the morbidity and increase the safety of these procedures.

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Since the advent of diagnostic cardiac catheterization >25 years ago, the complexity of diagnostic and therapeutic coronary angiographic procedures has increased considerably. This has resulted, in part, from an expansion of the indications for percutaneous coronary intervention to include older and more hemodynamically unstable patients, and patients with more extensive coronary and peripheral vascular disease.[1-4] In addition, the introduction of a variety of new devices for the treatment of coronary arterial disease, including atherectomy catheters, metallic stents and circulatory support devices, has necessitated the use of both large caliber guiding catheters and arterial sheaths, and intensive periprocedural anticoagulant and fibrinolytic therapy.[5-7] The hazards associated with the use of these new devices include a potentially greater risk of arterial injury at the access site. Previous studies have reported the incidence of arterial complications after diagnostic cardiac catheterization[1-2,8-11] and percutaneous transluminal coronary angioplasty (PTCA),[3,12-15] but the incidence of peripheral vascular complications after more complex interventional procedures has not been systematically evaluated. The aims of this study, therefore, were (1) to characterize and to compare the risks of peripheral vascular injury after diagnostic cardiac catheterization, conventional PTCA, and complex coronary interventional procedures; and (2) to identify clinical and procedural factors that predict the likelihood of these complications.

METHODS

Patient selection and clinical assessment: All patients undergoing diagnostic or therapeutic cardiac catheterization at the University of Michigan Medical Center were prospectively evaluated over a 12-month study period. Each patient was interviewed and examined by a physician or physician's assistant immediately before the procedure. The clinical variables recorded included patient age, sex, height and weight, presenting symptoms, risk factors for arteriosclerotic disease, and the presence or absence of clinically detectable peripheral vascular disease. The procedural parameters recorded included the type of catheterization procedure performed, the size of the arterial and venous sheaths, the peri- or postprocedural use of antiplatelet, anticoagulant or fibrinolytic therapy, the duration of the procedure, the length of time from procedure completion until sheath removal, and the duration of bedrest after sheath removal. Patients undergoing outpatient diagnostic procedures were examined for evidence of access site complications immediately before discharge and were then interviewed by telephone 48 to 72 hours later. Pa-

tients remaining in the hospital were examined daily for the duration of the hospital stay. When vascular injury was suspected, duplex color flow Doppler imaging was performed as previously described,[16] and a vascular surgical opinion was obtained. All complications were prospectively recorded, and the subsequent course of each patient in this group was then followed to document the need for and timing of surgical repair, and the nature of the arterial injury as identified at the time of surgery. Details of the vascular surgical management of the peripheral vascular complications of cardiac catheterization procedures at our institution have been previously published.[17]

Procedural details: Ninety-nine percent of the cardiac catheterization procedures during the study period were performed from a percutaneous femoral arterial or venous approach; the remainder were performed from the brachial approach. Arterial punctures for diagnostic procedures were performed predominantly by junior cardiology fellows; those for interventional procedures were performed by senior cardiology fellows or by 1 of 6 attending physicians. Diagnostic procedures were performed through 6, 7 or 8Fr arterial sheaths. Heparin was not administered routinely during elective procedures; in stable patients, intravenous heparin infusions were discontinued ≥4 hours before arterial needle puncture. In patients undergoing emergency cardiac catheterization soon after the administration of thrombolytic therapy and heparin for acute myocardial infarction, the sheaths remained in situ after the completion of the procedure until the fibrinogen level had risen to ≥150 mg/dl and the activated partial thromboplastin time had returned to the normal range. All patients undergoing elective PTCA were pretreated with oral aspirin (325 mg/day) and received intraprocedural heparin (10,000 to 15,000 U intravenous bolus, then 5,000 U intravenously each hour). Therapy with heparin was not continued after uncomplicated procedures, and the sheaths (7 or 8Fr) were removed approximately 4 hours after the last heparin bolus. Patients with suboptimal angiographic results were treated overnight with an infusion of intravenous heparin (approximately 1,000 U/hour) and had their sheaths removed the following morning, 4 hours after discontinuation of heparin. Procedural details of the complex procedures have been previously described.[5-7] In brief, coronary stents were placed through 8, 9 or 10Fr guiding catheters and arterial sheaths, coronary atherectomy was performed through 11Fr guiding catheters, intraaortic balloon pumps were placed through 9.5 or 10.5Fr sheaths, aortic balloon valvuloplasty procedures were performed through 12 or 14Fr sheaths, and percutaneous cardiopulmonary support was instituted through 18 or 21Fr arterial and venous sheaths. The anticoagulation regimen for most complex interventions was similar to that described for conventional PTCA. Patients in whom coronary stents were implanted were pretreated with oral persantine and intravenous dextran (in addition to oral aspirin), and continued with infusion of heparin at therapeutic concentrations until oral anticoagulation with coumadin was established. Before sheath removal, the heparin infusion rate was reduced to 400 U/hour for a period of approximately 4 hours. The rate was then increased to the therapeutic rate 1 hour after sheath removal and the achievement of secure hemostasis. In patients in whom cardiopulmonary support was instituted, sufficient heparin was given to maintain the activated clotting time ≥300 seconds for the duration of the procedure. After completion of the procedure, sheaths were removed either by elective vascular surgical repair or by removal and prolonged compression after the clotting parameters had returned to normal.

Complications: Access site complications were defined as (1) local or retroperitoneal hemorrhage requiring the transfusion of ≥2 U of blood, (2) the need for surgical drainage or nonelective arterial repair of the access site, or (3) local or systemic infection requiring oral or intravenous antibiotic therapy. Patients undergoing elective surgical removal of cardiopulmonary support device sheaths were not included. The cardiac catheterization procedures performed were classified as diagnostic procedures (including right-sided cardiac catheterization, selective coronary angiography, left ventriculography and aortography), conventional coronary balloon angioplasty (including the adjunctive use of intracoronary or systemic fibrinolytic therapy) or complex interventional procedures. The latter classification included aortic balloon valvuloplasty, and the use of new percutaneous coronary revascularization devices (directional coronary atherectomy, endovascular stents or laser ablation catheters), or circulatory support devices (intraaortic balloon counterpulsation or percutaneous cardiopulmonary bypass). Predictive risk factors for peripheral vascular complications were identified by comparing the prevalence of selected clinical variables (patient age, presence of ≥3 risk factors for coronary arterial disease, and the presence of peripheral vascular disease) and procedural variables (arterial sheath size, and use of intraprocedural heparin or periprocedural fibrinolytic therapy) in the group of patients with access site complications and in a group of 150 patients randomly selected from the computerized database of event-free cardiac catheterization procedures.

Statistics: Differences in the incidence of complications between groups were compared using chi-square analysis. Univariate chi-square analysis with a Bonferroni correction for multiple comparisons was performed to identify individual clinical and procedural factors predicting the likelihood of arterial complications. A 2-tailed probability value <0.05 was considered statistically significant.

RESULTS

Access site complications: During the study period, 2,400 consecutive elective or emergency cardiac catheterization procedures were performed. These procedures included, 1,519 diagnostic procedures, 698 conventional coronary balloon angioplasties and 183 complex interventional procedures. The complex procedures included 69 coronary atherectomies, 25 coronary stent implantations, 34 aortic valvuloplasties, and the use of an intraaortic balloon pump in 45 patients and percutaneous

TABLE I Peripheral Vascular Complications: All Catheterization Procedures

Complications	Number (%)
Vascular	
Pseudoaneurysm	8 (21)
Laceration	6 (15)
Arterial occlusion	3 (8)
Arteriovenous fistula	3 (8)
Hematoma	1 (3)
Need for blood transfusion (≥ 2 U)	
With vascular surgery	14 (36)
Without vascular surgery	14 (36)
Sepsis	7 (18)
Death	2 (6)

TABLE II Demographic Variables and Peripheral Vascular Complications

Variable	Complication (%) (n = 39)	No Complications (%) (n = 150)
Age ≥ 65 years	20 (51)	39 (26)
Men/women	21/18 (54/46)	105/45 (70/30)
Systemic hypertension	22 (56)	56 (37)
Diabetes mellitus	12 (31)	56 (15)
Cigarette smoking	24 (62)	75 (50)
Hypercholesterolemia	22 (56)	55 (34)
Peripheral vascular disease	11 (28)	15 (10)
Obesity (body mass index ≥ 28 kg/m^2)	8 (21)	65 (43)

cardiopulmonary bypass support in 10 patients. Access site complications were identified in 36 patients (21 men, 15 women) after 39 procedures, each of which was performed using a percutaneous femoral arterial approach. The incidence of complications after diagnostic procedures was 0.6%, after conventional balloon angioplasty 2.6%, and after complex interventional procedures 6.6% ($p < 0.0001$) (Figure 1). Complications occurred in 4% of patients requiring intraaortic balloon counterpulsation, in 6% of patients undergoing atherectomy, 6% after aortic valvuloplasty, 8% after coronary stent implantation, and 20% after use of percutaneous cardiopulmonary support.

The complications encountered were predominantly associated with femoral arterial injury that occurred after 21 procedures (Table I). The most frequent injury was a femoral arterial pseudoaneurysm, which was identified by color flow Doppler imaging or at the time of surgery. Five of the 8 pseudoaneurysms were surgically repaired and 3 were treated conservatively. Each of the other vascular complications, including a femoral arterial laceration in 6 patients, arterial occlusion or thromboembolism in 3 patients, and femoral arteriovenous fistulas in 3 patients, required surgical treatment. Overall, surgical repair was required after 0.3% of diagnostic procedures, 0.7% of conventional angioplasty procedures and 3.8% of complex interventions ($p < 0.0001$) (Figure 1). Blood transfusion of ≥2 U of blood was required after 28 procedures (72%); 14 of these transfusions were administered to patients requiring vascular surgical repair of the access site and the remainder were

TABLE III Univariate Analysis of Risk Factors

Variable	Univariate Chi-Square	Corrected p Value	Odds Ratio	95% CI
Arterial sheath size ≥ 8Fr	23.3	< 0.001	5.0	2.3–10.6
Thrombolytic therapy	29.0	< 0.001	4.9	3.2–7.4
Periprocedural heparin	20.8	< 0.001	4.2	2.1–8.6
Age ≥ 65 years	9.8	0.01	2.4	1.4–4.1
Peripheral vascular disease	8.2	0.03	2.4	1.4–4.3
≥ 3 coronary risk factors	2.3	0.06	2.3	1.3–4.0

CI = confidence interval.

administered to patients with local hemorrhage who were treated nonsurgically. Antibiotic therapy was administered to 7 patients (Table I), each of whom had infection limited to the local access site with no evidence of systemic infection by multiple blood cultures. One patient died from multisystem organ failure after diagnostic cardiac catheterization, and 1 patient died 24 hours after coronary balloon angioplasty from abrupt closure of the dilated right coronary artery. In this series, there were no postprocedural deaths after complex interventional procedures.

Demographic risk factors for vascular complications: When compared with the 150 randomly selected patients without complications, patients with access site complications tended to be older, had a greater prevalence of individual risk factors for atherosclerotic disease and a higher incidence of peripheral vascular disease, but had a lower incidence of obesity (defined as a body mass index ≥28 kg/m^2, where body mass index = weight/height^2) (Table II). By univariate analysis after correction for multiple comparisons, patient age ≥65 years and the presence of peripheral vascular disease remained statistically significant risk factors ($p = 0.01$ and $p = 0.03$, respectively) (Table III).

Procedural risk factors for vascular complications: The strongest procedural predictors of the likelihood of peripheral vascular complications were the use of large caliber introducing sheaths and the use of periprocedural anticoagulant and fibrinolytic therapy (Tables III

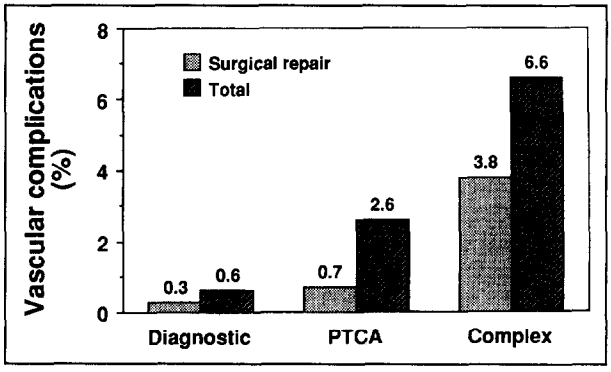

FIGURE 1. Comparison of the incidence of access site complications and need for surgical intervention in patients undergoing diagnostic cardiac catheterization, conventional percutaneous transluminal coronary angioplasty (PTCA), and complex cardiovascular interventional procedures. Differences between the groups were highly statistically significant ($p < 0.0001$).

TABLE IV Procedural Variables and Vascular Complications

Variable	Complication (%) (n = 39)	No Complications (%) (n = 150)
Procedure performed		
Diagnostic cardiac catheterization	6 (24)	100 (67)
Coronary angioplasty	18 (46)	38 (25)
Atherectomy	4 (10)	2 (1.3)
Stent	2 (5)	3 (2.0)
Valvuloplasty	2 (5)	3 (2.0)
Intraaortic balloon pump	2 (5)	2 (1.3)
Cardiopulmonary support device	2 (5)	1 (0.7)
Adjunctive therapy		
Preprocedural aspirin	36 (92)	110 (73)
Intraprocedural heparin therapy	32 (83)	53 (35)
Intraprocedural lytic therapy	11 (29)	2 (1.3)
Procedural details		
Arterial sheath size ≥8Fr	32 (82)	56 (37)
Procedure duration >2 hours	17 (43)	5 (3)
Sheaths in situ >24 hours	5 (14)	—

and IV). Arterial sheaths with a caliber ≥8Fr were used in 82% of patients who developed complications compared with 37% of those without complications ($p < 0.001$); arterial sheath sizes ≥9Fr were used in 29% of patients with arterial complications. Intraprocedural heparin was administered to 83% of patients with complications compared with 35% of event-free patients ($p < 0.001$), and fibrinolytic therapy was used in 29 and 1.4% of patients, respectively ($p < 0.001$). The preprocedural use of aspirin was also somewhat higher in the complicated group (92 vs 73%). In the group with arterial complications, 43% underwent cardiac catheterization lasting >2 hours, and in 14% the arterial sheaths remained in situ for >24 hours because of the periprocedural administration of fibrinolytic therapy or the need for uninterrupted postprocedural anticoagulant therapy.

DISCUSSION

The principal findings of this study are that the incidence of peripheral arterial complications after complex interventional procedures is significantly higher than after conventional diagnostic and therapeutic procedures. The incidence of complications was most closely associated with the use of large caliber introducing sheaths and the use of periprocedural anticoagulant or fibrinolytic therapy.

Vascular complications after diagnostic cardiac catheterization: Several large, multicenter registries[1,2,8,9] and single center studies[10,11] have documented the frequency of vascular complications after diagnostic cardiac catheterization. In studies that have excluded patients aged <1 year, the incidence of arterial complications has ranged from 0.2 to 1.9%, depending on the access site. In general, thrombotic ischemic arterial complications have been somewhat higher after procedures performed from the brachial approach than from the femoral route, but the latter approach has been associated with a higher incidence of hemorrhagic complications.[1,2,8–11] The overall incidence of 0.6% and the need for surgical repair in 0.3% in this study is comparable to that noted for femoral vascular access in the larger series.

Diagnostic procedures versus conventional percutaneous transluminal coronary angioplasty: The overall incidence of vascular complications after conventional PTCA in this study (2.6%), and the need for operative arterial repair (0.7%), also compare favorably with the frequencies quoted in previous reports. Two single center studies have compared the incidence of local vascular access site complications after diagnostic cardiac catheterization and conventional PTCA.[12,13] In these studies, coronary angioplasty was not associated with an increased incidence of complications but, in both studies, the frequency of vascular complications after diagnostic procedures was relatively high. In the study of Wyman et al,[12] surgical repair of the femoral artery was required after 1.6% of diagnostic procedures compared with 1.5% after coronary angioplasty, and Kaufman et al[13] noted an incidence of vascular complications of 0.9% after coronary angioplasty compared with 1.2% after diagnostic procedures. Three other studies have reported the incidence of peripheral vascular complications after PTCA.[3,14,15] In the 1977 to 1981 National Heart, Lung, and Blood Institute's PTCA registry of 1,500 patients,[3] local vascular complications occurred after 1.5% of the procedures, and in 2 large studies from Emory University, vascular complications occurred after 0.6% of 3,500 coronary angioplasties performed between 1980 and 1984,[14] and 1% of 4,988 PTCA procedures performed between 1985 and 1988.[15] In the latter study, peripheral vascular complications correlated strongly with patient age and the postprocedural use of heparin.

Complex coronary interventional procedures: Over the past 10 years, an increasing number of percutaneous coronary interventions have been performed in patients with unstable coronary syndromes, severe multivessel coronary artery disease, complex coronary lesion morphology, previous coronary artery bypass graft surgery and severely impaired left ventricular function.[4] In an effort to improve the safety of these high-risk procedures, a variety of new devices have been developed to reduce the likelihood of arterial dissection and abrupt closure, or to provide circulatory support in the event of profound myocardial ischemia and dysfunction. The use of these devices has necessitated the placement of large caliber catheters in peripheral arteries and veins, often in association with intensive anticoagulation or the administration of fibrinolytic therapy. Although previous reports have described the frequency of access site complications occurring after the use of some of these devices,[5,18] no study has previously compared the vascular morbidity of these new procedures with that of conventional coronary interventions.

One of the earliest devices used to increase the safety of conventional PTCA was the intraaortic balloon pump. Several studies have reported an increased incidence of vascular complications and sepsis after the use of these devices.[19–22] In these studies, the need for vas-

cular surgical repair ranged from 10.7 to 37%, and correlated with a history of diabetes mellitus,[19,21] the presence of peripheral vascular disease,[19] and with prolonged circulatory support (>20 days).[20] In the current study, the use of intraaortic balloon pumping for high-risk coronary interventions was associated with an incidence of access site complications of only 4.4%. The frequency of complications reported after the use of percutaneous cardiopulmonary support devices has also been high.[23,24] In 1 single center experience, vascular repair was required after 10% of procedures in which cardiopulmonary support was used, and 30% of the patients required blood transfusion.[23] Vascular morbidity was also high in a report from a multicenter cardiopulmonary support registry[24]; blood transfusion was required in 43% of 105 patients and significant arterial injury occurred in 26% of the study group. In the current study, 2 of 10 patients treated with percutaneous cardiopulmonary support required both nonelective vascular surgical repair and blood transfusion.

Relatively little has been published on the frequency of arterial complications after coronary atherectomy or stent implantation. In 1 study, vascular surgical repair was required in 2% of 67 patients after coronary atherectomy.[5] After Palmaz-Schatz stent implantation, 10 of 174 patients (5.7%) treated with the current intensive anticoagulant regimen required blood transfusion or vascular surgical repair.[18] In our own experience, although the incidence of access site complications was 8% in this study, the need for blood transfusion has been as high as 15% after elective stent implantation.[25,26] This high incidence of bleeding was attributed to excessive anticoagulation with heparin and has fallen considerably since the introduction of more vigorous monitoring of the patients' coagulation status. Aortic balloon valvuloplasty, another procedure requiring the use of large caliber introducing sheaths and balloon catheters, has been associated with major vascular complication rates ranging from 7 to 10%[12,27] and in 1 series[28] was associated with the need for leg amputation in 3 of 492 (0.6%) patients. A similar incidence of complications was noted in this study.

Clinical implications: In the current study, the strongest predictors of the need for vascular surgical repair, blood transfusion or systemic antibiotic therapy after percutaneous cardiovascular interventional procedures were the size of the arterial catheters, and the use of anticoagulant or fibrinolytic therapy. Patient age and the presence of peripheral vascular disease were also important variables, but patient gender, individual risk factors for coronary artery disease, obesity and the extent of coronary disease did not appear to be important factors. These findings suggest that the incidence of vascular complications might be reduced by further technical refinements such as a reduction in device caliber. In recent years, the caliber of directional coronary atherectomy catheters, intraaortic balloon pumps and the arterial and venous catheters of the percutaneous cardiopulmonary support device have all been effectively reduced. Furthermore, a reduction in the profile of both fixed-wire and over-the-wire balloon angioplasty systems has permitted an increasing number of coronary angioplasties to be performed through 6 and 7Fr guiding catheters.[29] Efforts to reduce the thrombogenicity of metallic stents are also clearly warranted so that the need for intensive antiplatelet and antithrombotic therapy may be reduced. Finally, although less predictive of the likelihood of complications, patient selection remains an important consideration, particularly in the choice of 2 procedures of apparently equivalent efficacy in elderly patients or those with overt peripheral vascular disease.

Study limitations: The relatively small number of access site complications in this study limits the number of clinical and procedural variables that can be legitimately evaluated as predictive factors. Similarly, the low event rate does not permit any direct comparison of the likelihood of complications after the respective coronary interventional procedures. Finally, multivariable regression analysis was not performed; the variables identified by univariate analysis may thus be interrelated.

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