Clinical Studies

Stenting in acute coronary syndromes: a comparison of radial versus femoral access sites

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Abstract

Objectives. The purpose of the present study was to compare the radial approach with the femoral approach for coronary stenting in patients with acute coronary syndromes.

Background. Aggressive anticoagulation in patients with acute coronary syndromes increases the risk of femoral vascular complications. The transradial approach has the potential to significantly reduce the incidence of access site bleeding complications in this group of patients.

Methods. One hundred forty-two patients with acute coronary syndromes undergoing coronary stenting were prospectively randomized to have their procedure performed from either the radial or femoral access site and the results compared.

Results. Nine of 74 patients randomized to the radial group crossed over to the femoral group (6 negative Allen tests, 3 access failures). Patient demographics were

the same in both groups. Primary success was identical: 96% radial, 96% femoral, ns. There were no procedural myocardial infarctions or deaths, and no patient was referred for emergency bypass surgery. There were no access site bleeding complications in the radial group as opposed to 3 (4%) in the femoral group, $p < 0.01$. Postprocedure length of stay, days (1.4 ± 0.2 radial vs. 2.3 ± 0.4 femoral, $p < 0.01$) as well as total hospital length of stay (3.0 ± 0.3 radial vs. 4.5 ± 0.5 femoral, $p < 0.01$) were significantly reduced in the radial group. Total hospital charge was also significantly lower in the radial group ($20,476 ± 811 radial versus $23,389 ± 1,180 femoral, $p < 0.01$).

Conclusion. Coronary stenting from the radial approach is efficacious in patients with acute coronary syndromes. Access site bleeding complications are less, and early ambulation results in a shorter hospital length of stay. There was a 15% reduction in total hospital charge in the radial group.

Abbreviations: EKG, electrocardiogram; CPK, creatinine phosphokinase; NHLBI, National Heart Lung and Blood Institute; PTCA, Percutaneous transluminal coronary angioplasty

Article Outline

The transradial approach for coronary intervention was first introduced by Kiemeneij et al. and its benefits have subsequently been clearly demonstrated in several studies from different centers [1]. Access site bleeding complications are virtually eliminated [2, 3 and 4]. Patients may ambulate immediately after the procedure and hospital

lengths of stay are significantly reduced [2, 3 and 4]. There is a substantial economic benefit with the transradial approach, and this can be demonstrated with either evaluation of hospital costs or total hospital charge [3, 4, 5 and 6]. Procedural morbidity is less, and patients overwhelmingly prefer the transradial over the femoral approach [2 and 7].

The contemporary management of acute coronary syndromes involves intensive anticoagulation which may include thrombolytic therapy or platelet glycoprotein IIb/IIIa receptor inhibition in addition to heparin and aspirin. Coronary stenting from the femoral approach in these patients is associated with an increased incidence of access site complications [8, 9, 10, 11 and 12]. These bleeding vascular complications are an important cause of increased patient morbidity, longer hospital stays, and higher hospital costs [12, 13 and 14]. Thus, the transradial approach may be particularly beneficial in patients with acute coronary syndromes.

The purpose of the present randomized prospective study was to evaluate the transradial approach in these patients.

Methods

Patients

The study population was drawn from the 341 patients with acute coronary syndromes who were admitted to our hospital between April and July 1997. All patients within this group who underwent coronary stenting were included in the study. There were 142 patients (42%) who met this criteria. The remaining patients were managed with medications alone, angioplasty alone, or coronary bypass surgery. The study was performed in compliance with our Human Studies Committee and written informed consent was obtained in every patient.

Acute coronary syndromes included unstable angina, non-Q wave myocardial infarction, and transmural myocardial infarction. Unstable angina was defined as new onset or rest angina associated with ST and T wave changes and >75% coronary stenosis by visual angiographic assessment corresponding to the distribution of the EKG changes. Patients with the same findings and, in addition, a significant rise in

their serum CPK level, were considered to have a nontransmural myocardial infarction. Transmural myocardial infarction was defined by the presence of persistent ST segment elevation or Q wave formation associated with their chest pain syndrome. Most of these patients were managed with thrombolytic therapy at an outside hospital and subsequently referred to our institution for possible intervention.

Most patients underwent cardiac angiography and the coronary intervention as part of the same procedure. Thus, randomization to either radial or femoral group access occurred prior to the catheterization procedure. Patients were included in the study only if coronary stenting was planned. All of the transradial procedures were performed by two of the authors (TM, JS). Transfemoral procedures were performed by five different interventionalists (TM, JS, WN, MZ, GR).

All patients randomized to the radial group underwent an Allen test as well as Doppler analysis of the radial and ulnar arteries prior to the procedure [15]. Patients randomized to the radial group whose evaluation suggested an incomplete palmer arch had their procedures performed from the femoral approach. Patients randomized to the radial group whose radial artery could not be successfully catheterized were counted as a radial failure and had their procedure performed from the femoral approach.

Procedure. The technique of radial artery cannulation has been previously described [16]. This technique was slightly altered during the latter stages of the study, in that verapamil 2 mg was injected directly into the radial artery prior to insertion of the sheath and these patients were not premedicated with Procardia sublingually. Catheterization was performed with 6 French Cordis multipurpose diagnostic catheters. Subsequent angioplasty and stent implantation was performed using 6 French SCIMED 0.064 Triguide guide catheters. Alternatively, Schneider 0.061 Pink Power guide catheters were commonly utilized when deep seating of the guide catheter was required [16].

In the femoral group, catheterization was performed using 6 French diagnostic catheters, usually Judkins curves. All patients in the femoral group underwent coronary stenting using the same bare stent technique as in the radial group. Twenty

of these patients had their procedure performed using 6 French guide catheters, and 57 using 7 French guide catheters.

The bare stent technique used in all patients in the present study has been previously described [16]. Palmaz-Schatz stents were removed from the manufacturer's delivery system and hand crimped on a noncompliant balloon. All stents were delivered using 14–18 atmosphere balloon inflations. Subsequent postdelivery inflations were performed as dictated by the angiographic appearance of the lesion. Intravascular ultrasound is not a part of our routine clinical practice and was not performed in the present study.

Anticoagulation

All patients received 325 mg aspirin prior to the procedure. Heparin 5,000 units was administered during the catheterization procedure and additional heparin was given on a weight-adjusted basis prior to the interventional procedure. Activated clotting times were measured q 30 minutes during the procedure and were maintained greater than 300 s with additional heparin as necessary. Abciximab was administered as clinically indicated during the procedure. A weight-adjusted intracoronary or intravenous dose was administered and this was followed by a 12-h intravenous infusion without additional heparin therapy. In those patients who did not receive ReoPro, intravenous heparin was continued for 12–24 h at a dose sufficient to maintain the partial thromboplastin time in the 50–100 s range. All patients received ticlopidine 500 mg p.o. at the completion of the procedure followed by 250 mg p.o. b.i.d. for 2–4 weeks. None of the patients were pretreated with ticlopidine.

Sheath management

In the radial group, the radial artery sheath was immediately removed at the completion of the procedure and hemostasis was obtained using a selective radial artery compression device [17]. In these patients, anticoagulation was continued without interruption. The compression device was removed in 2–4 h and a nonocclusive pressure bandage was subsequently placed over the operative site. Patients were then allowed to ambulate immediately, unless their clinical status dictated otherwise.

In the femoral group, patients were transferred to a holding area where the sheath was removed when the activated clotting time was less than 180 s. Hemostasis was obtained using manual compression followed by a FemoStop which was left in place for 4–6 h. These patients remained at bedrest overnight and were allowed to ambulate the following morning as clinically indicated.

Data management and procedural analysis

Procedural success was defined as a reduction of the target lesion to less than 25% luminal diameter by visual angiographic assessment without complication. Data were collected from analysis of the patient's hospital charts, angioplasty event reports, cine-angiograms, and UB-92 Discharge Forms. Lesions were classified according to the NHLBI Task Force on PTCA [18]. Access site complications were defined as a bleeding vascular complication that prolonged hospitalization. Procedural myocardial infarction was defined as an abnormal CPK elevation following the procedure.

Statistical analysis was performed using an unpaired *t* test. The differences between groups were statistically significant with a p value of <0.01. Means were calculated and expressed as standard error of the mean.

Results

Study population

The outcome of patients randomized to radial access is shown in Figure 1. During the course of the study, six of the 74 (8%) patients randomized to the radial group had a negative Allen test and/or Doppler examination suggesting an incomplete palmer arch; these were included in the femoral group. Of the remaining 68 patients in the radial group, 65 patients had their procedures performed transradially. In three patients, the radial artery was not successfully cannulated, and these were also included in the femoral group. Thus, 77 patients who had their procedures performed from the femoral approach included 9 radial crossovers.

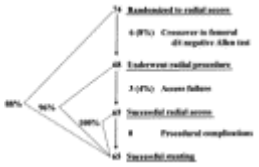
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Figure 1. Outcome of patients randomized to radial access.

Baseline demographic and clinical characteristics are shown in Table 1. The mean age was the same in both groups. The majority of patients were males, although 23 (35%) of patients in the radial group as opposed to 25 (32%) in the femoral group, ns, were female.

Table 1. Baseline Clinical Characteristics of the Study Patients

	Radial	Femoral	p Value
Patients	65	77	NS
Age, mean	63	62	NS
Female sex	23 (35%)	25 (32%)	NS
Clinic presentation			
Unstable angina	37 (57%)	42 (56%)	NS
Non-Q myocardial infarction	19 (29%)	24 (30%)	NS
Q myocardial infarction	9 (14%)	11 (14%)	NS
Adjunctive therapy			
tPA	13 (20%)	16 (21%)	NS
Abciximab	10 (15%)	8 (10%)	NS
Number of stents/patient	1.3	1.3	NS

There was no significant difference in the incidence of the various acute coronary syndromes between the two study groups. The majority of patients in both groups had unstable angina. Twenty-eight (43%) in the radial group versus 34 (44%) in the femoral group (p = ns) had evidence of myocardial infarction. A minority of patients presented with acute transmural myocardial infarction, and this reflects the referral patterns of our practice. No patient underwent direct angioplasty for his myocardial infarction. No patients presented with cardiogenic shock, and none required intra-aortic balloon counterpulsation.

There was no significant difference in the two groups in the incidence of patients receiving tPA. A slightly higher percentage of patients in the radial group received ReoPro although this difference was not significant. A minority of patients received multiple stents, and the number of stents delivered was the same in both groups (average 1.3 stents per patient).

Angiographic data are shown in Table 2. The vessel distribution between the two groups was the same. Lesion morphology was also the same in both groups. Note the majority of patients did have complex lesion morphology although all had TIMI grade III coronary flow at the time of the procedure.

Table 2. Baseline Angiographic Findings of the Study Patients

	Radial	Femoral	p Value
Number of lesions treated	86	88	NS
Lesion location			
LAD	32	35	NS
LCX	16	13	NS
RCA	24	26	NS
SVBG	11	9	NS
Other	3	5	NS
Lesion type			
A	30	35	NS
B_1	36	37	NS
B_2	16	15	NS
C	4	1	NS

Procedural outcome

The procedural outcomes in both groups are shown in Table 3. Primary success was high in both groups and not statistically different. Sixty-five of the 68 patients randomized to the radial approach had a successful procedure (96%). The three primary failures were due to inability to access the radial artery. All 65 patients whose radial artery was cannulated had successful procedures (see Fig. 1).

Table 3. Comparison of Procedural Results

	Radial	Femoral	p Value
	n = 68	n = 77	
Primary success	65 (96%)	74 (96%)	NS
Death/CABG/MI	0	0	NS
Access site complications	0	3 (4%)	$p < 0.01$

Seventy-four of the 77 femoral patients had successful procedures (96%). The three femoral failures were due to inability to successfully stent the target lesion, and these patients were managed with angioplasty alone. One of these patients had stent embolization without clinical sequelae; the stent was not retrieved and final location was uncertain.

There were no deaths in the present study and no patients were referred for emergency bypass surgery. No patient had a myocardial infarction as a result of their procedure.

Access site bleeding complications occurred only in the femoral group. There were three (4%) large hematomas which prolonged hospitalization. None of these required surgical correction, although two required transfusion. No patients in the radial group developed an access site bleeding complication. This difference was statistically significant ($p < 0.01$). All patients had a palpable radial artery postprocedure and no patient had symptoms or physical signs of hand ischemia. However, Doppler examination was not routinely performed and the incidence of asymptomatic radial artery occlusion was thus not determined.

Economic variables are shown in Table 4 and illustrated in Figure 2. Preprocedure length of stay was slightly longer in the femoral group although this difference was not statistically significant (1.6 ± 0.5, radial versus 2.1 ± 0.4 femoral, ns). Postprocedure length of stay was 1.4 ± 0.2 days in the radial group as compared to 2.3 ± 0.4 days in the femoral group ($p < 0.01$). Total hospital length of stay was 3.0 ± 0.3 days in the radial group as compared to 4.5 ± 0.5 days in the femoral group ($p < 0.01$). Total hospital charge was $\$20,476 \pm 811$ in the radial group as compared to $\$23,389 \pm 1,180$ in the femoral group ($p < 0.01$).

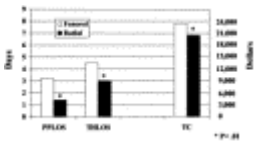

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Figure 2. Comparison of economic variables between femoral and radial groups. PPLOS = postprocedure length of stay. THLOS = total hospital length of stay. TC = total hospital charge.

Table 4. Comparison of Economic Variables

	Radial	Femoral	p Value
Postprocedure length of stay, days	1.4	2.3	$p < 0.01$
Total hospital length of stay, days	3.0	4.5	$p < 0.01$
Total hospital charge, $	20,476	23,389	$p < 0.01$

Discussion

The present study suggests that the transradial approach has important advantages for coronary stenting in patients with acute coronary syndromes. In this randomized, prospective trial, the primary success rate was the same (96%), regardless of whether the procedure was performed from the radial or femoral approach. However, access site bleeding complications were significantly less in the transradial group. In addition, more rapid ambulation in this group resulted in a shorter hospital length of stay and a 15% reduction in total hospital charge.

The pathogenesis of acute coronary syndromes involves the disruption of atherosclerotic plaque with subsequent superimposed thrombus formation [19]. Thus, aggressive antithrombotic therapy is a cornerstone of contemporary management of these syndromes. All patients receive aspirin and intravenous heparin; in addition, selected patients receive thrombolytic therapy and/or platelet glycoprotein IIb/IIIa receptor inhibitors. Transfemoral coronary intervention in the presence of this intensive antithrombotic therapy is associated with a significantly increased risk of access site complications [8, 9, 10, 11 and 12].

The incidence of these groin complications has been reduced by several strategies. These include the use of ticlopidine and aspirin alone following coronary stenting, weight-adjusting the dose of both heparin and platelet glycoprotein IIb/IIIa inhibitors, and the use of smaller guide catheters. Postprocedure mechanical devices, sutures, and vascular sealants are being increasingly used for local hemostasis. In the present study, the incidence of bleeding vascular complications in the femoral group was 4%, which is as low as has been reported in the literature in a controlled study of these unstable patients.

Benefits of the transradial approach

In spite of this low incidence of bleeding vascular complications in the femoral group, access site complications were still reduced in the present study by using the transradial approach. Indeed, no bleeding complications were encountered in the radial group. The superficial location of the radial artery allows easy hemostasis, and the use of a mechanical compression device minimizes utilization of personnel [17 and 20].

The ability to rapidly ambulate patients is a significant benefit of the transradial approach. In the present study, both postprocedure and total hospital lengths of stay were significantly shortened. It has previously been demonstrated that this rapid ambulation results in less immediate and overall discomfort with the catheterization procedure [7]. As a result, patients overwhelmingly prefer having these procedures performed from the radial approach [2 and 7].

Total hospital charge was reduced 15% in the radial group as compared to the femoral group. While a detailed cost analysis was not made, this basic figure is important as it represents a bottom line charge presented to the patient and his insurance carriers. This cost savings with the radial approach has now been repeatedly demonstrated [2, 3, 5 and 6]. While not specifically evaluated in the present study, previous reports have demonstrated this economic benefit is the result of a shorter hospital stay as well as fewer diagnostic and therapeutic procedures for stent related bleeding vascular complications [5, 6 and 13].

Limitations of the transradial approach

An important criticism of the radial approach is that it is not suitable for every patient. In the present study, 12% of the patients randomized to the radial group subsequently had the procedure performed via the transfemoral approach. This was a result of either a negative Allen test or failure to obtain vascular access. The need for the use of small guide catheters has been felt to be a significant limitation of the transradial approach because of poor visualization and inadequate backup support [21]. However, with experience and the recent continued miniaturization of interventional devices, this no longer is a serious drawback. Indeed, in the present study, no patient crossed over to the femoral approach for technical reasons and the primary success rate was equivalent in both groups. Several reports attest to the use of the transradial approach in virtually all clinical situations [22, 23, 24, 25, 26, 27, 28, 29, 30 and 31].

Coronary stenting from the radial approach involves a significant learning curve, particularly when the bare stent technique is utilized [16]. Alternative 6 French stent delivery systems are now available, and this should significantly shorten the learning curve. It should be emphasized that the present study was performed by operators with substantial transradial experience, as the benefits of the technique are less apparent with inexperienced operators [32 and 33].

An important limitation of the present study is the lack of follow-up Doppler information regarding the patency of the radial artery from which the procedure was performed. Although no patient in the present study had an absent pulse or symptoms suggesting vascular ischemia of the hand, it is likely that asymptomatic radial artery occlusion occurred in a small percentage of patients. Previous studies have demonstrated the incidence of asymptomatic radial occlusion in the 3–5% range, but the benign nature of this problem has been emphasized [3, 15 and 32].

Conclusion

The present study demonstrates that transradial coronary stenting is a useful procedure in managing high risk coronary patients. In patients with unstable coronary syndromes, procedural success rates are similar to the femoral approach and there is a significant reduction in access site complications. Early ambulation leads to a reduction in total hospital stay and a significant reduction in total hospital charge.

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