Vascular complications and clinical outcome after coronary angioplasty with platelet IIb/IIIa receptor blockade

Comparison of transradial vs transfemoral arterial access

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Aims Vascular complications associated with femoral artery access for interventional cardiological procedures may increase morbidity especially in patients receiving anticoagulants, aspirin, ticlopidine and platelet glycoprotein IIb/IIIa receptor inhibitors. The use of radial arterial access has the potential to reduce the incidence of access site bleeding complications. The purpose of this study was to compare outcomes after the radial and femoral approaches in patients treated with the platelet IIb/IIIa inhibitor, abciximab.

Methods and Results One hundred and fifty consecutive patients treated by abciximab underwent angioplasty by the radial or femoral approach in 83 and 67 cases, respectively. Outcome variables were major cardiac events and major access site bleeding at 1-month follow-up. Freedom from major cardiac events at 1-month follow-up occurred in 78 (93·9%) and 63 (94·0%) patients in the radial and femoral groups, respectively (P=0·99). There were no major access site bleeding complications in the radial group, as opposed to five (7·4%) in the femoral group, P=0·04. Postprocedure length of stay, days (3·7±6·0 radial vs 3·7±2·6 femoral, P=0·96) as well as total hospital length of stay (5·0±4·3 radial vs 4·9±3·0 femoral, P=0·72) were similar in both groups.

Conclusion Coronary angioplasty in patients treated by abciximab using the transradial approach is efficacious with fewer major access site complications than with the transfemoral approach.

Key Words: Coronary angioplasty, transradial, complications.

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Methods

Patients

Between 1 January 1997 and 30 April 1999, 4231 percutaneous coronary revascularization procedures were performed in our institution of which 150 (3.5%) were performed with the use of the platelet glycoprotein IIb/IIIa receptor inhibitor, abciximab. The indications for the prophylactic administration of abciximab (n=133) were acute myocardial infarction, degenerated and stenosed saphenous vein grafts, the presence of intracoronary thrombus before the angioplasty procedure or unfavourable lesion features. Abciximab was administered intraprocedurally in the presence of thrombotic complications occurring during the interventional procedure.

Eighty-three patients, with a normal radial pulse and a good collateral flow via the palmar arch as indicated by a normal Allen test, were considered for transradial catheterization. The femoral route was utilized in 67 patients; patients admitted for restenosis and acute myocardial infarction were generally treated via the femoral route that had been utilized for the diagnostic component of the procedure.

Anticoagulant and antiplatelet regimen

All patients except those presenting with acute myocardial infarction or restenosis were pre-treated for at least 3 days with aspirin (100–250 mg o.d.), ticlopidine (250 mg b.d.) and enoxaparin (100 UI . kg\(^{-1}\) b.d.). A bolus of heparin (70 UI . kg\(^{-1}\)) was administered after arterial sheath placement and additional heparin boluses were repeated as necessary to maintain the activated clotting time ≥ 250 s. The heparin dose was reduced to 50 UI . kg\(^{-1}\) in the case of pre-treatment with low molecular weight heparin. Abciximab administration, before or during the procedure in a rescue setting, included a 0.25 mg . kg\(^{-1}\) bolus followed by a 0.125 μg . kg\(^{-1}\) min\(^{-1}\) infusion for 12 h. After the procedure, heparin was discontinued and all patients received ticlopidine (250 o.d. or b.d.) for 1 month and long-term aspirin (100–250 mg o.d.).

None of the patients admitted for acute myocardial infarction (delay <12 h; 19 patients in the femoral group, 11 patients in the radial group) were treated by fibrinolysis before the invasive procedure. Eleven patients were treated by thrombolytic therapy 24 h to 1 week before the invasive procedure (five patients in the femoral group, six patients in the radial group).

Vascular access/haemostasis

Patients were typically sedated using midazolam and propofol administered by a cardiac anaesthesiologist. For the radial approach, the arm and forearm were extended with the wrist supine and secured to an arm-board with adhesive tape. After local anaesthesia with 2% lidocaine, the radial artery was cannulated with a 19-gauge needle through which a 0.022 inch guide wire was advanced before the introduction of a short (7 cm) arterial sheath. Intra-arterial vasodilators (isosorbide dinitrate 3 mg and verapamil 5 mg) were injected directly into the radial artery through the sheath. Transradial procedures were performed using 6 F and 7 F guide catheters in 26 (31%) and 57 (69%) cases, respectively.

The arterial access sheaths were removed immediately following transradial procedures and haemostasis was achieved by radial compression with a tourniquet for 1 h.

For the femoral approach, local anaesthesia with 2% lidocaine was performed and after the appearance of pulsatile blood from the arterial needle, a 0.035 inch guide wire was advanced, followed by insertion of an 11 cm arterial introducer. Transfemoral procedures were performed using 6 F, 7 F and 8 F guide catheters in 36 (54%), 24 (36%) and seven (10%) cases, respectively. The arterial access sheaths were removed immediately following transfemoral procedures when haemostasis was achieved by using the Perclose device (25 patients), and 4 to 6 h after the procedure when haemostasis was achieved by mechanical compression (Femostop device; 42 patients).

Patients were allowed to ambulate 1 h after removal of the radial sheath or Perclose device, and 12 to 24 h after femoral sheath removal associated with mechanical compression, unless their clinical status dictated otherwise.

Angiographic analysis

Coronary angiography was obtained in a routine manner. All patients received intracoronary isosorbide dinitrate before initial and post-procedural angiograms to achieve maximal vasodilatation. The vessels and lesions were analysed using a computerized quantitative analysis system (Philips Medical System, The Netherlands) according to previously described and validated edge-detection algorithms. Minimum lumen diameter, reference vessel diameter and percent diameter stenosis were measured before and after angioplasty.

End-points and definitions

End-points were recorded from the start of the procedure to 1-month follow-up and were divided into major access site bleeding and major cardiac events. Access site bleeding was defined as major if associated with haemoglobin loss of at least 2 mmol . l\(^{-1}\), administration of blood transfusions, vascular repair or prolonged hospitalization and minor if bleeding at vascular access site only resulted in haematoma formation which did not require specific therapy.
Major cardiac events were defined as death, myocardial infarction (defined as an abnormal CPK elevation following the procedure and/or development of new Q waves), coronary artery bypass graft surgery or repeat target-vessel coronary angioplasty.

Angiographic success was defined as a reduction in percent diameter stenosis to <30%.

Data collection

Clinical, angiographic and procedural data, and post-procedural complications were prospectively entered into a computerized database (AS400, Showcase Strategy). One-month follow-up was performed by an experienced physician who made telephone contact with the patients or their referring physicians.

Statistical analysis

Continuous variables are expressed as mean ± standard deviation or mean and range, and are compared using unpaired t-tests. Categorical variables are expressed as absolute or relative frequencies and are compared using chi-squared analysis.

Results

Study patients

The baseline clinical characteristics of the 150 study patients are shown in Table 1. There was a high incidence of acute coronary syndromes in both groups (56 in the radial group vs 42 in the femoral group, *P*=ns), particularly of acute myocardial infarction in the femoral group (19 versus 11; *P*=0.02) and unstable angina in the radial group (45 vs 23; *P*=0.02). Previous PCTA had been performed in 44 patients (29±3%) of whom seven (4±7%) had restenosis of the target vessel. Median age, male gender, height, weight and coronary risk factors were similar in both groups. Angiographic and quantitative coronary analysis data are detailed in Table 2. Single and three-vessel coronary artery disease was present in 32% and 45% of the patients, respectively. Angiographic evidence of significant thrombus before the procedure was found in 59 patients (39±3%). Baseline angiographic and quantitative coronary analysis data were not significantly different between the radial and femoral groups.

Procedural results

Vascular access

The transradial approach was unsuccessful in two cases (2±4%) because of inability to puncture the radial artery. Both procedures were successfully completed by the femoral approach. All cases of femoral cannulation were successful.

Coronary angioplasty

Of the 83 patients undergoing percutaneous coronary angioplasty by the radial approach, 71 received one or more stents (85±5%) with an implantation of a total of 94 stents. Sixty patients who were treated by the femoral approach underwent stent implantation (89±5%) with a total of 83 stents. There was no significant difference in the frequency of stent implantation between the radial and femoral groups (*P*=0.75). Angiographic success was achieved in 98±8% and 100% in the radial and femoral groups, respectively (*P*=0.98). Results of
Table 2 Qualitative and quantitative coronary angiographic data

<table>
<thead>
<tr>
<th>Extent of coronary disease</th>
<th>Radial group</th>
<th>Femoral group</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>1-vessel</td>
<td>25 (30-1)</td>
<td>23 (34-3)</td>
<td>0.70</td>
</tr>
<tr>
<td>2 and 3-vessel</td>
<td>58 (69-9)</td>
<td>44 (65-7)</td>
<td>0.70</td>
</tr>
<tr>
<td>Vessel treated by PTCA</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>LAD</td>
<td>31 (37-5)</td>
<td>25 (37-3)</td>
<td>0.99</td>
</tr>
<tr>
<td>LCx/obtuse marginal</td>
<td>16 (19-3)</td>
<td>18 (26-8)</td>
<td>0.36</td>
</tr>
<tr>
<td>RCA</td>
<td>27 (32-5)</td>
<td>25 (37-3)</td>
<td>0.66</td>
</tr>
<tr>
<td>SVG</td>
<td>26 (31-3)</td>
<td>12 (17-9)</td>
<td>0.21</td>
</tr>
<tr>
<td>Presence of thrombus</td>
<td>29 (34-9)</td>
<td>30 (44-7)</td>
<td>0.29</td>
</tr>
<tr>
<td>Complex lesion</td>
<td>10 (12-0)</td>
<td>7 (10-4)</td>
<td>0.96</td>
</tr>
<tr>
<td>Pre-PTCA QCA</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>RD (mm)</td>
<td>3.4 ± 0.6</td>
<td>3.5 ± 0.6</td>
<td>0.40</td>
</tr>
<tr>
<td>MLD (mm)</td>
<td>0.8 ± 0.5</td>
<td>0.8 ± 1.2</td>
<td>0.60</td>
</tr>
<tr>
<td>DS (%)</td>
<td>78 ± 14</td>
<td>77 ± 18</td>
<td>0.34</td>
</tr>
<tr>
<td>PTCA QCA</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>RD (mm)</td>
<td>3.5 ± 0.5</td>
<td>3.5 ± 0.6</td>
<td>0.98</td>
</tr>
<tr>
<td>MLD (mm)</td>
<td>3.5 ± 0.5</td>
<td>3.5 ± 0.6</td>
<td>0.90</td>
</tr>
<tr>
<td>DS (%)</td>
<td>1.4 ± 4.6</td>
<td>2.0 ± 6.0</td>
<td>0.34</td>
</tr>
</tbody>
</table>

Data presented are mean ± SD or number (%) of patients. DS = diameter stenosis; LAD = left anterior descending coronary artery; LCx = left circumflex coronary artery; LV = left ventricular; MLD = minimal lumen diameter; PTCA = percutaneous transluminal coronary angioplasty; RCA = right coronary artery; RD = reference diameter; SVG = saphenous vein graft.

Final quantitative and qualitative coronary analysis were similar (Table 2).

Procedure duration

Procedural time (recorded from the start of the first attempt to puncture the artery to the end of the procedure) of transradial coronary angioplasty (40 ± 26 min) was similar to transfemoral coronary angioplasty (37 ± 21 min, P = 0.74).

Clinical outcome at 1-month follow-up

Cardiac events

Five patients in the radial group developed myocardial infarction, including one patient who required a repeat target-vessel coronary angioplasty. None in the radial group died or underwent coronary artery surgery during the 1-month follow-up. In the femoral group two patients died 1 and 5 days after the procedure from irreversible cardiogenic shock. Two other patients had myocardial infarction during 1 month follow-up. None of the patients in the femoral group underwent coronary artery surgery or repeat target-vessel coronary angioplasty at 1-month follow-up. Freedom from major cardiac events at 1-month follow-up was achieved in 78 (93.9%) and 63 (94.0%) patients in the radial and femoral groups, respectively (P = 0.99) (Table 3).

Entry site complications

Major access site complications occurred only in the femoral group. After femoral access, five major vascular entry site complications occurred (7.5%). Two patients required vascular surgery. Of them, one had a decrease in haemoglobin >2 mmol·l⁻¹ and required blood transfusion. The three other patients had large haematomas which prolonged hospitalization and were treated conservatively by femoral compression. Among the five patients who experienced a major vascular entry site complication, the Perclose device was used in two (2/25; 8%) and mechanical compression (Femostop) in three (3/42; 7.1%). None of the five patients treated by thrombolytic therapy, 24 h to 1 week before the invasive procedure by femoral approach, experienced a major access site complication. No patients in the radial group developed a major access site bleeding complication. This difference was statistically significant (five vs 0; P = 0.04) (Table 4). All patients in the radial group had a palpable radial artery post-procedure and no patients had symptoms or physical signs of hand ischaemia. However, Doppler examination was not performed and the incidence of asymptomatic radial artery occlusion was not determined.

An uncomplicated clinical course (freedom from major cardiac event and major access site bleeding complication) at 1-month follow-up was achieved in 78 (93.9%) and 58 (86.6%) patients in the radial and femoral groups, respectively (P = 0.20).

Table 3 Major cardiac events and their ranking from percutaneous transluminal coronary angioplasty to 1-month follow-up

<table>
<thead>
<tr>
<th>Cardiac event</th>
<th>Radial group (n=83)</th>
<th>Femoral group (n=67)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Total</td>
<td>Ranking</td>
<td></td>
</tr>
<tr>
<td>Death</td>
<td>0</td>
<td>2 (3-0)</td>
<td>2 (3-0)</td>
</tr>
<tr>
<td>MI</td>
<td>5 (6-0)</td>
<td>3 (4-5)</td>
<td>2 (3-0)</td>
</tr>
<tr>
<td>CABG</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Re-PTCA</td>
<td>1 (1-2)</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Total</td>
<td>6 (7-2)</td>
<td>5 (7-5)</td>
<td>4 (6-0) 0.99</td>
</tr>
</tbody>
</table>

Data presented are number (%) of patients. Ranking = frequency of events in descending order (death (worst outcome)), followed in order of rank by myocardial infarction (MI), bypass surgery (CABG), repeat target vessel intervention (Re-PTCA).
challenge.

site management, bleeding complications remain a haemostasis. However, despite improvement of access removal, mechanical devices and sutures for local doses of heparin and IIb/IIIa inhibitors, early sheath discontinuation of anticoagulation, weight-adjusted order to limit the occurrence of thrombotic compli-

c contemporaneous percutaneous coronary angioplasty in radial group.

signi

approach. However, major access site bleeding was the procedure was performed from the radial or femoral cardiac events rate were the same, regardless of whether with abciximab the angiographic success and major platelet IIb/IIIa receptor inhibitors. In our series of 150 consecutive patients undergoing coronary angioplasty who are treated with angioplasty to 1-month follow-up

Table 4 Major access site bleeding complications and their ranking from percutaneous transluminal coronary angioplasty to 1-month follow-up

<table>
<thead>
<tr>
<th>Major access site bleeding complications</th>
<th>Radial group (n=83)</th>
<th>Femoral group (n=67)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Total</td>
<td>Ranking</td>
<td>Total</td>
</tr>
<tr>
<td>Surgical repair</td>
<td>0</td>
<td>0</td>
<td>2 (3.0)</td>
</tr>
<tr>
<td>Blood transfusion</td>
<td>0</td>
<td>0</td>
<td>1 (1.5)</td>
</tr>
<tr>
<td>Haematoma associated with prolonged hospitalization</td>
<td>0</td>
<td>0</td>
<td>3 (4.4)</td>
</tr>
<tr>
<td>Total</td>
<td>0</td>
<td>0</td>
<td>6 (8.5)</td>
</tr>
</tbody>
</table>

Data presented are number (% of patients. Ranking=frequency of events in descending order (surgical repair, followed in order of rank by blood transfusion and haematoma).

Minor access site complications

Two other patients with minor haematoma were treated by local femoral artery compression. After radial artery cannulation, minor forearm haematoma occurred in two patients and was treated conservatively by local compression.

Hospital stay

The total hospital stay was $5.0 \pm 4.3$ and $4.9 \pm 3.0$ ($P=0.72$) and the delay between percutaneous coronary angioplasty and discharge was $3.7 \pm 6.0$ and $3.7 \pm 2.5$ ($P=0.96$) in the radial and femoral groups, respectively.

Discussion

The present study suggests that the transradial approach may offer advantages for patients undergoing percu-
taneous coronary angioplasty who are treated with platelet IIb/IIa receptor inhibitors. In our series of 150 consecutive patients undergoing coronary angioplasty with abciximab the angiographic success and major cardiac events rate were the same, regardless of whether the procedure was performed from the radial or femoral approach. However, major access site bleeding was significantly commoner in the femoral than the trans-
radial group.

Aggressive antithrombotic therapy is a cornerstone of contemporary percutaneous coronary angioplasty in order to limit the occurrence of thrombolic complications during and after the procedure$^{[1,10–13]}$. Nevertheless, during transfemoral coronary intervention, intensive antithrombotic therapy is associated with an increased risk of access site complications$^{[1–4,15]}$. Several strategies have been used in order to limit the occurrence of groin complications$^{[4,10]}$, including post-procedural discontinuation of anticoagulation, weight-adjusted doses of heparin and IIb/IIa inhibitors, early sheath removal, mechanical devices and sutures for local haemostasis. However, despite improvement of access site management, bleeding complications remain a challenge.

In our study, in spite of the low incidence of bleeding complications in the femoral group, access site complications were still significantly lower when the transradial approach was used. The superficial location of the radial artery allows easy haemostasis and major vascular complications were absent after transradial coronary angioplasty$^{[16]}$. Kiemeneij et al$^{[8]}$ compared the results of the radial approach with those of brachial and femoral access in a randomized study (Access). They found that the vascular access site complication rate was significantly lower after the radial approach (0%) than after the femoral (2%) or brachial approaches (2.3%) ($P=0.035$). A further randomized comparison of radial and femoral access for coronary stenting in patients with acute coronary syndromes by Mann et al$^{[9]}$ showed a similar reduction of access-site complications, hospital stay and resultant procedural costs in the radial group. Patients undergoing radial catheterization had a statistically signifi-
cantly reduction in access site complications (0 vs 4%, $P<0.04$), as well as a decrease in hospital stay after the procedure ($2.1 \pm 0.1$ vs $2.6 \pm 0.3$ days, $P<0.04$). However, in these two studies, antithrombotic treatment was less aggressive with no patients treated by abcixi-

mab in the Access study$^{[6]}$ and with less than 15% patients treated by abciximab in the study published by Mann et al$^{[9]}$. In our study, abciximab was used in addition to pre-treatment for at least 3 days with potent anti-platelet drugs in all patients except those presenting with acute myocardial infarction or restenosis. This strategy was based on the proven beneficial effects of ticlogipide–aspirin pre-treatment to reduce platelet aggregation and coagulation during angioplasty procedures$^{[17]}$ and on data from several trials using abciximab$^{[10–13]}$.

More than 85% of patients in our study underwent coronary stent implantation using a variety of commercially available stent types. Stent implantation via the transradial route was first described in the initial publica-
tion of Kiemeneij et al$^{[18]}$ and has been a consistent feature of more recent publications$^{[8–9]}$, suggesting that the use of the transradial approach does not pose any great technical limitations in experienced hands. Never-
theless, it should be emphasized that the present study was performed by operators with substantial transradial
experience, and that the benefits of this technique may be less apparent with inexperienced operators[19,20].

**Limitations of the study**

An important limitation of the present study is the lack of randomization between the femoral and radial approach. Although procedural antithrombotic treatment and baseline clinical characteristics of the patients were similar in both groups, the patients undergoing transradial catheterization were more likely to be ‘elective’ and therefore more likely to have received prolonged pre-procedural antiplatelet treatment. However, this difference might be expected to bias the risk of bleeding complications toward the transradial group rather than the transfemoral.

Another limitation is the lack of ultrasonic assessment of post-procedural radial artery patency. Recently, Nagai *et al.*[21] reported absent radial flow by Doppler assessment in 9% of patients 2 days after transradial catheterization, falling to 5% at 29 days. Previous studies[8,19,22] have also found that asymptomatic radial occlusion occurred in 3–5%.

**Conclusion**

From the present study we can conclude that transradial percutaneous coronary angioplasty yields comparable procedural success with less access site bleeding complications than the transfemoral approach in patients treated by aggressive antithrombotic therapy including abciximab. The combination of this type of therapeutic regimen with the use of transradial access for coronary angioplasty should provide an optimal combination of reduced ischaemic complications and an acceptable rate of access site bleeding complications.

**References**


