Radial Approach to Percutaneous Coronary Intervention

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ABSTRACT

The radial approach is considered alternative to the traditional femoral approach to perform coronary angiography and percutaneous coronary intervention (PCI). Transradial compared to transfemoral PCI has been consistently shown to be equally effective but safer, since it significantly reduces access site related and bleeding complications. Additionally, it increases patient comfort and reduces hospitalization cost. Modern interventional strategies and aggressive antithrombotic regimens have limited ischemic adverse events following PCI. At the downside, bleeding complications remain a serious problem and adversely affect outcomes. They can be reduced with novel pharmacologic agents but still have unacceptably high rates and are mostly related to femoral access. In this context the radial approach seems a reasonable choice to further reduce access related bleeding. A concise overview of recent data supporting a more widespread dissemination of transradial PCI and a brief presentation of the most important pertinent technical issues are attempted herein.

INTRODUCTION

Percutaneous coronary intervention (PCI) can be performed via the femoral, brachial, or radial arteries. The femoral approach has traditionally been and still is the primary approach for most operators. Campeau et al first described the radial approach for coronary angiography in 1989.1 The first transradial PCI was reported by Kiemeneij and Laarman in 1993.2 Later, their group published the first series of balloon angioplasty and bare-metal stent implantation performed through the radial artery.3,4 Transradial compared to classic transfemoral PCI has been shown to have similar efficacy rates, while being more cost-effective and most importantly safer due to fewer access site or bleeding complications.5 Furthermore, patient comfort is increased and outpatient treatment may be feasible.6,7 However, the penetration of radial approach is heterogeneous worldwide. It is mostly developed in northwestern Europe, Canada and Eastern Asia. Especially in France 60% of PCI procedures are performed transradially, while in Europe the percentage currently is around 20%.8 Despite the presence of dedicated radialists, utilization of the radial approach in the U.S. remains quite low. As recently reported by Rao et al the percentage of radial PCIs increased from approximately 1.3% to only 3.5% by the first quarter of 2007 for centers participating in the National Cardiovascular Data Registry database.9 This is largely due to lack of widespread training and subsequent trepidation involving the learning curve.10
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RADIAL VERSUS FEMORAL APPROACH

Since first described in 1989, multiple studies have shown a lower rate of access site complications and major bleeding with the radial approach. In the first randomized comparison of elective PCI via the radial, brachial or femoral approaches, Kiemeneij et al found similar procedural success regardless of strategy but a significantly lower risk of access site complications in the radial group (no complications in the radial group compared with 2.3% and 2.0% in the brachial and femoral groups, p=0.035).11 Subsequently several randomized trials have consistently demonstrated that radial access reduces access site complications compared to femoral approach. One of the largest meta-analysis comparing radial versus femoral approach for diagnostic catheterization and interventional procedures by Agostoni et al included 12 randomized trials (3224 patients). Major adverse cardiovascular events were similar between radial and femoral groups (2.1 vs. 2.4%, OR: 0.92, p=0.7). The radial approach was superior to the femoral approach regarding entry site complications (0.3 vs. 2.8%; OR: 0.20, p = 0.0001), mean hospital stay (1.8 days vs. 2.4 days, p <0.001) and lower total hospital charge. Conversely, radial access was associated with a significantly higher number of procedural failures in comparison to femoral access (7.2 vs 2.4%; OR: 3.30, p =0.001), as well as longer fluoroscopy time (8.9 versus 7.8 min, P <0.001). Of note, procedural failure was significantly reduced after 1999 indicating increased operator experience.5

The single greatest advantage of the radial approach is reduced bleeding and vascular access complications. Every center that predominantly performs the radial technique delight in reporting no retroperitoneal hematomas, femoral pseudoaneurysms, fistula, painful large hematomas, artery occlusions, or emboli.7 The analysis by Rao et al reviewed data from the National Cardiovascular Data Registry from 2004 to 2007 and indicated significantly lower bleeding with the radial approach compared to femoral (OR:0.42) with similar success rate.9 These advantages extend to elderly patients also, as suggested by Achenbach et al in their randomized trial involving patients more than 75 years of age.12 The rate of major complications (bleeding requiring surgery or transfusion, stroke) was 0% for the radial and 3.2% for the femoral approach (p< 0.001).13 Jolly et al in a recent meta-analysis found that radial artery access reduced major bleeding 73% compared to femoral (0.05% vs. 2.3%, p=0.001) and interestingly identified a trend for reductions in the composite of death, myocardial infarction, and stroke (2.5% vs. 3.8%, p=0.058).13 There was no difference in death alone between the 2 techniques. For PCI, a higher trend for inability to cross lesions from radial compared with femoral access was noted (p=0.21). Radial access reduced hospital stay by 0.4 days (p=0.001) and was associated with reduced major bleeding and strong trends for reduction in ischemic events compared with femoral artery access. These findings differ from the meta-analysis of Agostoni et al performed in 2004, which showed similar rates of major adverse cardiac events with radial access (death, MI, stroke, emergent PCI, or coronary artery bypass surgery).5 This may be due to the fact that the 2009 meta-analysis by Jolly et al had increased power with the addition of 5 randomized trials (3 of which were in STEMI) composed of more than 2000 additional patients.13

Recently Brueck et al presented another detailed study randomizing 1024 patients to one of the two vascular access methods.14 Femoral access had slightly higher procedural success rates (97% transradial, 99.8% transfemoral, p=0.0001). The radial approach had longer procedure times (40 min vs 37 min), and slightly more radiation exposure (42 Gy/cm² vs 38 Gy/cm²). Unique to this study compared with other reports is the fact that despite the use of femoral vascular access closure devices (used in 93% of PCI patients), the femoral group still had 6 times more vascular access site complications (3.7% vs. 0.6%, p=0.0008) compared with the radial group.

TRANSRADIAL PCI IN ACUTE CORONARY SYNDROMES (ACS)

Femoral access bleeding complications remain an important cause of morbidity and mortality in patients undergoing PCI.15 Femoral closure devices have had an impact since femoral sheaths may be removed immediately with their use. However, they have not solved the problem because these devices even in experienced hands have not been found to reduce the rate of hemorrhagic or vascular complications in randomized trials.16,17 A recent study by Scialbasi et al showed significant reduction of access site bleeding with the radial approach compared to femoral even when vascular closure devices were used. Radial access significantly reduced major complications (0.7%) compared with manual compression (2.9%, p=0.03) or vascular closure devices [StarClose® 2.7%, AngioSeal® 3.9%, p=0.003].18 The major advantage of transradial PCI is the near elimination of clinically significant access site complications, even in patients at high risk (ie, patients treated with GP IIb/IIIa inhibitors or shortly after systemic thrombolysis).

In ACS patients the rate of major bleeding is between 3 to 5%.19,20 Bleeding events and the consequent need for transfusion are independent determinants of survival and their relation to short- and long-term mortality has been demonstrated in major randomized trials as well as through the evaluation of registries.21-23 As shown by Bertrand et al in a cohort of 1348 patients with ACS all treated by transradial PCI and maximal antiplatelet therapy the incidence of major bleeding was low (1.4%).24 In patients with major bleeding, the incidence of major adverse cardiac events was higher at 30 days (37% vs 3%), 6 months (42% vs 8%), and 12 months
vascular access site complications, the use of the radial approach has been recently demonstrated in a large PCI registry study. The MORTAL study retrospectively examined the association between access site, transfusion, and outcomes in over 32,000 patients who underwent PCI in British Columbia from 1999 to 2005. The main finding was that by reducing vascular access site complications, the use of the radial access site was associated with a 50% reduction in transfusion rate and a relative reduction in 30-day and 1-year mortality of 29% and 17%, respectively (p<0.001), which corresponds to around 1% absolute risk reduction at one year. Similarly, in the PRESTO-ACS observational study that included over 1,000 non-ST-segment elevation ACS patients it has been shown that the radial group had a statistically significant decrease in death or re-infarction (4.9 vs. 8.3%, p=0.05) and bleeding (0.7 vs. 2.7%, p=0.03) at 1-year follow-up. In this study the rate of bleeding complications in the radial group was only 0.7%, an incidence lower than that derived from published reports with the use of bivalirudin (3%) or fondaparinux (2.4%) and a femoral approach. However, as is the case for observational studies, potential biases might have played a role in the selection of patients in these two studies, with patients considered at lower risk scheduled for radial and patients at higher risk scheduled for femoral approach. Thus, definite conclusions cannot be drawn, but they could represent good hypothesis-generating studies for randomized trials.

The two largest comprehensive meta-analyses of randomised comparisons of radial and femoral accesses demonstrated that radial access reduces bleeding and access site complications. Neither of them found a significant link between the frequency of adverse events or mortality. It should be noted that these analyses included studies performed predominantly in elective settings and thus the potential benefits for the higher risk patients could have been concealed by the lower risk cases that formed the majority. Clinical trials, such as OASIS-5 and HORIZONS-AMI have shown that therapies that reduce bleeding also reduce mortality and ischemic outcomes. The CURRENT-OASIS 7 study includes a femoral versus radial access sub-study with more than 2,000 randomized patients, which is expected to confirm or refute the hypothesis that radial access is better than femoral access not only in reduction of access site bleeding but also for ischemic events.
bleeding event. Interestingly, the greatest absolute benefit appeared in the setting of primary or rescue angioplasty for STEMI with an absolute risk reduction of 3.1% (p= 0.001). However, the possible greater occurrence of procedural failure and longer procedural times occasioned by difficulty in puncturing the radial artery, inability to cannulate the coronaries, or impossibility to perform the angioplasty are factors that raise distrust as to whether radial access remains beneficial in a setting where timely reperfusion is critical as in STEMI.

In the prospective multi-center randomized TEMPURA study comprising 149 patients, Saito et al were the pioneers to report that the radial access was feasible and safe for primary PCI in patients with STEMI. They demonstrated that for selective patients with STEMI, the radial is comparable to femoral approach in terms of the reperfusion success rate and the incidence of in-hospital major adverse clinical events. The choice of arterial access route had no significant impact on the 30-day mortality rate. However, the combined vascular and bleeding complications were significantly less in the radial group. Other registry studies have also reported superior results. Louvard et al were able to demonstrate the efficacy and safety of transradial primary PCI in a prospective two-center registry of 277 cases. Intervention was successful in >95% of both radial and femoral access patients. Total procedural time did not differ between the two groups. However, severe access site-related bleeding complications, were observed in femoral group patients only. Cruden et al were able to demonstrate in their retrospective analysis of 287 patients undergoing rescue PCI that the radial route was associated with similar procedural success rate compared to femoral. There were no differences in procedural or in-hospital mortality, procedure duration, or radiation dose, but reduced vascular complications and post-procedural length of stay for patients who underwent transradial PCI. Recently Yip et al reported the results from a single-center observational analysis of 506 transradial compared to 810 transfemoral primary PCI cases,
which is the largest number to date.\textsuperscript{38} Initial puncture to first balloon inflation time and rates of post procedure TIMI III flow in the infarct-related artery were similar in both groups. Although the 30-day mortality rate did not differ between the 2 groups (4.9\% vs 3.8\%, \textit{p}=0.341), the rate of combined major vascular and bleeding complications was higher in the femoral than in the radial access group (6.1\% vs 0\%, \textit{p}<0.0001). Duration of hospital stay was also longer in the femoral group (6 vs 3.3 days, \textit{p}=0.032).

A recently published meta-analysis by Vorobcsuk et al, which included 12 studies comprising 3324 patients, demonstrated that the transradial coronary intervention is highly effective and safe in the setting of STEMI for both primary and rescue PCI.\textsuperscript{39} There were no differences in procedural time and in time to reperfusion between the two access routes. Transradial PCI reduced major bleeding compared to transfemoral (0.77\% vs 2.61\%, \textit{OR}=0.3, \textit{p}=0.0001), and significant reductions were found in the composite of death, myocardial infarction, or stroke (3.65\% vs 6.55\%, \textit{OR}=0.56, \textit{p}=0.001). Mortality reduction showed a significant toward benefit in the case of transradial PCI (2.04\% vs 3.06\%, \textit{OR}=0.54, \textit{p}=0.01). The fluoroscopic time was longer, and access site crossover was more frequent for the radial approach. Of note, patients suffering from cardiogenic shock and with need for intra-aortic balloon pump (IABP) insertion were generally excluded from these studies and treated via the femoral route.

### Transradial PCI: Concerns and Limitations

The radial approach has certain advantages and disadvantages (Table 1). Before embarking on the radial approach for coronary intervention one should be aware of the technique’s drawbacks and limitations.

The learning curve for transradial is steeper than for transfemoral intervention.\textsuperscript{40} Crossover from radial to femoral access is significantly higher than in the opposite way.\textsuperscript{13} Puncture failure, radial artery spasm, and tortuous brachiocephalic trunk are the most common reasons (Figure 1). In a large meta-analysis by Agostoni et al all the overall rate of procedural failure was 7.2\% in the radial group compared with 2.4\% in the femoral (\textit{OR}: 3.30, \textit{p}=0.001).\textsuperscript{41} Louvard et al. reported a rate of 10\% in the first 50 cases, 3\% to 4\% after other 500 cases, whereas it stabilizes at less than 1\% only after 1,000 procedures.\textsuperscript{41} A recent report identified advanced age, prior coronary bypass surgery, and short stature as independent predictors of radial approach failure.\textsuperscript{42} In the meta-analysis by Jolly et al when studies were divided into those performed in the early era of radial access (prior to 1999), the odds of access site crossover with radial was 5-fold higher (\textit{OR} 5.63, \textit{p}<0.001) versus the modern era (1999-2008) where radial access had a 3-fold increase in access site crossover (\textit{OR} 2.96, \textit{p}<0.001, interaction \textit{p}=0.04), suggesting that improvements in expertise and technology have narrowed the gap.\textsuperscript{13}

#### Table 1. Advantages and disadvantages of the radial approach to PCI.

<table>
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<tr>
<th>Advantages</th>
<th>Disadvantages</th>
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<tr>
<td>Easy hemostasis at the end of the procedure.</td>
<td>Long learning curve.</td>
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<tr>
<td>Negligible access site bleeding (&lt;0.6% vs 3-4% with femoral approach).</td>
<td>Not advised in case of abnormal Allen test. Crossover rate to femoral approach more frequent than vice versa.</td>
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<tr>
<td>Negligible risk for arteriovenous fistula, pseudoaneurysm, retroperitoneal bleeding, painful hematoma or nerve damage.</td>
<td>Perceived longer procedure time and radiation exposure (operator dependent, mainly in the first part of the learning curve).</td>
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<tr>
<td>No ischemic complications in case of occlusion (3-6% of cases) if Allen test is not abnormal.</td>
<td>Risk of spasm. Difficult manipulation in case of tortuous brachiocephalic trunk.</td>
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<tr>
<td>Better patient comfort, immediate ambulation.</td>
<td>Sometimes movement of catheters with respiration, which can render stent positioning difficult.</td>
</tr>
<tr>
<td>Cost saving, outpatient procedures possible.</td>
<td>Sometimes limited backup support requiring more manipulation (deep intubation possible, especially with 5F guiding catheters).</td>
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<td>Ideal for certain patient subsets: obese, those who can not lie flat (heart failure, back pain, urinary retention), iliofemoral disease, abdominal aorta aneurysms with mural thrombus, if INR &gt;2.</td>
<td>Limitations possible with interventional material: maximum catheter size 7F (only in large arteries), rotablator with larger burr sizes, some thrombus aspiration, debulking and distal protection devices.</td>
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<tr>
<td>Better guiding catheter back up for LIMA PCI with left radial approach.</td>
<td>Femoral access prefered if IABP or temporary pacemaker needed.</td>
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The incidence of an abnormal Allen’s test in patients undergoing coronary angiography ranges from 6.4% to 27%.\textsuperscript{43,44} The visual assessment of the Allen’s test has a limited specificity because of delayed recruitment of collateral flow. Studies using Doppler ultrasound, plethysmography, and pulse oximetry revealed a sufficient supply by the ulnar artery in most patients with a pathologic Allen’s test.\textsuperscript{44,45} However, an elevated thumb capillary lactate level was measured in these patients.\textsuperscript{46} Transradial catheterization should be avoided in the presence of an abnormal Allen’s test unless the risk of using the transfemoral approach is exceedingly increased (e.g., severe peripheral vascular disease, morbid obesity, large abdominal aortic aneurysm, Leriche syndrome).

The risk of transient or permanent radial artery occlusion with a normal Allen’s test is 5.3% and 2.8% respectively.\textsuperscript{37} Medication is required to avoid vasospasm and thrombosis.\textsuperscript{48,49} Patent hemostasis has been shown to decrease the incidence of radial artery occlusion which is directly related to the ratio between the sheath and artery size.\textsuperscript{50,51} Therefore, smaller guiding catheters are potentially advantageous leading to less arterial spasm, pain, and post-procedural vessel occlusion. However, it has been shown that during PCI 5 Fr catheters offer no advantages concerning radial artery occlusion as compared with 6 Fr catheters, with the drawback of a 7% crossover rate from 5 to 6 Fr.\textsuperscript{52} The suitability of the radial artery after transradial catheterization as a bypass conduit has been of great concern to surgeons. Although there were no redo angiographies through the same radial artery in the transradial group, it could be demonstrated by Kamiya et al and Yoo et al that after transradial catheterization the radial artery could be used for both coronary artery bypass surgery as an arterial graft and repeat catheterization.\textsuperscript{53,54}

During transradial PCI some difficulty may be encountered due to reduced guiding catheter backup force, particularly when using the Judkins catheter.\textsuperscript{55} The backup force is ruled by physics not by the approach site and is determined by the size and shape of the guiding catheter. Thus, less backup force of the guiding catheter can be overcome by using a properly shaped guiding catheter for transradial intervention, such as the Ikari.\textsuperscript{56}

There are some technical concerns about transradial PCI for treating bifurcation lesions. A radial artery of patients less than 1.72 m tall can easily accommodate a 6 Fr sheath and a 6 Fr guide catheter, and patients taller than 1.72 m can accommodate a 7 Fr guide for an intervention. A bifurcation lesion with two wires in the main branch and side branch and subsequent provisional stenting and final balloon kissing can easily be performed in most patients using a 6 Fr guide catheter. In a recent meta-analysis of various randomized controlled trials for coronary bifurcation interventions Niccoli et al. showed that there was no association between the choice of the access site and the outcomes of the procedure.\textsuperscript{57} The radial artery size restricts interventional device options in some cases. The femoral approach is the approach of choice when guiding catheters ≥7 Fr are required (simultaneous two stent deployment, large bore rotablation, some debulking, thrombus aspiration and distal protection devices). Femoral access is also preferred when IABP or temporary pacemaker is needed. To the contrary, pressure wire, intravascular ultrasound, individual stents, and the “kissing balloon” technique for the treatment of bifurcations can all be accommodated by modern 6 Fr guide catheters used transradially.

Difficult or tortuous anatomy can lead to longer procedures with higher radiation exposure compared to similar femoral access procedures.\textsuperscript{58} In the meta-analysis by Jolly et al radial access was associated with a significantly longer procedural time with a mean difference of 3.1 min (p=0.001). However, there was significant heterogeneity with a larger difference in procedural time found in studies performed by non–radial experts compared to radial experts (mean difference 4.8 vs 1.7 minutes respectively, p <0.001).\textsuperscript{13} Similarly, in the above mentioned study by Brueck et al the procedural time in the radial group (40.2 min) was slightly longer than in the femoral approach group (37.0 min), but the difference was significant (p=0.048).\textsuperscript{14} However, under most circumstances it is unlikely that this time period would be clinically significant. Additionally, this time difference of 3.2 min did not include the time interval required for hemostasis, which may exceed 15 min after transfemoral procedures. The time required to obtain hemostasis using the radial route is markedly shorter because manual compression is not necessary and a bandage can be applied immediately after the procedure. Therefore,
procedural time does not constitute a strong rationale in favor of femoral approach, especially for experienced operators. Fluoroscopy time, which is a surrogate of radiation dose, was significantly longer for radial access in the meta-analysis by Jolly et al., with mean difference of 0.4 minutes (p=0.001).13 Brasselet et al. reported that the radiation exposure of the operator in a transradial approach was increased as well, despite using optimized specific protection devices, reflecting technical difficulties and a slightly closer position of the interventional cardiologist to the X-ray source.58 There were important methodological issues with this study since it had a non-randomized design and a high probability that most of the operators were amidst their learning curve.34 Yet, reports showing increased radiation exposure are currently casting a shadow of caution on the radial approach. For the right radial approach operators usually use adapted catheterization-laboratory suites where after sheath insertion they work at almost the same distance from the X-ray source as with conventional femoral route. With experience and overcoming the learning curve the procedural and fluoroscopy times between a femoral and radial case become very close.40

**CONCLUSION**

Transradial PCI is feasible, effective and safe and can be applied in the majority of cases. The technique is limited by a steep learning curve and about 7% crossover rate to the femoral route. Procedural and fluoroscopy times are slightly longer compared to femoral approach, but as experience accumulates the difference becomes insignificant. The radial approach increases patient comfort and decreases hospitalization time and cost. However, its most important feature is that it minimizes major bleeding by nearly abolishing serious access site complications. The evidence base that is currently available supports a wider application of the radial approach for most PCI procedures with the aim of improving outcomes by reduction in access site bleeding.

**REFERENCES**


