

# Radial Angioplasty: Historical Sketch and Recent Advances

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## Abstract

The objective of this article is to review the currently available information regarding the efficacy, safety, benefits and limitations of radial angioplasty. A thorough review of the literature was conducted by the authors and the results are summarized in this article. Research has provided evidence that the radial approach is safe in most populations and has many added benefits over other, more traditional approaches. In addition, the use of the radial approach has been shown to be more cost effective than other popular procedures. There is sufficient evidence to warrant more wide-spread use of the radial approach to angioplasty in appropriate patients. More research needs to be conducted comparing different treatment types in order to best define the patients in which this approach is most effective.

## REVIEW

There have been numerous advances in coronary angiography since Hales performed the first angiogram in 1711 on a horse (1). In humans, the femoral artery has traditionally been the preferred site of arterial access for coronary procedures, but numerous factors, including patient intolerance and relatively high complication rates (2, 3), led to the advent of radial artery access. The radial approach to angioplasty has become increasingly popular since its initial use in 1989 due to its relative safety, cost effectiveness and less patient burden than other approaches (4). This review will serve as a brief, comprehensive overview of the history and recent advances in radial angioplasty. We will describe the radial approach to angioplasty and the recent literature regarding its efficacy and safety, and well as some of the likely future advances in the field.

## LAYING THE FOUNDATION FOR ANGIOPLASTY

In 1844, the French physiologist Claude Bernard used catheters to record intra-cardiac pressures in animals, coining the term "cardiac catheterization" (5). The first documented human cardiac catheterization was performed in 1929 by Werner Forsmann, a German surgical resident, who postulated that catheterization of the right heart via the venous system would allow for safer access to cardiac chambers. Using himself as a subject, Forsmann anesthetized his elbow, introduced a catheter through his antecubital vein and inserted the length of the catheter

(65cm). A subsequent x-ray performed documented the catheter's position in the right atrium, a historic landmark for the development of angioplasty (1). Cournard and Richards furthered this intervention in 1941 when they employed a catheter to measure the cardiac output, for which they were awarded a Nobel Prize in 1956 (1).

Numerous advances relevant to angioplasty were made in the 1950's and 60's. Mason Jones, a pediatric cardiologist using catheter dye techniques to work on the aortic valve, inadvertently catheterized the coronary artery of a patient, leading to the observation that the coronary arteries could tolerate contrast dye, thereby giving birth to the diagnostic coronary angiogram. Melvin Judkins perfected the technique of coronary angiography via the femoral route by introducing more advanced catheters in the late 1960's (1).

In 1963 Charles Dotter recanalized an occluded right iliac artery by passing a percutaneously-introduced catheter retrograde through the occlusion to perform an abdominal aortogram in a patient with renal artery stenosis (6).

Recognizing the potential of his finding, he conducted the first transluminal dilatation in an 82-year-old woman with popliteal artery stenosis with Judkins in 1967. Initial criticism of these techniques focused on the need for large bore rigid dilators, large shear forces to atherosclerotic plaque which made the technique cumbersome and risky, and potential risk to branch vessels. However, Dotter's European peers improved upon these techniques to devise

new methods for peripheral artery angioplasty, despite that his techniques were not received favorably in the United States for several years (<sub>1</sub>).

In the mid-1970's, Andréas Gruentzig miniaturized equipment to be used in coronary arteries. With Myler, he performed the first coronary angioplasty in a human in the late 1970's, using retrograde passage of a balloon catheter through an arteriotomy made in the left anterior descending coronary artery distal to the stenosis before the placement of the bypass graft. After balloon deflation and catheter removal, a cannula was introduced and the artery flushed. Notably, there was no evidence of distal plaque embolization when the effluent was collected on filter paper. In 1977, he presented his results to a favorable reception at an American Heart Association conference, and angioplasty subsequently progressed with the introduction of newer devices that could be delivered through smaller guiding catheters (<sub>1</sub>).

### THE RISE OF CORONARY ANGIOPLASTY

Percutaneous transluminal coronary angioplasty (PTCA) became increasingly popular as a safe and cost effective alternative to bypass surgery in appropriately selected patients. Among the first trials describing its use in 1979, Gruentzig et al. presented the results of angioplasty in 50 patients with coronary artery stenosis. The success rate of PTCA was reported to be 64% with mean stenosis reduction from 84% to 34% and mean coronary pressure gradient reduction from 58 to 19 mm Hg. Immediate non-successes included acute deterioration in clinical state leading to emergency bypass (10%) and evidence of infarcts (6%) (<sub>7</sub>). Subsequent studies using PTCA conducted in patients with unstable angina (<sub>8,9</sub>), total coronary artery occlusion (<sub>10,11</sub>), high-grade coronary stenosis (<sub>12</sub>), and multivessel coronary angioplasty (<sub>13</sub>) found similar to higher initial success rates (53-89%), with most unsuccessful treatments being followed with bypass surgery.

Studies using PTCA that have observed long-term outcome have shown mixed results, with some finding increased risk of major complications (non-fatal myocardial infarction (MI), death, etc.) (<sub>9</sub>), and others finding relatively high survival rates (e.g. 88% after 5 years) (<sub>13</sub>). These differences may in part be due to large ranges in sample sizes (50-700 patients), follow-up periods (2-5 years), and variability in baseline characteristics (patients with unstable angina, multivessel coronary angioplasty, varying age ranges). Undoubtedly, varying operator experience likely contributed to the discrepancies in results (<sub>14</sub>).

During the 1980's and 90's, PTCA was found to be a superior modality in comparison with intravenous streptokinase in the setting of acute myocardial infarction with respect to rates of death due to cardiac causes, unsatisfactory outcomes, and overall left ventricular function (<sub>15,16</sub>). There have been some reports of increased clinical stability when both are used sequentially (<sub>17,18</sub>), though results have been inconsistent and it remains uncertain whether the combination of PTCA and intravenous thrombolysis is beneficial enough to warrant its use (<sub>19,20</sub>).

Studies focusing on the use of PTCA in different age groups have provided evidence that older patients (age > 65) are more likely to require emergency or elective coronary artery bypass grafting (CABG) and have significantly higher rates of in-hospital death (<sub>21</sub>). At least one study, however, reported a 96% immediate success rate in patients in this age group (<sub>22</sub>). In patients <35 years old, reports of success using PTCA have been much higher. Stone et al reported a 96% immediate success rate in 71 younger patients; 73% of these patients remained asymptomatic after 32 months of follow-up (<sub>23</sub>). Again, fluctuations may in part be due to variable baseline characteristics as well as operator experience.

Risk factors associated with poorer outcome in patients treated with PTCA include left main dilation, left main equivalent dilation, left ventricular ejection fraction <40%, age >70 years, dilation of all three vessels, combined diagnostic catheterization and angioplasty for unstable angina (<sub>24</sub>), and PTCA for acute MI (<sub>13,24</sub>). Consequently, contraindications to PTCA generally include significant obstructive lesion in the left main coronary artery and severe diffuse atherosclerosis (<sub>25</sub>).

### HISTORY OF RADIAL ANGIOPLASTY

During the early 1980's, the transbrachial and femoral routes were the most commonly used entry sites for angiography and angioplasty (as in the above reviewed studies). However, significant complications were associated with these approaches, including hematomas, neuropathies, psuedoaneurysms, arteriovenous fistulae, and limb ischemia (<sub>25</sub>).

In 1989 Lucien Campeau attempted the first radial artery approach to cardiac catheterization, postulating that this approach would prove free of significant vascular complications, primarily because the hand has collateral circulation and the cannulation site is devoid of nerves or veins of significant size. Campeau studied this approach in

100 patients using French 5 introducer sheaths and pre-shaped catheters<sup>(25)</sup>. Although radial artery puncture and cannulation were difficult, these impediments likely would be overcome with experience and improved equipment. Few significant complications, like radial artery aneurysm, hematoma, and compartment syndromes, arose, providing evidence that benefits most likely outweighed risks of the procedure.

Following Campeau's report, studies using the radial approach were conducted in patients in whom the femoral approach was difficult or contraindicated because of advanced arteriosclerosis<sup>(26,27)</sup>. Otaki followed with a series of 40 patients, all with indications for coronary angiography, easily palpable radial and ulnar arteries, and a normal Allen test<sup>(28)</sup>. One patient was converted to the brachial approach secondary to inability to advance the catheter to the brachial artery. In the remaining 39 patients, selective left coronary angiography was accomplished using a left Judkins catheter and the right coronary artery and the saphenous vein graft entered successfully using right Judkins or Amplatz catheters. In 5 patients (13%), the radial pulse remained acutely diminished, but there were no complaints of pain; bleeding at the puncture site occurred in one patient (3%) and subcutaneous bleeding around the puncture site occurred in 5 patients (13%). Pseudoaneurysm, neuropathy and arteriovenous fistulae were not detected at the time of discharge and there was no evidence of ischemia, pain or radial artery occlusion or dissection in any patients.

In 1995, Kiemeneij et al<sup>(29)</sup> conducted a study on transradial artery angioplasty using 6F introducer sheaths with new 6F guiding catheters. At the time, there was a trend towards using smaller PTCA guiding catheters. This evolution toward smaller equipment made the radial artery a suitable access site for PTCA. In 100 patients with collateral blood supply to the right hand, PTCA was attempted using 6F guiding catheters and rapid exchange balloon for exertional angina (87%) or nonexertional angina (13%). Angioplasty was attempted on 122 lesions (type A n=67 [57%], type B n=37 [30%], and type C n=18 [15%]). Coronary cannulation was successful in 94 patients. The six unsuccessful interventions had successful PTCA through the femoral artery (n=5) or the brachial artery (n=1). Average minimal luminal diameter was increased from  $0.9 \pm 0.3$  to  $2.0 \pm 0.5$  and diameter stenosis was reduced from  $74\% \pm 11\%$  to  $24\% \pm 11\%$ <sup>27</sup>. The authors speculated that early withdrawal of the sheath immediately after the angioplasty, and aggressive anticoagulation may be important factors in the prevention

of radial artery thrombosis. They showed the radial artery was a low risk entry site for angioplasty despite radial artery occlusion, provided the ulnar artery was patent.

In a follow-up study of 100 consecutive patients<sup>(30)</sup>, stent placement was attempted via the radial approach for 122 lesions in 104 vessels. Immediately after stent placement and final angiography, the introducer sheath was withdrawn, intense anticoagulation and mobilization was initiated, and the radial artery puncture site was studied by two-dimensional and Doppler ultrasound. Successful stent implantation via the radial artery was achieved in 96 patients. In two patients, arterial puncture failed but was followed by successful stenting via another entry site. In one patient, stent implantation was achieved with a stent delivery system via the femoral artery after a failed attempt to cross the lesion with a bare stent via the radial approach, but was complicated by bleeding at the femoral site, requiring transfusions and vascular surgical intervention. One patient was referred for coronary bypass surgery. Average minimal luminal diameter increased from  $1.1 \pm 0.4\text{mm}$  to  $3.1 \pm 0.5\text{mm}$ ; diameter stenosis was reduced from  $67\% \pm 11\%$  to  $13\% \pm 10\%$ . 93% of patients enjoyed procedural success and an uncomplicated clinical course. Subacute stent thrombosis occurred in one patient. None of the four patients with post-procedural radial artery occlusion showed signs of hand ischemia. Average hospital stay was  $5.2 \pm 4.1$  days. Patients receiving warfarin (n=64) at the time of admission were hospitalized for  $4.1 \pm 4.2$  days with 22 (34%) patients discharged within 24 hours of stenting. Despite heparinization, early major entry site related complications were rarely encountered. The authors concluded that by combining 6F guiding catheters and low profile dilatation catheters with bare Palmaz Schatz stents, smaller vessels, such as the radial artery, could be selected as the entry site and that transradial artery Palmaz-Schatz coronary stenting was feasible and safe<sup>(30)</sup>.

Kiemeneij et al have noted similar rates of procedural success and suboptimal result when they compared angioplasty via the radial, brachial, and femoral approaches<sup>(2)</sup>. Additionally, artery occlusion rates were 5% in the radial artery at the time of discharge. No occlusions were found in the brachial and femoral groups, the length of hospital stay was similar in all three groups.

### LIMITATIONS OF THE RADIAL APPROACH

The transradial approach to coronary intervention is now recognized as being associated with lower vascular

complication rates, earlier mobilization, less patient discomfort, and lower procedural costs than the femoral approach (3). However, radial artery spasm related to circulating catecholamines and vessel trauma is a major limitation of this approach, occurring in up to 10% of cases. These difficulties required more operator experience and materials better suited for the radial artery route (4). Despite these shortcomings, the radial artery approach was considered safe and preferable to the transfemoral route in appropriate patients. It has been demonstrated clearly by Kiemeneij that administration of an intra-arterial vasodilating cocktail (0.8 mg verapamil), prior to sheath insertion reduces the incidence and severity of radial artery spasm in patients undergoing these procedures (31).

The transradial artery route is suitable only for 6F catheters, thereby limiting the choice of devices available for coronary interventions (2). Prefabricated, sheath-protected stent delivery systems cannot be advanced through the 6F guiding catheters. Additionally this approach is unable to accommodate the use of intravascular ultrasound (IVUS) or angioscopy to assess stenoses distal to a stent. Therefore coronary interventions using this approach in high risk patients with complex lesions, acute MI and severely compromised left ventricular function should be avoided.

It is understood that stent implantation through 6F guiding catheters requires optimal backup and coaxial alignment to facilitate advancement of the stent-loaded balloon and to prevent stent loss and embolization. Furthermore, 6F catheters have less torque control and seating stability at the coronary ostia. Given that most catheters are designed for the femoral approach, higher degree of operator expertise is often required for a safe and successful cannulation. This is particularly true for Amplatz catheters, which are generally more difficult to manipulate and prone to traumatizing the artery. Finally, lack of adequate opacification and visualization of coronary circulation can be encountered when the balloon catheter is positioned within the guiding catheter, obstructing delivery of the contrast medium (32).

Difficulties encountered during the catheterization procedure itself include arterial dissection resulting from advancement of wires through tortuous arteries, as well as difficulty advancing of the catheter from the subclavian artery into the aortic arch and ascending aorta. Many of these problems are ultimately avoided through the use of longer sheaths and exchange wires (33).

Stella et al. also reported on the incidence of radial artery

occlusion following transradial artery coronary angioplasty (34). Of 563 patients, 5.3% had evidence of radial artery occlusion at discharge. After 1 month, 46.6% of these patients showed evidence of spontaneous recanalization, and persistent occlusion was found in 2.8%. There was no evidence of de novo radial artery occlusion after discharge. In comparison to Campeau, they found very low incidence of radial artery occlusion and dissection. It was concluded that the key factors in the prevention of occlusion were likely the short duration of cannulation and immediate sheath removal. Spaulding et al. also reported that increasing the intra-arterial heparin dose from 1000 I.U. to 5000 I.U. was important in reducing the incidence of occlusion (35). In 1995 ultrasound imaging of the radial artery following cardiac catheterization was studied to check the incidence of the radial artery occlusion and it was concluded that radial artery occlusion, while uncommon, results in no ischemic sequelae in the setting of a patent ulnar artery (36).

In 1997, Wu et al. (37) found that, although the radial artery was free of the usual femoral artery complications, it could not be used for all the patients. They intimated certain indications for radial artery angioplasty, including inaccessibility of the femoral approach, elective PTCA for noncomplex lesions in patients with previously defined coronary anatomy, follow-up angiography for previous interventions in non-complex lesions, and outpatient diagnostic angiography. This study was done in Chinese patients who were noted to have smaller arteries than the Western population. Coincidentally, Kiemeneij and Laarman noted that the incidence of female patients with radial artery occlusion was low (30). These two studies contradicted existing theory that a smaller vessel diameter is more prone to occlusion after cannulation.

In more recent years, indications for transradial approach have broadened significantly. Multiple studies have shown both efficacy and safety of transradial access for renal artery angioplasty, particularly in patients with unfavorable femoral artery anatomy (37,38). Further, Gilchrist et al. reported on the safety and feasibility of left and right heart catheterization by transradial and transbrachial approach, respectively (39). In 2006, Lo and colleagues subsequently reported on the safety of transradial right and left heart catheterization in 28 consecutive patients who were anticoagulated to an INR of 2.5, showing low bleeding and thromboembolic risk (40). Also in 2006, Sanmartin et al. (41) described the safety and feasibility of transradial coronary bypass graft catheterization in 280 patients, when compared

to the transfemoral approach.

Finally, since 2003, multiple studies have demonstrated safety and efficacy of the transradial approach for primary coronary angioplasty in the setting of acute myocardial infarction. Valsecchi and colleagues reported on its safety and feasibility in 726 patients, noting similar results to transfemoral approach (<sub>42</sub>). Ranjan et al. described similar results in 2005, both acutely and at six-month follow-up, in 103 Indian patients (<sub>43</sub>), while Philippe reported on safety and efficacy of transradial access in 119 consecutive patients undergoing primary angioplasty during acute myocardial infarction who were also treated with glycoprotein IIb/IIIa inhibitors (<sub>44</sub>).

Among the questions remaining regarding the routine use of transradial approach is the potential for increased radiation exposure to the operator. Although some speculate no relative increase in radiation exposure (<sub>45</sub>), Lange and von Boetticher reported an increase in radiation exposure to the operator by radial approach in a randomized comparison to femoral approach (<sub>46</sub>). However one could surmise that with increasing operator experience, fluoroscopy time by radial approach would decrease, ultimately limiting overall exposure.

### CONCLUSIONS AND IMPLICATIONS FOR LONG-TERM USE

The radial artery has been increasingly accepted as a reasonable alternative route for angioplasty. The safe, immediate mobilization of patients following transradial intervention allows for safe outpatient coronary angioplasty techniques. Outpatient intervention is a strong tool for coping with increasing patient volume and reducing wait time for elective coronary angioplasty. Overall, the transradial approach can prove cost effective (<sub>47</sub>). Given data being presented recently on the safety and efficacy of the transradial approach for more complex (e.g. bifurcation) lesions, peripheral disease, coronary bypass graft angiography, as well as potentially right and left heart catheterization and primary angioplasty during acute myocardial infarction, it is likely the indications for radial artery access to coronary angioplasty will continue to grow.

In conclusion, various new methods and materials have been introduced over the years. The transradial approach to cardiac catheterization and percutaneous coronary intervention is promising, with many advantages that seemingly outweigh the relatively few limitations when employed in the appropriate patient population. This

approach carries the potential to be the standard approach in the setting of elective, outpatient angioplasty, with increasing use in the inpatient setting as well.

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