The Safety and Feasibility of Transradial Cutting Balloon Angioplasty

Immediate results, benefits, and limitations

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SUMMARY
Cutting balloon angioplasty can reduce the restenosis rate more than conventional balloon angioplasty, but is traditionally performed through a femoral artery. However, it is not clear how useful a transradial approach would be for cutting balloon angioplasty. This study was conducted to examine the safety, feasibility, and limitations of transradial as opposed to transfemoral cutting balloon angioplasty.

From November 1999 to August 2001, 177 patients underwent cutting balloon coronary angioplasty. We compared the success rate, angiographic results, and complication rates of two groups of patients, those undergoing transradial (168 lesions from 153 patients) and those undergoing transfemoral (24 lesions from 24 patients) cutting balloon angioplasty. In both groups of patients who had similar clinical and target lesion characteristics, the percentage of lesions that required balloon predilation (27.4% vs 29.2%), stenting (7.7% vs 4.2%), and adjunct balloon dilation (28.0% vs 33.3%) due to dissection (35.7% vs 33.3%) or suboptimal results were comparable. Both approaches achieved a 100% primary success rate with similar acute gain (2.02±0.68 mm vs 1.94±0.70 mm), residual (luminal) diameter stenosis (19.2±11.7% vs 17.0±12.7%), proportion of lesions that achieved TIMI 3 flow (98.8% vs 100%), and clinical success rate (98.8% vs 95.8%). However, patients undergoing transradial cutting balloon angioplasty had earlier ambulation and a significantly shorter hospital stay than those undergoing a transfemoral approach (2.80±2.67 days vs 4.75±5.44 days, P=0.005).

We conclude that the transradial approach is a feasible and safe alternative to the transfemoral approach for cutting balloon angioplasty. In addition, it offers patients early ambulation and a short hospital stay. (Jpn Heart J 2003; 44: 51-60)

Key words: Transradial catheterization, Transfemoral catheterization, Cutting balloon angioplasty

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SINCE Andreas Gruntzig performed the first percutaneous transluminal coronary angioplasty (PTCA) in 1977, restenosis has always been a challenging issue for interventional cardiologists. Although many new devices and techniques have been developed for PTCA, the restenosis rate has remained significantly high.

The acute gain, final luminal diameter achieved, early elastic recoil, and thrombus formation have been identified as determinants of restenosis after conventional balloon angioplasty. Also playing a very important role in restenosis is the severity of the tissue damage or dissection, which determines subsequent neointimal hyperplasia. This tissue damage is an inevitable outcome, however, and its severity cannot be controlled, as the damage pattern is unpredictable during conventional balloon angioplasty. The cutting balloon, a newly designed balloon equipped with microtome sharp cutting blades mounted on its surface by advanced microsurgical engineering, can dissect in a predictable and favorable pattern during angioplasty, and therefore, reduce the severity of vessel trauma as well as subsequent restenosis. In terms of restenosis, several studies have confirmed the advantage of cutting balloon over the conventional balloon angioplasty.

Like conventional PTCA, cutting balloon angioplasty has usually been performed through a femoral approach with the support of a large-size guiding catheter (7 Fr or 8 Fr). Recently, transradial coronary intervention has gained popularity because it reduces bleeding complications at the puncture site and offers comfort to patients as a result of early ambulation and a short hospital stay. However, it has not been made clear whether cutting balloon angioplasty can be performed through a radial artery. The purpose of this study was to assess the safety, feasibility, and limitations of cutting balloon angioplasty through a radial artery as opposed to a femoral artery. Since the radial artery is relatively small in most Asians, we performed this procedure with a 6 Fr guiding catheter on most of the patients.

**Patients and Methods**

**Patients:** From November 1999 to August 2001, patients who had received standard medications for angina pectoris but remained symptomatic were screened for this study. Inclusion criteria were 18 years of age or older; stable hemodynamics; myocardial ischemia based on symptoms or laboratory tests (changes in ECG, positive treadmill exercise test or thallium scan); stenosis severity of more than 70% in de novo lesions or lesions with restenosis as a result of previous balloon angioplasty or stenting. Exclusion criteria were myocardial infarction within 3 days; poor cardiopulmonary conditions requiring support of a
ventilator or intravenous inotropic agents; and very tortuous proximal lesions that were not suitable for cutting balloon angioplasty. The selection of a transradial or transfemoral approach in a particular patient was decided by the individual operator. The Institutional Review Committee on Human Research at our institution approved the protocols and all patients signed written informed consent forms. 

**Study protocol:** In the transradial group, after a negative Allen's test and local anesthesia with 2% lidocaine, we punctured and inserted a sheath into the radial artery. Once the sheath was in position, we immediately administered through it a solution containing lidocaine, nitroglycerin, verapamil, and 5000 IU of unfractionated heparin to reduce radial artery spasm and clotting. An additional 5000 IU of unfractionated heparin was routinely given before coronary intervention. We used a 6 Fr Kimny mini radial guiding catheter first for both diagnostic purposes and percutaneous intervention (PCI) in most cases and then switched to Judkin, Amplatz, or XB catheters if needed. We also used a 7 Fr or 8 Fr guiding catheter in some cases for intravascular ultrasound-guided PCI (IVUS, a 3.2 Fr ultracross system), rotational atherectomy or the kissing balloon technique.

In the transfemoral group after local anesthesia with lidocaine, we punctured the femoral artery and introduced a 7 Fr or 8 Fr artery sheath, which was flushed only with heparinized saline. Standard Judkin catheters were used for the diagnostic procedures and after 10000 IU of unfractionated heparin was administered, appropriate guiding catheters were used for cutting balloon angioplasty.

After a selected guiding catheter was engaged to the orifice of the diseased coronary artery, a 0.014 inch guide wire was used to cross the stenotic lesion. The guide wire was advanced distally followed by cutting balloon catheter dilatation. Lesions that could not initially be advanced by a cutting balloon were predilated using a smaller size conventional balloon. Multiple inflations were allowed for both *de novo* lesions and lesions with restenosis. If the final result was suboptimal, defined as a residual (luminal) diameter stenosis >50% or resulting in a significant dissection flap, it was left to the individual operator to decide whether to perform adjunctive balloon angioplasty or stent implantation.

In the transradial group, after the angioplastic procedure, the arterial sheath was removed in the catheterization laboratory and the puncture site was compressed with gauge and adhesive tape for hemostasis. The patients were allowed to ambulate immediately but were asked to limit wrist motion. One hour later, the adhesive tape was loosened slightly but adequate compression was maintained till the next day. In the transfemoral group, the femoral artery sheath was removed 6 hours after the angioplastic procedure when activated clotting time went below 150 seconds. Hemostasis of the puncture wound was achieved by manual compression followed by further compression with a gauge, adhesive tape, and a 2-kilogram sand bag for another 4 hours with the patients remaining in a supine
Whether to use overnight heparinization or not after angioplasty was left to the operator's discretion. The patients were discharged the next day if they were hemodynamically stable and had no evidence of angina pectoris.

Digital angiograms were analyzed offline by quantitative computerized analysis (Phillip Medical System). The percent diameter stenosis (DS), minimal luminal diameter (MLD) of the lesion, and the length of the lesion in the most stenotic projections were determined before and after the angioplasty procedure. The reference luminal diameter (RD) was determined from the normal segment adjacent to the stenotic lesion. We also calculated the acute gain, defined as the increase in the MLD of the target lesion immediately after the procedure. A procedure was considered technically successful if the residual (luminal) diameter stenosis of the lesion was reduced to less than 50% without immediate major complications, and a procedure was considered optimal if the residual (luminal) diameter stenosis was reduced to less than 30%. Furthermore, the procedure was considered clinically successful only if a patient was discharged from the hospital without emergency bypass surgery or myocardial infarction.

**Statistics:** The data from the two groups of patients are expressed as the mean±SD or percentage (%). Chi-square, Fisher's exact test, or Student's t-test was used to determine differences in categorical data or continuous variables between the groups. A probability value of less than 0.05 was considered statistically significant.

**RESULTS**

A total of 177 patients were enrolled in the study. One hundred and fifty-three patients underwent cutting balloon angioplasty through a radial artery. These patients made up our study group. The remaining 24 patients, who underwent cutting balloon angioplasty through a femoral artery, served as a control group. The baseline characteristics of the subjects are shown in Table I. There was a larger proportion of males but a smaller proportion of patients with diabetic mellitus in the transradial group than in the transfemoral group. There were no significant group differences in any of the other clinical variables.

A transradial approach was used in 168 lesions and a transfemoral approach was used in 24 lesions. In the transradial group, 76.5% of the angioplasties were performed via the left radial artery. In 135 lesions (80.3%), a 6 Fr guiding catheter was used. We used 7 Fr guiding catheters in 31 lesions (18.5%) and 8 Fr guiding catheters in 2 (1.2%) lesions, as intravascular ultrasound-guided intervention, rotational atherectomy, or a kissing balloon technique were required. In the transfemoral group, the right femoral artery was routinely used for angioplasty. None of the patients in the two groups had compromised peripheral neuromuscular
The lesion characteristics were similar in the two groups, except there were more target vessels in the left anterior descending coronary artery (58.9% vs 37.5%, *P*=0.048) in the transradial group than in the transfemoral group (Table II). The lesions in both groups also had similar percent diameter stenosis, minimal luminal diameter, and TIMI flow\(^1\), even though they were longer and their reference luminal diameter was larger in the transradial group (Table III). However, technical demands (the balloon to artery ratio, balloon size, number of balloon inflations, inflation pressure, conventional balloon predilatation, and adjunctive balloon inflation or stenting) were similar in the two groups (Table III).

Both approaches achieved similar acute gain, residual percent diameter stenosis, and minimal luminal diameter after intervention (Table III). After angioplasty, 98.8% of the transradial group and 100% of the transfemoral group achieved TIMI 3 flow (*P*=NS) (Table III). However, the transradial group had significantly shorter times in terms of angioplasty to patient discharge and total hospital stay than did the transfemoral group (Table III).

The complications encountered in both groups of patients are summarized in Table IV. Both groups had similar complication rates, ranging from minor dissections\(^7\) to serious complications that required bail-out stenting or intraaortic balloon pump support as a result of acute occlusion or unstable hemodynamics.
Table II. Characteristics of Lesions Undergoing Transradial or Transfemoral Cutting Balloon Angioplasty

<table>
<thead>
<tr>
<th>Lesion Class</th>
<th>Transradial (n=168)</th>
<th>Transfemoral (n=24)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>LAD (Target)</td>
<td>99 (58.9%)</td>
<td>9 (37.5%)</td>
<td>0.048</td>
</tr>
<tr>
<td>LCX (Target)</td>
<td>30 (17.9%)</td>
<td>7 (29.2%)</td>
<td>0.27</td>
</tr>
<tr>
<td>RCA (Target)</td>
<td>39 (23.2%)</td>
<td>8 (33.3%)</td>
<td>0.28</td>
</tr>
<tr>
<td>Type A</td>
<td>11 (6.5%)</td>
<td>3 (12.5%)</td>
<td>0.39</td>
</tr>
<tr>
<td>Type B1</td>
<td>28 (16.7%)</td>
<td>7 (29.2%)</td>
<td>0.16</td>
</tr>
<tr>
<td>Type B2</td>
<td>81 (48.2%)</td>
<td>11 (45.8%)</td>
<td>0.83</td>
</tr>
<tr>
<td>Type C</td>
<td>48 (28.6%)</td>
<td>3 (12.5%)</td>
<td>0.14</td>
</tr>
<tr>
<td>De novo</td>
<td>95 (56.5%)</td>
<td>14 (58.3%)</td>
<td>0.87</td>
</tr>
<tr>
<td>In stent restenosis</td>
<td>64 (38.1%)</td>
<td>8 (33.3%)</td>
<td>0.65</td>
</tr>
<tr>
<td>Balloon PTCA restenosis</td>
<td>9 (5.4%)</td>
<td>2 (8.3%)</td>
<td>0.63</td>
</tr>
</tbody>
</table>

Data presented are number (%) of lesions. LAD=left anterior descending artery; LCX=left circumflex artery; RCA=right coronary artery; PTCA=percutaneous transluminal coronary angioplasty; Type A, B1, B2 and C; lesion classification by American Heart Association.6,11

Table III. Angiographic Results of the Lesions Before and after Transradial (n=168) or Transfemoral (n=24) Cutting Balloon Angioplasty

<table>
<thead>
<tr>
<th>Lesion Parameter</th>
<th>Transradial (n=168)</th>
<th>Transfemoral (n=24)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>DS (%) (before)</td>
<td>80.1±9.2%</td>
<td>79.9±9.2%</td>
<td>0.73</td>
</tr>
<tr>
<td>MLD (mm) (before)</td>
<td>0.62±0.36</td>
<td>0.58±0.31</td>
<td>0.77</td>
</tr>
<tr>
<td>DS (%) (after)</td>
<td>19.2±11.7%</td>
<td>17.0±12.7%</td>
<td>0.38</td>
</tr>
<tr>
<td>MLD (mm) (after)</td>
<td>2.65±0.66</td>
<td>2.52±0.72</td>
<td>0.15</td>
</tr>
<tr>
<td>RD (mm)</td>
<td>3.22±0.63</td>
<td>3.03±0.59</td>
<td>0.04</td>
</tr>
<tr>
<td>Acute gain (mm)</td>
<td>2.02±0.68</td>
<td>1.94±0.70</td>
<td>0.45</td>
</tr>
<tr>
<td>Balloon/Artery ratio</td>
<td>1.06±0.18</td>
<td>1.12±0.16</td>
<td>0.10</td>
</tr>
<tr>
<td>Lesion length (mm)</td>
<td>16.03±6.80</td>
<td>12.67±6.88</td>
<td>0.008</td>
</tr>
<tr>
<td>Balloon size (mm)</td>
<td>3.35±0.45</td>
<td>3.30±0.39</td>
<td>0.59</td>
</tr>
<tr>
<td>Number of inflations</td>
<td>3.21±1.73</td>
<td>3.33±1.40</td>
<td>0.41</td>
</tr>
<tr>
<td>Inflation pressure (Bar)</td>
<td>9.60±2.21</td>
<td>9.50±2.23</td>
<td>0.80</td>
</tr>
<tr>
<td>Predilatation</td>
<td>46 (27.4%)</td>
<td>7 (29.2%)</td>
<td>0.86</td>
</tr>
<tr>
<td>Adjunctive balloon</td>
<td>47 (28.0%)</td>
<td>8 (33.3%)</td>
<td>0.59</td>
</tr>
<tr>
<td>TIMI 0 flow (before)</td>
<td>6 (3.6%)</td>
<td>2 (8.3%)</td>
<td>0.26</td>
</tr>
<tr>
<td>TIMI 1 flow (before)</td>
<td>9 (5.4%)</td>
<td>0 (0%)</td>
<td>0.61</td>
</tr>
<tr>
<td>TIMI II flow (before)</td>
<td>40 (23.8%)</td>
<td>4 (16.7%)</td>
<td>0.61</td>
</tr>
<tr>
<td>TIMI III flow (before)</td>
<td>113 (67.2%)</td>
<td>18 (75%)</td>
<td>0.45</td>
</tr>
<tr>
<td>TIMI 0 flow (post)</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td></td>
</tr>
<tr>
<td>TIMI 1 flow (post)</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
<td></td>
</tr>
<tr>
<td>TIMI II flow (post)</td>
<td>2 (1.2%)</td>
<td>0 (0%)</td>
<td>1.00</td>
</tr>
<tr>
<td>TIMI III flow (post)</td>
<td>166 (98.8%)</td>
<td>24 (100%)</td>
<td>1.00</td>
</tr>
<tr>
<td>PTCA to discharge</td>
<td>1.95±2.09 days</td>
<td>3.17±4.21 days</td>
<td>0.04</td>
</tr>
<tr>
<td>Hospital stay</td>
<td>2.80±2.67 days</td>
<td>4.75±5.44 days</td>
<td>0.005</td>
</tr>
</tbody>
</table>

Data presented are mean values (±SD) or number (%) of lesions. DS=percent diameter stenosis; MLD=minimal luminal diameter; RD=reference luminal diameter; PTCA=percutaneous transluminal coronary angioplasty; TIMI=Thrombolysis and Angioplasty in Myocardial Infarction.19
In the transradial group, one patient developed contrast nephropathy and pneumonia and died 20 days after the angioplastic procedure. Another patient suffered acute occlusion that resulted in inferior wall Q wave myocardial infarction after cutting balloon angioplasty. His condition improved after bail-out stenting with perfusion balloon dilatation and IABP support. In the transfemoral group, one patient suffered from acute occlusion after the angioplastic procedure. Although the lesion was sealed off with bail-out stenting, her condition deteriorated and she died shortly after the procedure on the same day. Overall, the transradial and transfemoral groups had clinical success rates of 98.8% vs 95.8% \((P=0.33)\) and in-hospital mortality rates of 0.6% vs 4.2% \((P=0.24)\), respectively.

**DISCUSSION**

Previous studies\(^9\text{-}^{12}\) have shown that cutting balloon angioplasty results in shorter inflation times, lower inflation pressures, less major dissections, and lower restenosis rates than conventional balloon PTCA. Cutting balloon angioplasty, however, has traditionally been performed under the support of a larger size (7 or 8 Fr) guiding catheter, thus necessitating a femoral approach. In this study, we performed transradial cutting balloon angioplasty in 168 lesions, with most cases (80.3%) successfully performed with the support of a 6 Fr guiding
catheter. Using this approach, we successfully dilated all of the lesions and achieved a similar clinical success rate in this group to that in the transfemoral group (98.8% vs 95.8%, \(P=0.33\)). In addition, the transradial approach yielded an acceptable complication rate similar to that for the transfemoral approach (Table IV).

It should be pointed out that the patients undergoing a transradial approach enjoyed earlier ambulation and significantly shorter hospital stays than those undergoing a transfemoral approach. Our data represent the first report to indicate that cutting balloon angioplasty through the radial artery is safe and feasible even when supported by a small guiding catheter.

There are several concerns regarding the use of transradial cutting balloon for coronary angioplasty. First, because the radial artery is a relatively small vessel, the intervention is usually performed through a 6 Fr guiding catheter. With this size of guiding catheter, visualization of the balloon position may not always be clear during a contrast medium test. However, this did not seem to be a limitation for a transradial approach. In this study, we used a 6 Fr guiding catheter for cutting balloon PTCA in 80.3% of the lesions and we were able to achieve results as satisfactory as those achieved by a transfemoral approach. In addition, despite the different sizes of the guiding catheters used in cutting balloon PTCA, the transradial and transfemoral groups also had comparable incidences of bail-out stenting (7.7% vs 4.2%), IABP support (3.6% vs 0%), and myocardial infarction (0.6% vs 0%). Second, the relatively large profile and rigidity of a cutting balloon catheter as opposed to conventional balloon usually make it difficult to cross very tortuous or tight lesions. For this reason, a smaller size conventional balloon pre-dilatation was required in 27.4% of the lesions in the transradial group and 29.2% of the lesions in the transfemoral group \(P=0.86\) (Table III). Thus, it is a problem common to both approaches even though a larger-size guiding catheter was inserted in the transfemoral group.

Our operators tended to adopt transfemoral angioplasty for patients with complications or poor medical conditions. However, both the transradial and transfemoral groups each had only one in-hospital death (0.6% vs 4.2%, \(P=0.24\)). **Limitation:** This study was not randomized and the number of patients was relatively small. Whether a patient would undergo transradial or transfemoral cutting balloon angioplasty was decided by the individual operator. In our hospital, most of the elective coronary interventions have shifted toward a transradial approach. Thus, we only had 24 patients in the transfemoral group. However, the acute results from the transfemoral group in our study were similar to those of previous studies.1-8) Therefore, the comparable results obtained for both approaches in our study support our assertion that transradial cutting balloon angioplasty is a feasible alternative. Although our study was restricted to one hos-
hospitalization, with such encouraging results a randomized study with a large num-
ber of patients and long-term follow-up is warranted.

**Conclusion:** A transradial approach to cutting balloon coronary angioplasty can
achieve a favorable success rate and a complication rate similar to that of the
transfemoral approach. In addition to the benefits brought about by increasing
patient comfort due to early ambulation and allowing a short hospital stay, the
transradial approach can be easily performed with a 6 Fr guiding catheter in most
patients without damaging the peripheral vasculature. Our data suggest that,
unless dictated by other situations, the use of a transradial approach for cutting
balloon angioplasty is feasible, safe, and can be used routinely.

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