Directional Coronary Atherectomy versus Coronary Angioplasty in Vessels Larger than 3 mm in Diameter

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SUMMARY

It has been proposed that directional coronary atherectomy (DCA) should be an intervention of choice in larger vessels as one can achieve a greater minimal luminal diameter with DCA than with percutaneous transluminal coronary angioplasty (PTCA). This in turn should translate into a higher success rate and may even reduce the restenosis rate. The aim of this study was to compare DCA versus PTCA in vessels > 3 mm in diameter. One hundred fifty consecutive patients who met the inclusion criteria and had DCA were compared to 150 similarly selected PTCA patients. PTCA patients were selected from the era immediately preceding the advent of DCA so that selection bias could be excluded. All patients with ostial lesions, restenosis, vessels < 3 mm in diameter, and vessels with more than two significant lesions were excluded. Distal segments and circumflex cases were excluded as they formed a small subsegment. Both groups were similar in terms of demographic, clinical and angiographic variables. Quantitative analysis showed that the initial net gain was significantly greater in the DCA group than in the PTCA group (2.36 ± 0.8 mm vs. 1.78 ± 0.7 mm; p < 0.05). Residual stenosis was 11% with DCA compared to 33% with PTCA (p < 0.05). Despite these improved anatomical results the procedural success rates were similar (91.5% vs 84%). Major in hospital complications (death, acute occlusion, MI, emergency CABG, re-do) were higher in the DCA group than in the PTCA group (12% vs 6%). Clinical follow-up on 276 patients (150 DCA vs 126 PTCA) showed a 6 month clinical restenosis rate of 18% vs 28%, respectively. The incidence of re-do in 24 hours for acute occlusion was 6% for DCA and 1% for PTCA. In large-sized vessels DCA results in a lower restenosis rate. However, despite a lower incidence of residual stenosis, the complication rate tends to be higher with DCA (p < 0.05).

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**Key words:** Directional coronary atherectomy (DCA), Percutaneous transluminal coronary angioplasty (PTCA)

**DIRECTIONAL** coronary atherectomy (DCA) has become the second most commonly used nonsurgical coronary revascularization technique in the United States after balloon angioplasty, following its development by Simpson in 1984.1) It has been proposed and shown that the actual removal of atherosclerotic material debunks the artery which results in a larger and angiographically smoother residual luminal diameter with or without accompanying balloon angioplasty.2-6) This in turn has been suggested as translating into a reduction of the 6 month restenosis rate.7-14) However, the bulk of the accumulated data has shown that DCA has a higher immediate complication rate as compared to balloon angioplasty. It has been suggested that the immediate success rate of PTCA and DCA are comparable.1,13-23) In this retrospective study we tested the hypothesis that atherectomy leads to a higher success rate with a comparable complication rate and lower restenosis rate in vessels > 3 mm in diameter, as compared to balloon angioplasty.

**Materials and Methods**

**Study population:** 104 and 96 consecutive patients who had DCA and PTCA, respectively, from the periods immediately following and preceding the initiation of the DCA procedure at Millard Fillmore Hospital in 1992 were included in this study as it was felt that once DCA was used there was an interventionist bias towards performing DCA in larger vessels. DCA and PTCA patients were chosen from the interval January 1992 to May 1994 and January 1990 to January 1992, respectively. Forty-six DCA and 54 PTCA cases, which were performed between August 1995 (the date when we started DCA procedures at Dokuz Eylül University Medical Faculty Hospital) and August 1996 and January 1994 and August 1995 were also added to this population. Only CCS class 3 and 4 patients were included in the study. No emergency case was included in the study cohort.

The study cohort included proximal and mid LAD and RCA stenoses in vessels > 3 mm in diameter based on the most normal adjacent segment measurements proximal or distal to the target lesion. Each target lesion was entered as a separate case. Patients with more than 1 target lesion in the indicated segments of an artery were excluded. The ostial lesions, distal segment lesions, branch lesions and all circumflex lesions were excluded. Restenosis, bail out atherectomy, graft procedures, and lesions in which a < 7 Fr device was used were also excluded.

**Procedures:** All patients received aspirin and a calcium channel blocker (usually diltiazem 60 mg) before the procedures. The procedures were performed via
the usual femoral approach and all the patients were heparinized with a bolus of 10,000 units of heparin. The activated clotting time (ACT) was kept between 300–350 seconds throughout the procedure by giving additional boluses of heparin when needed. Aspirin was continued as the only antiaggregant therapy in all cases without any major complications requiring any kind of bail-out procedure. Cardiac enzymes were measured routinely for all patients during their hospital stay and before discharge.

**Definitions:** Initial success was defined as a greater than 20% gain in the luminal diameter or a reduction of the stenosis rate below 50% in the absence of major in-hospital complications defined as death, emergency coronary artery bypass grafting (ECABG) and Q-wave myocardial infarction (Q MI).

Major acute complications were defined as major in-hospital complications plus acute occlusion, re-do and cerebrovascular accident.

Re-do was defined as repeat PTCA or DCA of the target lesion within 24 hours after the procedure due to either acute occlusion or continuing ischemia secondary to suboptimal initial result.

Non-Q-wave myocardial infarction (non-Q MI) was defined as a greater than 4-fold increase of the level of cardiac creatinine phosphokinase (CPK-MB) above the upper limit of normal in the absence of newly developed pathologic Q waves.

**Angiography and angiographic analysis:** Quantitative measurements were performed with a caliper using at least two orthogonal views of the angiographic films obtained during DCA or PTCA. A sizeable segment of the guiding catheter full of dye was included to compare the measurements performed before and after the procedure.

**Clinical and procedural variables:** Clinical and procedural variables were collected by reviewing the patient hospital charts, cardiac cath lab files and coronary angioplasty report sheets of the New York State Department of Health State Cardiac Advisory Committee and the patient office charts which included the stress testing, nuclear testing, echocardiography, angiography and angioplasty reports. The data for the patients in Izmir were collected from their hospital charts and cath lab records in a similar fashion.

**Statistics:** All data are expressed as mean ± 1 standard deviation (SD). Chi square analyses were used to test differences in categorical variables and unpaired Student's t tests were used to assess differences in continuous variables. Differences were considered statistically significant at $p < 0.05$.

**Results**

Tables I and II show the study population and its distribution based on the
type of procedure and the artery involved, baseline demographic, clinical and angiographic characteristics of the DCA and PTCA groups. The groups were well matched for age, sex, risk factors, clinical findings and lesion morphology. LAD lesions constitute the majority of cases.

Before the interventional procedure the severity of the coronary stenosis was similar in each of the groups (Table II, Figure 1). Similarly, the vessel size, diameter stenosis (%), lesion morphology (American College of Cardiology/American Heart Association classification24), lesion length, left ventricular ejection fraction and CCS classification of both groups were well matched.

DCA resulted in significantly greater improvements in minimal luminal diameter as compared to PTCA (3.22 ± 0.7 mm vs 2.54 ± 0.64 mm, p < 0.05) (Table III, Figure 1). The post-atherectomy residual stenosis was reduced to 11 ± 17% while post-angioplasty residual stenosis was 33 ± 16% (p < 0.01) which represented a considerable residual stenosis. There were only 13 cases (7 major in-hospital complications and 6 significant residual stenosis) which failed to achieve a successful initial result in the atherectomy group while 24 angioplasty

Table I. Comparison of Demographic and Clinical Characteristics of the Groups.

<table>
<thead>
<tr>
<th>Variable</th>
<th>PTCA (n = 150)</th>
<th>DCA (n = 150)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>59 ± 11</td>
<td>57 ± 11</td>
<td>ns*</td>
</tr>
<tr>
<td>Male</td>
<td>110</td>
<td>115</td>
<td>ns</td>
</tr>
<tr>
<td>Female</td>
<td>40</td>
<td>35</td>
<td>ns</td>
</tr>
<tr>
<td>Hyperlipidemia</td>
<td>103</td>
<td>89</td>
<td>ns</td>
</tr>
<tr>
<td>Hypertension</td>
<td>51</td>
<td>63</td>
<td>ns</td>
</tr>
<tr>
<td>Diabetes mellitus</td>
<td>20</td>
<td>21</td>
<td>ns</td>
</tr>
<tr>
<td>Smoking</td>
<td>71</td>
<td>67</td>
<td>ns</td>
</tr>
<tr>
<td>+ FH/CAD</td>
<td>72</td>
<td>55</td>
<td>ns</td>
</tr>
<tr>
<td>History of MI</td>
<td>63</td>
<td>70</td>
<td>ns</td>
</tr>
<tr>
<td>BSA</td>
<td>1.95 ± 0.21</td>
<td>2.01 ± 0.2</td>
<td>ns</td>
</tr>
<tr>
<td>CCS classification¹</td>
<td>3.4 ± 0.4</td>
<td>3.6 ± 0.3</td>
<td>ns</td>
</tr>
</tbody>
</table>

¹Only Class 3 and 4;  ns* = non-significant.

Table II. Comparison of Pre-procedure Angiographic Findings

<table>
<thead>
<tr>
<th>Variable</th>
<th>PTCA (n = 150)</th>
<th>DCA (n = 150)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reference vessel diameter (mm)</td>
<td>3.83 ± 0.65</td>
<td>3.62 ± 0.65</td>
<td>ns*</td>
</tr>
<tr>
<td>Minimal luminal diameter (mm)</td>
<td>0.78 ± 0.55</td>
<td>0.86 ± 0.53</td>
<td>ns</td>
</tr>
<tr>
<td>Pre-procedure % stenosis</td>
<td>79 ± 15</td>
<td>76 ± 13</td>
<td>ns</td>
</tr>
<tr>
<td>Pre-procedure lesion length (mm)</td>
<td>13.2 ± 17</td>
<td>12.6 ± 8</td>
<td>ns</td>
</tr>
<tr>
<td>LVEF (%)</td>
<td>60 ± 13</td>
<td>57 ± 12</td>
<td>ns</td>
</tr>
<tr>
<td>Lesion type A</td>
<td>11</td>
<td>3</td>
<td>ns</td>
</tr>
<tr>
<td>Lesion type B</td>
<td>102</td>
<td>105</td>
<td>ns</td>
</tr>
<tr>
<td>Lesion type C</td>
<td>37</td>
<td>42</td>
<td>ns</td>
</tr>
</tbody>
</table>

ns* = non-significant.
cases (4 major in-hospital complications and 20 significant residual stenosis) failed to achieve initial success (defined as reduction of the percent diameter stenosis below 50% and/or net gain of at least 20% and absence of major in-hospital complications consisting of death, cerebrovascular accident, Q wave MI and ECABG). The initial success rates were similar in both groups (91% vs 84%).

There were 87 dissections in the DCA arm and 63 in the PTCA group (type A to F). Twenty seven DCA and 31 PTCA cases required perfusion balloon inflations due to C-F type dissections. However, post-DCA balloon dilatations were performed in 55 DCA cases either to further reduce the residual stenosis or further smooth the luminal borders while two simultaneous balloon inflations (4 mm + 2 mm) were performed in a PTCA case to match the 6 mm artery size.

The complications are listed in Table IV. Re-do cases were significantly higher in the DCA group (p<0.05). The difference between the DCA and PTCA groups in terms of major in-hospital complication rates were not statistically significant (2.7% vs 4.7%). However when we add acute occlusion and re-do as major acute complications the difference reaches statistical significance (12% vs 6%, p<0.05). Significant dissections requiring perfusion balloon occurred equally in both groups (18% vs 20.5%).

When we look closer at the distribution of the complications we see that 3 PTCA patients with acute occlusions received intracoronary urokinase treatment. One resolved with non-Q MI while another resolved in a Q-vave MI. The third was redone successfully by using various balloons, including a perfusion balloon.

Figure 1. Comparison of pre and post procedural minimal luminal diameter and net gain. DCA group was significantly better (p<0.05).

### Table III. Comparison of Procedural Results

<table>
<thead>
<tr>
<th>Variable</th>
<th>PTCA (n = 150)</th>
<th>DCA (n = 150)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Post-procedure MLD (mm)</td>
<td>2.54 ± 0.6</td>
<td>3.22 ± 0.7</td>
<td>&lt;0.05</td>
</tr>
<tr>
<td>% Residual stenosis</td>
<td>33 ± 16</td>
<td>11 ± 17</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Net gain (mm)</td>
<td>1.78 ± 0.7</td>
<td>2.36 ± 0.8</td>
<td>&lt;0.05</td>
</tr>
<tr>
<td>% Net gain</td>
<td>46 ± 18</td>
<td>66 ± 20</td>
<td>&lt;0.05</td>
</tr>
</tbody>
</table>
Three patients from Izmir received intracoronary streptokinase. Two patients resolved with non-Q MI and the third one was bailed out by successful stent implantation without any other complication. Three patients with severe dissections from Buffalo were sent for ECABG.

Six DCA patients from Buffalo developed acute occlusion. Five received intracoronary urokinase which resulted in 2 Q and 2 non-Q MI while two patients were redone developing a non-Q MI. Three patients were sent to ECABG and three patients in Buffalo were redone by combined repeat DCA and PTCA due to severe dissections and continuing chest pain. Two of these patients developed non-Q MI (one from each group).

Three DCA patients from Izmir developed acute occlusion. One of these patients received intracoronary streptokinase and resolved with a non-Q MI. Two were bailed out by stent implantation which resulted in one Q and one non-Q MI. One patient was sent to ECABG due to massive dissection of LAD involving all proximal and mid segments of the artery. The patient developed non-Q MI. There were two more patients with type D dissection and continuing chest pain who were successfully stented.

In addition, 3 PTCA and 3 DCA patients from Buffalo and 3 DCA and one PTCA patient from Izmir developed cardiac enzyme elevations which met the criteria for non-Q MI. There were two cases of pseudoaneurysm formation and one groin bleeding requiring blood transfusion following DCA in the Buffalo group.

In 49 (33%) of the patients in the DCA group zero or a negative residual stenosis rate was achieved while in only 8 (5%) of the angioplasty group zero
residual stenosis was achieved. The mean residual stenosis rate in the angioplasty group represents suboptimal results (more than 20% residual stenosis).

The minimal luminal diameter in the DCA group was increased by $2.36 \pm 0.77$ mm compared to $1.78 \pm 0.71$ mm in the PTCA group (Table IV). This net gain was considerably better in the DCA group ($p < 0.05$).

The mean procedure time was not different between the groups ($85 \pm 47$ minutes for the DCA vs $75 \pm 45$ minutes for the PTCA groups) while the average amount of dye consumed during the procedure tended to be higher with DCA, reaching statistical significance ($288 \pm 154$ ml vs. $214 \pm 109$ ml, $p < 0.05$).

Clinical follow-up data were available for 276 cases (150 DCA and 126 PTCA cases); (92% of all patients). Two hundred sixty five of these patients were initially successfully treated. Table V summarizes the clinical follow-up data which are similar for both groups. Patients were followed-up clinically. Reappearance of ischemic symptoms and/or positive stress testing and presence of lesions other than the target lesion were the indications for repeat coronary

<table>
<thead>
<tr>
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<th>PTCA 122(^1)</th>
<th>DCA 137(^1)</th>
<th>Total 259</th>
</tr>
</thead>
<tbody>
<tr>
<td>Coronary angiography(^2)</td>
<td>58% (70/122)</td>
<td>32% (44/137)</td>
<td>44% (114/259)</td>
</tr>
<tr>
<td>Stress test</td>
<td>91% (111/122)</td>
<td>85% (116/137)</td>
<td>88% (227/259)</td>
</tr>
<tr>
<td>+ Stress test</td>
<td>24% (27/111)</td>
<td>11% (13/116)</td>
<td>17% (40/227)</td>
</tr>
<tr>
<td>Repeat PTCA(^3)</td>
<td>24</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>Repeat DCA(^4)</td>
<td>54</td>
<td>13</td>
<td></td>
</tr>
<tr>
<td>CABG(^5)</td>
<td>8</td>
<td>10</td>
<td></td>
</tr>
<tr>
<td>Restenosis(^6)</td>
<td>28% (36/122)</td>
<td>18% (25/137)</td>
<td></td>
</tr>
</tbody>
</table>

\(^1\)Initially successful cases with the exception of 4 PTCA cases for whom no follow-up data was available;
\(^2\)For all patients with restenosis and with lesions other than the target lesion;
\(^3\)One patient had DCA + STENT;
\(^4\)The reason for the repeat procedure was not the restenotic lesions in all cases;
\(^5\)The reason for CABG was not restenosis for one case in PTCA and for two; cases in DCA groups;
\(^6\)Angiographically proven clinical restenosis rate.

Figure 2. Clinical restenosis rate was lower in DCA group within 6 months after the procedure ($p < 0.05$).
angiography and repeat procedures. The cause of symptoms and/or positive stress test were lesions other than the target lesion for which the patients were included in the study cohort in a fairly large number of patients. We only considered those patients with angiographically proven restenosis of the index lesion as true restenotic cases. The angiographically proven restenosis rate within 6 months after the procedure was 18% for the DCA group and 28% for the PTCA group (Figure 2). However, the difference again failed to reach statistical significance.

**DISCUSSION**

The principle finding of this study was that DCA achieved a greater reduction in the severity of stenosis than was achieved in a similar population using conventional balloon angioplasty in vessels larger than 3 mm in diameter. This is consistent with the findings in CAVEAT and CCAT studies and the data reported by Kimball B.P. et al.\(^1,14,17\) This increased success in initial gain was obtained by paying the price of a tendency toward a higher major in-hospital complication and major acute complication rate. When we examine Table IV we see that re-dos are higher in the DCA group (1.3% vs 6%; \(p < 0.05\)) with acute occlusion and non-Q and Q MIs being higher in the DCA group without reaching statistical significance (4% vs 6%, 4.3% vs 10.6% and 0.7% vs 2%, respectively). We believe that this difference was principally due to a higher rate of distal embolization and nose-cone traumatization of healthy vessel segments, which are inherent complications of DCA. We believe that unlike the CCAT and CAVEAT study groups the operator experience was not a factor in creating these higher rates of complications in our study. Higher groin and bleeding complications are most likely due to the usage of large bore sheaths (larger than 9.5 F). This is also consistent with the findings of previous studies including the CAVEAT study.\(^1,15-23,26-27\) Our data showed equal significant dissection rates while Rowe et al. reported almost three times as many dissections in their PTCA group as compared to the DCA group which included a wide range of arteries and segments.\(^23\) This study showed a lower 6-month restenosis rate which was thought to be a translation of better initial results in contradiction to the findings of some previous major studies.\(^1,15,21-23\) In fact, the rate of clinical restenosis was estimated to be approximately 35% for both the DCA and PTCA groups in the CAVEAT study which is consistent with 28% clinical restenosis rate in the PTCA group in this study, while the DCA group had an 18% restenosis rate. Considering the fact that the interventionists in the CAVEAT study were not aggressive enough to achieve a better initial result (their residual stenosis rate was 29% as compared to our residual stenosis rate of 11%) and based on the fact that
a bigger residual diameter translates into less restenosis we can conclude that DCA can be an effective tool for reducing the restenosis rate provided the interventionists are as aggressive as they need to be.

We can speculate that the fact that only vessels larger than 3 mm in diameter were included in our study seemed to have very little impact if any on the restenosis rate, since the restenosis rate for the PTCA group was comparable to the CAVEAT group which included a considerable number of smaller vessels as well.

Despite the more aggressive approach to our patient groups, the major in-hospital complication rates were almost identical with those of the CAVEAT groups. This suggests that further reduction in complication rates might be possible with adherence to careful and meticulous procedure techniques and increasing experience.

There are two multicenter studies (BOAT and OARS) which are still unpublished to test this hypothesis.28,29) The preliminary results are confirmatory (unpublished data).

**Study limitations:** This is a retrospective case control study which carries the inherent limitations of selection bias both before the procedure at the stage of decision making and at the inclusion of the cases to this cohort.

The patients recruited in the United States were chosen mostly from the era before the introduction of elective stents while DCA procedures were virtually unknown in the Turkish hospital before June 1995. The stents were available since 1994 in the Turkish hospital which might have caused serious selection bias for the large sized vessels which were also suitable for stenting.

However, both centers perform large numbers of DCA procedures and have become highly experienced in this technique. This might have resulted in better atherectomy results as compared to the combined results of the numerous centers with small DCA volumes who participated in the CCAT and CAVEAT studies.

The angiographic variables were basically measured by hand calipers as it was felt that the routine QCA measurements were not performed in a standardized fashion although QCA data were available.

**Clinical significance:** Rational and appropriate case selection involves operator judgement regarding the segments involved, lesion type, selection of proper device size and performance in regard to individualized, case specific anatomic features. We think that at least in large sized proximal and mid coronary artery segments DCA with 7Fr or larger devices is a safe, reliable alternative to PTCA and results in better initial results along with lower clinical restenosis rates.
REFERENCES


