

# Percutaneous intervention in unprotected left main coronary disease

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## Abstract

**A** significant left main coronary artery (LMCA) stenosis is an important predictor of survival in patients with coronary artery disease. In the past, percutaneous coronary intervention (PCI) was generally restricted to patients with protected left main disease; and >50% stenosis of the LMCA was a contraindication to balloon angioplasty.

In the pre-stent era, results of left main balloon angioplasty were poor. For example, in one series, in-hospital mortality was 9.1% in the elective group and 50% in the acute group.

The development of coronary stenting and effective antiplatelet therapy in the 1990s stimulated renewed interest in PCI for LMCA disease. A number of studies reported good outcomes for protected LMCA lesions, though results in haemodynamically unstable patients remained poor.

The figures for a number of studies of elective PCI for unprotected left main stenosis are also described. The best documented outcomes so far are one-year actuarial survival of 89% in high-risk patients and 98% in low-risk patients.

If severe calcification is obvious on angiography or ultrasound then debulking seems sensible. The data suggest that directional coronary atherectomy alone or with stenting may be associated with reduced restenosis rates.

The use of glycoprotein IIb/IIIa inhibitors and drug-eluting stents may further improve the outlook for patients with LMCA stenosis.

**Key words:** left main coronary artery (LMCA) stenosis; percutaneous coronary intervention; angioplasty; coronary stenting.

*Br J Cardiol (Acute Interv Cardiol)* 2003;**10**(1):AIC 22–AIC 27

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## Introduction

The presence of a significant left main coronary artery (LMCA) stenosis (>50% by diameter angiographically) is one of the important predictors of long-term survival in patients with coronary artery disease. This is true irrespective of left ventricular function, associated co-morbid factors and the presence or absence of symptoms. Studies have demonstrated three-year mortality in excess of 50% in this group of patients when treated medically.<sup>1</sup> The important and influential multicentre, randomised trials in chronic stable angina have demonstrated the benefit of coronary artery bypass surgery (CABG) over medical therapy in this group of patients.<sup>2–4</sup> The ACC/AHA/ACP-ASIM guidelines place CABG as a Class 1 recommendation for patients with significant LMCA disease and chronic stable angina.<sup>5</sup> There is no reason to believe that CABG is not also the treatment of choice in unstable coronary syndromes, despite the paucity of randomised trials in this setting. The Veterans Administration Cooperative Study of Unstable Angina demonstrated that benefit from surgical revascularisation was greatest in patients with advanced coronary disease (including LMCA stenosis) and left ventricular dysfunction.<sup>6</sup>

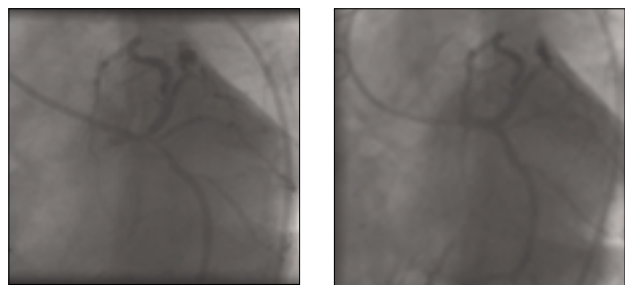
The role of percutaneous coronary intervention (PCI) has in the past been limited and was generally restricted to patients with one or more patent grafts to the left coronary artery (usually referred to as protected left main disease). The presence of a >50% narrowing of the LMCA was considered to be a contraindication to balloon angioplasty due to technical difficulties and increased mortality. Stents and glycoprotein IIb/IIIa receptor blockers have improved the immediate, short- and medium-term outcomes of PCI but there are no randomised trials comparing CABG and PCI in LMCA disease. However, the various studies that have compared CABG and PCI in multivessel disease may be a pointer to their potential advantages and disadvantages.<sup>7–9</sup>

## Studies performed prior to coronary stenting

In the late 1970s Gruntzig himself performed balloon angioplasty in a few patients with unprotected left main stenosis but this strategy was promptly abandoned due to the poor results and the publication of several papers describing survival benefit with surgical treatment over conservative medical therapy.

In 1989 O'Keefe *et al.* reported the results of 127 left main balloon angioplasties.<sup>10</sup> Despite successful dilatation in 94% of elective and 90% of emergency cases, the in-hospital mortality was 9.1% in the elective group and 50% in the acute group. Long-term follow-up in the elective group revealed actuarial

**Figure 1.** T stenting of a distal left main stem bifurcation stenosis



three-year survival of 36% in the unprotected subgroup compared to 90% in the protected subgroup. Only three of the 10 emergency patients were alive on follow-up and all had undergone bypass surgery. Smaller observational studies by Stertzer *et al.* in patients with stable angina<sup>11</sup> and Crowley *et al.* in patients with unstable angina<sup>12</sup> reported better in-hospital outcomes but reintervention rates remained unacceptably high; 40% in Stertzer's group required CABG and 30% of Crowley's group required repeat left main angioplasty. Interestingly, none of the patients in Crowley's series had required CABG at one-year follow-up despite their unstable presentation.

The poor outcomes were probably due to inadequate balloon dilatation and elastic recoil coupled with what was, in retrospect, clearly suboptimal antithrombotic and antiplatelet therapy. In addition, abrupt vessel closure and/or late restenosis in the LMCA are associated with a high risk of serious morbidity and mortality. Overall, these early studies confirmed CABG as the gold standard treatment.

### PCI for (protected) left main stenosis

In the 1990s the introduction and rapid development of coronary stenting with effective antiplatelet therapy provided dramatic reductions in thrombotic complications<sup>13-16</sup> and reduced rates of restenosis.<sup>17,18</sup> This stimulated renewed interest in PCI for LMCA disease. An example of stent placement in LMCA disease is shown in figure 1.

From Vancouver, Canada, Chauhan *et al.* reported outcomes in 28 unselected, consecutive patients considered unsuitable for (re-)CABG (14 unprotected) in 1997.<sup>19</sup> Stents were implanted in 61% of these patients. There were nine deaths (five in-hospital and four during follow-up). All of the in-hospital deaths occurred in the acute patients who presented either with myocardial infarction or cardiogenic shock. This series demonstrated that prohibitive surgical risk does not preclude PCI but the results in haemodynamically unstable patients were still poor.

In the same year Lopez *et al.* from Boston, US, reported a 100% procedural success rate, 78% six-month event-free rate and 98% nine-month survival rate in 46 patients with LMCA disease, of whom 42 were protected by one or more patent grafts.<sup>20</sup>

In 1998 Yasuda *et al.* from Osaka, Japan, reported higher angiographic success rates (100% vs. 81%) and lower rates of restenosis (18% vs. 56%,  $p < 0.05$ ) in patients undergoing directional atherectomy compared to conventional angioplasty in protected LMCA lesions.<sup>21</sup> This was a non-randomised comparison but nevertheless it suggested that debulking might be of particular benefit in LMCA disease.

The same year Kornowski *et al.* from Washington DC, US, reported a similar non-randomised comparison of stenting with non-stent procedures (balloon angioplasty and/or atherectomy) in patients with previous CABG. Stenting was not associated with a reduction in major cardiac events at one year despite better in-hospital outcomes.<sup>22</sup>

One of the largest series was reported by Keeley *et al.* from Royal Oak, Michigan, US, who carried out 273 LMCA interventions between 1990 and 1997. Of these, 219 procedures were to a protected left main and 183 were elective. Balloon angioplasty alone was performed in 42% and stents were used in only 12%. A significant number underwent some form of atherectomy or excimer laser angioplasty. The in-hospital mortality was 5% and the overall in-hospital event rate (recurrent ischaemia, myocardial infarction [MI], CABG and death) was 24%. The outcomes on follow-up (24 $\pm$ 10 months) were poor, with 29 patients (52%) in the unprotected group suffering major events (17 deaths, five repeat PCI, five MI and three CABG). However, nearly 60% of these were emergency cases performed in the context of acute MI or cardiogenic shock.<sup>23</sup>

In a much lower risk group of elective patients with protected LMCA disease considered unsuitable for re-CABG, Ghavami *et al.* from Liege, Belgium, reported high procedural success rates, low in-hospital mortality and good medium-term outcomes with elective stent implantation.<sup>24</sup>

These studies confirmed that PCI of protected LMCA lesions could be carried out electively, with good outcomes in patients considered to be at acceptable or high surgical risk. The results following acute interventions in haemodynamically unstable patients remained unsatisfactory despite the use of newer devices. The success seen with protected left main intervention encouraged several centres to offer this option to patients with unprotected left main disease.

### Elective PCI for unprotected left main stenosis

The US Cleveland Clinic Multicentre Registry was the first study to report outcomes in a substantial number of patients from multiple centres.<sup>25</sup> The study reported 107 consecutive patients, of whom 91 were treated electively. Of these 52% were considered to be inoperable or at high surgical risk. Stents were used in 50% and directional atherectomy in 24%. Procedural success was high (99%), and a good clinical outcome was positively correlated with ejection fraction ( $p < 0.001$ ) and inversely related to presentation with rest or progressive angina ( $p < 0.001$ ). Good surgical candidates with an ejection fraction of  $>40\%$  had an in-hospital mortality of 2% and an event-free survival at nine months of 86%. This contrasted with 33% in-hospital mortality and 22% nine-month event-free survival in patients with a baseline

ejection fraction of <40%. There was a trend towards better outcomes in patients following stenting and directional atherectomy as opposed to balloon angioplasty. Disconcertingly, however, nine patients experienced sudden cardiac death within six months of discharge. The authors concluded that although results appeared promising in selected patients, PCI of unprotected LMCA lesions could not be considered to be an alternative to CABG until the problem of early cardiac death had been resolved.

In the series from the Asan Medical Center, South Korea, Park *et al.* reported outcomes in 42 good surgical candidates with normal left ventricular function and LMCA stenosis who underwent elective stenting.<sup>26</sup> Aspirin and ticlopidine were used in all patients and 14 patients received warfarin. The procedural success rate was 100%, with no episodes of subacute stent thrombosis. Angiographic restenosis occurred in seven patients (22%, 95% CI 7–37%), of whom five underwent CABG and two were retreated percutaneously with rotational atherectomy plus adjunct balloon angioplasty. The only death occurred two days following elective CABG for in-stent restenosis.

Excellent results from the Adventist Hospital, Hong Kong, were reported by Wong *et al.* in 55 patients undergoing elective stenting.<sup>27</sup> Once again the patients were considered to be of low risk for surgery and had normal or mild left ventricular dysfunction (LVEF 55±11%). Procedural success was 100%, with no in-hospital events. Symptomatic recurrence occurred in 11 patients (20%) during a mean follow-up period of 16±9.6 months. Seven patients underwent elective CABG, two had repeat intervention, one continued with medical therapy and one died before planned angiography.

From the Shiga Medical Center, Japan, Kosuga *et al.* reported outcomes in 107 patients, of whom 83 had the procedure performed electively.<sup>28</sup> In-hospital mortality and estimated five-year survival rates in this group were much better than in patients undergoing emergency procedures.

Plokker's group from St. Antonius, the Netherlands, reported 10 patients who underwent elective stenting for stable angina and were all discharged alive.<sup>29</sup> There was one (non-cardiac) death after an average of 10 months follow-up.

Hofmann *et al.* from Linz, Austria, reported 13 patients without contraindications to CABG in whom stents were deployed.<sup>30</sup> One patient required emergency CABG following LMS dissection. All patients were discharged alive. Six patients had repeat angiography due to suspicion of recurrent ischaemia: two of these had restenosis and both were redilated (17%).

The group of Marco and Fajadet in Toulouse, France, have reported outcomes in 39 patients.<sup>31</sup> Elective stenting was performed in 36 patients for a prohibitive surgical risk, defined as a Parsonnet score of >15 and unfavourable anatomy for CABG. The three other patients underwent emergency stenting for an acute myocardial infarction. Procedural success was 100%, with in-hospital mortality of 8% (three deaths). There were six additional deaths on follow-up (five cardiac and one non-cardiac). Of the 30 surviving patients, 23 (76%) remained asymptomatic. Two patients had symptomatic restenosis at three and six months: one was treated by balloon angioplasty and the other by CABG.

**Table 1.** Summary of outcomes following elective PCI to left main stenosis in five contemporary studies with significant stent use

| Study                                 | Year | N   | Stent % | Risk              | LV function  | In-hospital mortality | 1-year survival |
|---------------------------------------|------|-----|---------|-------------------|--------------|-----------------------|-----------------|
| Ellis <i>et al.</i> <sup>25</sup>     | 1997 | 91  | 50      | 47 high<br>44 low | <40%<br>>40% | 38%<br>2%             | 27%<br>87%      |
| Karam <i>et al.</i> <sup>31</sup>     | 1998 | 39* | 100     | High              | Not defined  | 8%                    | 77%             |
| Wong <i>et al.</i> <sup>27</sup>      | 1999 | 55  | 100     | Low               | >45%         | 0%                    | 98%             |
| Silvestri <i>et al.</i> <sup>32</sup> | 2000 | 140 | 100     | 47 high<br>93 low | <35%<br>>35% | 9%<br>0%              | 89%<br>97%      |
| Park <i>et al.</i> <sup>37</sup>      | 2001 | 127 | 100     | Low               | Normal       | 0%                    | 98%             |

\*Three patients underwent emergency PCI

In the Marseilles, France, series of Silvestri *et al.*, 140 consecutive elective patients were treated by stent implantation. Forty-seven were considered to be at high risk for surgery because they had one (or more) of the following: age >75 years, previous heart surgery, left ventricular ejection fraction <35%, renal failure, inadequate distal coronary runoff or severe respiratory failure. An unusual anticoagulant protocol was used, with ticlopidine alone being commenced three days before the procedure and continued for one month. This was followed by aspirin at a dose of 250 mg/day indefinitely.

The results were encouraging, with 100% procedural success.<sup>32</sup> The incidence of major adverse events (death, non-fatal MI and CABG) at one month was 0% in the low-risk group and 13% in the high-risk group (four deaths, including two due to stent thrombosis and two non-fatal MI). Six-month angiographic follow-up was performed in 94 of the 115 eligible patients and revealed a 23% restenosis rate. During this period there were five further events (13%) in the high-risk group (one cardiac death, three repeat PCI and one CABG) and 19 further events (25%) in the low-risk group (two non-cardiac deaths, one non-fatal MI, five repeat PCI and 11 CABG). The overall target lesion revascularisation rate was 17%. No identifiable factor, including the site of the LMCA lesion, was predictive of restenosis. One-year actuarial survival was 89% in the high-risk patients and 98% in the low-risk patients. These outcomes are the best documented so far for high-risk patients. Table 1 summarises the outcomes of elective PCI to left main stenosis in five contemporary studies.

### Emergency PCI for unprotected left main stenosis

Patients presenting as an emergency due to unstable coronary syndromes and found to have a significant LMCA stenosis at angiography have a poor prognosis. These patients are haemodynamically unstable, if not in overt cardiogenic shock. Medical management is associated with very poor outcomes and often

**Table 2.** In-hospital outcomes following emergency PCI to left main stenosis in five contemporary studies

| Study                                | Year | Number | Indication               | In-hospital mortality |
|--------------------------------------|------|--------|--------------------------|-----------------------|
| Chauhan <i>et al.</i> <sup>19</sup>  | 1997 | 6      | Acute MI +/- shock       | 80%                   |
| Ellis <i>et al.</i> <sup>25</sup>    | 1997 | 16     | Acute MI                 | 69%                   |
| Laruelle <i>et al.</i> <sup>29</sup> | 1998 | 8      | Acute MI/unstable angina | 25%                   |
| Kosuga <i>et al.</i> <sup>28</sup>   | 1999 | 14     | Acute MI                 | 36%                   |
|                                      |      | 10     | Cardiogenic shock        | 40%                   |
| Marso <i>et al.</i> <sup>33</sup>    | 1999 | 40     | Acute MI                 | 55%                   |

PCI is the only option for revascularisation. Many of the studies referred to above included patients with acute myocardial infarction and/or cardiogenic shock, with in-hospital mortalities ranging from 40% to 83%.

The original Cleveland Clinic Multicentre Registry has been expanded and renamed the ULTIMA Registry (Unprotected Left Main Trunk Intervention Multi-center Assessment).<sup>33</sup> In the original series procedural success was 75% in the emergency group but overall results were poor, with 69% in-hospital mortality. In addition the rates of other major non-fatal complications (recurrent MI or reintervention) were high. The status of the left ventricle was critical in that patients presenting with acute coronary syndromes but with normal LV function had better outcomes.<sup>25</sup>

In the expanded ULTIMA registry 40 patients underwent emergency PCI to an unprotected left main following an acute myocardial infarction: 23 underwent primary angioplasty and 17 underwent primary stenting. The angiographic success was 88% in the whole cohort. The in-hospital mortality was 53% for the whole cohort, 70% for the angioplasty group and 35% for the stent group ( $p=0.1$ ). The 12-month survival rates were 35% and 53% for the angioplasty and stent groups respectively ( $p=0.18$ ). When 12-month rates of mortality/CABG were combined there was a statistically significant difference between the two treatment strategies (83% and 58% for the angioplasty and stent groups,  $p=0.047$ ).

In a further publication from the Shiga Medical Center, Japan, Kosuga *et al.* looked at predictors of cardiac death following PCI to unprotected LMCA lesions in patients without acute myocardial infarction.<sup>34</sup> Univariate analysis identified the following predictors of death: emergency PCI, decreased left ventricular ejection fraction, multivessel disease, unstable angina and heart failure. In a regression model renal failure and multivessel disease were the only significant predictors of death. Table 2 shows in-hospital mortality following emergency PCI to left main stenosis in five contemporary studies.

### Impact of intracoronary ultrasound on outcomes of LMCA-PCI

The Washington Heart Center/Asan Medical Center collaborative

**Table 3.** Restenosis rates comparing directional atherectomy (DCA)+/-stenting versus stenting alone

| Study                             | Year | Stent alone | Restenosis | Stent +DCA | Restenosis | Significance |
|-----------------------------------|------|-------------|------------|------------|------------|--------------|
| Park <i>et al.</i> <sup>37</sup>  | 2001 | n=87        | 25%        | n=47       | 8%         | $p=0.03$     |
| Ellis <i>et al.</i> <sup>25</sup> | 1997 | n=51        | 14%        | n=25*      | 17%        | $p=ns$       |

\*Underwent DCA alone without stenting

group has shown that the use of intracoronary ultrasound (ICUS) during LMCA-PCI results in more frequent post-intervention dilatation with higher pressure and/or bigger balloons compared to non-left main intervention.<sup>35</sup> In a separate publication from the same group reporting 87 consecutive cases of LMCA-PCI, the only independent predictor of target vessel revascularisation (TVR) was the post-procedural minimum lumen area measured by ICUS: if this was  $< 7 \text{ mm}^2$  the TVR rate was 50%; if  $> 7 \text{ mm}^2$  the TVR rate was 7%.<sup>36</sup> However, data from the most recent series by Park *et al.* comparing restenosis rates between ICUS-guided and angiographic-guided stenting did not reveal any significant difference at six months (18.6% vs. 19.5%;  $p=0.5$ ) despite superior post-intervention minimal lumen diameter (MLD) in the ICUS-guided group ( $4.2 \pm 0.6$  vs.  $4.0 \pm 0.6$ ;  $p=0.003$ ).<sup>37</sup>

### Debulking strategies in LMCA-PCI

#### Rotational atherectomy

There have been isolated reports of rotational atherectomy +/-stenting in patients undergoing LMCA-PCI.<sup>38</sup> The procedure is clearly technically feasible but there are no data to indicate that clinical outcomes are improved. Nevertheless, if there is obvious severe calcification either on angiography or on ICUS it seems reasonable to debulk this first with the aim of allowing optimal stent expansion.

#### Directional coronary atherectomy (DCA)

DCA has been used in both protected and unprotected lesions, either on its own or followed by stenting. The data suggest that this strategy may be associated with reduced restenosis rates. The results from Osaka Medical Center, Japan, in protected lesions have been referred to above.<sup>21</sup> In the Cleveland Clinic Foundation series 24% of patients underwent DCA, and restenosis rates were lower in this group compared to conventional balloon angioplasty.

Park *et al.* have reported the outcomes following stenting in 127 consecutive patients and compared restenosis rates in the debulking/stenting group ( $n=40$ ) with those in the stenting group ( $n=87$ ). Aggressive debulking with adjunct balloon angioplasty was performed until the residual lumen diameter was  $< 10\%$  by visual assessment. The overall restenosis rate was 19% but this was influenced by reference diameter size and interven-





## Key messages

- Unprotected LMCA stenosis is no longer an absolute contraindication to PCI
- Although the results of emergency LMCA-PCI for cardiogenic shock are poor, this is usually the only option in these very high-risk patients
- Good outcomes are seen after elective PCI of protected LMCA lesions
- Patients with LVEF <40% have unsatisfactory medium-term outcomes with PCI

tional strategy. In vessels < 3.6 mm, binary restenosis was 13% in the debulking/stenting group versus 40% in the stent-only group ( $p=0.16$ ); in vessels > 3.6 mm the rate was 7% in the debulking group versus 18% in the stent-only group ( $p=0.19$ ). In this study the only significant predictor of restenosis was the reference vessel diameter. The same study indicated that routine ICUS was not associated with lower restenosis rates despite superior post-stenting minimal lumen diameter (MLD) in the ICUS group.<sup>37</sup> Table 3 shows the restenosis rates found in two studies that compared directional atherectomy +/-stenting against stenting alone.

## Conclusion

Unprotected LMCA stenosis is no longer an absolute contraindication to PCI. Stenting has made this procedure technically feasible and many of the problems associated with conventional balloon angioplasty are now of historical interest only. Calcified lesions can be debulked by rotational atherectomy prior to stent implantation. Directional atherectomy either alone or as an adjunct to stenting may have a role, particularly in left main bifurcation lesions.

Although the results of emergency LMCA-PCI for cardiogenic shock are poor this is usually the only option in these very high-risk patients, even if only as a bridge to more complete surgical revascularisation. In elective patients with prohibitive surgical risk PCI is again justifiable. In patients who are considered to be at low risk for surgery and who have normal LV function, elective PCI with routine stenting can be carried out with negligible in-hospital mortality and excellent medium-term outcomes. Indeed the one-year mortality in this subgroup is less than 5% and is comparable to the outcome of surgical revascularisation. However, despite high initial procedural success rates, patients with ejection fractions of less than 40% have unsatisfactory medium-term outcomes with PCI.

Most of the series described here predate the use of glycoprotein IIb/IIIa receptor blockers that may further improve outcomes. In addition drug-eluting stents may resolve the problem of restenosis, which is a particular concern in the LMCA where it may present as sudden death. A surgical conduit still has the

potential advantage over a stent of maintaining myocardial perfusion even if a new, not necessarily restenotic, lesion develops proximal to the graft insertion. Nevertheless some centres have begun to offer PCI as an alternative to CABG in patients with LMCA disease, clearly setting the stage for a randomised trial. In any such trial, as with previous comparisons of PCI and CABG, the goal should be to achieve equivalent revascularisation of all surgically significant disease in addition to the left main stenosis.

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