Early graft patency after off-pump and on-pump coronary bypass surgery: a prospective randomized study

Miguel Sousa Uva1*, Sara Cavaco2, António G. Oliveira3, Fernando Matias1, Catarina Silva4, Armindo Mesquita1, Pedro Aguiar4, José Bau1, Albino Pedro1, and Manuel Pedro Magalhães1

1Department of Cardiac Surgery, Hospital da Cruz Vermelha Portuguesa, Lisbon 1549-008, Portugal; 2Laboratory of Neurobiology of Human Behaviour, Centro Hospitalar do Porto, Porto, Portugal; 3Faculdade de Ciências Médicas, Department of Biostatistics, da Universidade Nova de Lisboa, Lisboa, Portugal; and 4Eurotrials Scientific Consultants, Lisbon, Portugal

Received 7 March 2010; revised 28 April 2010; accepted 25 May 2010; online publish-ahead-of-print 1 July 2010

See page 2441 for the editorial comment on this article (doi:10.1093/eurheartj/ehq257)

Aims

Uncertainty persists regarding the impact of the off-pump technique on coronary bypass graft patency. The primary objective of this study was to assess coronary artery bypass graft patency in patients randomized to off-pump and on-pump multivessel coronary artery bypass grafting (CABG). Secondary objectives were clinical outcomes and neuropsychological functioning.

Methods and results

One hundred and fifty patients were randomized to off-pump (n = 75) or on-pump CABG (n = 75). Graft patency was assessed by multidetector computed tomography 5 weeks after surgery. The two groups were similar regarding patients’ characteristics and logistic Euroscore (3.6 vs. 3.7%). Mean number of grafts performed was 3.5 ± 0.6 in off-pump and on-pump, respectively (P = 0.7). Raw graft patency rate was 89.9% in off-pump and 95.0% in on-pump (OR 2.2, 95% CI 1.07–4.44; P = 0.03). Nineteen (27%) off-pump and 9 (13%) on-pump patients had at least one occluded graft (P = 0.04) and the proportion of patent grafts per patient was 0.91 ± 0.2 in off-pump vs. 0.96 ± 0.1 in on-pump (P = 0.06). However, after adjusting by heparin dose, graft patency was not statistically different between groups (OR 0.87, 95% CI 0.25–2.98, P = 0.83). At 30 days, there was no statistically significant difference in major adverse events and neuropsychological functioning between off-pump and on-pump groups. One-year follow-up showed similar functional class and positive treadmill exercise tests.

Conclusions

Under the conditions this trial was conducted, CABG performed off-pump had lower overall graft patency rate than on-pump, which was not statistically different after controlling for total heparin dose. Thirty-day complications, neuropsychological functioning, and one-year clinical and functional outcomes were not statistically different between the two techniques.

Keywords

Myocardial revascularization • Coronary artery bypass grafting • Cardiopulmonary bypass • Off-pump

There is evidence that performing coronary artery bypass grafting without cardiopulmonary bypass (CPB) (off-pump CABG) decreases the incidence of post-operative adverse events.1 Large databases have reported that off-pump CABG reduces operative mortality in high-risk patients and provides similar long-term survival.2–4 Despite reassuring data showing no statistically significant difference in graft patency between the two techniques,5–9 three randomized studies10–12 and three meta-analyses13–15 have shown that graft patency in patients who underwent off-pump CABG was lower than in patients submitted to on-pump CABG. These conflicting results may be due to differences in patient selection, surgical expertise, operative technique, antithrombotic protocols, and timing of patency control. We hypothesized that with uniform standardized techniques and large experience in
off-pump CABG, there would be no difference in early graft patency in patients undergoing CABG with or without CPB. To test this hypothesis, we studied coronary artery bypass graft patency with multidetector computer tomography (MDCT) 4–6 weeks after surgery in patients operated with the two techniques.

Methods

The Prospective Randomized Comparison of Off-Pump and On-Pump Multi-vessel Coronary Artery Bypass Surgery (PROMISS) was a prospective, single-blinded, single surgeon study, comparing early graft patency assessed by MDCT in patients with multivessel disease randomized to off-pump or on-pump CABG.

PROMISS was registered in The International Society for Clinical Randomized Trials (ISRCTN58800729).

This study complies with the principles of The Declaration of Helsinki and was approved by the local ethics committee. All patients signed an informed consent form.

Inclusion criteria were age between 30 and 90 years, multivessel coronary artery disease with an indication for first-time CABG with at least three distal coronary artery anastomoses. Exclusion criteria were: patients requiring i.v. inotropes, intra-aortic balloon or ventilation prior to surgery, associated surgical procedure, serum creatinine >1.5 x the upper limit of normal, atrial fibrillation, allergy to contrast material, pre-menopausal women, and inability to give informed consent. No patient was excluded because of recent myocardial infarction, ventricular dysfunction, or poor-quality target vessels. No patient was excluded due to associated morbid conditions with the exception of renal insufficiency or atrial fibrillation.

A computer-generated randomization list was drawn using random permuted blocks and a sealed envelope containing the patient’s number was opened in the operating room before the beginning of the operation. Cross-over from one group to another was authorized in case patient safety was deemed at risk. Protocol adherence, reliability of data collection, and double data entry into a dedicated database were performed and monitored by an independent Contract Research Organisation. Event adjudication during hospital stay and follow-up was made by an internal medicine specialist and a cardiologist who were blinded to group assignment.

Pre-medication, anaesthetic protocol, patient opening and closing, graft harvesting and anastomotic techniques were identical in both groups. Heparin dose was 300 and 200 IU/Kg to achieve a target ACT >400 s and >250 s in the on-pump and off-pump groups, respectively. Heparin was reversed with the same protamine dose of 1.3 mg/100 IU of heparin in both groups.

Surgical technique

On-pump CABG used a conventional roller pump CPB machine (Jostra HL 2000) and myocardial protection was provided by 34°C antegrade blood-potassium cardioplegia. In off-pump CABG, cardiac enucleation was obtained with a deep pericardial stitch and apex vacuum suction (Medtronic-STARfish™), stabilization was achieved with vacuum stabilizers (Medtronic-Octopus 3™ or Guidant-Expose™), and intra-coronary shunts were systematically used (Medtronic, Clearview™) together with a CO2 blower. Autologous blood was re-injected at the end of CPB in on-pump group and after filtration (Medtronic Autotransfusion Collection Reservoir EL2™) in off-pump group. A cell saver device (Dideco Autotransfusion System™) was used in patients who had abnormal bleeding mainly due to unstopped double antiplatelet therapy. Target coronary artery vessels were classified in a 4-degree scale (good, fair, poor, bad) according to diameter, atherosclerotic wall infiltration, and distal vascular bed. All the operations were performed by an experienced senior cardiac surgeon (M.S.U.) who had performed 212 off-pump CABG procedures in the year prior to study initiation.

Outcome measures

The primary endpoint was patency per graft at 4–6 weeks, assessed with 16 slice MDCT angiography (GE Lightspeed Pro™) using a standard protocol previously described. A cardiologist and a radiologist, blinded to group assignment, assessed the grafts using multiplane reformatted images, maximal intensity projection images, and three-dimensional reconstructions. Graft occlusion was defined as absence of contrast material along the course of the graft, through the graft anastomosis to the native coronary artery or to the following graft segment and native vessel. In sequential bypass grafts, each anastomosis of one graft was counted as a separate graft.

Secondary endpoints were:

1. Completeness of revascularization
2. Number of patients with ≥1 occluded graft and the proportion of patent grafts per patient
3. Incidence of combined major events at 30 days: myocardial infarction, stroke/TIA, dialysis, and reoperation for ischaemia
4. Neuropsychological functioning. A battery of eight tests was composed by the auditory verbal learning test (AVLT, immediate and 30’ recall and recognition), the Trail Making Test A and B, the Grooved Pegboard Test, the Digit-Symbol Coding Test and the Digit Span Test, and the Rey Complex Figure and the Letter Word Fluency test. Mood state was also assessed through the Hospital Anxiety and Depression State (HADS) and the Beck Depression Inventory (BDI). The tests were performed on the day before surgery and 5 weeks after the operation. Thirty-two healthy subjects with similar age and education to the patient population, without neurological or psychiatric disease, underwent the same battery of tests at the same interval. Based on these healthy subjects performances, the patient’s raw scores on each neuropsychological test at each time points were transformed into a Z-score where Z = (X−M)/SD, where X is the patient result, M the mean of healthy subjects, and SD the standard deviation of healthy subjects. Z-scores were then transformed into T-scores where T = 10Z + 50. This transformation was used to control for possible practice effects.

Patients were followed up for 1 year and assessed for major cardiovascular, functional status, exercise treadmill test (Bruce protocol), and quality of life by the Euro Quality of Life (EQ 5D). Statistical methods

In order to detect a difference of 5 per cent points in patency rates between off-pump and on-pump CABG, with a power of 80% and a two-tailed 5% significance level, and assuming patency rates of 94 and 99%, a total of 426 distal graft anastomoses (213 grafts per group) were required. Since each patient had, by inclusion criteria, at least three grafts, a total of 142 patients would be necessary (71 patients in each arm.) To compensate for eventual dropouts, we planned to enrol 150 patients. Analysis was by intention to treat, including all randomized patients who provided patency data by MDCTA scan. Patients were analysed according to the group to which they were originally randomized. Graft patency rates between groups were compared using the Fisher’s exact test. In order to account for the fact that each patient contributed with more than one graft, a sensitivity analysis was performed with logistic regression with robust standard errors. Robust logistic regression was also used.
for a confirmatory analysis adjusting for total dose of heparin administered and for utilization of a cell saver. Graft patency was further analysed as the number of patients with one or more occluded grafts and the proportion of patent grafts per patient, using the Fisher’s exact test and the Student’s t-test, respectively. For subgroup analyses, robust logistic regression was used to test the interaction between treatment groups and vessel quality, coronary territory, and graft material.

For the neuropsychological measures and mood questionnaires, Student’s t-test for independent samples and for paired samples and repeated measures ANOVA were used for within and between groups analyses.

All statistical tests were two-tailed and P-values, 0.05 were considered statistically significant. Analysis was made using SPSS v16.0.

**Results**

Patient enrolment ran from April 2005 to July 2007. Figure 1 shows the study flow chart. During the study period, the primary investigator performed a total of 251 isolated CABG. One patient crossed over from off-pump to on-pump group (conversion rate 1.3%) and two
patients with porcelain aorta crossed from on-pump to off-pump group. Outcome of these three patients was uneventful.

Patient’s characteristics were well matched between the two groups (Table 1). Antithrombotic therapy and blood conservation data are summarized in Table 2. All patients received 150 mg of aspirin the next morning following the operation and 40 mg/day of subcutaneous enoxaparin.

All patients received a left internal mammary artery. A double mammary artery was used in 27 (37%) and 30 (40.5%) patients. Two hundred and fifty-eight grafts were performed in the off-pump group and 260 in the on-pump group (total = 518). Target vessel quality, as assessed intra-operatively, was classified as poor or bad in 96/258 (37.2%) in the off-pump group and 106/260 (40.8%) in the on-pump group ($P = 0.4$). An intracoronary shunt was used in 249/258 (96.5%) of anastomoses in the off-pump group and its mean diameter was 1.49 ± 0.23 (1.00–2.50 mm).

### Primary endpoint: patency per graft
Seventy-one patients in the off-pump group (97.3%) and 70 patients in the on-pump (94.6%) group had a MDCTA scan performed at a median of 34 days (27–59 days) after surgery. Six patients did not undergo MDCTA scan due to refusal ($n = 2$), atrial fibrillation ($n = 2$), and technical issues ($n = 2$). Among the 518 grafts performed, 501 grafts were assessed by MDCTA and 487 (97%) were considered evaluable (245 grafts in the off-pump group and 242 grafts in the on-pump group). Distribution of graft material and grafted coronary artery territories assessed by MDCT were similar in the two groups (Table 3).

The percentage of grafts classified as occluded was higher in the off-pump group (25/245, 10.2%) than the on-pump group (12/242, 5.0%) ($P = 0.03$). A sensitivity analysis with logistic regression, which accounts for non-independence of graft occlusion within each patient, gave results that were consistent with the above (OR 2.2, 95% CI 0.96–4.95, $P = 0.06$). This result was unchanged when adjusting for the utilization of a cell saver. However, when the total administered dose of heparin was accounted for, there was no statistical difference between treatment groups (OR 0.87, 95% CI 0.25–2.98, $P = 0.83$).

### Secondary endpoints

#### Completeness of revascularization
The ratio of the number of planned to the number of performed distal anastomoses was 1.0 in both groups. A mean number of 3.5 ± 0.6 grafts was performed in both groups with a mean number of 1.7 ± 0.7 internal mammary artery grafts in both groups.

#### Graft patency
The number of patients with at least one occluded graft was higher in the off-pump group than in the on-pump group (19/71, 26.7% vs. 9/70, 12.9%, $P = 0.04$) and the mean proportion of patent grafts

### Table 3  Graft material and grafted territories assessed by multidetector computer tomography

<table>
<thead>
<tr>
<th>Graft material</th>
<th>Off-pump</th>
<th>On-pump</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>$n$</td>
<td>%</td>
<td>$n$</td>
</tr>
<tr>
<td>LIMA</td>
<td>91</td>
<td>37.1</td>
<td>88</td>
</tr>
<tr>
<td>RIMA</td>
<td>28</td>
<td>11.4</td>
<td>31</td>
</tr>
<tr>
<td>Radial artery</td>
<td>35</td>
<td>14.3</td>
<td>33</td>
</tr>
<tr>
<td>Saphenous vein</td>
<td>91</td>
<td>37.1</td>
<td>90</td>
</tr>
<tr>
<td>Total</td>
<td>245</td>
<td>242</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Target coronary artery</th>
<th>Off-pump</th>
<th>On-pump</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Left anterior descending</td>
<td>72</td>
<td>29.4</td>
<td>69</td>
</tr>
<tr>
<td>Diagonal</td>
<td>28</td>
<td>11.4</td>
<td>34</td>
</tr>
<tr>
<td>Circunflex</td>
<td>78</td>
<td>31.8</td>
<td>73</td>
</tr>
<tr>
<td>Right coronary artery</td>
<td>67</td>
<td>27.3</td>
<td>66</td>
</tr>
<tr>
<td>Total</td>
<td>245</td>
<td>242</td>
<td></td>
</tr>
</tbody>
</table>

$n$, number of distal anastomoses; LIMA, left internal mammary artery; RIMA, right internal mammary artery.

### Figure 2  Patency according to graft material. *$P = 0.03$.}
per patient was 0.91 ± 0.17 in the off-pump group vs. 0.96 ± 0.12 in the on-pump group (P = 0.06). However, when these analyses were adjusted by total administered dose of heparin, the differences were no longer statistically significant (P = 0.85 and P = 0.88, respectively).

Coronary territory, graft material (Figure 2), and target vessel quality all correlated with graft patency (Table 4), but the analysis of their interaction with treatment group did not show a statistically significant influence on effect size.

Adverse events at 30 days
There was no in-hospital or 30-day mortality in this study. There was no statistically significant difference in any adverse event at 30 days between the off-pump and the on-pump groups (Table 5).

Neuropsychological functioning and mood assessment
There was no significant difference in T-score at baseline evaluation between groups. Both groups showed significant decline in T-scores for the AVLT, Grooved Pegboard Test, Digit-Symbol Coding Test, Digit-Span test, and Rey Complex Figure 30' recall. Repeated measures ANOVA showed a significant interaction between evaluations and groups for the Digit Symbol Coding Test (P = 0.01) with a greater decline for patients in the on-pump group. However, the on-pump group tended to have better performance at baseline. There were no other significant interactions between groups and evaluations for the remaining tests and mood measures.

Follow-up
Mean duration of follow-up was 498 days (242–1164) and there were no drop-outs. There were four late deaths, one in the off-pump group (from colonic cancer), and three in the on-pump group (two cardiac related and one traumatic). Three patients in each group underwent PCI. Readmission for cardiovascular causes was required in eight and seven patients in the off-pump and on-pump groups, respectively. The percentage of patients with no angina at last follow-up was 89 and 93% in the off-pump and on-pump groups, respectively (P = 0.4). An exercise treadmill test (Bruce protocol) was performed in 101 patients between 6 and 12 months after surgery. A positive exercise treadmill test by electrocardiographic and/or clinical criteria was observed in 15/51 (29%) and 8/50 (16%) in the off-pump and on-pump groups, respectively (P = 0.10). Quality of life as assessed by the visual scale EQ-VAS at 6 months was 75.6 and 76.4, respectively, in the off-pump and on-pump groups (P = 0.40).

Discussion
The question addressed by this study was whether early coronary bypass graft patency, assessed by MDCT, was lower in patients randomized to off-pump vs. on-pump CABG. Raw graft patency 5 weeks after surgery was lower in the off-pump group (90%) compared with the on-pump group (95%) (OR 0.46, 95% CI 0.23–0.94; P = 0.03). After adjusting for non-independence of grafts within the same patient by logistic regression, the difference in overall graft patency between groups was borderline significant (P = 0.06), but the percentage of patients with ≥1 occluded grafts was higher in the off-pump group. Lower patency rates in the off-pump group in saphenous vein (86 vs. 93%) and radial artery grafts (86 vs. 94%) (Figure 2) might be responsible for most of these differences, although an interaction of graft material by treatment group was not demonstrated. There was no evidence that target vessel quality and coronary artery territory influenced the differences between the two techniques. On the other hand, lower anticoagulation levels might explain the difference in patency rates between off-pump and on-pump because the observed differences in patency per graft, number of patients with ≥1 occluded graft, and proportion of patent grafts per

---

**Table 4** Percentage of occluded grafts according to grafted territory, graft material, and target vessel quality

<table>
<thead>
<tr>
<th>Graft Territory</th>
<th>Off-pump</th>
<th>On-pump</th>
<th>P, for interaction</th>
</tr>
</thead>
<tbody>
<tr>
<td>RCA</td>
<td>11/67</td>
<td>2/66</td>
<td>0.31</td>
</tr>
<tr>
<td>LAD</td>
<td>3/72</td>
<td>1/69</td>
<td>1.4</td>
</tr>
<tr>
<td>Diag</td>
<td>2/28</td>
<td>3/34</td>
<td>8.8</td>
</tr>
<tr>
<td>Circumflex</td>
<td>9/78</td>
<td>6/73</td>
<td>8.2</td>
</tr>
</tbody>
</table>

**Table 5** Clinical outcomes at 30 days

<table>
<thead>
<tr>
<th>Clinical Outcome</th>
<th>Off-pump</th>
<th>On-pump</th>
</tr>
</thead>
<tbody>
<tr>
<td>Operative mortality</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Reoperation</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Stroke</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>TIA</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td>Non-STEMI</td>
<td>1</td>
<td>3</td>
</tr>
<tr>
<td>Ventilation &gt;24 h</td>
<td>2</td>
<td>0</td>
</tr>
<tr>
<td>New dialysis</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Sternal infection</td>
<td>1</td>
<td>3</td>
</tr>
<tr>
<td>Blood transfusion</td>
<td>22 (30%)</td>
<td>25 (34%)</td>
</tr>
<tr>
<td>Combined adverse</td>
<td>1.3%</td>
<td>5.4%</td>
</tr>
<tr>
<td>ICU stay (median, IQR)</td>
<td>22 h (6)</td>
<td>24 h (4)</td>
</tr>
<tr>
<td>Hospital stay (median, IQR)</td>
<td>6 days (2)</td>
<td>6 days (2)</td>
</tr>
</tbody>
</table>

IQR, interquartile range.
Early graft patency after off-pump and on-pump coronary bypass surgery

Patient were no longer statistically different when total heparin dose was accounted for in the analyses.

Eight randomized trials5–12 reported CAGB graft patency in patients operated on with the off-pump and on-pump techniques (Table 6) showing a 1–10% lower graft patency in patients operated on off-pump. Although there was no statistically significant difference in most of these trials, interpretation of these results has generated much controversy.20 To add to this discussion, three meta-analyses of randomized studies reported that graft patency was negatively influenced by the off-pump technique.13–15 Finally, a recent multicentre study (ROOBY trial) showed a significantly lower graft patency rate at 1 year (83 vs. 88%) in patients operated with the off-pump technique.12

Technical issues and the learning curve effect have always been put forward as the sole explanation for the observed trend to an inferior graft patency rate with off-pump CABG.10,20 This may apply in the ROOBY trial (12.4% conversion rate, significantly lower number of performed bypasses in the off-pump group) that included surgeons with widely variable experience. However, as our results would tend to suggest, the technical aspect may not be the only one involved. Several lines of evidence show that, independent of the technique, there is an inflammatory and prothrombotic state after coronary bypass surgery lasting for at least 1 month.21,22 However, in off-pump patients platelet aggregation remains stable relative to pre-operative levels, with normal bleeding time, despite aspirin administration, whereas in on-pump patients platelet aggregation decreases and bleeding time increases.23,24 Moreover, endothelial cell disruption and aspirin resistance have also been suggested to play an additional role in the pathogenesis of early vein graft thrombosis in off-pump patients.25 There is also evidence that patients operated on-pump have significantly higher saphenous mean graft flow in comparison with patients operated off-pump with no difference in these parameters for arterial grafts.26

In our study, the difference in early graft patency seemed mainly due to lower saphenous vein and radial artery graft patency in the off-pump group. This observation is consistent with the findings by other investigators reporting similar patency rate with internal mammary grafts between the two techniques, but lower patency in saphenous grafts performed off-pump compared with on-pump (Table 6).27 Although it was not the purpose of the present study, the antithrombotic protocol (<300 U/Kg of heparin), still used by a majority of off-pump surgeons, may have been responsible for the higher likelihood of graft thrombosis in the off-pump group.28 Since these are hypothesis-generating analyses, studies of alternative anti-thrombotic strategies for off pump CABG are needed, including the use of double antiplatelet therapy.

In our study, the same number of grafts (3.5) was performed in the off-pump and on-pump groups. Interestingly, graft occlusions were clinically silent, except for one patient, and only three patients in each group underwent PCI during follow-up. Absence of statistical difference, between the two techniques, in exercise treadmill tests 1 year after the operation, is an important finding that requires confirmation in a larger group of patients.

Neuropsychological evaluation performed at baseline and 5 weeks after surgery showed that off-pump patients were only slightly better preserved (one test) than patients operated on-pump. Both groups declined on measures of attention, memory, and psychomotor speed. The on-pump patients had a slightly steeper decline than patients operated off-pump. This difference is unlikely to have clinical significance and recent data have confirmed similar cognitive outcome regardless of the operative technique.29

Table 6

<table>
<thead>
<tr>
<th>Reference</th>
<th>Timing (%angio)</th>
<th>Off-pump (%)</th>
<th>On-pump (%)</th>
<th>P (AD; %; 95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>-----------</td>
<td>----------------</td>
<td>-------------</td>
<td>-------------</td>
<td>------------------</td>
</tr>
<tr>
<td>Nathoe et al.5</td>
<td>12 m (25)</td>
<td>91 na</td>
<td>93 na</td>
<td>ns, 2.0, –6.5, 10.4</td>
</tr>
<tr>
<td>Widimsky et al.11</td>
<td>12 m (64)</td>
<td>70 91 49</td>
<td>74 91 59</td>
<td>0.02</td>
</tr>
<tr>
<td>Khan et al.10</td>
<td>3 m (80)</td>
<td>88 92 (76) 91</td>
<td>98 100 (100) 95</td>
<td>0.3</td>
</tr>
<tr>
<td>Puskas et al.6</td>
<td>12 m (81)</td>
<td>94 94 93</td>
<td>96 98 94</td>
<td>0.15</td>
</tr>
<tr>
<td>Kobayashi et al.27</td>
<td>3 wks (100)</td>
<td>93 93 (95) 94</td>
<td>96 94 (99) 100</td>
<td>0.09 (RA; 0.055)</td>
</tr>
<tr>
<td>Al-Ruzeh et al.8</td>
<td>3 m (90)</td>
<td>92 98 (91) 82</td>
<td>93 97 (88) 88</td>
<td>0.86</td>
</tr>
<tr>
<td>Lingas et al.7</td>
<td>12 m (91)</td>
<td>85 94 80</td>
<td>90 96 87</td>
<td>0.15</td>
</tr>
<tr>
<td>Shroyer et al.12</td>
<td>12 m (61)</td>
<td>83 95 77</td>
<td>88 96 84</td>
<td>0.002</td>
</tr>
</tbody>
</table>

Patient without stenosis.

AD, absolute difference; CI, confidence intervals; m, months; wks, weeks; na, not available; IMA, internal mammary artery; RA, radial artery.

Limitations

The lower anticoagulation level in the off-pump group is the main limitation of this study but is shared with other randomized trials except the SMART trial.6 The protamine dose in both groups was also higher than that used by most surgeons, some authors suggesting only partial protamine reversal in off-pump surgery, allowing residual heparin activity.30 We did not use clopidogrel after surgery, as suggested by some, since, at the time of study design there was no evidence that this could be safe and potentially beneficial.31 Another limitation was the absence of intra-operative

Downloaded from https://academic.oup.com/eurheartj/article-abstract/31/20/2492/612078 by guest on 10 February 2019
graff patency control. Finally, early graft patency was assessed by MDCT which, despite its accuracy for detection of coronary bypass graft occlusion, does not provide information on graft flow but was used in a recent large study comparing late off-pump and on-pump graft patency.22 Timing of graft patency evaluation at 5 weeks might be considered too early, but was dictated by logistical reasons since a large proportion of patients were out of region referrals.

**Conclusion**

Raw overall early graft patency in patients randomized to off-pump CABG was lower than patients operated on-pump. There was no statistically significant difference in graft patency after adjustment for heparin dose, in neuropsychological functioning or in clinical outcomes after 1 year. The mechanisms behind these findings require further investigation.

**Acknowledgements**

The Authors thank Boban Thomas for reviewing the manuscript; Rogério Costa for assistance with the MDCT assessment; Sofia Nunes da Silva, Grazziela Nero, Raquel Travassos, João Costa, Vanessa Rodrigues, and Carla Martinho for organizational and secretarial support.

**Funding**

This work was supported by Merck Foundation and Sociedade de Gestão Hospitalar Cruz Vermelha Portuguesa SA.

**Conflict of interest:** none declared.

**References**


Implantation of a new extracorporeal life support system during resuscitation in complicated percutaneous coronary intervention with occlusion of the left main artery

Thomas Puehler1*, Alois Philipp1, Christof Schmid1, and Andreas Luchner2
1Department of Cardiothoracic Surgery, University Medical Center Regensburg, D-93053 Regensburg, Germany and 2Department of Internal Medicine II—Cardiology, University Medical Center Regensburg, D-93053 Regensburg, Germany
* Corresponding author. Tel: +49 9419449824, Fax: +49 9419449811, Email: thomas.puehler@klinik.uni-regensburg.de

The current case highlights the application of a new type of minimized extracorporeal circulation system (MECC). A 68-year-old diabetic male was diagnosed with non-ST-elevating myocardial infarction and a three-vessel disease. Coronary bypass surgery was not feasible due to infection with a methicillin-resistant Staphylococcus aureus and insufficient graft vessels owing to previous removal of lower limb veins for arterial reconstruction. Upon percutaneous coronary intervention, rupture of a left main (LM) plaque with complete vessel occlusion occurred during assessment by intravascular ultrasound (Panel A). The patient went into permanent ventricular fibrillation and required continuous cardiopulmonary resuscitation. Owing to the lacking option of surgical revascularization, interventional recanalization under protection of the MECC system was attempted. The arterial sheath was exchanged for a 17 F cannula and a 21 F venous cannula was inserted into the same groin. Extracorporeal veno-arterial assistance with the novel device (Maquet Cardiopulmonary AG, Hirrlingen, Germany, predecessor of the Cardiohelp extracorporeal life support system) was initiated at a blood flow of 4 L/min (Panel B). Interventional revascularization succeeded after stenting of all proximal artery segments including the LM (Panel C). Approximately 120 min after initial occlusion of the LM, attempts for defibrillation were successful and the patient was transferred to the intensive care unit (Panel D). After 4 days of extracorporeal support, left ventricular function had recovered and the patient could be weaned from the MECC device. Maximum increase in high-sensitive troponin I was 503 ng/mL (normal, 0.04 ng/mL) on Day 1 and maximum N-terminal pro-brain natriuretic peptide was 33,564 pg/mL (normal < 125 pg/mL) at Day 10. After 6 weeks, the patient could be discharged from the hospital without neurological sequelae and was alive, 3 months after the initial event.

Published on behalf of the European Society of Cardiology. All rights reserved. © The Author 2010. For permissions please email: journals.permissions@oxfordjournals.org.