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# Indication and patient selection in minimally invasive and ‘off-pump’ coronary artery bypass grafting<sup>☆</sup>

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## Abstract

**Background:** The selection criteria to perform ‘off-pump’ coronary bypass (OPCAB) grafting are not well defined. The aim of this presentation is to outline the indications and the patient selection on the basis of 2 years experience with 572 OPCAB procedures. **Materials and Methods:** From November 1996 minimally invasive coronary bypass grafting was performed in 406 patients using a limited mini-thoracotomy for single left anterior descending artery (LAD) revascularization (group A). In 166 patients full sternotomy and OPCAB grafting for single or multiple vessel revascularization was performed (group B). **Results:** In group A the procedure could be performed ‘off-pump’ together with a limited thoracotomy in 406 out of 457 patients (88.8%) who were scheduled for single graft revascularization to LAD. Exposure and quality of the LAD was good in 308/406 (76.0%) of the patients. The decision for sternotomy was made for different preoperative characteristics of these patients: Obese female patients 16/457 (3.5%), angiographic evidence of an intramyocardial running LAD 6/457 (1.4%), diffusely diseased and small LAD 11/457 (2.4%) severe COPD 3/457 (0.7%), unstable angina 11/457 (2.4%), emergency revascularization after failed PTCA 4/457 (0.8%). In 315/406 (77.8%) of the minimally invasive direct coronary artery bypass (MIDCAB)-patients exposure and quality of the LAD was good, in 97/406 (22.2%) moderate or even bad. In the latter subgroup stenosis free anastomosis was reduced (86.5%) compared to the subgroup of good exposure and quality with 98.3%. In group B selection for sternotomy and ‘off-pump’ procedure was made in 117/166 (70.4%) patients with a normal preoperative status (stable angina, ejection fraction > 35%) and with coronary lesions amenable for beating heart surgery (proximal RCA lesion > 80%, not calcified and well defined POD and marginal branches). In 49/166 (29.5%) decision for ‘off-pump’ procedure was made on the basis of a potential risk for cardiopulmonary bypass (CPB) such as acute myocardial infarction in 10/166 (6.0%), reduced ventricular function with EF < 35 in 28/166 (16.9%), calcified ascending aorta 4/166 (2.4%) or concomitant diseases 7/166 (2.5). **Conclusion:** To maintain excellent results after single LAD revascularization using the MIDCAB-approach, appropriate patient selection is crucial. Indication for sternotomy and ‘off-pump’ single LAD revascularization should be made in those patients excluded for MIDCAB and in patients scheduled for multiple vessel-CABG who are at high risk for CPB (concomitant pulmonary, renal, neurological diseases or severely impaired left ventricular dysfunction) and have suitable target coronary arteries in term of location and quality. © 1999 Elsevier Science B.V. All rights reserved.

**Keywords:** Indications; Selection criteria; Coronary artery bypass grafting

## 1. Introduction

Indication and patient selection is a major determinant for the success of minimally invasive direct coronary artery bypass (MIDCAB) grafting and ‘off-pump’ coronary bypass (OPCAB) grafting. For both procedures standardized criteria for indication or patient selection have not been defined so far. Based on our own data some guidelines are discussed to help clarify further decisions on when to perform MIDCAB or OPCAB surgery.

## 2. Materials and methods

From November 1996 to December 1998, 572 patients underwent coronary artery revascularization without using cardiopulmonary bypass (CPB). These patients were either operated via a small left antero-lateral minithoracotomy,  $n = 406$  (group A-MIDCAB), or via a conventional sternotomy approach,  $n = 166$  (group B-OPCAB).

The MIDCAB technique (group A) has been described in detail elsewhere [1,2]. In brief a 7–9 cm minithoracotomy through the 4th intercostal space was performed. The ITA-graft was harvested under direct vision using special commercially available retractors. Heparin was applied at a dosage of 100 IU/kg. Temporary occlusion of the target coronary artery was achieved by proximal and distal 4/0 monofilament suture-snare supported by a piece of pericardium.

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Local immobilization of the anastomosis was achieved using a variety of stabilizers, depending on individual anatomy. The anastomosis was performed using a single running 8/0 polypropylene suture, starting at the heel. Protamine was applied to neutralize 80% of the heparin dosage.

The operative technique of group B included median sternotomy and harvesting of the right, left or both ITA grafts as a pedicle for the use of the radial and the gastroepiploic artery as needed. Heparine was given in a dose of 100 IU/kg. Three stay-sutures on the left inner side of the pericardium and an additional stay-suture on the bottom between the inferior vena cava and the left lower pulmonary vein were used to place and rotate the heart to the right. For local immobilization of the myocardium at the anastomotic site commercially available mechanical stabilization were used. To achieve better exposure of the lateral wall and to maintain mean arterial blood pressure above 55 mmHg, the patient was rotated to the right and placed in a Trendelenburg position as described elsewhere [3]. The anastomoses were performed as described above. Protamine was applied to neutralize 80% of the Heparine.

Data collection was performed prospectively and given as numbers with mean  $\pm$  standard deviation (SD) or percentage of the whole group.

### 3. Results

#### 3.1. Group A (MIDCAB)

##### 3.1.1. Preoperative criteria

Indication for MIDCAB was a single vessel disease in 298/406 patients (73.4%) a double vessel disease in 64/406 (15.7%) and a triple vessel disease in 44/406 (10%) of the patients. In 34 patients MIDCAB to the left anterior descending artery (LAD) and PTCA of another coronary artery was performed. Seventy-eight out of 406 patients (19.2%) presented with an occlusion of the LAD, a grade Type C-lesion  $> 80\%$  was present in 207/406 patients (51.0%), a stenosis  $< 80\%$  in 20/406 patients (4.9%), and a restenosis after PTCA and stenting in 101/406 (24.8%). Forty-nine patients (10.7%) were excluded from the primarily scheduled MIDCAB procedure due to a small diameter of the LAD ( $< 1.5$  mm), diffuse calcification of the coronary artery, evidence of an intramyocardial running LAD, or severe obesity in females (Table 1).

##### 3.1.2. Perioperative results

Single grafting of the ITA to the LAD was performed in 382/406 patients (94.1 %), double grafting (radial artery T-graft) for additional revascularization of the diagonal branch in 24 patients (5.9%).

Conversion to sternotomy, CPB or both was necessary in 22/406 (5.4%) due to an intramyocardial running LAD in 12/406 (2.9%), injury of the ITA during harvest in 4/406 (1 %), injury of the right ventricle in 2/406 (0.5%) and func-

Table 1  
Preoperative characteristics (MIDCAB)<sup>a</sup>

| <i>Patients characteristics n = 406</i>      |                           |                   |
|--|---------------------------|-------------------|
| Gender                                       | Female 119                | Male 287          |
| Age (mean)                                   | 37–86 years               | (61.1 $\pm$ 10.3) |
| Disease                                      | 1-vessel                  | 298 (73.4%)       |
|  | 2-vessel                  | 64 (15.8%)        |
|  | 3-vessel                  | 44 (10.8%)        |
| LAD-lesion                                   | $< 80\%$                  | 207 (51.0%)       |
|  | $> 80\%$                  | 20 (4.9%)         |
|  | 100%                      | 78 (19.2%)        |
| Previous PTCA/stent                          |                           | 101 (24.9%)       |
| CCS  | Mean                      | 2.4               |
| EF   | 15–88% (56.8 $\pm$ 10.5%) |                   |
| <i>Exclusion criteria n = 491457 (10.7%)</i> |                           |                   |
| LAD $< 1.5$ mm                               |                           | 22 (4.8%)         |
| LAD calcified                                |                           | 10 (2.2%)         |
| LAD intramyocardial                          |                           | 4 (0.9%)          |
| COPD (severe)                                |                           | 2 (0.4%)          |
| Obese female                                 |                           | 11 (2.4%)         |

<sup>a</sup> CCS, Canadian Cardiovascular Society; EF, ejection fraction.

tional impairment during temporary occlusion of the LAD in 4/406 (1.0%) of the patients. Perioperative conditions in term of exposition and quality of the coronary artery and ITA graft was individually graded by the surgeon as being good in 77.6% of the cases. In these patients surgical outcome with a stenosis free anastomosis of 98.3% was clearly superior compared with 86.6% in the group with moderate or even bad quality and exposure. Early graft failure with the need of a redo procedure occurred in 8/406 patient. The 30-day mortality was 2/406 (0.5%). Early graft patency was confirmed in 311/328 controlled patients (94.8%).

##### 3.1.3. Six months follow-up

The 6-month follow-up of the ongoing clinical trial has been completed in 153 patients. Two patients died during the follow-up, both from an unknown cause. In 6/153 patients (3.9%) a re-intervention was performed in patients with recurrence of angina symptoms due to an occlusion (3/153) or severe stenosis of the graft (3/153). The patients with an occluded graft were successfully reoperated, those with a stenosis were successfully treated with PTCA and stenting.

#### 3.2. Group B (OPCAB)

##### 3.2.1. Preoperative criteria

Indication for coronary bypass grafting using the conventional sternotomy approach (Group A) was single vessel disease in 24/166 patients (14.5%), double vessel disease in 41/166 (24.7%), and triple vessel disease in 101/166 (60.8%) of the patients. Selection criteria was a normal preoperative status (stable angina, ejection fraction  $> 35\%$ ) in 107/166 (64.4%). In the early phase of the experience only patients having proximal LAD- or RCA-lesion  $>$

Table 2  
Preoperative characteristics (OPCAB)<sup>b</sup>

| <i>Patients characteristics n = 166</i> |                       |               |
|---|-----------------------|---------------|
| Gender                                  | Female 45             | Male 121      |
| Age (mean)                              | 29–83 years           | (59.6 ± 11.7) |
| Disease                                 | 1-vessel              | 24 (14.5%)    |
|   | 2-vessel              | 41 (24.7%)    |
|   | 3-vessel              | 101 (60.8%)   |
| CCS                                     | Mean                  | 2.5           |
| EF                                      | 12–88% (55.3 ± 10.4%) |               |
| <i>Patient selection</i>                |                       |               |
| Normal status                           |                       | 107 (64.4%)   |
| Risk for CPB                            |                       | 59 (25.6%)    |
| EF < 35%                                |                       | 28 (16.9%)    |
| Acute MI                                |                       | 10 (6.0%)     |
| Calcified aorta                         |                       | 4 (2.4%)      |
| Concomitant disease                     | 17 (10.2%)            |               |

<sup>a</sup> CCS, Canadian Cardiovascular Society; EF, ejection fraction; MI, myocardial infarction.

80% and easy exposure of the target coronary arteries were included. In a later operated subgroup of 59/166 patients (25.6%) individual criteria were the basis for selection for the ‘off-pump’ procedure such as reduced ventricular function (ejection fraction (EF) < 35%) in 28/166 patients (16.9%), acute myocardial infarction or acute failed PTCA in 10/166 (6.0%), calcified ascending aorta in 4/166 patients (2.4%) or other concomitant diseases in 17/166 (10.2%) (Table 2).

### 3.2.2. Perioperative results

In 18/166 patients (10.8%) the initially performed ‘off-pump’ procedure had to be converted to CPB due to hemodynamic intolerance during displacement of the heart (15/166) and/or ischemic dysfunction during temporary occlusion of the coronary artery (3/166). In all 15 patients who showed intolerance following displacement of the heart, the postero-lateral marginal branch or the circumflex branch was the target coronary artery. Two postoperative deaths occurred in patients with severe preoperative left ventricular dysfunction (EF < 20%). One of these patients suffered acute myocardial infarction due to graft occlusion. Another patient died from acute postoperative pneumonia and sepsis. A third patient with a preoperative EF of 12% had to be treated with long term left ventricular assist due to repeated therapy refractory ventricular fibrillation after uneventful surgery and despite patent grafts. Two patients had clinical inapparent myocardial infarction. All remaining patients had an uneventful postoperative course.

### 3.2.3. Follow-up results

The 6-month follow-up of this ongoing clinical trial is complete for 86/166 patients (51.8%). Three patients died during follow-up (2.1%), one death was cardiac related, one patient died of stroke and one of unknown cause. Two patients required repeated hospital admissions due to ventri-

cular arrhythmia or congestive heart failure. The remaining patients have improved clinically and are free from angina. Postoperative angiography demonstrated 140/154 open grafts (90.2%).

## 4. Discussion

The goals of less invasive coronary artery bypass surgery are to avoid CPB and the minimization of the access (antero-lateral minithoracotomy, full endoscopic approach) [4–6]. Despite the recent advancements CPB, cardioplegic arrested heart is still considered to be the ‘golden standard’ in coronary bypass surgery as it enables optimal exposure for even difficult coronary revascularization. The introduction of new technology has to comply to the safety standards and the good results that are possible with the conventional approach. One has to take into account that coronary bypass surgery on the beating heart is a microsurgical procedure on a moving target and technically somewhat demanding when the procedure is performed through a limited access. To minimize the risk, appropriate indication and patient selection is crucial. There are no ‘hard’ data to support the indication for the OPCAB or selection criteria to use a limited access so far. The rationales to use ‘off-pump’ coronary surgery is mainly based on theoretical considerations and indicates that indicate potential benefits for patients operated without CPB.

Our early data confirm that single- and multiple coronary revascularization can be performed safely with good early and mid-term results with both MIDCAB and OPCAB. On the other hand the data demonstrate the need for good intraoperative exposure, immobilization and good quality of the target coronary artery to achieve a high quality anastomosis without obstruction. To select patients for MIDCAB single LAD-revascularization different anatomical conditions (grade of stenosis, supply by collateral, diameter and quality of the coronary artery, evidence of an intramyocardial running vessel), and the patients constitution in terms of expected difficulties in exposure of the ITA and the target coronary artery have to be considered. On the basis of our experience we currently exclude patients with a small (< 1.5 mm), diffusely diseased, calcified or intramyocardial running LAD. Obese female patients are the most difficult candidates for MIDCAB. The necessity to achieve a good exposure of the ITA and LAD result in a considerable injury to the soft tissue of the lateral thoracic wall especially in the presence of a large breast. Thus we recommend performing a full sternotomy approach and an OPCAB grafting in these patients. Based on our recent experience, the OPCAB procedure is feasible in an increasing number of patients. This technique and the extent of its use to all coronary sites is still under development and a matter for the individual surgeon’s experience. Usually it is easy to perform an anastomosis to the LAD, diagonal branches, proximal RCA and the first marginal branch with-

out CPB. But there are technical limitations especially for the revascularization of the more posterior located marginal branches, since major displacement of the heart may cause hemodynamic instability or ischemic myocardial dysfunction. Therefore we have established some selection criteria and recommendations for technical considerations.

- The number of target vessels should be limited to three or four.
- Sequential grafting can be performed only under ideal circumstances.
- Calcified arteries should not be grafted on a beating heart.
- Patients with diffuse and distal coronary lesions should be excluded.
- Patients with congestive heart failure can be operated 'off-pump' only when there is excellent exposure of the target vessel without the necessity for major displacement of the heart.
- Patients should be converted to CPB if the mean arterial pressure can not be maintained above 55 mmHg despite using Trendelenburg positioning.
- An intraoperative shunt should be used during revascularization of non-occlusive dominant right coronary artery.
- The additional use of an intra and postoperative intraaortal balloon pump (IABP) is helpful for emergency revascularization after failed PTCA or during acute myocardial infarction.

Our early experience with the group of high risk patients emphasizes the benefit of avoiding CPB. There were no neurological deficits, no renal failure, no wound infections and only one patient had postoperative pneumonia. We recommend using OPCAB for patients at risk for CPB due to concomitant diseases such as cerebral artery disease, central neurological dysfunction, renal dysfunction, chronic pulmonary disease, peripheral artery disease, calcified ascending aorta and octogenarians. Nevertheless randomized studies are necessary to confirm the benefit of this technique in comparison to the conventional procedure.

As a result of the development of aggressive catheter-

based interventional treatment, many patients are not referred for surgical therapy. In order to reverse this trend, the surgical approach to coronary artery disease needs to be redefined. Complete arterial revascularization and 'off-pump' surgery may offer good long term results while at the same time reducing perioperative morbidity. High long-term patency rates at low operative risk, reduced invasiveness, early recovery and short hospital stay will make the surgical approach attractive even for young patients who are currently almost exclusively treated by interventionists. MIDCAB can already be considered as a true alternative to PTCA and stenting as the primary treatment for high graded proximal LAD stenosis or occlusion. First results of an ongoing randomized clinical trial demonstrate better functional results and higher patency rates for MIDCAB patients. With appropriate patient selection, MIDCAB and OPCAB will have an important role in the treatment of coronary artery disease.

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