"Hybrid" percutaneous and surgical coronary revascularization: selection criteria from a single-center experience

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Background. **The association of minimally invasive direct coronary artery bypass (MIDCAB) to percutaneous transluminal coronary angioplasty (PTCA) of large arteries with focal lesions can be an alternative therapeutic method for patients with multivessel coronary artery disease. We reviewed our experience regarding 42 patients treated at our Institute.**

Methods. **MIDCAB and PTCA of the circumflex or right coronary arteries > 3 mm were performed in 42 patients from September 1997 to December 1999.**

Results. **One patient died after MIDCAB in the operating room because of rupture of the left anterior descending anastomosis. Postoperative angiography confirmed patency of the internal mammary artery (IMA) graft in 92.3% of cases: 3 early IMA graft failures occurred. The success rate for PTCA was 98%: in 1 case the wire just would not cross a chronically and totally occluded right coronary artery. The in-hospital morbidity was 12.2%: 2 patients required urgent sternotomy respectively for cardiac tamponade and coronary artery bypass grafting on cardiopulmonary bypass. One patient developed atheroembolism after PTCA with recurrence of symptoms, progressive multiorgan failure and death. Two patients required PTCA on the IMA anastomosis because of early failure of the arterial graft. At a medium follow-up of 535 days, all 40 survivors are in Canadian Cardiovascular Society class I.**

Conclusions. **Hybrid revascularization appears to be an effective treatment for selected patients with multivessel coronary artery disease. The immediate success seems related to the learning curve for MIDCAB.**

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Introduction

Even though nowadays coronary artery bypass grafting (CABG) is a surgical procedure with an operative mortality around 1-5%[1] even for patients with a low left ventricular ejection fraction, morbidity due to renal, neurologic and pulmonary complications is high. Furthermore, the long-term fate of venous grafts still constitutes a relevant problem[1-4].

Hybrid revascularization is a combined technique performed using both surgical revascularization without cardiopulmonary bypass and percutaneous transluminal coronary angioplasty (PTCA) in selected patients with multivessel coronary artery disease.

Angelini et al.[5,6] proposed the combination of minimally invasive direct coronary artery bypass (MIDCAB) and PTCA to treat patients with multivessel disease by minimally invasive approaches thus avoiding the potential complications of cardiopulmonary bypass.

PTCA is an accepted method for the treatment of coronary artery disease in patients with multivessel involvement. Randomized clinical trials comparing PTCA and CABG in multivessel disease have shown no survival benefit for surgery at 5 years of follow-up but an increased incidence of angina and of the need of repeated procedures in the PTCA group, due to restenosis[7,8]. However the use of stents in vessels > 3 mm and with focal lesions reduced the restenosis rate to 10-12%[9,10].

MIDCAB has been originally advocated for the management of patients with single-vessel disease[11,12]. It is performed through a small left anterior thoracotomy. The left internal mammary artery (LIMA) is used to revascularize the left anterior descending coronary artery (LAD)[12]. The major limitation of the MIDCAB technique is that it results only in revascularization of the LAD territory.

Combined coronary revascularization including MIDCAB of the LAD and PTCA of

other arteries ≥ 3 mm in diameter and with focal lesions can be an alternative method for the treatment of patients with multivessel disease[6,13-15].

The immediate and mid-term results of the first 42 consecutive patients treated at our institution are reported.

Methods

Between September 1997 and December 1999, 42 patients underwent hybrid revascularization at the Istituto Clinico Humanitas in Milan. Thirty-two were male (76%) and the mean age of the population was 66.3 ± 9.2 years (range 47-85 years); 22 patients (52%) had clinical and/or electrocardiographic evidence of a previous myocardial infarction and 21 patients (50%) had unstable angina.

Severe systemic hypertension was present in 10 patients (24%). Diabetes was present in 7 cases (16.6%) and 4 patients (9.5%) had chronic obstructive pulmonary disease. Severe calcifications of the wall of the ascending aorta were present in 8 patients (19%), 1 patient had chronic renal failure necessitating dialysis and another one had previously been submitted to renal transplantation because of chronic glomerulonephritis.

All patients had multivessel disease with LAD involvement. The LAD was occluded in 15 patients (36%) and severely stenosed (> 70%) with type C lesions in the remaining 27 (64%). Thirty-five patients (83%) had two-vessel disease and the remaining 7 had three-vessel involvement.

The territory of the circumflex coronary artery was involved in 22 (52%) and that of the right coronary artery in 23 patients (55%).

The mean ejection fraction was 55 ± 10.6% (range 30-70%): 10 patients (24%) had an ejection fraction < 35%.

MIDCAB procedures were performed under general anesthesia. A small incision was made in the fourth intercostal space. Harvesting of the LIMA was accomplished with the help of a thoracotomy retractor (CTS Cardiothoracic Systems Inc., Cupertino, CA, USA). The same device was used to stabilize the LAD. Having identified the anastomotic site, two elastic bands were passed around the LAD proximally and distally to the site of arteriotomy in order to achieve hemostasis. No intraluminal shunts were used. Continuous monofilament sutures were used for anastomosis.

A hybrid approach, consisting of the combination of MIDCAB for the LAD (Fig. 1) and of percutaneous procedures (angioplasty or stenting) for focal lesions in large-sized vessels in the circumflex or right coronary territories (Fig. 2), was employed in our series of patients. For this purpose, a different "timing" was used in performing the procedures.

At the beginning of our experience, 4 patients (9.5%) underwent PTCA first, followed by MIDCAB after a mean interval of 51 days in order to assess the patency of the angioplasty site before surgery.

Thereafter, both procedures were performed during the same hospital stay in order to avoid potential ischemic events in the LAD territory during the interval and to limit the number of hospitalizations.
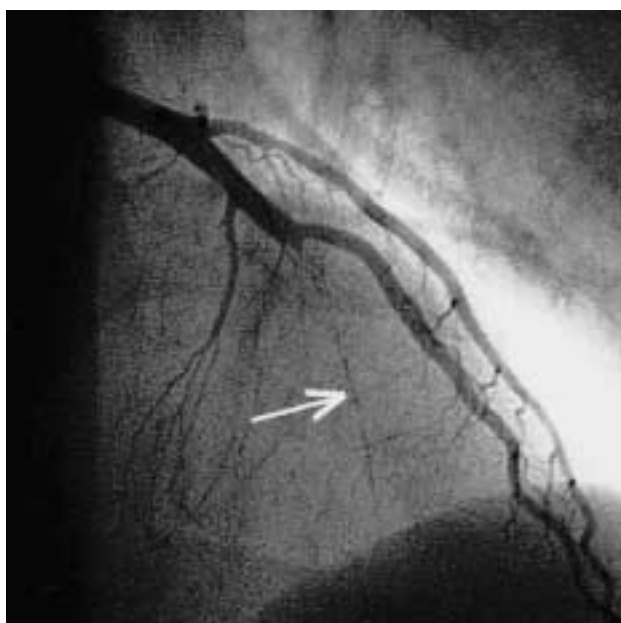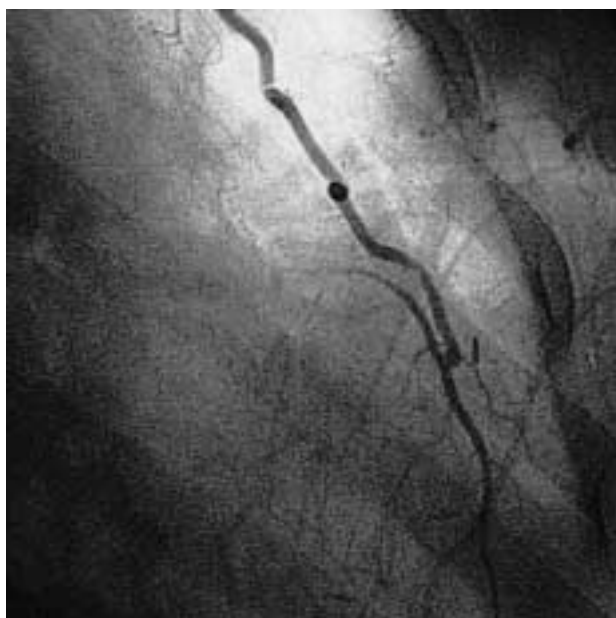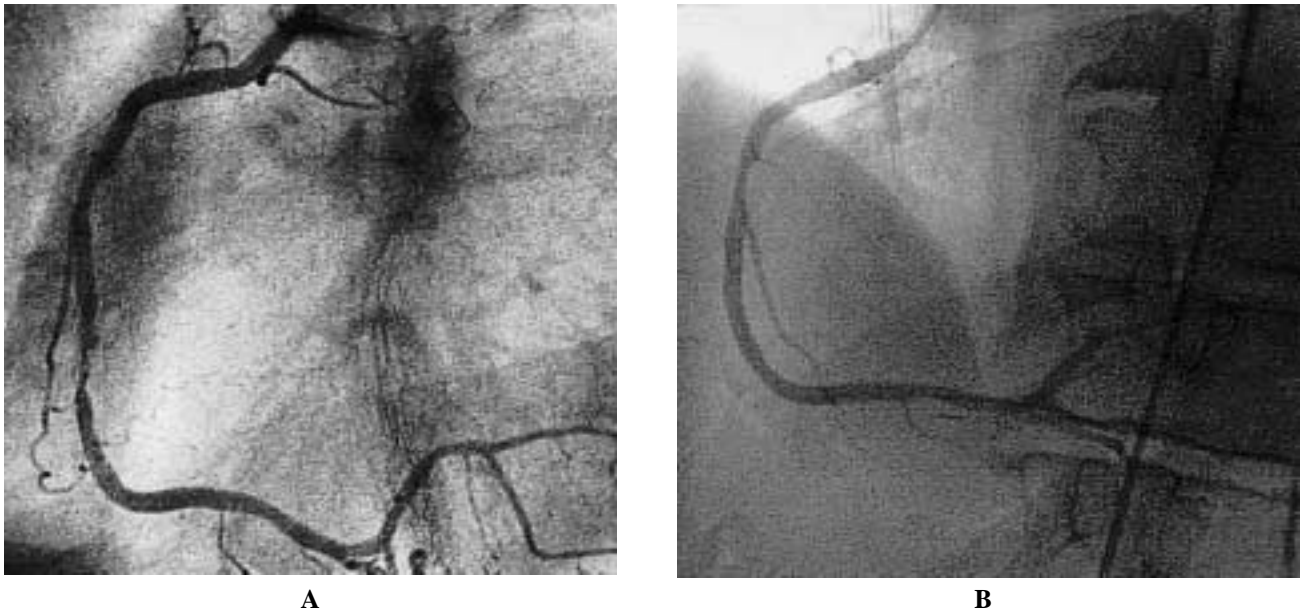

Figure 1. A: *antero-posterior cranial view. Occlusion in a long segment of the left anterior descending coronary artery before revascularization* (arrow). B: *the left anterior descending coronary artery in the same patient after minimally invasive direct coronary artery bypass.*

A   **B**

Figure 2. A: *left anterior oblique cranial view. Focal stenosis in the middle segment of the right coronary artery.* B: *same patient after successful angioplasty and stenting of the right coronary artery.*

Then, according to this schedule, in 27 patients (64.3%) we performed MIDCAB first and then completed myocardial revascularization by PTCA on the other vessels during the same hospital stay. The mean interval between the two procedures was 2.3 days. One patient presented with postoperative uncontrollable bleeding at the left thoracotomy site and was submitted to an urgent exploratory midline sternotomy. In this case PTCA was performed 61 days later.

However, we still performed PTCA first in the remaining 11 patients (26.2%). This was due to acute clinical and electrocardiographic instability at the time of catheterization attributable to critical lesions in the circumflex or right coronary territories: in such cases, MIDCAB could be performed during the same hospital stay or else delayed for a few months.

Forty-nine lesions in 42 patients were treated with percutaneous revascularization. The target vessel for PTCA was the right coronary artery in 17 patients, the circumflex coronary artery in 16 patients, the diagonal branch of the LAD in 2 patients, and a venous bypass to the circumflex coronary artery in 1.

Out of 49 lesions, 35 were focal lesions ($\leq$ 20 mm in length, 63.8%), 13 were tubular lesions (> 20 mm, 33.3%), and 1 was a total occlusion (2.7%).

The mean reference vessel size was 3.08 $\pm$ 0.6 mm (range 2.5 to 5 mm) and the mean percentage diameter stenosis was 85% (range 70 to 100%).

With regard to the antiplatelet regimen, aspirin and ticlopidine were started 24 hours after MIDCAB just before PTCA. Our poststenting protocol, which includes 300 mg aspirin and 500 mg ticlopidine daily for 1 month, was adopted.

Results

The in-hospital survival was 97.6%. Following MID-CAB, one patient developed left lung hyperinflation while still in the operating room. This resulted in laceration of the anastomotic site where the internal mammary artery (IMA) had been grafted. This patient died of hemorrhagic shock.

Surgical results. All patients except 3 underwent postoperative angiography to assess the patency of the IMA graft: a wide patent arterial anastomosis was found in 92.3% of the angiographically controlled cases; 3 cases of early failure due to occlusion or malfunction of the IMA graft on the LAD occurred.

Five patients developed in-hospital postoperative complications (12.2%). One patient, who presented with proximal dissection of the right coronary artery was submitted to multiple stenting. MIDCAB was performed the next day. The postoperative course was complicated by acute recurrence of angina with diffuse ST segment elevation anteriorly and inferiorly. This patient was submitted to emergency reoperation, including cardiopulmonary bypass and without angiographic control. The anastomosis of the LIMA graft to the LAD was redone and the saphenous vein was grafted to the distal right coronary artery. The postoperative course was uneventful.

Another patient required urgent surgical exploration by sternotomy because of post-MIDCAB bleeding with impending cardiac tamponade. This patient was on antiplatelet treatment because PTCA and stenting had been performed 48 hours previously.

One female patient underwent unsuccessful PTCA because of early failure of the IMA anastomosis on the LAD. Following PTCA, this patient, who also had an abdominal aortic aneurysm, developed an atheroembolic syndrome with peripheral limb ischemia and livedo reticularis confirmed by skin biopsy.

Forty-eight hours following surgery, 2 asymptomatic patients with obstruction at the site of the LIMA to the LAD anastomosis were submitted to PTCA with stenting of this site as well as of the other vessels (left circumflex and right coronary arteries).

Coronary angioplasty results. Out of 49 procedures, 48 were successful (98%); an attempt to open a chronic right coronary artery total occlusion was unsuccessful because the wire would not cross the lesion.

After PTCA, the mean residual stenosis was 8% (range 0 to 20%). Thirty-six stents (73.4% of procedures) were implanted; 19 stents were < 16 mm in length (53% focal stenting) and 17 were > 16 mm or multiple (47%). Out of 36 stents, 7 were implanted because of angiographic evidence of non-occlusive dissection (19.4%), and 29 were implanted because of suboptimal results or electively (80.6%). In 1 patient with a suboptimal result, the stent was not implanted because of ticlopidine allergy. In the other lesions in which the stent was not implanted a stent-like result was obtained and in this setting the superiority of the stent in reducing restenosis has not been proven.

Follow-up results. All patients had routine clinical follow-up and were contacted to assess outcomes and symptoms. The Canadian Cardiovascular Society (CCS) classification was used to grade the eventual recurrence of angina.

The delayed mortality was 2.4% (1/41). A patient died 2 months after the hybrid procedure because of progressive multiorgan system failure, due to a recurrence of symptoms and a worsening of general conditions related to the previously described atheroembolic syndrome.

In 1 patient (2.4%), a delayed PTCA-related complication occurred: subacute stent thrombosis retreated with successful PTCA after 3 weeks.

A patient with preoperative severely impaired left ventricular function developed an acute pulmonary edema 6 months after the combined procedure and was successfully treated with intensive medical therapy.

At a medium follow-up of 535 days (range 152 to 985 days), all 40 survivors are alive and in CCS class I.

Thirty patients (75%) underwent a stress test at an average of 6 months after surgery. No signs of residual ischemia were observed in any of them.

Discussion

Although cardiopulmonary bypass provides a motionless and bloodless operative field, significant morbidity related to the procedure has been described. Recent data from the Society of Thoracic Surgeons national database show that the incidence of neurologic deficits associated with coronary bypass surgery ranges from 4 to 6%: it is known that manipulation of the ascending aorta during cross-clamping maneuvers and placement of proximal graft anastomoses can lead to dislodgment of atherosclerotic emboli[1,2,4].

Other adverse effects related to the conventional cardiopulmonary bypass include renal failure, coagulopathic bleeding, pulmonary dysfunction, and the activation of the systemic inflammatory response[4,16]. Moreover, cardiopulmonary bypass can lead to wound pain, respiratory dysfunction, and deep sternal wound infection[17].

Furthermore, the long-term fate of saphenous vein grafts is still a relevant problem because their patency rate at 10 years is 50%[18].

MIDCAB has recently been introduced as a technique of coronary revascularization. Its advantages include the elimination of the cardiopulmonary bypass and the avoidance of sternotomy and aortic manipulation. This results in a shorter hospital stay and a more rapid return to work[1,4,12,13]. Nevertheless, this procedure has a number of disadvantages including a limited approach to the heart, the lack of circulatory support, presence of blood in the surgical field and, most important, its applicability limited to the LAD[1]. During the last few years, off-pump coronary surgery has become more and more popular and in many centers, including ours, off-pump multiple vessel grafting via a midline sternotomy has become common. However, even in the present cohort of patients some surgical procedures have been completed at PTCA, confirming the value of a hybrid approach. Furthermore, in our view, patients at high risk for surgery and in whom revascularization of the LAD is the main goal, the less invasive MIDCAB approach maintains its advantage over a midline sternotomy.

The major drawback of MIDCAB surgery is a higher prevalence of anastomotic stenosis in comparison to a standard procedure, particularly at the beginning of the learning curve or in low-volume centers[12]. Recent angiographic mid-term follow-up data showed that minimally invasive CABG is associated with a patency rate ranging from 93.7[19] to 95.4%[20].

PTCA has become an accepted and effective treatment of coronary artery disease even in patients with complex multivessel disease[7]. Randomized trials have shown that CABG and PTCA have the same mortality rate at mid-term follow-up, but CABG patients are more frequently free from angina[7,8] while PTCA patients have a higher number of repeated procedures for restenosis[7,21]. Stenting has improved PTCA results with lower rates of restenosis and of repeated procedures.

The ERACI II randomized trial that has compared multivessel stenting with CABG showed that patients randomized to the stent group had a significantly lower incidence of major procedural adverse cardiac events (1.8

vs 11.4% in patients undergoing CABG). However, the 6-month incidence of target lesion revascularization was 13.7% in the stent group and 4.8% in the CABG group[22]. Initial results of the Arterial Revascularization Therapy Study (ARTS) show the same trend[23].

The surgical treatment of LAD lesions using the LIMA is known to be the best treatment of this artery as far as long-term results are concerned. When the operation is performed in association with cardiopulmonary bypass, the IMA graft has a very high patency rate (over 90% at 10 years)[18,24-26]. Moreover, a recent angiographic 20-year follow-up in patients with internal thoracic artery grafts showed a patency rate of 88.9%[27]. On the other hand, percutaneous treatment with PTCA and stenting of isolated lesions of the proximal LAD in a vessel at least 3 mm in diameter, particularly if preceded by plaque removal procedures, is associated with quite good immediate and long-term outcomes (13-20% restenosis rate)[28].

However, in case of type C lesions of the LAD, in small vessels (≤ 3 mm) and in case of total occlusions, the restenosis rate, using any technique, remains quite high (25-40%)[29-31].

The association of MIDCAB on the LAD combined with PTCA/stenting of the other arteries in patients with multivessel disease and with a LAD at high risk for restenosis can be an optimal revascularization strategy, allowing a combination of some of the advantages of both techniques[5,6,13-15].

Only a few series with small numbers of patients and short- or mid-term follow-up have been published[6,13,14,19,31,32]. Good results with an overall in-hospital success rate of the combined procedure ranging from 82 to 100% were reported[6,13,14,19,32]. Late problems either due to IMA graft stenosis (0-7%) or stent restenosis (0-5%) were reported[13,14,33].

Our experience shows that complications of the procedure are mainly related to MIDCAB. In the present series, the case in which one patient died of severe bleeding at the anastomotic site and that in which another patient presented with cardiac tamponade underline the limited control the surgeon has on the operative field in case technical complications occur.

Narrowing of the anastomosis could be related to the learning curve or to broad anatomical lesions (small, diffusely diseased and calcified LAD arteries). For this reason we think that this procedure should be performed only in high-volume MIDCAB centers (≥ 100/year) and when the LAD is not diffusely diseased, calcified or < 2 mm. Our current approach is to perform MIDCAB first, followed by percutaneous intervention on the other vessels 48 or 72 hours later, during the same hospital stay. This approach allows an immediate "protection" of the LAD territory, testing of the IMA graft patency and a safe use of antiaggregant and/or anticoagulant drugs. This can lead to bleeding when both procedures are performed at the same time[32]. However, this approach necessitates caution when using IIb and IIIa inhibitors during the first 5-6 days after surgery.

The mean postoperative stay was 4.5 days, a bit less than that of patients undergoing standard CABG at our Institution (5.5 days). This is mainly because the PTCA procedure is performed 36-48 hours after MIDCAB in order to allow the patient to recover after surgery. So the advantage of a shorter hospital stay does not seem to justify this procedure.

In accordance with our protocol, when possible patients were submitted to postoperative non-invasive evaluation in order to determine whether LAD revascularization had already resolved the myocardial ischemia and, therefore, whether the intervention on the other vessels could be postponed. This is because we do not want to leave a severely stenotic vessel which is a potential source of acute ischemic attacks and to postpone the resolution of the patient's problems for several days or months.

As far as the indications were concerned, at the beginning of our experience we adopted this combined strategy in surgical candidates who, owing to poor general clinical conditions, renal failure or cerebrovascular disease, were at high-risk for cardiopulmonary bypass-related complications.

Later we extended this hybrid procedure to patients who prefer a minimally invasive surgical approach because it is more attractive than conventional sternotomy. However, because in our Center the surgical risk for elective CABG is < 1% and since the LIMA-LAD graft patency rate equals 98%, we think that this combined procedure should presently be reserved 1) to high risk patients with diffuse aortic calcifications (patients on chronic dialysis), and 2) to those cases in which it is necessary to re-do a previous non-IMA CABG when the following angiographic findings are present: LAD lesions not amenable to percutaneous intervention because of a probable poor immediate or delayed outcome and focal lesions in large-sized (≥ 3 mm) right coronary or left circumflex arteries.

In consideration of these selection criteria, the patients who could benefit of this combined procedure probably constitute 4% of the candidates for standard CABG.

In order to precisely assess the superiority of this procedure, in particular with regard to morbidity, randomized trials are necessary.

In conclusion, our initial experience suggests that hybrid revascularization is a novel alternative approach for the efficacious treatment of selected patients with multivessel coronary disease. The immediate success without complications is very much dependent on the success and learning curve of MIDCAB. The mid-term outcome, as far as the mortality rate, cardiac events and quality of life are concerned, is excellent.

Acknowledgments

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