

First Turkish Experiences of Assisted Beating-Heart Coronary Artery Bypass Graft with the Impella Microaxial Ventricular Assist Device®

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ABSTRACT

The importance of minimally invasive cardiac operations, performed off-pump, without the support of cardiopulmonary bypass (CPB), is continuously increasing. Complete revascularization of obstructed coronary arteries is needed to obtain a better long-term outcome. Insertion into the left ventricle of an efficient microaxial pump can be useful when targeting an important coronary artery located at posterior wall of the heart in a patient with hemodynamic deficiency. The use of such a device can enable surgeons to avoid conversion from a preplanned off-pump strategy to traditional on-pump coronary bypass surgery. The Impella Microaxial Ventricular Assist Device® (VAD) (Abiomed, Aachen, Germany) is a miniature pump with a 7-mm catheter and a flow rate of approximately 2.5-5 L/min. This device can enable cardiovascular surgery to be performed without damaging the left ventricle and causing serious aortic deficiency. Therefore, in patients with serious comorbidity, complete revascularization may be performed off pump, with the heart beating, because of the hemodynamic stability provided with the support of the microaxial intracardiac pump. If required, this pump can also support the heart during the early postoperative period. We report the first assisted beating-heart coronary artery bypass graft surgery performed with the Impella Microaxial VAD in our country. The surgery was performed on 2 patients considered high risk on the basis of EUROSCORE® testing.

INTRODUCTION

The use of an assist device that avoids the need for on-pump procedures is very important in patients with high comorbidity, in whom full revascularization must be performed under the most appropriate conditions for a sensitive and critically ill heart. As is widely known, the full body

inflammatory response, also referred to as the systemic inflammatory response syndrome, has negative effects on many organs and is an undesirable side effect of the use of an oxygenator pump [Kirklin 1991]. Adverse events encountered with oxygenator pump use include blood coagulation because of contact with the nonphysiological foreign surface of the oxygenator pump, postoperative blood loss, complement activation, hemodilution, and microcirculation impairment, which can lead to decreased cognitive performance [Isgro 2001]. Because of the undesirable effects of extracorporeal circulation (ECC), surgeons have advanced the use of minimally invasive surgical procedures that can be performed without the support of an oxygenator pump. In addition, some new biomedical materials have been developed. Hemodynamic instability negatively affects the quality of anastomosis, which is highly important for the wall functions of the posterior and the lateral left ventricle, particularly in multiple-artery lesions [Gründeman 1999; Dekker 2001]. There are many new reports of data indicating that mortality and morbidity rates are decreased by off-pump coronary artery bypass (CAB) surgery techniques [Cleveland 2001]. Here we report the first assisted beating-heart CAB graft surgery performed with the support of the Impella Microaxial Ventricular Assist Device® (VAD) (Abiomed, Aachen, Germany), a device that can provide myocardial protection and increase surgical quality and comfort.

CASES

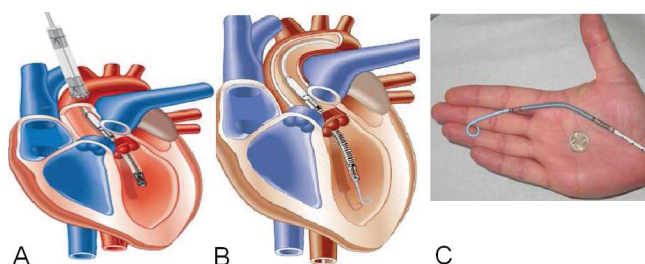
The first patient was a 60-year-old man with chronic renal insufficiency, who had been bound to portable peritoneal dialysis for 2 years. Approximately 6 months after undergoing drug-coated stent insertion to the left anterior descending (LAD) and circumflex coronary arteries, the patient sought medical care at the emergency department because of severe chest pain. An emergency angiography revealed intraluminal restenosis of the stent and severe obstruction in other native arteries. The patient was treated for peritonitis, and because of the persistence of unstable chest pain, the presence of chronic renal insufficiency, and the decrease in left ventricle performance as measured by echocardiography (left ventricular ejection fraction 30%), the decision was made to perform bypass surgery.

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A beating-heart method was used with the assistance of an Impella Microaxial VAD, the world's smallest axial pump. This system is generally applied via a percutaneous route. In this patient, because of plaques found in femoral and iliac arteries (Figure, A), the device was inserted into the left ventricle bypassing it through an anastomosed 10-mm Dacron graft attached to the aorta by using side clamps under transesophageal echocardiography control. A C-armed scope device was used to assess the effective function of the device by measuring the alignment of the groove-marked section at the level of the cap. Subsequently, full revascularization (left internal mammary artery–LAD, ascending aorta–circumflex coronary artery obtuse marginal branch, and ascending aorta–right coronary artery) was ensured with the support of the Impella Microaxial VAD, giving an axial turnover rate of 20,000–30,000 rpm and blood flow rate of 3–5 L/min. The system operated for approximately 122 minutes. With this turnover rate, the blood pressure of the patient varied between 100 and 120 mm Hg. A 50-IU dose of heparin, adjusted to the weight of the patient, was administered before coronary anastomosis was performed. After completion of the distal and proximal anastomoses, the system was removed when bleeding was controlled and hemodynamic parameters were stable. The patient was extubated 4 hours postoperatively and transferred to the inpatient clinic on postoperative day 1. The patient's condition stabilized, and he was discharged on postoperative day 7.

The second patient was a 67-year-old man with a 20-year history of insulin-dependent diabetes mellitus and a 3-year history of chronic renal insufficiency. He was hemodialysis dependent. This patient was hospitalized owing to complaints of shortness of breath and chest pain. Coronary angiography revealed 2-vascular disease and intraluminal stent stenosis in the right coronary artery. Echocardiography revealed that the left ventricular ejection fraction was substantially low (15%), pulmonary artery pressures were high (45 mm Hg), and dilated cardiomyopathy findings were present. After viable tissue was found on the anteroseptal and inferior wall via myocardial perfusion scintigraphy (F-18 fluorodeoxyglucose positron emission tomography), a decision was made to carry out the high-risk operation. Because of severe left ventricle dysfunction (Figure, B), this patient underwent beating-heart bypass surgery, assisted by an Impella LP 2.5 Microaxial VAD inserted into the left ventricle via the femoral artery using the routine Seldinger method. This placement path was easily accessed because the patient's femoral artery did not have any problems. During the insertion of the system into the left ventricle, a C-armed scope device and transesophageal echocardiography were again used. Before anastomosis was performed the patient was administered 50 IU/kg of heparin. The patient underwent an off-pump dual bypass (left anterior mammary artery–left anterior descending artery and ascending aorta–right coronary artery), assisted by an Impella Microaxial VAD operating at a turnover rate of 30,000 rpm and a blood flow rate of 2.5 L/min. The surgical procedure lasted for approximately 95 minutes. Blood pressure was maintained at 120 mm Hg with the support of the device, which was removed by gradually reducing operation parameters after



A, Impella Microaxial Ventricular Assist Device® (VAD) (Abiomed, Danvers, Massachusetts, USA) placed into the left ventricle through the aorta within 10-mm Dacron graft. B, Impella Microaxial VAD placed into the left ventricle via arteria femoralis, the usual insertion method. C, Impella Microaxial VAD (the world's smallest microaxial pump).

bleeding was under control and hemodynamic parameters were stable. The patient experienced no postoperative problems and was discharged on postoperative day 8.

DISCUSSION

Coronary revascularization operations without ECC support are not only cost-effective but also result in many significant benefits. Cost-benefit analyses of the use of this method in bypass operations on beating hearts have been reported [Calafiore 1997]. In addition, because of decreased mortality and morbidity, many surgeons advocate the use of off-pump CAB, particularly in high-risk patients [Gundry 1998; Arom 1999; Boyd 1999]. Full revascularization is very important for both surgical efficiency and long-term prognosis, but in patients with multiple artery disease full revascularization by beating-heart bypass surgery with low mortality and morbidity rates is difficult to perform. For several reasons, in many patients the planned off-pump surgical procedure frequently must be converted to the traditional method assisted by ECC. Cartier et al reported that the full revascularization rate without ECC was 90%, the rate of conversion to the traditional ECC method was <1%, and only <1% of patients, those with an LAD coronary artery with deep intramyocardial localization or who were very hemodynamically unstable, were not considered eligible for this procedure [Cartier 2000]. The conversion rate from the off-pump technique to the traditional method (on-pump) is about 20% in patients with borderline left ventricular functions. This conversion rate can be decreased with the assistance of microaxial pumps implanted into the left ventricle during the minimally invasive bypass procedure. An animal model study conducted by Meyns et al demonstrated positive myocardium-protective effects of biventricularly inserted Impella Microaxial VAD [Meyns 2000]. A multiple-center study conducted by Autschbach et al demonstrated the safety and benefits of clinical practices using an Impella Microaxial VAD [Autschbach 2001]. This miniature pump can be easily implanted for both left and right ventricular support. Isgro et al found that an Impella Microaxial VAD inserted into the left ventricle was associated with a substantial decrease in the conversion rate to traditional procedures [Isgro 2003]. In our first surgical

experience with beating-heart bypass surgery with myocardial protection assisted by a left ventricular support device, we performed a successful full revascularization on high-risk patients with poor left ventricular function. Moreover, when the heart was elevated during posterior and lateral anastomosis, both mean arterial pressure and central venous oxygen saturation were preserved, conditions that are relevant for efficiency of the device. Two other studies of left ventricular support devices have shown that myocardial oxygenation consumption was reduced throughout the procedure and that the devices ensured high myocardial performance in the postoperative period [Meyns 2000]. Echocardiographic findings in animal model studies demonstrated that left ventricle filling and emptying times were limited during anastomosis, particularly when performed on circumflex coronary artery branches within scope of a bypass procedure on beating hearts, and thus the procedure caused instability in hemodynamic parameters [Dekker 2001]. In bypass operations in beating hearts, centrifugal pumps or pumps with microaxial currents can be used as a support device. When those devices are compared, the new-generation miniature microaxial pumps are superior owing to ease of use, small size, lack of hemolysis at high flow rates (0-30,000 rpm), a small foreign material surface, and a current-adjustment option that prevents high operating currents (Figure, C). Moreover, the use of new-generation pumps can easily be continued into the postoperative period, during which post-myocardiotomy syndrome is a risk. Approximately 10 days of support can be provided from this miniature pump and its use is associated with lower doses of systemic anticoagulant administration [Meyns 2000].

When we used this device, we chose the routine femoral arterial route for placement in the second patient because the femoral artery of this patient did not have any problems and the procedures could be performed easily. But the first patient presented with severe plaques and severe stenosis in his femoral and iliac arteries. In that case we chose to insert the device through the aorta, directly into our surgical field in the most comfortable position possible. The device was placed within a 10-mm Dacron graft to avoid excessive damage to the aorta and to prevent shrinkage of the aorta after removal of the device. Thanks to this support device, the population of patients eligible for off-pump procedures can be increased. In our first surgical experience, hemodynamic stability was ensured by the device when the heart was elevated to perform the anastomoses. However, more studies are required to validate the benefits and the use of this device and the patient selection criteria for its use in beating-heart bypass surgery.

In conclusion, the Impella Microaxial VAD miniature pump system can provide hemodynamic support during beating-heart CAB surgery. The device can be efficiently used in full revascularization of patients with poor left ventricular function, even in presence of additional risk factors pertaining to cardiopulmonary bypass (ECC). Because the device promotes hemodynamic stability, it may prevent the development of postcardiotomy deficiency syndrome in

off-pump bypass surgery. In this context, themodynamic benefit is gained by use of a left ventricular application of the microaxial miniature pump, and thus cardiac manipulation is made easier. The clinical relevance of the device is very significant, because it is associated with decreased cost, rapid and easy implantation, and increased surgical quality and comfort. The device has also been shown to improve regional myocardial ischemic tolerance. Because of their protective effects, these devices can be a determining factor for performing surgical procedures on high-risk patients with poor left ventricular function and on patients with acute infarction.

REFERENCES

- Arom KV, Emery RW, Flavin TF, Peterson RJ. 1999. Cost-effectiveness of minimally invasive coronary artery bypass surgery. *Ann Thorac Surg* 68:1562-6.
- Autschbach R, Rauch T, Engel M, et al. 2001. A new intracardiac microaxial pump: first results of a multicenter study. *Artif Organs* 25:327-30.
- Boyd WD, Desai ND, Del Rizzo DF, Novick RJ, McKenzie FN, Menkis AH. 1999. Off-pump surgery decreases postoperative complications and resource utilization in the elderly. *Ann Thorac Surg* 68:1490-3.
- Calafiore AM, Teodori G, Di Giammarco G, et al. 1997. Minimally invasive coronary artery bypass grafting on a beating heart. *Ann Thorac Surg* 63:S72-5.
- Cartier R, Brann S, Dagenais F, Martineau R, Couturier A. 2000. Systematic off-pump coronary artery revascularization in multivessel disease: experience of three hundred cases. *J Thorac Cardiovasc Surg* 119:221-9.
- Cleveland JC Jr, Shroyer AL, Chen AY, Peterson E, Grover FL. 2001. Off-pump coronary artery bypass grafting decreases risk-adjusted mortality and morbidity. *Ann Thorac Surg* 72:1282-8.
- Dekker AL, Geskes GG, Cramers AA, et al. 2001. Right ventricular support for off-pump coronary artery bypass grafting studied with bi-ventricular pressure—volume loops in sheep. *Eur J Cardiothorac Surg* 19:179-84.
- Gründeman PF, Borst C, Verlaan CW, Meijburg H, Mouës CM, Jansen EW. 1999. Exposure of circumflex branches in the tilted, beating porcine heart: echocardiographic evidence of right ventricular deformation and the effect of right or left heart bypass. *J Thorac Cardiovasc Surg* 118:316-23.
- Gundry SR, Romano MA, Shattuck OH, Razzouk AJ, Bailey LL. 1998. Seven-year follow-up of coronary artery bypass performed with and without cardiopulmonary bypass. *J Thorac Cardiovasc Surg* 115:1273-7.
- Isgro F, Kiessling AH, Mittelstaedt H, Saggau W. 2001. Surface modification of extracorporeal circuits: is there really an impact on cerebral performance after cardiopulmonary bypass? *Thorac Cardiovasc Surg* 49:65-9.
- Isgro F, Kiessling AH, Rehn E, Lang J, Saggau W. 2003. Intracardiac left ventricular support in beating heart, multi-vessel revascularization. *J Card Surg* 18:240-4.
- Kirklin JK. 1991. Prospects for understanding and eliminating the deleterious effects of cardiopulmonary bypass. *Ann Thorac Surg* 51:529-31.
- Meyns B, Sergeant P, Nishida T, Perek B, Zietkiewicz M, Flameng W. 2000. Micropumps to support the heart during CABG. *Eur J Cardiothorac Surg* 17:169-74.