High-tech primary percutaneous coronary intervention

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Key words:
Angioplasty, primary; Myocardial infarction.

Coronary recanalization by means of primary percutaneous coronary intervention is actually the treatment of choice in patients with ST-elevation myocardial infarction. However, conventional primary percutaneous coronary intervention still presents several limitations. In recent years sophisticated new devices and techniques have been developed to further improve the results of primary percutaneous coronary intervention: it seems to be appropriate to refer to their utilization using the definition "high-tech primary percutaneous coronary intervention". Although the study data available are controversial and clinical benefits have not clearly been shown, adjunctive devices have been used in many procedures. Patient and lesion selection appears to be crucial and the health economics as well as the safety of high-tech devices should be carefully evaluated.

(Ital Heart J 2005; 6 (6): 465-474)

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Introduction

Coronary recanalization by means of primary percutaneous coronary intervention (PCI) has been shown to be the treatment of choice in patients with ST-elevation myocardial infarction (STEMI). Primary PCI achieves higher rates of vessel opening and guarantees more sustained patency of the infarct-related artery (IRA) if compared to thrombolytic therapy[1]. The superiority of primary PCI in the treatment of STEMI has been determined mostly thanks to the refinement of interventional techniques, materials, and pharmaceutical aids. The routine use of stents, which should be considered the standard of care, and glycoprotein IIb/IIIa inhibitors during primary PCI has led to high procedural success rates (TIMI 3 flow rate 96%) and to an improvement in clinical outcome[2-7]. Despite these achievements, conventional primary PCI still presents several limitations and, in some clinical circumstances, is not sufficient for an optimal therapy of STEMI. In recent years sophisticated new devices and techniques have been developed to further improve the results of primary PCI. It may be appropriate to refer to their utilization using the definition "high-tech primary PCI". The present review focuses on the technical features and clinical experiences of these new high-tech tools in the armamentarium of the interventional cardiologist.

Rationale for high-tech primary percutaneous coronary intervention

Distal embolization and the no-reflow phenomenon. Conventional primary PCI techniques encompass the risk of mobilizing thrombus or plaque debris, leading to macroscopic distal embolization, which has been correlated to a poor prognosis[8]. Moreover, several studies have shown that the IRA recanalization does not automatically stand for successful myocardial reperfusion. In up to 29% of STEMI patients treated with primary PCI none or incomplete myocardial reperfusion occurs despite the patency of infarct-related epicardial coronary artery[9]. The inability to reperfuse a portion of the myocardium after reopening a previously occluded epicardial coronary artery has been described as the no-reflow phenomenon[10] and is diagnosed *in vivo* by ST-segment analysis at ECG[11], myocardial contrast echocardiography[12], nuclear imaging techniques[13], magnetic resonance imaging[14], coronary Doppler flow wire[15], corrected TIMI frame count[16] or myocardial blush grade[17] at coronary angiography. It is noteworthy to distinguish between the no-reflow phenomenon and the angiographic no-reflow. The latter is confined to angiographic observations in the cath lab and is defined as the presence of a TIMI flow ≤ 2 in the absence of dissection, spasm, stenosis or thrombus of the epicardial vessel undergoing angioplasty[18].

The no-reflow phenomenon occurs in all patients with a TIMI flow ≤ 2 following primary PCI but also in about 15% of patients with TIMI flow 3[19]. The pathophysiology of the no-reflow phenomenon is tightly related to the microvasculature, and possible causes are endothelial dysfunction due to ischemia and reperfusion injury, leukocyte plugging in small vessels, compression of small vessels by tissue edema, and distal dislocation of thrombus and plaque debris[10]. The importance of distal embolization in the setting of acute myocardial ischemia has been investigated in an experimental canine model. Dörge et al.[20] studied the effects of coronary microembolization on the extent of myocardial inflammation and necrosis, showing that the injection of inert microspheres in the microvascular coronary circulation of the canine heart led to a similar amount of myocardial necrosis and systolic dysfunction and to a more pronounced inflammatory response compared to an epicardial coronary occlusion model. Regardless of the mechanisms, failure to restore myocardial perfusion is associated with a poorer outcome[16,21-24]. In recent years, several attempts have been made to reduce or eliminate the no-reflow phenomenon. The main efforts were focused on the prevention of distal embolization of thrombus and plaque debris using devices able to aspirate the thrombus (thrombectomy devices) or to trap and remove dislocated thrombus or atheroma fragments in the distal part of the epicardial vessel (protection devices).

Other attempts to protect the microvasculature and the myocardium from injury were the use of intracoronary hyperoxemic infusion. Although oxygen-free radicals are generated during normoxemic reperfusion, paradoxically, reperfusion injury can be attenuated by treatment with high oxygen tension[25,26]. This beneficial effect is probably mediated by increasing functional capillary density[25], prevention of lipid peroxidation[27], and inhibition of leukocyte plugging[28]. Since in experimental models systemic hypothermia resulted in a reduction of no-reflow[29], an effort has been made to limit the extension of no-reflow by using systemic hypothermia in the periprocedural phase of primary PCI. Finally, in order to prevent the no-reflow phenomenon or to treat the angiographic no-reflow when present, a hyperselective drug administration into the distal bed of IRA using microcatheters has been widely introduced in routine practice of primary PCI.

Hemodynamic support during primary percutaneous coronary intervention in ST-elevation myocardial infarction complicated by cardiogenic shock. The benefit of primary PCI in terms of reduced mortality is particularly high in the setting of STEMI with signs of heart failure or in case of overt cardiogenic shock[30,31]. In this serious complication of STEMI, inotropic drugs and intra-aortic balloon counterpulsation (IABP) are used in combination, in order to maintain hemodynamic stability during primary PCI and to support the circulation after recanalization of IRA, allowing the heart to recover from stunning. However, IABP does not give an active cardiac support and requires a certain level of left ventricular function. In some patients with extremely severe left ventricular dysfunction, IABP may not be sufficient to sustain the circulation. In order to overcome these limitations, in recent years, percutaneous left ventricular assist devices have been developed to actively support the circulation during primary PCI in patients with impaired hemodynamics.

Techniques and devices for high-tech primary percutaneous coronary intervention

Thrombectomy. Thrombectomy devices (Fig. 1) are able to remove soft thrombus and atheroma debris before balloon dilation and stent implantation. This treatment aims at minimizing or avoiding the risk of macroscopic and microscopic distal embolization and allows an easier identification of lesion characteristics and length, particularly in patients with totally occluded arteries. The X-Sizer (ev-3, White Bear Lake, MN, USA) is a two-lumen, over-the-wire system (available diameters 1.5, 2.0, and 2.3 mm), 0.014" guidewire compatible, with a helical shape cutter at its distal tip (Fig. 1A). The cutter rotates at 2100 rpm driven by a hand-held battery motor unit. One catheter lumen is connected to a 250-ml vacuum bottle, and the aspirated debris is collected in an in-line filter. Repeat passages from the proximal to the distal lesions are performed by slowly advancing the activated catheter (Figs. 2 and 3). The AngioJet (Possis Medical Inc., Minneapolis, MN, USA) is a two-lumen, over-the-wire system, 0.014'' guidewire compatible, which uses the Venturi effect to create a hydrodynamic vortex that fragments the surrounding thrombus (rheolytic thrombectomy) (Fig. 1B). The clot is evacuated through the exhaust catheter lumen. The system requires a pump-drive unit that generates a high pressure to increase the efficacy of the catheter to remove more material. Technically more simple thrombectomy devices are the Rescue thrombectomy catheter (Boston Scientific, Natick, MA, USA), the Diver catheter (Invatec, Roncadelle-BS, Italy) and the Pronto extraction catheter (Vascular Solutions, Minneapolis, MN, USA), which have been recently introduced in clinical practice (Fig. 1C).

The technical success rate of thrombectomy is over 90%. The main technical limitations of thrombectomy devices are the large profile and the low trackability. These technical characteristics have several consequences. First, when proximal vessel tortuosity or diffuse calcifications are present, it may be difficult to advance the device in the coronary artery. Second, it is frequently not possible to cross severe lesions with the device. In any case it is not advisable to "force" the lesion to avoid the risk of dislocate material in the down-

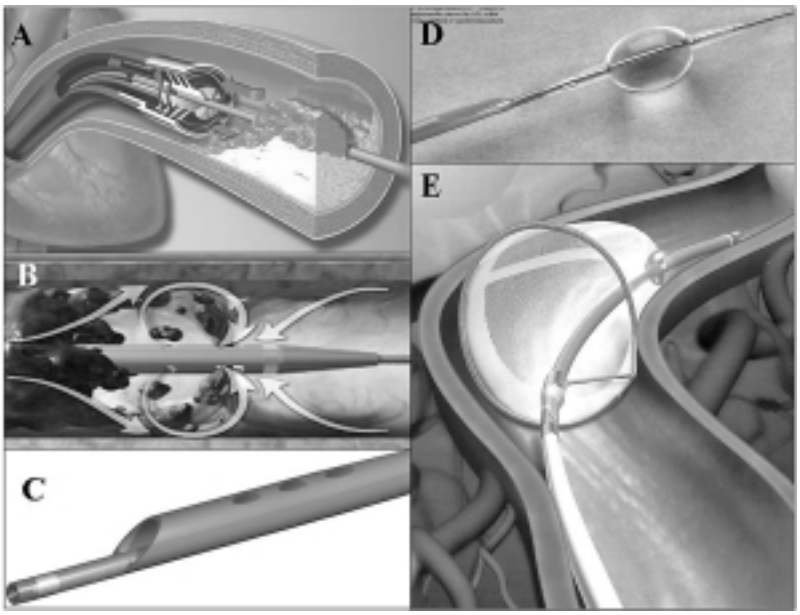

Figure 1. *Schematic representation of thrombectomy and protection devices.* A: *X-Sizer;* B: *AngioJet;* C: *Diver catheter;* D: *PercuSurge;* E: *FilterWire EX.*

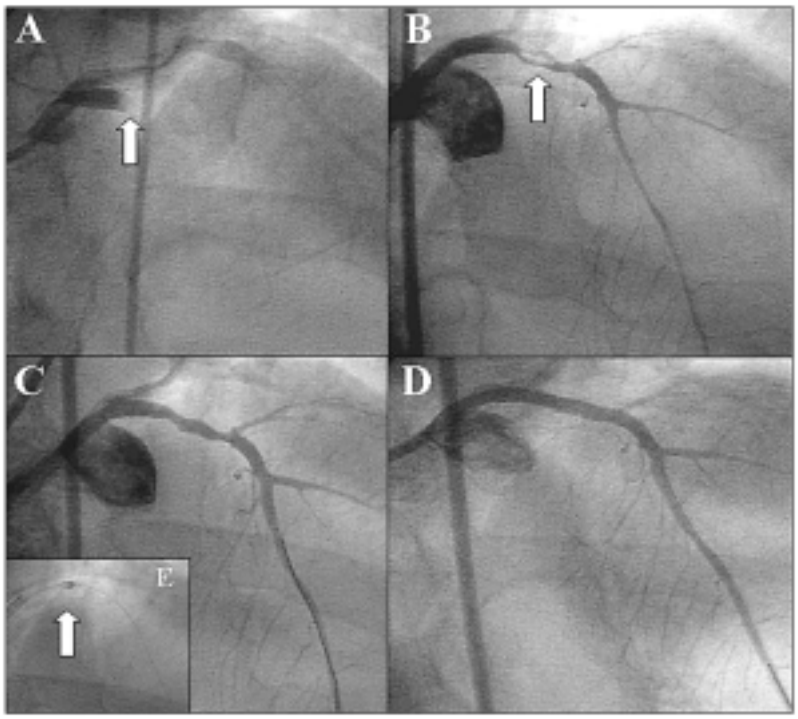

Figure 2. *Thrombectomy with the X-Sizer catheter in a case of anterior ST-elevation myocardial infarction due to proximal left anterior descending coronary artery (LAD) occlusion.* A: *proximal LAD occlusion* (arrow)*;* B: *visualization of a large thrombus in the proximal LAD after guidewire crossing* (arrow)*;* C: *intermediate result after thrombectomy with the X-Sizer;* D: *final result after stent implantation;* E: *magnification showing thrombectomy with the X-Sizer* (arrow).

stream circulation and to minimize the risk of vessel dissection or perforation.

Distal protection. Protection devices are systems able to prevent distal thrombus embolization or plaque debris during PCI. Three different protection approaches are available: distal occlusive balloons, distal filters, and proximal protection systems. At present, only the distal protection systems have undergone extensive evaluation in the setting of primary PCI. The prototype of distal occlusive balloons is the PercuSurge GuardWire (Medtronic AVE, Santa Rosa, CA, USA), which consists of a 0.014'' guidewire which presents, in the distal portion, a balloon inflated and deflated through a

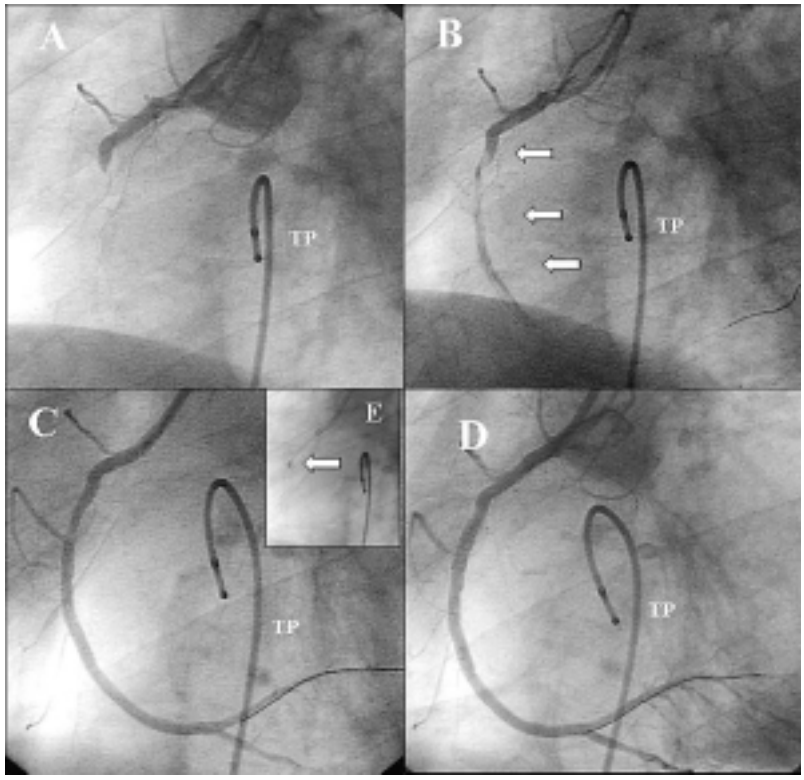

Figure 3. *Thrombectomy with the X-Sizer catheter in a case of infero-posterior ST-elevation myocardial infarction due to proximal right coronary artery (RCA) occlusion.* A: *proximal RCA occlusion;* B: *visualization of a large thrombus in the proximal and mid RCA after guidewire crossing* (three arrows)*;* C: *intermediate result after thrombectomy with the X-Sizer;* D: *final result after stent implantation;* E: *magnification showing thrombectomy with the X-Sizer* (arrow)*. TP = temporary pacemaker.*

very small channel contained in the guide itself (Fig. 1D). The lesion is crossed by means of the guidewire positioning the balloon distally to the stenosis where it is inflated: the procedure of angioplasty and stenting is then performed. Subsequently, a catheter is advanced into the distal balloon and the column of blood contained in the occluded coronary artery is aspirated. In this way clot and plaque debris possibly dislodged during the stent procedure are eliminated. Finally, the balloon is deflated and the guide is removed (Fig. 4).

Distal filter systems consist of a metallic structure (or skeleton) coated by a membrane presenting micropores. The filters are usually positioned at the distal portion of a guidewire. At the beginning of the procedure the filters are folded into a delivery catheter with which they are advanced distally to the stenosis. Once the lesion is crossed, the filter is opened by removing the delivery sheath. At the end of the stenting procedure the filter is closed with a retrieval catheter and removed from the coronary artery. Some of the more widely used distal filters are described. The FilterWire EX (Boston Scientific), is a 0.014" guidewire that incorporates a non-occluding porous membrane filter (100 μm pores) in the shape of a windsock in order to allow retention and removal of embolized particles (Figs. 1E and 5). The filter is delivered and retrieved through a 3.9F monorail sheath. The Angioguard (Cordis, Warren, NJ, USA) consists of a 0.014" stainless steel guidewire with a filter at the distal end. The filter is made of a nitinol skeleton which supports a porous polyurethane membrane with a pore diameter of 100 μm. Filters with diameter ranging from 4-5 mm are used. A 7F guiding catheter is needed to accommodate the delivery sheath (diameter 3.2-3.4F).

Both distal occlusive balloons and distal filters are placed at least 1.5 cm distally to the lesion in order to allow balloon and stent treatment ("landing zone"). The distal protection system is positioned, if possible, proximal to the origin of major side branches. The advantages of distal balloon systems are the low profile and the good trackability, which allow a better negotiation of tortuous and calcific vessels. Possible disadvantages are the impossibility to visualize the vessel with contrast medium during the balloon inflation. The advantages of distal filter systems are their easiness of use, flow maintenance, and the possibility of visualizing the distal vessel during protection. The main limitations are their large profile and a low torqueability. These characteristics limit the possibility of negotiating the vessel in the presence of proximal tortuosity or calcification.

Hyperoxemic reperfusion. Myocardial hyperoxemic reperfusion is performed following completion of primary PCI. Hyperoxemic reperfusion is obtained using aqueous oxygen solution, a liquid combination of wa-

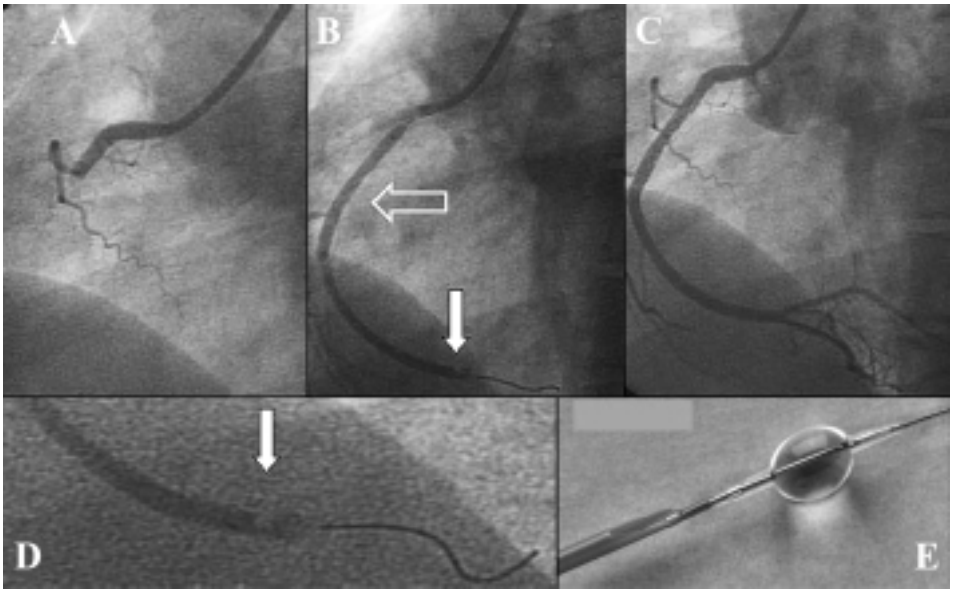

Figure 4. *Distal protection with the PercuSurge GuardWire in a case of infero-posterior ST-elevation myocardial infarction due to proximal right coronary artery (RCA) occlusion.* A: *proximal RCA occlusion;* B: *stent implantation* (open arrow) *during protection with distal balloon inflated* (closed arrow)*;* C: *final result;* D: *magnification showing the balloon* (arrow) *of the PercuSurge GuardWire inflated in the distal RCA;* E: *the PercuSurge GuardWire protection device.*

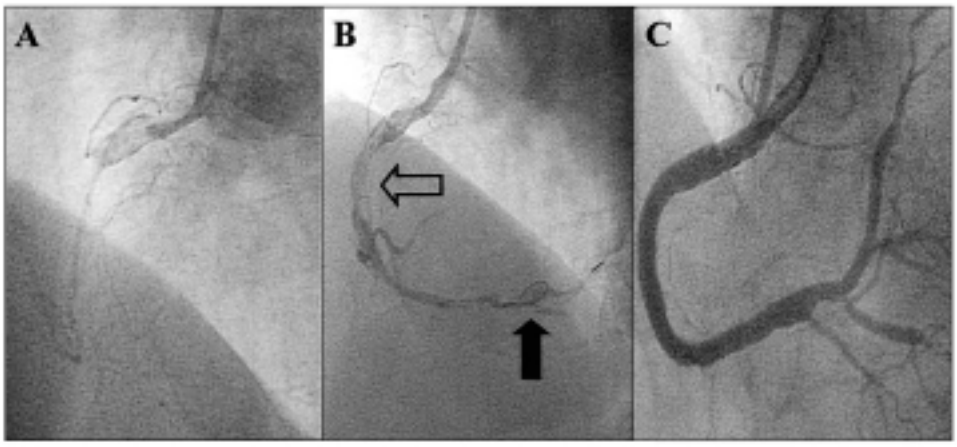

Figure 5. *Distal protection with the FilterWire EX in a case of infero-posterior ST-elevation myocardial infarction due to proximal right coronary artery (RCA) occlusion.* A: *proximal RCA occlusion;* B: *visualization of a large thrombus in the proximal and mid RCA* (open arrow) *and of the open filter in the distal RCA* (closed arrow)*;* C: *final result.*

ter and oxygen that can be mixed with blood[32]. The blood is withdrawn from the patient by means of a sheath in the radial or femoral artery and mixed with aqueous oxygen in a mixing chamber (TherOx, Inc., Irvine, CA, USA). The hyperoxemic blood (pO_2 600-800 mmHg) is then selectively infused via a guiding catheter or superselectively via a coronary infusion catheter, for 60-90 min[33].

Systemic hypothermia. Systemic hypothermia is obtained using a closed loop heat exchange catheter. The heat exchanger consists of a 10F catheter placed into the inferior vena cava via the femoral vein and cooled with sterile saline. The cooling starts immediately before primary PCI and lasts 3 hours with a target temperature of 33°C. The main side effect is the shivering, which is efficaciously controlled using buspirone and meperidine.

Hyperselective intracoronary drug administration. This is an elementary approach which requires the use of a microcatheter such as the over-the-wire balloons, the open-end catheters, or the probing catheter (Multifunctional Probing, Boston Scientific). The latter allows drug administration without the guidewire removal from the vessel. These microcatheters are used to administrate drugs (e.g. vasodilators) hyperselectively in the distal bed of IRA, achieving a high local effect and reducing systemic effects (e.g., hypotension or bradycardia).

Intra-aortic balloon counterpulsation. The physiologic principle of the counterpulsation is a rapid decrease in intra-aortic pressure synchronized to left ventricular ejection followed by a rapid increase in intra-aortic pressure during left ventricular isovolumic relaxation. Impedance to left ventricular ejection is reduced (systolic unloading), decreasing the afterload, and diastolic pressure is increased (diastolic augmentation), which improves coronary perfusion pressure. Cardiac work is therefore reduced and myocardial oxygen demand is decreased with a concomitant increase in myocardial oxygen supply. These effects are particularly beneficial in patients with cardiogenic shock. The technical characteristics of IABP are widely known: it is sufficient to remember that refinements have reduced the catheter size to 8F for 30-50 ml balloons, and have introduced technically advanced consoles, which can rapidly shuttle the helium gas with automatic timing[34].

Percutaneous left ventricular assist devices. Percutaneous left ventricular assist devices can maintain an optimal tissue perfusion and thus unload the left ventricle, avoiding the tissue injury due to shock and allowing the damaged heart to rest and eventually recover. Two kinds of percutaneous left ventricular assist device have been widely used in clinical practice. The Tandemheart (Cardiac Assist Technologies Inc., Pittsburgh, PA, USA) consists of a 21F venous catheter placed transseptally into the left atrium, a centrifugal continuous-flow pump, and a 9-17F arterial sheath inserted into the femoral artery. The oxygenated blood from the left atrium is supplied to a centrifugal pump, which returns the blood to the patient through a femoral route. The system may deliver up to 4 l/min for up to 18 days and requires heparinization maintaining the activated clotting time at ≈200 s. Limitations to the use of this device are the need for transseptal catheterization which may be technically-demanding, especially in the emergency setting of cardiogenic shock (bib), and the continuous presence of an experienced perfusion technician during the procedure. The Impella acute (Impella Cardiosystems, Aachen, Germany) is an intracardiac axial flow pump consisting of a 9F inflow catheter placed into the left ventricle and a rotor driven by an electrical motor. The catheter is inserted percutaneously via the femoral artery through a peel-away introducer with a removable hemostatic valve. The device aspirates blood from the left ventricle and expels it into the ascending aorta. The performance is ≈2.5 l/min and the operating time is up to 5 days. The main determinants of the device functioning are the pressure difference between the left ventricle and the ascending aorta and the rotary speed. The correct position of the inflow catheter may be continuously monitored using the pressure signal.

Clinical results of high-tech primary percutaneous coronary intervention

Thrombectomy. Three randomized trials (two single-center and one multicenter), have been carried out using the X-Sizer catheter in the setting of primary PCI. These studies found a statistically significant better outcome in the group treated with the X-Sizer than in the control group, in terms of corrected TIMI frame count[35], ST-segment resolution[35-37], myocardial blush grade[36] and distal embolization[37]. Moreover, the X-Sizer utilization was identified as independent predictor of ST-segment resolution[35,37] or myocardial blush grade 3[36]. Therefore, the available clinical data indicate that this device is effective in improving myocardial reperfusion as assessed by angiographic and electrocardiographic parameters. However, no benefit has been found in terms of clinical outcome.

After preliminary clinical studies showing the safety and feasibility of the AngioJet[38,39], the device underwent a clinical evaluation in two recent randomized trials, whose findings were discordant. In a single-center study[40] that compared thrombectomy with AngioJet plus direct stenting vs direct stenting alone, the patients randomized to thrombectomy showed a statistically significant improvement in terms of ST-segment resolution, TIMI frame count, and infarct size than the control group. On the other hand, a multicenter randomized trial (Ali A., 2004, unpublished data) failed to show any benefit in the group treated with AngioJet, whose use was even associated with a statistically significant larger infarct size and a higher 30-day mortality. In small single-center studies using Rescue, Diver, and Pronto catheters in the setting of primary PCI, favorable results in terms of improved TIMI flow and myocardial reperfusion parameters have been found[41-43]. These preliminary data need a further evaluation and have to be confirmed in larger prospective, multicenter, randomized trials.

Distal protection. At present, the distal protection device that underwent the most extensive clinical evaluation is the PercuSurge GuardWire. The ability of the PercuSurge in avoiding thrombus distal embolization and plaque fragments during primary PCI has been clearly demonstrated in a recent clinical study using intracoronary Doppler to detect embolic particles as high-intensity transient signals[44]. However, despite favorable preliminary results of small single-center studies[45-48], the ability of the PercuSurge GuardWire in avoiding embolization has not translated into favorable clinical results in larger randomized trials. The EMERALD trial, a multicenter, prospective, randomized trial comparing primary PCI with and without the PercuSurge GuardWire, showed a high procedural success of the device (95%) and a high incidence of visibly removed debris (73%). However, considering the whole

study population, no benefits were obtained from the use of PercuSurge GuardWire in terms of infarct size, myocardial reperfusion parameters (ST-segment resolution, TIMI frame count, myocardial blush grade), and major adverse cardiac events at 30 days. The only benefits in patients randomized to the PercuSurge GuardWire were: a significantly lower angiographic no-reflow rate; a significantly lower infarct size in the subgroup of patients whose debris were removed (Brodie B., 2004, unpublished data). The multicenter, prospective, randomized ASPARAGUS trial compared primary PCI alone vs primary PCI using the PercuSurge GuardWire. The procedural success rate was high (about 99%). The parameters of myocardial reperfusion (myocardial blush grade, corrected TIMI frame count and ST-segment resolution) and the 30-day major adverse cardiac events were similar among the protected and the control arms. The use of PercuSurge GuardWire was associated with a lower angiographic no-reflow incidence in the whole study population and with a more frequent myocardial blush grade 3 in the subgroup of patients whose IRA was the right coronary artery[49].

Distal filter systems have been investigated in recent years in the setting of primary PCI in the treatment of STEMI. The FilterWire EX was evaluated in a single-center, non-randomized study[50]. A high procedural success rate was found (89%), and the filter use was significantly associated with a lower final corrected TIMI frame count, a more frequent myocardial blush grade 3 and an ST-segment elevation resolution, a lower peak creatine kinase-MB release, and a greater 30-day improvement in the left ventricular wall motion score index and ejection fraction. The safety and feasibility of the Angioguard filter in the setting of primary PCI have been shown[51]. The DIPLOMAT Study, a prospective, randomized, multicenter study, showed a high rate of procedural success (94%) and captured debris (92%), and a trend toward a better ST-segment resolution (Morice M.C., 2004, unpublished data).

Hyperoxemic reperfusion. The safety and feasibility of hyperoxemic reperfusion have been proved in multicenter studies[33]. The clinical efficacy of hyperoxemic reperfusion was assessed in the prospective, randomized, multicenter AMIHOT trial, comparing primary PCI alone and with adjunctive hyperoxemic reperfusion. The utilization of hyperoxemic reperfusion was found to be significantly associated with a higher ST-segment elevation resolution rate. Moreover, in the subgroup of patients in whom the procedure was performed within 6 hours of symptom onset, hyperoxemic reperfusion was significantly associated with a smaller infarct size and a better regional wall motion. These benefits were particularly evident in patients with anterior STEMI (Martin J., 2004, unpublished data).

Systemic hypothermia. It has been clearly demonstrated that endovascular cooling as an adjunct to primary PCI is feasible and safe[52]. The COOL-MI, a prospective, randomized, multicenter trial tested the effect of systemic hypothermia added to primary PCI vs primary PCI alone (O'Neill W., 2003, unpublished data). The study found no advantages of systemic hypothermia over conventional therapy in the whole population but a non-statistically significant trend toward a smaller infarct size in the subgroup of patients with anterior myocardial infarction who were cooled at < 35°C.

Hyperselective intracoronary drug administration. This elementary approach has been shown to be highly safe and feasible. Its efficacy in preventing the no-reflow phenomenon and treating the angiographic no-reflow has been demonstrated using several drugs such as adenosine, verapamil, and nitroprusside[53-57].

Intra-aortic balloon counterpulsation. A benefit deriving from IABP utilization in patients with STEMI complicated by cardiogenic shock has been shown before the PCI era[58]. However, the use of IABP reduces the mortality risk in such patients when both fibrinolytic[59] and interventional[31] reperfusion therapies are performed. Therefore at present, IABP is recommended in STEMI patients in cardiogenic shock as a stabilizing measure for angiography and prompt revascularization[60].

Percutaneous ventricular assist devices. The Tandem heart pump has been specifically tested in patients with cardiogenic shock after acute myocardial infarction[61]. The percutaneous ventricular assist device significantly increased cardiac output and mean blood pressure and decreased pulmonary capillary and pulmonary artery pressures. Overall 30-day mortality was 44%. The safety and feasibility of cardiac support with the Impella system have been shown in single-center experiences[62,63]. As for its efficacy, a clinical study showed that the use of this device decreases pulmonary wedge pressure, increases cardiac output and mean blood pressure, and improves organ perfusion. In the same study the weaning and survival rates were respectively 68 and 37%[63].

Discussion

The aim of primary PCI in the treatment of STEMI is not only the restoration of normal epicardial flow, but also the achievement of optimal myocardial tissue reperfusion[64]. The myocardial reperfusion grade may be assessed by electrocardiographic parameters[11], myocardial contrast echocardiography[12], angiographic parameters[15-17], magnetic resonance imaging[14], and nuclear imaging techniques[13]. In previous studies, both myocardial blush and ST-segment reduction have been related to infarct size, left ventricular function[65], and long-term mortality after STEMI[17,66]. These ob-

servations have led to the introduction of so-called "surrogate endpoints" applied in randomized trials evaluating treatment and device strategies in myocardial infarction. The advantage of adopting surrogate endpoints is that statistically relevant results may be obtained with a much lower number of patients compared to trials with clinical endpoints (reinfarction or death) often requiring larger populations. The disadvantage of surrogate endpoints is that they can only indirectly show superiority, equality, or inferiority of one treatment over another. Several randomized studies have been recently performed to evaluate the values of adjunctive high-tech devices during primary PCI, mainly aiming at limiting the no-reflow phenomenon. The EMERALD trial evaluated the use of distal balloon protection in patients undergoing primary PCI. The primary endpoint (infarct size reduction evaluated at scintigraphy) failed to show the superiority of the procedure performed with protection. The AIMI trial, evaluating rheolytic thrombectomy, showed a larger infarct size in the thrombectomy group. This underscores the importance of the device safety and the possible learning curves when performing high-tech procedures. The AMIHOT trial using hyperoxemic reperfusion showed a favorable trend in ST-segment reduction, which achieved significance in the X-AMINE-ST thrombectomy trial. How can these data be interpreted? Probably, not all STEMI and in particular not all anatomical settings do require adjunctive high-tech devices. The X-AMINE-ST study, showing a significantly greater ST-reduction in patients treated with thrombectomy, included only patients with a total IRA occlusion (TIMI flow 0) and with angiographically documented intravascular thrombus following lesion crossing with the guidewire. In the EMERALD trial a benefit in terms of reduced infarct size was found in patients whose debris were removed, compared to patients without debris removal. Thus, the selection of patients and lesions (i.e. large thrombus, proximal vessel, etc.) that require adjunctive techniques is of great importance. Figures 3 and 5 show the thrombosed coronary arteries of acute myocardial infarction patients in whom angioplasty or stenting would have led to a very high risk of distal embolization. Although scientific data are still scanty, only a few interventionalists would have treated such patients without at least attempting thrombectomy and/or distal protection.

Another consideration is noteworthy. The etiology of the no-reflow phenomenon is multifactorial. In this process, distal embolization of thrombus and plaque debris is one, but not the only cause. An important role of endothelial damage, leukocyte abnormalities and mechanical small vessel compression has been suggested. In addition, the importance of these mechanisms might be different immediately after the recanalization of the coronary occlusion vs later during the time course of reperfusion. Therefore, a clinical research has been going well beyond device refinement, and pharmacological and cell therapy will certainly gain importance.

Conclusions

High-tech primary PCI is performed to increase myocardial salvage and improve hemodynamic status in the treatment of STEMI. Although the available study data are controversial and the clinical benefit has not clearly been shown, adjunctive devices have been widely used. Patient and lesion selection appears to be crucial and the health economics as well as the safety of high-tech devices should be carefully evaluated.

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