

Intracoronary Thrombectomy During Percutaneous Coronary Intervention in Acute Myocardial Infarction – Technology Showcase or True Need?

a report by

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Thrombectomy for patients with ST elevation myocardial infarction (STEMI) is an evolving issue. Randomised studies on suction and thrombectomy devices in a whole spectrum of STEMI patients provide conflicting results. New European Society of Cardiology (ESC) percutaneous coronary intervention (PCI) guidelines do not give definitive recommendations regarding the use of embolic protection devices for this group of patients. More randomised trials are needed; however, many operators expect beneficial clinical impact of easy-to-use manual thrombectomy devices in selected STEMI patients.

Distal Embolisation of Epicardial Artery Thrombus During Primary PCI may be a Major Contributor to Suboptimal Perfusion

In recent years it has been demonstrated that restoration of normal coronary flow in the infarct-related artery is not equivalent to the restoration of myocardial perfusion through cardiac microcirculation. After conventional primary PCI with stent implantation and IIb/IIIa blockade, the normal myocardial perfusion expressed on angiography by the tissue myocardial perfusion grade three (tMPG-3) is seen in one-third of patients. In the other two-thirds of cases, impaired microcirculatory perfusion is observed (tMPG-2 to tMPG-0), accompanied by only partial (30% to 70%) or no resolution (less than 30%) of ST segment elevation in electrocardiography (ECG). Conversely, it is recognised that complete resolution of ST segment elevation (more than 70%) in resting ECG is a good indicator of the restoration of myocardial perfusion. Accordingly, patients with impaired microperfusion have increased early and late mortality, larger irreversible myocardial injury and consequently higher incidence of adverse remodelling of the left ventricle (LV), leading to heart failure (HF).

One of the main causes of inadequate myocardial reperfusion despite restoration of epicardial flow in the infarct-related artery is embolisation of distal artery, side branches and/or microcirculation by embolic material consisted of fragmented thrombus, fragmented plaque, lipids released from the plaque

core as well as platelet and platelet-leukocyte aggregates released from the culprit lesion in the course of fibrinolytic therapy and/or primary PCI. Other reasons include increased microcirculatory resistance due to neutrophil obstruction of microcirculation and/or constriction of arterioles, progressing myocardial oedema and myocardial damage following reperfusion. In extreme cases these phenomena may amount to abrogation of epicardial flow despite removal of mechanical obstruction in the infarct-related artery (no reflow).

Distal Protection Systems in Primary PCI for Acute Myocardial Infarction (AMI)

Two distal protection devices (GuardWire and Filter WireEX) have proven to be clinically beneficial for the PCI of saphenous vein graft (SVG) lesions. The hope that the distal protection may improve results of primary PCI for STEMI is based on the fact that the PercuSurge GuardWire system provides protection from distal embolisation during each balloon inflation while thrombectomy is performed only before stent implantation. Consequently, intracoronary thrombectomy does not prevent distal embolisation from the material shed during stent implantation or following postdilatations.

Promising initial results with PercuSurge GuardWire have not yet been confirmed by the larger randomised studies, such as the Enhanced Myocardial Efficacy and Removal by Aspiration of Liberated Debris (EMERALD). Despite the fact that thrombotic and plaque debris were found in aspirates of 76% of patients, no differences were found between studied groups in angiographically assessed myocardial reperfusion, ST segment elevation resolution or infarct size measured by isotope scan at 30 days.

The results of the EMERALD trial have seriously impeached the concept of mechanical cardioprotection of microcirculation during primary PCI for AMI. The PercuSurge GuardWire system has important limitations. Aspiration of thromboembolic material is performed via an ordinary perfusion



catheter without the thrombus fragmentation – the hallmark of AngioJet or X-Sizer. It may result in the inability to remove large fragments of thrombotic debris. The GuardWire balloon is inflated 3–5cm beyond the occlusion site and as such has no ability to prevent distal embolisation of side branches originating in-between. Furthermore, if the GuardWire is advanced directly to serve as the so-called ‘buddy wire’, distal embolisation is possible from the mobilisation of thrombi in the entire arterial segment. Such a technique was used in a majority of EMERALD patients and may have accounted for some lack of distal protection efficacy.

Distal protection is also possible with intracoronary filters. Such devices have been demonstrated to improve outcomes in elective PCI in SVG. Data from large randomised studies of filters in the setting of primary PCI for AMI were not available at the time of press. At an American College of Cardiology (ACC) meeting, the 2005 Protection Devices in PCI-Treatment of Myocardial Infarction for Salvage of Endangered Myocardium Study (PROMISE) with FilterWire was announced as a negative one; however, the The FilterWire EZ System used in the Treatment of an Acute Myocardial Infarction for Embolic Protection (FLAME) large scale trial utilising FilterWire and assessing myocardial necrosis by cardiac magnetic resonance (CMR) is on-going.

Percutaneous Intracoronary Thrombectomy in AMI

Currently, there are several systems for percutaneous intracoronary thrombectomy. The most widely studied systems, both in clinical trials and everyday practice, are AngioJet (Possis Medical), X-Sizer (eV3) and Rescue (Boston Scientific). Furthermore, intracoronary thrombectomy is being performed with perfusion catheters such as the Transport Catheter (Medtronic), Diver CE (Invatec) as well as standard guiding catheters. The systems differ considerably in construction and principles of operation.

Several small studies have shown improved outcomes in AMI patients with large thrombus treated with thrombectomy during primary PCI. The initial results in small patient populations were encouraging but so far have not been confirmed in large randomised studies. During the Transcatheter Cardiovascular Therapeutics (TCT) conference 2004 in Washington DC, Arshad Ali presented the negative results of the study AngioJet Rheolytic Thrombectomy in Patients Undergoing Primary Angioplasty for Acute Myocardial Infarction (AIMI) for the first time. This failure has put the prospects of AngioJet in the treatment of AMI patients in severe doubt; however, the serious

limitations of the study have to be recognised. Only one-third of patients enrolled in AIMI presented with anterior MI. Thrombolysis in MI (TIMI) flow-0 was found in baseline angiography of only 55% of patients in the AngioJet group and 53% of patients in the control group. Conversely, absent or minimal thrombus were reported in 23% and 27% of patients, respectively. Furthermore, baseline TIMI flow-3 was statistically more frequently observed in the control group (19% compared with 27%; $p < 0.05$). Taking this into consideration, it appears that further studies will be necessary to finally elucidate the utility of AngioJet during primary PCI for AMI; specifically, higher-risk patients should be studied to determine the possible benefits.

It has been demonstrated that thrombectomy with X-Sizer prior to stent implantation during primary PCI for AMI effectively decreases thrombus mass in the culprit lesion, allowing restoration of TIMI-3 flow in a large proportion of patients and preventing slow flow, no reflow and distal embolisation, as measured by improved myocardial perfusion by angiography and improved ST segment elevation resolution at 60 minutes post-PCI. Larger scale studies will be necessary to confirm whether these favourable acute effects can result in an improvement of LV function and in the decrease of adverse coronary events in the long-term follow-up. Furthermore, technical limitations of X-sizer have to be acknowledged. The significant rigidity of the catheter decreases its ability to cope with tortuosity and excessive calcifications proximal to the culprit lesion. Its large profile disables it from crossing very tight lesions and limits its utility to arteries with reference diameter (2.5mm). The presence of the cutting blade in conjunction with difficult anatomy increases the probability of vessel perforation.

The thrombectomy system Rescue is safe and effective in thrombus removal from the coronary lumen; however, shortcomings include difficulties with complex coronary anatomy proximal to the culprit lesion. An additional limitation in comparison with X-Sizer and AngioJet is lack of active defragmentation of thrombus before removal. This seems to be the main reason why the Rescue system is less effective than the other two devices in handling massive thrombi in large coronary vessels.

Recently, the Diver CE aspiration catheter (Invatec) was introduced into clinical practice. It contains a central aspiration lumen and a soft atraumatic tip with multiple side holes communicating with the central lumen, allowing easy insertion and effective clot removal by blood

syringe aspiration from the proximal hub. The authors' preliminary experience with the Diver CE aspiration catheter in patients with STEMI undergoing primary PCI showed that it is possible and safe in the majority of patients to re-establish TIMI-3 flow in the culprit artery without balloon pre-dilatation. In most of these cases, direct stent implantation is the method of choice for a final lesion stabilisation. Whether the strategy of intracoronary thrombectomy with Diver CE followed by direct stent implantation is superior to standard balloon pre-dilatation followed by stent implantation should be confirmed in further clinical trials.

Conclusions

Despite achieving TIMI-3 flow, myocardial perfusion in STEMI remains suboptimal in a significant number of patients, resulting in larger final infarct size.

Effective removal of thrombi prior to stenting may reduce distal embolisation of thrombus, which could improve myocardial perfusion and salvage.

Distal embolic protection has not resulted in improved microvascular flow or function, nor reduction of infarct size or event free survival.

Randomised studies do not support routine use of thrombectomy devices with primary PCI in all STEMI patients for the reduction of major adverse cardiac event (MACE) rates.

Simple manual aspiration with easy-to-use catheters is able to extract atherothrombotic material from target lesions, restoring flow and increasing patency rate of an infarct-related artery before stenting. Such simple aspiration, instead of balloon pre-dilatation and direct stenting following thrombectomy, may be the hypothetical option for selected patients during primary PCI. ■

References

- Henriques J, Zijlstra J, Ottervanger J et al., "Incidence and clinical significance of distal embolization during primary angioplasty for acute myocardial infarction", *Eur. Heart J.* (2002);23: pp. 1,112–1,117.
- Anazi H, Yoneyama S, Tsukagoshi M et al., "Rescue percutaneous thrombectomy system provides better angiographic coronary flow and does not increase the in-hospital cost in patient with acute myocardial infarction", *Circ. J.* (2003);67: pp. 768–774.
- Dudek D, Mielecki W, Legutko J et al., "Percutaneous thrombectomy with the RESCUE system in acute myocardial infarction", *Kardiol. Pol.* (2004);12: pp. 523–533.
- Napodano M, Pasquetto G, Sacca S et al., "Intracoronary thrombectomy improves myocardial reperfusion in patients undergoing direct angioplasty for acute myocardial infarction", *J. Am. Coll. Cardiol.* (2003);42: pp. 1,395–1,402.
- Baran G, Lang I, Schreiber W et al., "Intracoronary Thrombectomy with the X-Sizer catheter system improves epicardial flow and accelerates ST-Segment resolution in patients with acute coronary syndrome", *Circulation* (2002);105: pp. 2,355–2,360.
- Lefèvre T, Ludvig J, "X-SIZER in AMI Patients for Negligible Embolization and Optimal ST Resolution. The X-AMINE ST Study" (2003); www.tctmd.com
- Antoniucci D, Valenti R, Migliorini A et al., "Comparison of rheolytic thrombectomy before direct infarct artery stenting versus direct stenting alone in patients undergoing percutaneous coronary intervention for acute myocardial infarction", *Am. J. Cardiol.* (2004);93: pp. 1,033–1,035.
- Arshad A, "AngioJet Reolytic Thrombectomy In Patients Undergoing Primary Angioplasty for Acute Myocardial Infarction. The AIMI Study" (2004); www.tctmd.com
- Stone G, Webb J, Cox D et al., "Distal microcirculatory protection during percutaneous coronary intervention in acute ST-segment elevation myocardial infarction. The EMERALD Trial", *JAMA* (2005);293: pp. 1,063–1,072.
- Wang H, Kao H, Liao C et al., "Export aspiration catheter thrombosuction before actual angioplasty in primary coronary intervention for acute myocardial infarction", *Catheter Cardiovasc. Interv.* (2002);57: pp. 332–339.