

## Mechanical Thrombectomy Catheter Systems

a report by

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Myocardial infarction (MI) is the leading cause of death worldwide in both men and women.<sup>1</sup> An impending infarction is recognised by ST elevation, which is predominantly the result of an occlusive thrombosis in a coronary artery. An immediate goal in MI is to restore blood flow through the occluded coronary artery. Reperfusion is carried out using primary percutaneous coronary intervention (PCI) or thrombolytic therapy; as a last resort, a coronary bypass is performed. For acute ST segment elevation, the benefits of prompt primary PCI have long been proved to be superior to those of thrombolytic therapy and coronary bypass.<sup>2</sup>

Primary PCI involves performing a coronary angiogram to determine the precise location of the infarcting vessel, followed by angioplasty. Typically, a balloon-tipped catheter is threaded through the thrombus and then inflated, widening the coronary artery. In most cases, reperfusion is successful with primary PCI; however, macro- and microembolisation of thrombotic debris occurs frequently, which may disrupt microvessel blood flow. This is where mechanical thrombectomy, which involves the use of a catheter system with a mechanical attachment, for example a pump, is advantageous. Mechanical thrombectomy allows removal of the vast majority of thrombus burden and hence prevents sections of the thrombus from travelling downstream, thus eliminating the risk of embolism. Despite the superiority of mechanical PCI for MI, systemic thrombolysis is currently the most widely used treatment.<sup>3</sup> In the US, the thrombectomy procedure is restricted to hospitals with or in reach of cardiac surgery facilities in case of complications, and can be performed only by surgeons who participate in more than 75 procedures per year.<sup>4,5</sup> This limits the number of facilities able to carry out the procedure.

### Mechanical Thrombectomy Catheter Devices

There are several devices for mechanical thrombectomy that differ considerably in construction, principles of operation and management.<sup>6-8</sup>

#### Aspiration Thrombectomy

Aspiration thrombectomy uses an 8 or 9F guiding catheter placed through a 10F arrow sheath to form a double-layered catheter.<sup>9</sup>

Aspiration is carried out manually through suction with a 60ml syringe. Manual aspiration thrombectomy effects were examined on myocardial perfusion and left ventricular remodelling in 78 patients with ST-segment elevation and clear evidence of an intracoronary thrombus.<sup>10</sup> Significant benefits were noted in patients treated with the aspiration device. However, because of the small scale of the trial, no conclusions can be drawn about the clinical outcome of the technique.

#### Rheolytic Thrombectomy

Rheolytic thrombectomy involves a high-velocity jet of saline solution ejected from a drive unit control console to create a Venturi effect at the tip of a 5F catheter.<sup>9</sup> In essence, the Venturi effect creates a pressure gradient where the pressure is lower in the catheter than in the vessel, so the thrombi are sucked into the catheter tip. Several small-scale studies demonstrate the benefits of using this technique.<sup>11-13</sup> However, the AngioJet Rheolytic Thrombectomy In Patients Undergoing Primary Angioplasty for Acute Myocardial Infarction (AIMI) study concluded that there were no benefits in terms of reduced infarct size or in thrombolysis in MI, and that this technique had an increased risk of major adverse cardiac events.<sup>13</sup> This trial was on a much larger scale than previous studies, including 480 patients across the US and Canada over three years. Further studies need to be carried out in order to come to a conclusion regarding the effectiveness of rheolytic thrombectomy in reperfusion.

#### Fragmentation Thrombectomy

The third type of catheter system used employs the fragmentation technique. This uses an 8F catheter with an enclosed impeller driven at 150,000rpm by an air turbine. The rapid spinning of the impeller creates a vortex that agitates the thrombus and drags it towards the tip, where it is broken down into particles of approximately 13µm.<sup>14</sup> One such device has been examined in a multicentre trial in Europe that enrolled 60 patients. Over 90% device safety was achieved, with 70% thrombus removal by volume.<sup>15</sup> The device was proved to be safe, effective and easy to use in comparison with other devices.

#### Benefits of Mechanical Thrombectomy Catheter Devices

The benefits of mechanical thrombectomy techniques have mainly been demonstrated in short-term studies. In one such trial, the benefit of using thrombectomy devices alongside any adjuvant therapy was examined.<sup>16</sup> With the exception of aspirin and thienopyridine, which are used to prevent stroke, combined usage of adjuvant therapy and thrombectomy provides no long-term improvements in left ventricular systolic function. This indicates that thrombectomy alone is sufficient to remove thrombotic occlusion in the coronary artery. The main improvement offered by mechanical thrombectomy over standard angioplasty is the reduction in risk of distal embolism. The balloon



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catheter has to pass directly through the thrombus in order to be inflated, which frequently leads to the breaking off of small fragments from the thrombus that can cause a blockage elsewhere. In a study examining the microcirculation between mechanical thrombectomy and angioplasty patients, the thrombectomy method resulted in higher flow rates due to the reduced risk of distal embolism.<sup>12</sup> Occurrence of macroembolisation was also negligible with thrombectomy tested on both fresh and hardened thrombi.<sup>17</sup> In addition, the procedure time of both thrombectomy and the standard balloon technique is extremely comparable. Hence, the thrombectomy technique fits into the tight time constraints in cardiac blockage. Thrombectomy also has advantages over thrombolytics. Administration of thrombolytic substances is time-consuming: the drugs take from one hour to 90 minutes to reduce the thrombus. This time delay exposes the patient to a 1% haemorrhagic stroke rate, which is an unacceptable risk.<sup>18</sup>

Thrombectomy can effectively be carried out immediately after the patient's admission to the emergency room. Therefore, patients can be relieved of MI rapidly. Approximately one-third of patients with massive pulmonary embolism are not suitable for thrombolytic therapy because of contraindications.<sup>19</sup> Also, few tertiary care units offer coronary bypass surgery on a 24-hour basis. Therefore, mechanical thrombectomy is a useful technique to implement if contraindications for thrombolytic therapy are met and surgery is not available.

#### Limitations of Mechanical Thrombectomy Catheter Devices

A limiting factor with all currently available thrombectomy catheter devices is the inability to treat wall-adherent and organised thrombus sufficiently.<sup>20</sup> The flushing or sucking technique in rheolytic and aspiration thrombectomy does not effectively break the thrombus away from the wall of the vessel. Fragmentation thrombectomy is more successful at the removal of wall-adhered thrombi because different heads can be attached to the catheter to appropriately dislodge these thrombi. Distal emboli have been recognised as a potential risk factor in terms of procedural complications with catheter thrombectomy in high-risk thrombotic lesions. All of the thrombectomy devices are bulky and require careful and gentle movements towards the thrombus to avoid the risk of distal embolism. However, in taut vessels the thrombectomy devices are often unusable.

Another fundamental issue with thrombectomy is selecting those patients suitable for the technique. The thrombotic burden is extremely variable in acute coronary occlusion and MI. The mechanical thrombectomy devices have advised use on larger thrombi; however, the exact size constraints of the devices are unclear. In some cases, deciding whether mechanical thrombectomy is appropriate may be problematic. The aspiration device has received the most criticism, as the diameter of the catheter utilised limits its use to small thrombi. Large thrombi are mobilised through the sucking of the syringe, but will not pass into the catheter; this creates a risk of embolism. Because blood is extracted alongside the thrombus in the procedure, prolonged aspiration can potentially cause haemodynamic deterioration in patients with pulmonary-embolism-related shock. This is not as apparent in the fragmentation method and does not occur with the rheolytic device. Earlier fragmentation devices suffered from a lack of flexibility, making them difficult to steer into lower lobe segments.<sup>21</sup> This has now improved with more recent fragmentation devices, but the manoeuvrability and durability of the catheter system still limits the use of the device to proximal occlusions.

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## Distal Protection Systems

Mechanical thrombectomy devices offer an improvement in terms of risk of distal embolism, but do not eliminate it entirely; therefore, distal protection devices are still deemed necessary for protection from embolism. A distal protection device was used alongside mechanical thrombectomy in 42 patients with acute MI.<sup>22</sup> The device is a thin wire with a balloon attached at one end. The wire is passed through the thrombus and the balloon is inflated approximately 3–5cm beyond the occlusion site. Improved post-PCI epicardial and myocardial perfusions were noted post-thrombectomy using this technique. However, results from a large-scale study – Enhanced Myocardial Efficacy and Removal by Aspiration of Liberated Debris (EMERALD) – contradicted these results. In this trial, no differences in reperfusion were noted between control groups and those treated with the distal protection system. Further trials need to be carried out to determine the future of this distal protection device in MI.

The balloon wire system has some limitations. For example, the balloon is inflated past the site of occlusion and hence provides no protection to debris being dragged into vessels in the space between the balloon and thrombus. Also, as the device is passed through the thrombus, it may itself fragment the clot and cause a distal embolism. This may explain why the distal protection system was not successful in the EMERALD study. Intracoronary filters have also been used to provide protection from distal embolism. Small-scale studies have demonstrated a positive result; however, as with the balloon device, larger studies have not shown a beneficial effect.<sup>20,21</sup> A slight difference was noted in the rate of distal embolism, but it was not statistically significant. The filter, like the balloon, does not provide protection to vessels between the filter and the thrombus. The required pore size to permit blood flow is approximately 100µm, yet the average size of liberated thrombus particles during PCI is less than 100µm.<sup>23</sup> The extent to which the filter prevents distal embolism is therefore in question.

## Proximal Protection Systems

An alternative to a distal protection device is a proximal device, which can also be used alongside thrombectomy to protect the patient from distal embolism. A catheter is inserted proximal to the thrombus to interrupt antegrade blood flow before the lesion area. A Feasibility and Safety Trial European Registry (FASTER) for an embolic protection device demonstrated that retrograde blood flow could be achieved safely during occlusion.<sup>24</sup> This has the advantage of capturing any size of thrombus material and eliminating the risk of it travelling distally into a smaller vessel. Currently, the proximal protection device is extremely bulky and difficult to implement in the coronary arteries. In particular, difficulties are encountered when used in the left coronary artery, as the device has to be placed into the left main, completely blocking blood flow through the artery and creating an

ischaemic burden for the patient. Visualisation of the target region can also be limited with this technique. Large-scale multicentre studies are needed to confirm the safety and feasibility of using proximal protection devices.

## Ideal Thrombectomy Catheter

None of the devices currently available has yet achieved optimal results for use in MI and for treating massive pulmonary embolism. Improvements can be made. The ideal device would be highly manoeuvrable to allow rapid passage and advancement into the arteries in the heart. Currently, fragmentation devices have good access into the proximal branches of the coronary artery, but are unusable for distal thrombi. It is unclear whether devices will ever become available that can be used in the distal regions of the coronary arteries. An essential aspect of a thrombectomy device is its effectiveness at removing obstructive thrombi from coronary arteries, thereby achieving a rapid improvement in haemodynamics and avoiding ischaemic complications. The device also needs to be safe for the patient and be able to be used without causing damage to cardiac structures and pulmonary arteries. Blood loss during the procedure should be minimised, along with the risk of distal embolism. Currently, all devices for thrombectomy are extremely costly, and some medical institutions view this as a major disadvantage to their use. A government subsidisation scheme is necessary to reduce the cost to healthcare institutes.

## Future Directions

Conflicting results have been drawn from clinical trials testing thrombectomy catheter treatments. Fragmentation thrombectomy has achieved the best clinical results to date and is the thrombectomy method of choice for most healthcare institutes. Currently, implementation of the device depends on the personal opinion of the surgeon; pivotal long-term trials measuring clinical end-points of thrombectomy treatment are lacking. These need to be undertaken in order for the devices to be universally used. Success of a full-scale, long-term trial will also boost the chances of setting up a government subsidisation scheme.

## Summary

Mechanical thrombectomy catheter devices have been demonstrated to be beneficial in removing thrombotic occlusions in the coronary artery in small-scale trials. There are three types of thrombectomy device: aspiration, fragmentation and rheolytic. Both rheolytic and aspiration devices have been unsuccessful to some degree in clinical trials; fragmentation thrombectomy is therefore the most commonly used technique. Improvement is required in terms of manoeuvrability, effectiveness at removing the thrombus and reduction of damage to the patient. To date, no large-scale clinical trial has monitored the success of thrombectomy treatment at the clinical end-point or beyond. This needs to be accomplished to encourage more universal usage of the device. ■

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