A randomised comparison of the Omniflex and Magnarail systems in recanalisation of coronary occlusions

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Abstract

Objective—The reported success rates for angioplasty of occluded coronary arteries fall some way short of the success rates for angioplasty of sub-occlusive stenoses. Two angioplasty systems used in this setting were compared.

Design—A prospective randomised open study comparing the Magnarail system (Schneider) and the Omniflex system (Medtronic).

Setting—A regional cardiothoracic centre performing over 300 angioplasty procedures a year.

Patients and methods—50 consecutive patients with occluded (thrombolysis in myocardial infarction study (TIMI) grade 0 or 1) arteries thought to be suitable for recanalisation were assigned to undergo angioplasty with either the Magnarail or Omniflex as the primary system. Twenty minutes of fluoroscopic screening was allowed with the primary randomised system before it was considered a failure. The other non-randomised system could then be used at the operators' discretion, and a further 20 minutes' screening was permitted.

Main outcome measures—A patent coronary artery with a residual stenosis of <50% with prompt distal opacification (TIMI grade 3 flow) and a reduction in collateral supply to the index artery.

Results—The overall success rate in recanalising occluded vessels was 72%–64% for the Magnarail system used as the primary system and 51%–7% for the Omniflex (NS). The Magnarail was more successful in angioplasties of the right coronary artery (11/14 v 3/10, p = 0.02) and in mid and distal sites of occlusion (11/17 v 4/14, p < 0.05). There was a trend in favour of the Omniflex in the left anterior descending coronary artery.

Conclusion—Both systems would seem to be suitable for angioplasty of occluded coronary arteries. The improved steerability of the Magnarail may be advantageous in distal occlusions and lesions in tortuous arteries. The relatively stiffer Omniflex may be superior for proximal occlusions. The study group was too small to confirm this unequivocally.

Although totally occluded coronary arteries were not initially considered to be an indication for percutaneous transluminal coronary angioplasty, Gruentzig's first series of 1000 patients contained 13 whose arteries had occluded between the time of diagnostic angiography and angioplasty. Recanalisation was attempted in all and was successful in 62% (cited by Meier).

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We have undertaken a prospective randomised open study to compare the two systems.

Patients and methods

Patients

Fifty consecutive patients with non-acute coronary occlusions that were thought to be amenable to angioplasty by the operator were enrolled in a prospective, open, blind study. Table 1 shows the demographic and angiographic features. The groups randomised to either system were similar in demographic and angiographic variables. The vessel was considered occluded if there were no more than TIMI grade 1 flow to the index vessel. The occlusion was judged to be distal if it occurred in the distal two thirds of the index artery and proximal if it was located in the proximal one third. Occluded saphenous vein grafts and arterial occlusions without a stump, which have a low procedural success, were not considered suitable. Similarly, acute vessel occlusions after an acute myocardial infarction, which have a high success rate, were excluded.

Study protocol

After diagnostic angiography had confirmed the artery to be occluded, 25 patients were randomised to undergo attempted recanalisation with the Magnarail system and 25 the Omniflex system. The procedure was considered successful if there was a residual stenosis of \( < 50\% \) at the site of angioplasty at the end of the procedure. If the angioplasty resulted in an intimal dissection the procedure was only considered a success if there was also prompt distal opacification (TIMI grade 3 flow) and a reduction in collateralisation to the index artery.

Twenty minutes of fluoroscopic screening to cross the area of occlusion were permitted with the randomised system. Timing was started when the guide wire reached the end of the guide catheter. If this was unsuccessful the operator could then use the alternative non-randomised system and a further 20 minutes screening was allowed.

Angioplasty procedure

All patients were premedicated with 150 mg aspirin. A total of 20 000 units of heparin was routinely used throughout the procedure. Both systems required adequate support from the guide catheter necessitating deep engagement in the coronary ostium. This often damped off coronary pressure and it was often necessary to use a guide catheter with side holes to maintain perfusion to large side branches proximal to the site of occlusion.

Magnarail system

When the guide catheter was in a stable position, the Magnun wire was advanced to the lesion. With a series of half turns and continuous advancement of the wire, it was usually possible to cross the lesion. Injection of contrast through the guide catheter at this point often showed the vessel to be open and confirmed that the wire had not tracked into the intima. If there were no antegrade flow, multiple rotations of the guide wire that produced revolution and “dancing” of the floppy tip confirmed that the wire was intraluminal.

If the wire failed to cross the occlusion, the flexible tip could be braced by advancing the balloon catheter to the end and the whole rigid system advanced through the occlusion. These manoeuvres required a stable guide catheter position for support. Where this was inadequate, inflation of the balloon catheter proximal to the area of occlusion braced the equipment and provide a better foundation for the attempted recanalisation.

Once the area of occlusion was negotiated, the balloon catheter could be tracked over the wire and inflated. In the event of an inadequate result the rapid exchange facility allowed a larger balloon to be used without removing the wire from its position across the lesion.

Omniflex system

Use of the Omniflex system also required deep engagement of the guide catheter in the coronary ostium. The system was then advanced toward the point of occlusion. Steering of the Omniflex was facilitated by rotation of the integrated torqueing device at the proximal end that allowed the tip to flex to an angle of 90°. Once the Omniflex was in position, further axial force would usually allow the system to cross the occlusion. Repeated injections of contrast into the coronary artery through the guide catheter confirmed that the wire had remained intraluminal and had not tracked into the arterial wall.

If there was angiographic evidence of an intimal dissection, prolonged balloon inflation was used in an attempt to rectify the situation if the operator thought the dissection was prejudicial to a successful result.

All patients who had a successful procedure were treated with the anticoagulant warfarin for three months.

Table 1 Demographic and angiographic features of patients randomised to undergo angioplasty with Magnarail or Omniflex as the primary system

<table>
<thead>
<tr>
<th></th>
<th>Magnarail (n = 25)</th>
<th>Omniflex (n = 25)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (SD) (yr)</td>
<td>57-10(9-6)</td>
<td>56-0(8-6)</td>
</tr>
<tr>
<td>Sex</td>
<td>17:8</td>
<td>19:6</td>
</tr>
<tr>
<td>Estimated duration of occlusion (weeks)</td>
<td>8-6(6-9)</td>
<td>10-2(6-7)</td>
</tr>
<tr>
<td>Mean SD</td>
<td>2-26</td>
<td>2-5-32</td>
</tr>
<tr>
<td>Distance from the guiding catheter</td>
<td>Stable angina</td>
<td>17</td>
</tr>
<tr>
<td></td>
<td>Unstable angina</td>
<td>8</td>
</tr>
<tr>
<td>Coronary artery:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>LAD</td>
<td>9</td>
<td>11</td>
</tr>
<tr>
<td>RCA</td>
<td>11</td>
<td>8</td>
</tr>
<tr>
<td>LCX</td>
<td>5</td>
<td>6</td>
</tr>
<tr>
<td>Degree of occlusion:</td>
<td>TIMI grade 0</td>
<td>14</td>
</tr>
<tr>
<td></td>
<td>TIMI grade 1</td>
<td>11</td>
</tr>
<tr>
<td>Location of occlusion:</td>
<td>Proximal</td>
<td>12</td>
</tr>
<tr>
<td></td>
<td>Distal</td>
<td>13</td>
</tr>
</tbody>
</table>

LAD, left anterior descending coronary artery; RCA, right coronary artery; LCX, left circumflex coronary artery; TIMI, thrombolysis in myocardial infarction study.13
STATISTICAL ANALYSIS
Data are presented as mean (SD). Categorical variables were analysed with Fisher's exact test. Continuously distributed variable were analysed with an unpaired Students' t test. A p value < 0.05 was considered significant.

Results
The overall success rate for the primary system was 60% (30/50) and increased to 72% (36/50) after success with the non-randomised secondary system. No patients died during the procedure and no patients required immediate coronary surgery.

Table 2 shows the primary and overall success of each system. The success rate for the Magnarail used as the primary system was 64%. After including five extra cases in which it succeeded when used as a secondary system, the overall success rate was 63-6%. The Omniflex succeeded in 56% of primary procedures with an overall success rate of 51-7% when its single instance of success as a secondary system was included. These differences were not significantly different, perhaps because of small numbers.

There was a clear advantage of the Magnarail system in attempted recanalisation of the right coronary artery (11/14 v 3/10, p = 0-02) and also distal occlusions (11/17 v 4/14, p = 0-04). There was a trend towards greater success in angioplasty of the left anterior descending coronary artery with the Omniflex rather than the Magnarail as a primary system (9/11 v 8/9). When the additional use of each as a secondary system was included, the difference still failed to reach statistical significance.

Overall, the non-randomised apparatus was used in 12 instances and was successful in six where the primary, randomised system had failed. The Magnarail was used as the secondary system in eight instances and was successful in five. The Omniflex system was used four times as the secondary system and succeeded once. The operator did not proceed with the secondary system in seven cases. Four of these were after attempted recanalisation with a Magnarail system that had induced noticeable intimal dissections and the operator considered that further attempts would be hazardous. Similarly, the Omniflex induced a dissection in two procedures preventing cross over to the Magnarail and also in one attempt the patient became hypotensive and the procedure was abandoned.

The mean screening time to cross the occlusion for successful procedures with the Magnarail as the randomised or secondary system was 7-4 (6-5) minutes compared with 5-8 (3-8) minutes for the Omniflex system (NS). The total procedural screening time to achieve a successful radiological result was 11-2 (7-1) minutes with the Magnarail and 14-1 (8-7) minutes for the Omniflex system (NS).

Discussion
Both the Magnarail and the Omniflex systems have been advocated as the system of choice in attempted recanalisation of coronary occlusions but never compared in a prospective randomised trial although the Magnum wire/Magnarail system has been shown to be superior to conventional equipment in chronic total occlusions.

Overall, both systems are equally effective in recanalisation of occluded coronary arteries and achieve a satisfactory procedural success rate comparable with other reported successes. Both pieces of equipment have previously been reported to have primary success rates over 70%. Thus a very large study would be required to detect a difference. Both have a different design and require a different technique to achieve success. The study design was such that if either system had more than 30% superiority over the other, the study had an 80% chance of detecting it.

The Omniflex system superficially resembles the design of the original Gruentzig balloon in stiffness and relies largely on thrust transmitted to the tip to succeed. It differs from the Gruentzig balloon in that it is steerable, although the torquing device is perhaps more cumbersome than a bare wire and the system is less manoeuvrable as a result. This is reflected by its lower success rate in distal occlusions and in the naturally tortuous right coronary artery. Its rigidity and straightness may be more suited to occlusions of the left anterior descending coronary artery, which is often aligned directly with the guide catheter and is relatively straight in alignment. By contrast, the Magnum wire with the flexible tip is more easily steered but its flexibility may be a disadvantage when the occlusion is encountered. Thus it is often necessary to brace the tip with the balloon catheter. The steerability may account for its relative success in negotiating tortuosities in the right coronary artery.
and allowing successful recanalisation of distal occlusions.

In conclusion the Magnarail and Omniflex systems seem equally effective in angioplasty of occluded coronary arteries. The Magnarail may be more suited to tortuous vessels, especially the right coronary artery, because of its improved steerability whereas the stiffer Omniflex may be more suited to proximal occlusions in the left anterior descending coronary artery although the size of this study was not powerful enough to categorically confirm this.