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Novel Device for Recanalization of Chronic Total Occlusions

A.M. Babunashvili, A. D. Dundua, Z. A. Kavteladze, D. S. Kartashov, V. V. Korobov

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Introduction

Chronic total occlusions (CTO) of coronary arteries (CA) still are considered as ones of the most complicated atherosclerotic lesions for percutaneous interventions. In spite of some progress in the development of new devices and experience accumulation, the success rate of endovascular procedures for occlusive lesions of CA does not exceed 80–85%. At the same time the rate of successful percutaneous interventions in cases of atherosclerotic stenoses reaches 99–100%. The main reasons for the failure of recanalization in CTO are as follows:

a) Occlusion cannot be passed with metallic and/or hydrophilic guidewires.

b) Guiding catheter can not be adequately engaged at the orifice of recanalized CA.

c) Guidewire sometimes passes subintimally and can not be redirected into a distal part of true artery lumen beyond the occluded site.

d) Balloon catheter for predilatation of the occluded segment can not be passed even after successful guidewire recanalization.

It is necessary to visualize collateral blood circulation and the lumen of occluded coronary artery distal of the occlusion segment to make sure that the tip of a guidewire is inside the true artery lumen beyond the occluded segment. Though the second arterial access and catheterization of both coronary arteries are often required.

We introduced a novel device that may solve some of the abovementioned problems, increase safety and controllability of the endovascular recanalization of CTO.

The device description

The device is created on the base of a monorail dilatation balloon catheter. Of note, the balloon segment of any catheter enlarges the diameter (profile) of its distal end and in some cases even the balloon catheter with minimal profile (1.5F) can not be passed through the occluded site. For purpose of decreasing the catheter profile we have removed its balloon part carefully with a scalpel. The resulting dual-lumen catheter had one individual lumen for inserting over a wire guide and the other (balloon) lumen connected with catheter pavilion and remained open. This enabled injecting contrast medium and thereby controlling a position of the device tip in an artery lumen (Fig.1). Usually the profile of a distal part beyond a balloon segment of the majority of modern catheters is 0.018–0.020 inches (0.4–0.5 mm), which is comparable with a diameter of metallic coronary guidewires used for recanalization. After removal of a catheter balloon part this segment lengthened for 12–20 mm. Hereby, we have obtained ultra-low profile, relatively long (20–30mm) active part of a catheter for better penetration of a compact occluding material. Besides, it is important that it became possible to opacify a created tunnel

Table 1. Clinical and angiographic data of the patients

<table>
<thead>
<tr>
<th>Sex</th>
<th>Age</th>
<th>Artery</th>
<th>Duration of the occlusion, months**</th>
<th>Length of the occlusion, mm*</th>
<th>FC by CCS</th>
<th>Diabetes</th>
<th>EF &lt;0.5</th>
</tr>
</thead>
<tbody>
<tr>
<td>M</td>
<td>65</td>
<td>RCA</td>
<td>24</td>
<td>64</td>
<td>II</td>
<td>–</td>
<td>–</td>
</tr>
<tr>
<td>M</td>
<td>61</td>
<td>RCA</td>
<td>18</td>
<td>80</td>
<td>II</td>
<td>–</td>
<td>–</td>
</tr>
<tr>
<td>M</td>
<td>51</td>
<td>OMB</td>
<td>8</td>
<td>34</td>
<td>III</td>
<td>+</td>
<td>–</td>
</tr>
<tr>
<td>F</td>
<td>54</td>
<td>RCA</td>
<td>36</td>
<td>72</td>
<td>III</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>F</td>
<td>52</td>
<td>RCA</td>
<td>54</td>
<td>84</td>
<td>II</td>
<td>–</td>
<td>–</td>
</tr>
<tr>
<td>M</td>
<td>60</td>
<td>LAD</td>
<td>12</td>
<td>42</td>
<td>III</td>
<td>*</td>
<td>+</td>
</tr>
<tr>
<td>M</td>
<td>52</td>
<td>LAD</td>
<td>10</td>
<td>48</td>
<td>II</td>
<td>–</td>
<td>–</td>
</tr>
<tr>
<td>M</td>
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</tr>
<tr>
<td>M</td>
<td>64</td>
<td>RCA</td>
<td>4</td>
<td>17</td>
<td>III</td>
<td>–</td>
<td>+</td>
</tr>
</tbody>
</table>

Mean value 20.8 ± 6.9 54.9 ± 3.8 –

Note: * measured by digital computer angiography (DCA); ** approximate evaluation based on the medical history; FC by CCS — functional class of angina pectoris according to the Canadian Cardiac Society classification; EF — ejection fraction; RCA — right coronary artery; OMB CA — obtuse margin branch of circumflex artery; LAD — left anterior descending artery.
and verify catheter and guidewire insertion into a true lumen of recanalized artery.

**Clinical cases**

We used the novel device for recanalization of chronic CA occlusions in 9 patients (Table 1). A good visualization of a distal segment of the occluded CA by intercoronary collaterals have been noticed in all cases.

In all 9 cases the recanalization of the occlusion was first attempted by using a metallic guidewire (hydrophilic guidewires Shinobi, Pilot or Asahi family), but if passage of the low profile balloon catheter failed we tried to succeed by new device. Using it we managed to verify definitely that the catheter was located inside the true artery lumen and to create primary channel for subsequent passage of balloon catheters or stents in order to complete the procedure (Fig.2). In the majority of cases it was not technically difficult to pass the catheter through the occluded zone due to low profile of its distal segment. Only in two cases we had to use guiding catheter deep intubation into the CA lumen to secure adequate passage of the catheter.

**Discussion**

The suggested device is easy to make and does not require additional expenses. The device is based on “routine” single-rail balloon catheters manufactured by well-known brands. The described construction provides safe manipulation for a recanalization of occluded CA. It is known that in 10–15% of recanalization failures guidewire goes into a “false” lumen of an artery distal segment beyond the occlusion site (into a subintimal space, and in the worst case a perforation of an artery wall can occur).

Only three ways to verify threading a catheter through a true artery lumen are known for today:

1. Visualization of a distal segment of the occluded artery by opacification through collaterals;
2. Inserting a thin microcatheter (Transit type or perfusion catheter 3F) over a long (300cm) guidewire beyond the occlusion zone and visualization of a distal segment by injecting contrast medium through catheter lumen;
3. Intracoronary ultrasonic examination to detect the position of a guidewire and a catheter in the occluded and/or more distal segment.

It is important to note that the position of subintimally passed guidewire under fluoroscopic control coincides with suggested anatomic path of the distal segment of recanalized artery beyond the occlusion site (Fig.3). For this reason, to make sure that the tip of a guidewire is inside the true artery lumen it is necessary to catheterize the orifice of another CA (if intercoronary collaterals exist), that makes the procedure longer and much more complicated. This requires puncture and catheterization of another access artery (femoral or radial), therefore increasing the risk of bleeding and other complications associated with catheterization of peripheral artery.

Intracoronary ultrasound control of the guidewire and catheters passage through the true channel
of the occluded segment proved to be sufficiently effective in Colombo and Tobias studies. However, intracoronary ultrasound examination makes recanalization procedure significantly more complicated and expensive, and is technically applicable only in a limited number of cases.

For the same purposes over-the-wire balloon catheter (over the wire) can be used. After advancing the catheter tip to a distal segment beyond the occlusion site the guidewire should be removed from the central lumen and contrast medium injected. But first of all, a profile of dual-lumen balloon catheters is always larger than that of single-rail ones, and secondly, the body of monorail catheter unlike dual-lumen catheter is made out of a thin hollow metallic tube, which increases its rigidity and radial stability. This is especially important when passing through “old”, compact occluding masses. Thus, besides the opportunity to control the position of the catheter tip in a true lumen of artery, the new device provides adequate support while passing through chronic occlusive lesions. Furthermore, manipulations with monorail catheters require just a short guidewire, they are much easier to perform and usually can be done by one operator, whereas operations with dual-lumen balloon catheters (or other long thin catheters of Transit type) require a long guidewire and an assistant. Naturally, single operator is able to provide better coordination of manipulation when using a monorail catheter.

In 3 of 9 cases successful application of this device resulted in forming a tunnel about 1 mm in diameter in occluding material (Fig. 4), that enabled stenting without preliminary balloon dilatation and saving an expensive ultra mini-profile balloon catheter. Finally, making these devices out of hydrophilic balloon catheters (like that manufactured by Acrostak Company, Switzerland, or Arashi catheter, manufactured by Terumo Company) will improve the penetration ability of the device.

**Figure 4.** Coronary angiograms of a male patient aged 52:
A – Chronic RCA occlusion in the middle segment with filling of distal lumen only through intercoronary collaterals;
B – After penetration of the occluded vessel segment with the device. On the coronary angiogram distal RCA lumen (pointed with arrows) is clearly visualized through the open balloon channel. This confirms that the catheter tip is inside the true lumen;
C – After the extraction of the recanalization device a thin tunnel (pointed with arrows) in the occluded segment has formed. This tunnel facilitates passage of balloon catheters for additional predilatation.
D – After the balloon predilatation three drug-coated stents (pointed with arrows) have been implanted into the occluded RCA segment with good immediate angiographic result.