New Percutaneous Transluminal Coronary Angioscope

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A new percutaneous transluminal coronary angioscopic catheter has been developed for visualization of the coronary artery. A specially made balloon, fixed at the catheter tip, and an angulation mechanism made a precise coaxial alignment possible in the coronary lumen. This angioscopic catheter, 1.22 mm in outer diameter, has four channels, one for irrigation in which a 0.36 mm (0.014 in.) angioplasty guide wire can be used.

With the use of this angioscope, coronary lumens in 8 dogs, thrombi that were produced with copper coils in the left anterior descending coronary artery in 11 dogs, atherosclerotic coronary arteries in 20 patients during cardiac catheterization and the sequence of transluminal coronary angioplasty in 1 patient were observed. The angioscopic catheter was introduced into the coronary artery by an SF guide catheter. The steerable guide wire enabled the angioscopic catheter to be accurately and safely inserted into the target lesion in all cases. The inflated balloon and angulation mechanism allowed a curved coronary lumen and atheroma to be seen with a limited volume of irrigation fluid.

Visualization was good (complete visualization of the inner lumen) in 46% (10 of 22 lesions), moderate (visualization of <50% of the inner lumen) in 36% (8 of 22 lesions) and poor (visualization of <50% of the inner lumen) in 18% (4 of 22 lesions) in humans. There were no major complications.

These preliminary experiences in closed chest cardiac catheterization in dogs and in humans indicate the feasibility of this angioscope. The information yielded by angioscopy may be clinically useful in the study of the pathophysiologic changes in coronary disease that are not detected by coronary arteriography.

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neous transluminal coronary angioplasty guide wire can be used (Fig. 1), one (0.3 mm) is for balloon inflation, one (0.3 mm) is for angulation of the distal tip and one is for the image and light guide fibers. The essential function of visualization of the angioscope is built in a 0.5 mm diameter channel. The flow rate of irrigation is 0.6 ml/s.

A specially made inflatable polyurethane balloon is fixed at the tip of the angioscopic catheter (Fig. 1). The balloon was attached as close as possible to the distal end of the angioscopic catheter and the length of the balloon was shortened to obtain good coaxial alignment. The inflated balloon diameter ranges from 2.5 to 5.0 mm. The image guide (0.26 mm in diameter), consisting of 2,000 pixels made of doped silica glass, is flexible and compact. The permissible bending radius of this image guide is 8 mm in diameter. The visual angle is about 55°. The light guide consists of a bundle of multicomponent glass fibers set around the image guide. To indicate the location of the tip of the angioscopic catheter under X-ray monitoring, gold rings that are set at the proximal and distal sides of the balloon are used. These rings also are used to clamp the balloon to the angioscopic catheter.

The new angioscopic system consists of a CCD color camera, a xenon lamp light source, a cathode ray tube display, a video documentation system and an image processor. The color quality of the presentation is automatically controlled, but the intensity is manually controlled. This equipment is a modified version of the commercially available FCA-8000 (Fukuda Denshi Co., Ltd.).

Animal experiments. Nineteen mongrel dogs weighing 10 to 15 kg anesthetized with sodium pentobarbital (35 mg/kg body weight) were endotracheally intubated and ventilated with a ventilator (Harvard model SN-480-3). A right carotid artery exposure was made and a 9F guide catheter (thin wall Lehman catheter) was inserted into the left anterior descending coronary artery. The lumen was observed by flushing saline solution with balloon inflation. Normal saline solution, maintained at 37°C by a warming coil, was used as the irrigation fluid.

In 11 dogs a copper coil was inserted through the right carotid artery to the proximal left anterior descending artery with the use of an 8F Sones catheter and guide wire (0.035 in., [0.089 mm]). Thrombus formation was observed.

Clinical study. Angioscopic examination of 22 coronary stenotic lesions was performed in 20 consecutive patients (17 men and 3 women, 48 to 69 years old). Ten patients had stable angina, 9 had a previous myocardial infarction and 1 had an acute non-Q wave myocardial infarction. Visualiza- tion of 14 lesions was attempted in the left anterior descending artery, 7 lesions in the right coronary artery, and 1 lesion in the left circumflex artery. In one patient who underwent percutaneous transluminal coronary angioplasty, changes in the stenotic lesions were observed. Informed consent approved by our institutional review board was obtained from all patients.

Angioscopic procedure. Immediately before the angioscopic examination, heparin (5,000 U) was injected intravenously. Then an 8F Shiley guide catheter was inserted from the right femoral artery to the right or left coronary ostium. One arm of an Advanced Catheter Systems (ACS) angioplasty Y connector was attached to the proximal end of the guide catheter and was connected to a standard manifold for both pressure monitoring and injection of contrast material.

The angioscopic catheter was introduced into the other arm of the Y connector to the coronary artery by this guide catheter. The USC1 angioplasty Y connector was connected to the end of the irrigation channel. The 0.36 mm (0.014 in.) angioplasty guide wire was advanced through this Y connector to the target lesion and the angioscopic catheter was advanced through this guide wire. This catheter could reach the vicinity of the terminal (distal) segment of the anterior descending artery, to the distal segment of the circumflex artery and to the segment immediately proximal to the posterior descending branch of the right coronary artery. The location of the tip of the angioscopic catheter was easily confirmed by the gold marker (Fig. 2). The irrigation material
was similar to that used in the animal study, but heparin (10 U/ml saline solution) was added in the clinical study. When a good coaxial position of the angioscope could not be obtained, the balloon was inflated or the tip of the angioscope was angulated. When replacement of blood with saline solution in the coronary artery was not achieved or if there was a risk of embolization of thrombus by vigorous flushing in a patient with myocardial infarction, the balloon was inflated.

We performed microscopic examination in two live dogs and two fresh human cadaver hearts at the site of balloon inflation. Major changes such as intimal or medial splitting or thrombus formation were not seen by hematoxylin-eosin stain in the dogs. Mild splitting of the internal elastic lamina was observed by elastica Masson's trichome stain in one dog, but we did not observe this change in another dog or in the human cadaver coronary arteries. Because the splitting

Figure 3. A, An anterograde view of the thrombus that was made by a copper coil in a canine coronary artery. The copper coil (left side) and the red and white thrombus (right side) are observed. All pictures of coronary lumens were duplicated from video documentation. The plaque is yellow and the surface is smooth. B, Angioscopic view of the same patient shown in Figure 4A. C, Angioscopic view of the same patient shown in Figure 4B. An irregular surface with yellow atheroma is observed. The red area of the atheroma might be mural thrombus.

Figure 4. A, This patient had myocardial infarction 1 month previously. The right coronary arteriogram shows multiple stenoses. The segment observed by angioscopy is indicated by the arrow. B, Left coronary artery of a patient with acute non-Q wave myocardial infarction. An 80% stenosis is seen in the mid-left anterior descending coronary artery. The lesion is not irregular.
might be caused by overstretching of the coronary artery, we used a balloon with a smaller diameter than the coronary diameter at the proximal site of stenosis to prevent injury of the coronary lumen during balloon inflation. The balloon was inflated by hand with use of a small syringe to a volume of 0.15 to 0.4 ml. Clearer visualization and better coaxial alignment could be obtained by flushing and balloon inflation than by flushing alone. The ability to track this angioscopic catheter was slightly less than the ability to track a standard angioplasty balloon catheter. However, there was no problem in tracking over the guide wire.

### Results

**Animal experiments.** The inner lumen and copper coil were demonstrated by flushing with saline solution with or without balloon inflation and with or without an angulated tip. When the coronary artery was completely occluded with the balloon, only 0.5 to 1 ml of saline solution was needed to visualize the inner lumen. Observation continued until ST segment elevation appeared on the electrocardiogram (usually within approximately 25 s).

Thin mixed white and red thrombi formed around the copper coil, grew in size and finally obstructed the coronary lumen (Fig. 3A). Thrombi were not formed on the angioscopic catheter during the procedure.

**Clinical study.** In all cases the angioscopic catheter could be advanced with the guide wire to the target lesion. Balloon inflation was necessary to completely replace blood with saline solution in all cases in the left anterior descending artery and in three of six cases in the right coronary artery. Visualization, obtained with use of a 2 to 5 ml hand-controlled syringe injection, was maintained for 3 to 5 s.

During injection of saline solution as well as contrast material, transient (10 to 30 s) T wave inversion with or without ST segment depression developed without associated symptoms. Because the coronary artery is curved, coaxial alignment of the angioscope within the coronary lumen is difficult. We classified the observation of the target lesion into three groups in terms of coaxial alignment: good (complete visualization of the inner lumen); moderate (visualization of >50% of the inner lumen); and poor (visualization of <50% of the inner lumen; that is, most of the visualized field was vascular wall). The target lesion was defined by the severity of stenosis; the most severe or the second most severe stenosis was chosen for observation.

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<tr>
<th>Target Lesions Undergoing Angioscopy</th>
<th>Visualization</th>
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<tr>
<td></td>
<td>Good</td>
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<td>Left anterior descending coronary artery</td>
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<tr>
<td>Right coronary artery</td>
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<td>Left circumflex coronary artery</td>
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Figure 5. Coronary arteriograms before and after coronary angioplasty in a patient undergoing angioscopic examination. There is 68% stenosis in the proximal left anterior descending coronary artery (A); the stenosis is concentric and longitudinally extensive. After coronary angioplasty, the original degree of stenosis is reduced to 16% (B). On angioscopy before angioplasty, a round lumen is seen (C). After angioplasty, reddish and yellowish coloration is visible (D).
The degree of visualization and the target lesions undergoing angioscopy are summarized in Table 1. Good to moderate visualization was obtained in proximal lesions. Effectiveness of visualization depended on the radius of the coronary artery. It was difficult to observe the entire lumen in mid or distal lesions because the narrower curvature of the coronary artery in these segments of the artery prevented coaxial alignment.

The surface of atheroma was smooth and yellow in patients with stable coronary artery disease (Fig. 3B and 4A). However, yellow atheroma was not always observed. Irregular surfaces with yellow atheroma were observed in the patient with acute non-Q wave myocardial infarction (Fig. 3C and 4B). The red area on the atheroma might be mural thrombus. Reddish and yellowish areas were seen after coronary angioplasty (Fig. 5).

Complications. No major complications resulted from this procedure. In two patients, transient ST elevation with mild chest discomfort occurred for about 1 min after injection of saline solution. These symptoms were alleviated by withdrawing the angioscopic catheter from the site of observation to the proximal site of the coronary artery and, in one patient, by intracoronary injection of nitroglycerin. The obstruction of coronary flow by the angioscopic catheter was suspected to be the cause of ST elevation. We did not observe any angiographic or endoscopic findings such as spasm, intimal dissection, lumen enlargement or nonobstructive thrombus at the site of balloon inflation.

Discussion

Recent advances in angioscopes have enabled observation of the coronary artery. However, the difficulty of coaxial alignment within the coronary artery, the lack of a guiding system and flexibility, and the relatively large diameter of previous instruments have limited their use in patients undergoing cardiac catheterization. In most cases, angioscopy has been performed during coronary artery bypass surgery (5-8), animal experiments (8,9) or in postmortem examination (10,11), although the use of percutaneous coronary angioscopes has also been reported (1-3).

Advantages of the present angioscopic catheter. This angioscopic catheter has several advantages. First, because it is thin, soft and flexible, it permits observation of the coronary artery percutaneously at the time of diagnostic cardiac catheterization and during coronary angioplasty or thrombolytic therapy. The lumen can be visualized in both the proximal and the mid or distal coronary artery segments. Second, the use of a 0.36 mm (0.014 in.) angioplasty steerable guide wire enables the angioscopic catheter to be inserted accurately and safely into the target lesion in any branch of the coronary tree. This guiding system is effective in coronary arteries with many major branches such as the left coronary artery. Third, the inflated balloon, which can dislodge the tip of the angioscope from the endothelium, and the angulation mechanism can make possible precise coaxial alignment in the coronary lumen in most cases. However, because the angioscopic catheter cannot be rotated, the one-directional angulation system is still a problem.

Fourth, the inflated balloon enables the inner lumen to be visualized with use of only a small volume of irrigation fluid. This factor is important when the angioscope is used in large coronary arteries because the high rate of blood flow in such arteries makes it difficult to replace the blood with visualizing solution. Furthermore, because vigorous flushing is not needed, there is probably minimal risk that flushing will dislodge a thrombus from the endothelial surface with resultant risk of embolization. Fifth, although the image guide and light guide consist of stiff glass fibers, these fibers are mounted on the soft flexible catheter so that the tips of the fibers do not protrude from the catheter tip. Therefore, there is little risk of causing coronary dissection.

Clinical applications. Because our clinical cases consisted of only 20 patients, most of whom had stable angina, it is too early to draw conclusions on the usefulness of our new angioscope to perform coronary angioscopy. However, it is likely that further advances in coronary angioscopy will make it possible to correlate anatomic and pathologic features of coronary lesions, such as endothelial hemorrhage, ulceration of plaque and partially occlusive thrombus that are not detected by coronary arteriography. It may also be possible to differentiate atheroma from residual thrombus in patients undergoing thrombolytic treatment for acute myocardial infarction. Angioscopic observation after coronary angioplasty may provide insight into the mechanism of abrupt coronary closure and restenosis.

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References


