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A Versatile, Steerable, Flow-Guided Catheter for Delivery of Detachable Balloons

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Most delivery systems for embolization with detachable balloons depend on flow guidance for balloon delivery [1]. Such catheters must be light and flexible in order to be drawn along by blood flow; however, their flexibility imposes limitations. Penetration of the vascular tree is limited by friction between the catheter and the vessel wall; a problem that a rigid delivery system can overcome. A flexible catheter may progress faster than its balloon and so become knotted; with a more rigid system this is less likely. A flexible catheter preferentially enters branches on the outer aspect of a curved parent vessel or more forward-directed branches at a junction; a delivery system with a shaped tip and torque control is required for the direct catheterization of branches that arise unfavorably.

We describe a versatile system for embolization with detachable balloons that overcomes these limitations. The system uses a single catheter-balloon combination that can be adapted either to flow-guided delivery or to rigid-catheter, torque-controlled delivery. Conversion from one delivery method to the other is possible without withdrawing the catheter. The system is simple to assemble, and all its components are available commercially.

Materials and Methods

The steerable, flow-guided detachable balloon embolization system presently used in our department combines a Tracker-18 Infusion Catheter and Taper Steerable Guide Wire (Target Therapeutics, San Jose, CA) with a Goldvalve latex balloon (Ingenor Medical Systems, Paris, France).

To prepare the system, the Goldvalve balloon is purged of air and partially inflated with isosmotic contrast medium via the blunt cannula, which is provided, and a tap. It is inspected for possible defects and detached from the cannula to check the integrity of its valve. The Tracker catheter is assembled with a rotating hemostatic valve (Target Therapeutics) and is purged of air with isosmotic contrast medium. The Taper wire is inserted in the reverse direction, leaving about 1 mm of wire projecting from the distal end of the catheter (Fig. 1A). The wire is secured proximally with its torque device (Fig. 1B) to limit movement between wire and catheter when a balloon is mounted.

To mount the balloon, the catheter-wire combination is lubricated with saline and pushed gently through the neck of the partially inflated balloon. Prior inflation of the balloon minimizes the possibility of perforation by the wire. The wire is withdrawn slowly to allow the balloon to deflate and fill the lumen of the catheter with contrast medium. An underwater seal of isosmotic contrast medium is used to prevent any reflux of air into the catheter. Care is taken to ensure that the gold ball in the balloon is positioned at the tip of the catheter; a balloon that is too wide might obstruct its introduction through the introducer catheter.

In the process of mounting the balloon there is the potential to damage the balloon or the catheter. It is important to avoid inserting the catheter too many times through the neck of the balloon or else the balloon valve or tip of the catheter may become weakened. The balloon valve may be disrupted during insertion of the catheter: Fewer than one in 10 balloons fails in this way, more if saline lubrication is not used. During bench-testing such failures were seen either with the first insertion of the catheter, probably indicating the presence of a tighter valve in some balloons, or after an excessive number of catheter insertions; all the balloons that were mounted without difficulty on the first insertion of the catheter maintained their integrity for a further five or more cycles of inflation, detachment, and remounting. In 20 clinical procedures there has been no instance of premature detachment or of deflation during detachment.

Delivery of the catheter-balloon combination requires additional rigidity during the passage of the balloon through the introducer catheter. This is achieved by inserting the guidewire in the normal orientation into the catheter, again using the torque device to prevent displacement or perforation of the balloon. By advancing the wire slowly into the balloon catheter, excessive distension of the balloon can be avoided. Particular care is required if the wire has been shaped to provide torque control at the tip or if it has been trimmed to make its distal segment more rigid.

Once inserted, various strategies may be used to place the balloon at the site of embolization. Withdrawing the guidewire leaves the balloon on a flexible distal catheter, allowing its flow-guided delivery to the lesion. Leaving the wire in place allows the balloon to be advanced more rapidly than with flow guidance in most circumstances. This makes it possible to overcome friction between the catheter and the vessel wall and enables the catheter to be advanced against blood flow. Adding a curve to the distal part of the guidewire allows the balloon to be steered into branches that could not be entered with flow guidance alone (Fig. 2A). A combination of flow-guided and steerable techniques is possible by using a curve of the

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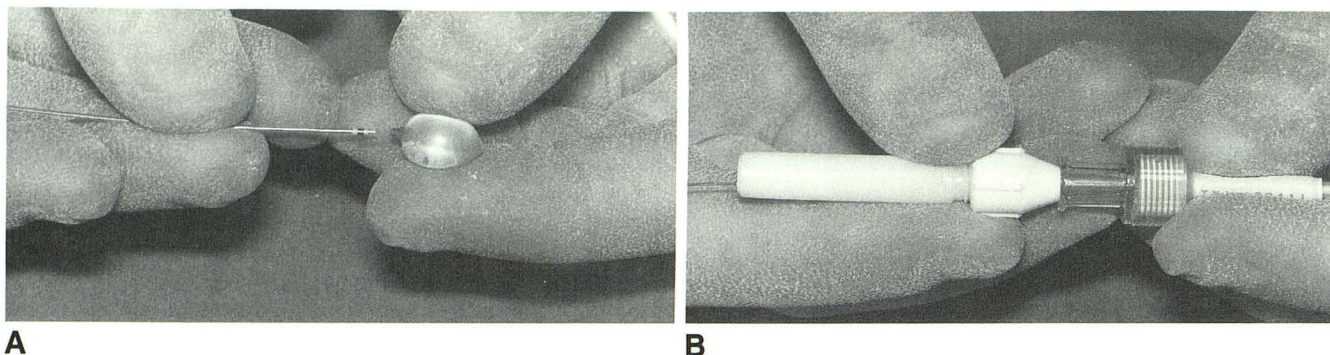


Fig. 1.—A, Distal end of Tracker-18 catheter with reversed Taper guidewire in place. Guidewire projects approximately 1 mm and assists catheter entry through valve neck of Goldvalve balloon.

B, Proximal end of Tracker-18 catheter with torque device and reversed Taper guidewire in place. Catheter and torque device are closely apposed by an assistant to maintain a constant relationship between the catheter and guidewire while the operator mounts the balloon.

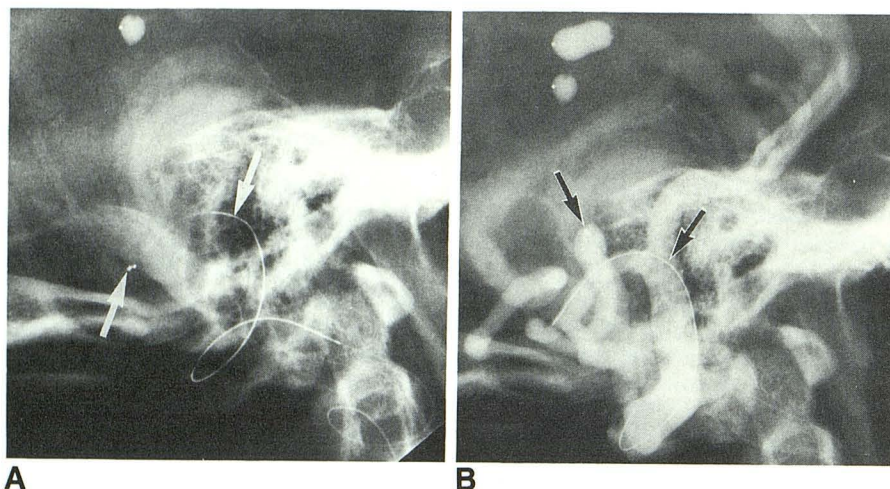


Fig. 2.—A, Multiple cerebellar arteriovenous fistulas (lateral view of skull base). Shaped tip of Taper guidewire (upper arrow) imparts tip deflection, rigidity, and torque control to Tracker-18 catheter bearing an Ingenor No. 17 balloon (lower arrow). This permitted catheterization of the left posterior inferior cerebellar artery (PICA), which previously could not be engaged by flow-guided techniques (see Fig. 2B).

B, Multiple cerebellar arteriovenous fistulas (lateral view of left vertebral angiogram). Uninflated Ingenor No. 17 balloon (arrow on left) on Tracker-18 catheter is advanced into distal PICA under flow guidance, while shaped Taper guidewire (arrow on right) maintains proximal curve and catheter direction at PICA origin.

guidewire to maintain the lie of the catheter around a difficult angle proximally while the distal segment of the catheter is advanced off the wire, allowing flow guidance to take the balloon to the lesion (Fig. 2B).

Discussion

Various attempts have been made to overcome the delivery problems of flow-guided systems that are caused by their lack of rigidity, tip direction, and torque control. Flow diversion by arterial compression or temporary balloon occlusion permits flow-guided catheters to be redirected in favorable circumstances [2]. Tip direction can be achieved by using thermoplastic materials for the balloon catheter, although such systems usually lack rigidity and torque control [3]. Rigidity and tip direction may be provided by the use of an outer thermoplastic coaxial catheter with the balloon catheter as in the original Debrun system [4]. In practice it is often difficult to advance the outer catheter around an acute angle or beyond more than two or three less severe curves. None of these systems has the versatility of the Tracker catheter-Taper guidewire combination.

The principle of a steerable and flow-guided catheter can be applied to other catheter-balloon combinations that have their own distinct advantages. Goldvalve latex balloons of any

size may be delivered on either the Mini-Torquer catheter (Ingenor) that has a distal balloon-mounting nozzle of Teflon or on the extended-tip version of the Tracker-18 catheter. These systems require a lower detachment force than the standard Tracker-18-Goldvalve combination. Detachable silicone balloons (International Therapeutics Corporation, San Francisco, CA) are available in three balloon sizes operating in three ranges of detachment force when used with the appropriate ITC delivery catheter. They may also be delivered on the extended-tip Tracker-18 catheter. Hence, commercially available, steerable, flow-guided catheter systems exist for the delivery of latex or silicone balloons in a range of balloon sizes and detachment forces.

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