Preliminary report of a hollow-centered balloon for intravascular occlusion of intracranial aneurysms or arteriovenous fistulas

Technical note

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A doughnut-shaped balloon has been designed that can be inserted intravascularly by catheter to occlude the orifice of an intracranial berry or giant aneurysm or arteriovenous fistula. The blood in the parent artery can continue to flow uninterrupted through the hole in the balloon. In a preliminary study, an arteriovenous fistula was successfully obliterated in a dog. The technique for placing the balloon is described.

KEY WORDS • balloon occlusion • temporary occlusion • aneurysm • arteriovenous fistula

INTRAVASCULAR balloon technology is now relatively well established, and includes simple balloons on catheters as well as complex detachable balloons. We have designed a double-walled doughnut-shaped, or hollow-centered, cylindrical balloon for intravascular occlusion of intracranial aneurysms or arteriovenous fistulas.

Initial studies in a dog confirm that a fistula can be successfully occluded with such a balloon, while still permitting blood flow through the main artery.

Materials and Methods

Description of Device

The balloon* is composed of silicone rubber. It can be made as small as 1.5 mm in outer diameter and 0.5 mm in inner diameter. Larger balloons may be constructed to a size adequate to function in the aorta. Balloons have been made 4, 6, 8, 10, 12, 16, and 18 mm in length, with diameters ranging from 1.5 to 4 mm in outer diameter when deflated (Fig. 1).

When the balloon is inserted into an artery, the blood passes not only around it, but through the central lumen as well. When the balloon is inflated, the outer wall expands outward to fit against the intima of the artery, but the inner wall of the balloon will not implode (Fig. 2). The central lumen remains patent, and therefore the arterial flow can continue unobstructed through the center of the balloon.

The purpose of this device is to temporarily occlude the orifice of an intracranial berry or giant aneurysm or of an arteriovenous fistula through the intravascular route without interrupting the flow of blood through the parent artery. This procedure may permit direct surgical attack upon the lesion with greater ease and without fear of hemorrhage. After the surgery is completed, the balloon may be deflated and removed.

Technique

The technique for inserting the balloon into the artery is illustrated in Fig. 3. The balloon is first tested to check its integrity of function. Using an open

*Balloon manufactured by Pudenz-Shulte Medical Research Corp., Santa Barbara, California.
Temporary balloon occlusion device

Fig. 1. Left: Balloon, 4 mm in outer diameter, with the needle in a self-sealing chamber. Upper Right: View of the inflated balloon. Lower Right: A rod has been passed through the lumen of the inflated balloon.

Fig. 2. Left: Balloon in place at the orifice of a giant carotid aneurysm. A.C.H.A. = anterior choroid artery; P.C.A. = posterior communicating artery; O.P.H.A. = ophthalmic artery. Upper Right: When the balloon is in the artery, the blood passes both around and through it. Lower Right: The outer wall of the inflated balloon expands to fit against the intima of the artery, but the inner wall does not implode.
technique, a carotid puncture is made with a No. 18 needle. A 0.035-in. guide wire is inserted. The needle is then removed, and a No. 8 French catheter introducer sheath (D) is passed into the artery. A doughnut balloon of 1 mm inner and 2.5 outer diameter (A) is affixed to the central tapered No. 4 French catheter (B), passed through the No. 7 French detaching catheter (1.59 mm in inner and 2.36 mm in outer diameter, C), and introduced into the No. 8 French Teflon sheath. The balloon is advanced on the end of

Fig. 4. *Left:* Carotid-jugular fistula in a dog. A = proximal carotid artery; B = site of fistula; C = distal carotid artery; D = jugular flow filling from the carotid artery. *Right:* Fistula after balloon occlusion. A = filling of the proximal carotid artery; B = proximal end of the balloon; C = distal end of the balloon; D = site of the occluded fistula; E = filling of the distal carotid artery.
Temporary balloon occlusion device

the No. 4 French central catheter to the proper position. The proximal and distal ends of the balloon are radiopaque, and are easily identified during fluoroscopy. The balloon is then inflated to occlude the fistula, as confirmed by injection of contrast material into the carotid tree through a femoral artery catheter positioned in the carotid orifice. When occlusion of the fistula is confirmed, the No. 7 French detaching catheter is advanced to the base of the balloon and the No. 4 French central catheter is withdrawn. This allows blood to flow through the central lumen of the cylinder balloon while the fistula is occluded.

An alternative technique consists of sliding the balloon over the guide wire (Fig. 3 lower, B) and pushing it into position with a catheter (C). When the position is confirmed and the balloon inflated, the guide wire and the pushing catheter can be removed.

Animal Study

A carotid-jugular side-to-side fistula with an orifice of 5 mm was established in a 60-lb dog (Fig. 4 left). Four weeks after surgery, a doughnut balloon, 2.5 mm in outer diameter and 10 mm in length, was inserted into the carotid artery at the site of the fistula. To insert the balloon we used a No. 8 French Teflon catheter introducer sheath (2.67 mm in inner and 2.84 mm in outer diameter, Fig. 3, D), a No. 7 French detaching catheter (Fig. 3, C), and a No. 4 French central catheter (Fig. 3 upper, B), with its tip tapered to 1 mm to fit into the lumen of the balloon. The balloon was then inflated with 0.6 cc of Amipaque (200 mgI). The carotid artery was opacified by a catheter from the femoral artery. This revealed filling of the distal carotid artery with obliteration of the flow to the carotid-jugular fistula (Fig. 4 right).

Comment

Since the principle underlying the balloon's design has been established in the laboratory animal, further studies are now planned to determine the duration the balloon may remain in the artery prior to thrombosis. It is expected that a 2- to 4-hour insertion time may be realized in vessels of 3 to 4 mm diameter. Heparin coatings may possibly extend this time limit.

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