Detachable balloon catheter

Its application in experimental arteriovenous fistulae

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Of utmost importance in the neurosurgical treatment of vascular lesions, whether congenital or traumatic in origin, is the complete obliteration of the defect and the subsequent preservation of distal blood flow. While intracranial clipping and ligation have fulfilled a therapeutic function in a majority of such cases, certain categories of neurovascular disease still remain difficult or even unmanageable problems. One such example is the carotid-cavernous fistula where the anatomical inaccessibility of the lesion limits direct surgical intervention. Recent Russian reports have described a safe and efficient technique in which a detachable balloon is employed not only to obstruct the venous outflow tract but also artificially to reconstitute the damaged wall of the cavernous segment of the involved carotid artery. Despite the growing interest of surgeons practicing in the Western hemisphere, attempts to reproduce this success...
FIG. 1. The entire apparatus consists of medical grade silicone. The uninflated balloon measures 0.3 cm in diameter. When this device is filled with fluid, subsequent leakage is prevented by means of a one-way valve located within the stem. Note the flexibility of the detached catheter.

have been thwarted by lack of a similarly reliable device. However, we have recently developed and now employ our own detachable balloon apparatus. This report describes the ease and simplicity with which this technique can be applied to eradicate arteriovenous fistulae.

Materials and Methods

Our study involved 18 adult male dogs weighing between 17 and 25 kg. After being anesthetized with sodium pentobarbital, they were intubated and allowed to breathe spontaneously. By means of an anterolateral incision in the midcervical region, the common carotid artery and external jugular vein were exposed and subsequently anastomosed in a side-to-side fashion. After this brief procedure, each of the dogs was allowed to recuperate before further manipulation. Several days later the animals were reanesthetized and brought to the radiology suite for angiographic visualization of the fistulous defect. The wound was re-explored in order to isolate a proximal portion of the common carotid artery. Under hemostatic control, the detachable balloon together with its No. 2.8 French catheter were inserted through a 3-mm arteriotomy.

The entire apparatus is made of Silastic, a nonreactive, easily sterilized material that affords a high degree of flexibility to allow ready navigation of the various angulations of the intracranial vasculature. We use several varieties and sizes of detachable balloons, ranging from 0.5 to 4.0 mm in diameter and 2.0 to 8.0 mm in length (Fig. 1). Because of a unique, miniature, one-way flap valve, devices that are larger than 1.5 mm in diameter need to be filled only with liquid contrast before separation from their parent catheter. Each valve contains a small lumen that is forced open by the stream of the injected fluid and subsequently sealed by the hydrostatic pressure within the inflated balloon. Conversely, the smaller balloons (0.5 and 1.0 mm in diameter), lacking such a self-sealing system, require inflation with a quickly solidifying material. In order to accomplish this, Dow-Corning Medical Grade Silastic 382 is mixed in a 50% dilution with Silicone Fluid 360.* After the addition of one drop of catalyst (stannous octoate) per 5 ml of silicone, vulcanization occurs within 20 minutes. During the first 5 to 7 minutes, the solution may be readily injected through a flexible No. 5 French catheter. In either instance, once the balloon has been filled, separation is accomplished by means of friction detachment. We used the larger balloons in this study, in accordance with the caliber of the vessels we were working with.

After its insertion into the carotid artery, each balloon was filled with 0.10 cc of radiopaque fluid to permit fluoroscopic visualization. The transient re-establishment of arterial blood flow was observed spontaneously to flush the entire apparatus through the ostium of the fistula into the venous outflow tract. After the balloon was positioned as close to the defect as possible, it was filled with a sufficient amount of contrast solution to provide adequate occlusive tamponade of the venous structure. During the critical period of inflation, carotid flow was again interrupted to avoid the possibility of premature separation. At this point in the procedure the catheter was gently detached and withdrawn from the artery. Angiography was then repeated to evaluate the necessity for additional balloon placements. When either the fistulous defect was obliterated or a more physiological hemo-

*Silastic and silicone fluid manufactured by Dow Corning Corp., Midland, Michigan.
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![Image](image-url)

**Fig. 2.** Dog 1. **Left:** Angiographic demonstration of carotid-jugular fistula before balloon placement. Note the absence of filling in the distal carotid artery. **A** = proximal carotid artery; **B** = external jugular vein, rostral portion; **C** = external jugular vein, caudal portion. **Center:** After placement and inflation of a balloon, the rostral portion of the jugular venous outflow tract has been occluded. In this film the catheter has been detached and withdrawn. The hemodynamics are such that there is still no flow into the distal carotid artery. **Right:** Subsequent positioning of an additional balloon not only obliterates the remainder of the fistulous communication but also allows the reconstitution of the arterial wall and the eventual re-establishment of carotid flow.

Dynamic situation was re-established, the procedure was terminated.

The results of the surgery were angiographically reassessed 8 days later. In addition, the subsequent integrity and position of the balloons were checked by serial x-ray films at weekly intervals. All animals were sacrificed after 2 months.

**Results**

As described above, repair of the carotid-jugular fistula was accomplished in each animal without any intraoperative complications. The angiographic sequence of events in two representative animals are demonstrated in Figs. 2 and 3. In each subject the initial radiograph documents the preferential patency of the arteriovenous communication at the expense (or in the absence) of distal carotid blood flow (Figs. 2 left and 3 left). Subsequent placement of a single balloon, despite concomitant obliteration of the rostral jugular vein, does little to enhance arterial perfusion (Figs. 2 center and 3 center left). Fortunately, the patency of the defect continues hemodynamically to favor positioning of additional balloons in the low resistance venous system. The ensuing inflation of a second device (Figs. 2 right and 3 center right) not only causes elimination of the fistulous tract, but also enables the therapeutic reconstruction of the arterial wall, and the beneficial re-establishment of ipsilateral cerebral blood flow. Angiographic studies repeated a week later demonstrated continued patency of the carotid artery (Fig. 3 right). At that time the balloons remained unaltered in size and position.

In several animals, the return to a more normal physiological situation was unfortunately not always associated with complete obliteration of the fistulous lesion. Figures 4 and 5 represent angiograms performed within 1 week of surgery. In these two cases, the elimination of rostral and caudal venous runoff contributed to the reconstitution of distal carotid blood flow. Despite the subsequent interposition of clot between the balloons, each of these animals was left with a residual aneurysmal defect. Even at the time of sacrifice, these lesions, although significantly smaller, were nevertheless still evident.
FIG. 3. Dog 2. Left: Angiogram showing that the preferential flow into the low resistance venous system eliminates any evidence of distal arterial perfusion, as in Dog 1. Center Left: The placement of a single detachable balloon does little either to eliminate the defect or to improve the hemodynamic situation. Center Right: The inflation of an additional device affords a more normal situation with the reestablishment of cerebral arterial perfusion. Right: Postoperative angiogram 1 week later fails to show any change in size or shape of either balloon. The previously reconstructed carotid artery remains patent.

FIG. 4. Dog 3. It was not always possible to position the balloons directly at the site of the fistulous defect. As seen in this follow-up angiogram, the original arterial defect is still evident despite the subsequent interposition of clot.

FIG. 5. Dog 4. Even the development of an adequate amount of clot does not assure complete obliteration of the venous outflow tract. In this animal the fistulous communication has been converted to an aneurysmal defect 1 week after the placement of the balloons.
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As noted above, 100% of the subjects experienced successful elimination of their artificially created fistulae. While this experimental model may not ideally replicate any specific intracranial vascular disease, it does provide some indication of the therapeutic applicability and overall reliability of this detachable balloon catheter. Notwithstanding our intraoperative results, some postsurgical complications occurred. In two animals the subsequent rupture or deflation of balloons ultimately resulted in delayed recurrence of the fistulous defect, an undesirable event that happened early in our balloon-making experience. This represented 11% of the experimental subjects and only 5.5% of all implanted devices. In two additional subjects, overzealous inflation of the balloons caused excessive intraluminal pressure with resultant rupture of the venous walls and subsequent transmural migration (Fig. 6). Also during the initial phase of our experiment, there were several episodes of early detachment and embolization of the balloons into the proximal venous system. This obvious hazard was soon overcome by a minor modification of the catheter device and by transient proximal control of the carotid artery during the brief but critical period of vascular occlusion.

Later cervical x-ray films taken at weekly intervals showed the balloons to be essentially unchanged in size or shape for approximately 2 weeks. After that period, most of the balloons were observed to increase in volume and assume an ovoid configuration. The explanation for this appears quite simple. When the balloons (made of a semipermeable membrane) are filled with a hypertonic radiopaque dye, an osmotic gradient is established which causes subsequent swelling. This is demonstrated in Figs. 7 and 8, representing radiographs taken just before the sacrifice of Dogs 2 and 3, respectively. By contrast, approximately 10% of the balloons shrank (Fig. 7, lower balloon), probably owing to membrane fatigue. Under no circumstances did a change in balloon size affect the status of the previously occluded fistulae. Nevertheless, because of the potential hazard associated with delayed swelling or shrinkage, we have begun inflating all balloons with the previously described rapidly polymerizing silicone solution.

Pathological studies are currently being performed to evaluate the long-term effect of intraluminal balloon devices.

Discussion

The use of intraluminal devices as an adjunct to traditional neurosurgical techniques has received increasing attention from individuals concerned with the treatment of various cerebrovascular disease processes. Intrigued by the theoretical consideration of intra-arterial navigation, Luessenhop and Velasquez7 were among the first to report upon the feasibility, safety, and potential benefit of selective catheterization of the proximal intracranial vasculature.

In 1963, Fogarty, et al.,6 described a balloon catheter specifically designed for the removal of arterial thrombi. Despite the benefits of this device in the alleviation of carotid artery occlusion,1,10 potential complications have included intimal tears,
When observed over a period of several months, all balloons were noted to have undergone minor changes in shape and volume. The upper and lower balloons demonstrated minimal evidence of expansion and shrinkage, respectively.

FIG. 8. Dog 3. Postoperative x-ray film documents mild swelling of both balloons. Compare with Fig. 4, taken 2 months earlier. This phenomenon is probably a consequence of the increased osmotic pressure associated with the hypertonic contrast solution within the balloons.

Several reports have noted other neurosurgical applications of this particular catheter. Kessler and Wholey employed it prophylactically to occlude the proximal internal carotid artery in two patients, each of whom had intracranial aneurysms. In a later paper, Prolo and Hanbery described the successful obliteration of a carotid-cavernous fistula secondary to localized balloon tamponade at the site of the arterial defect. An unfortunate disadvantage of the Fogarty apparatus has been the obligatory residual presence of the catheter and the potential for the proximal propagation of intra-arterial clot.

The therapeutic implications of an intraluminal approach have been advanced by the recent development of inflatable, detachable balloon catheters. Debrun, et al., have used such devices to occlude arteriovenous fistulae in two patients. In 1975, they described an apparatus in which a small finger-like balloon is attached to the tip of some polyethylene tubing by means of a thin latex string. After the balloon has been inflated with contrast and detached from its parent catheter, the elastic band tightens to prevent subsequent leakage of fluid. Debrun and colleagues made no reference in either of their articles to the reliability of this technique, but in our own laboratory we have found it difficult to reproduce consistently. Currently, the most interesting and successful study has been that of Serbinenko, in which selective catheterization of the distal intracranial vasculature has been used as a diagnostic and prognostic tool in 304 patients. By utilizing various sized balloons, he has also performed permanent therapeutic occlusion of the different major cerebral vessels for diseases such as aneurysms (10 cases), arteriovenous malformations (71 cases), and carotid-cavernous fistulae (68 cases). He has demonstrated that safe intravascular occlusion may be achieved without the necessity of a residual indwelling catheter.

It is evident from Serbinenko’s work that the detachable balloon catheter should play an important role in the future neurosurgical approach to certain cerebrovascular lesions. The most immediate benefit of this device may be its application in those patients suffer-
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ing from carotid-cavernous fistulae. Ser-
binenko was able by using this method to obliter-ate the defect and preserve arterial flow in almost half of the patients treated for that problem.

As a consequence of our success with a similarly reliable apparatus, we are optimistic about the diagnostic and therapeutic implications of this newly available technique. Future reports will describe our clinical experience with the application of detachable balloon devices.

References


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