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Two Different Calibrated-Leak Balloons: Experimental Work and Application in Humans

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Two different types of latex calibrated-leak balloon catheters have been developed. One consists of a Teflon catheter with a detachable latex balloon and is used to embolize branches of the external carotid artery. The other consists of a Silastic catheter with a nondetachable latex balloon and is used to embolize brain arteriovenous malformations. An experimental model and animal experiments have determined the best conditions for safe and reproducible embolization with isobutyl-2 cyanoacrylate (IBC-2). Selective catheterization of branches of external carotid, middle cerebral, anterior cerebral, and posterior cerebral arteries in humans is facilitated, and embolization with IBC-2 has been achieved with these balloon catheters.

Selective catheterization of branches of the external carotid artery has been extensively used during the past 10 years, but even with a small catheter (3 or 4 French) and small guide wires (0.021 or 0.025 inch [0.05 or 0.06 cm]) it is sometimes difficult to catheterize a distal branch of the internal maxillary artery.

Selective catheterization of branches of the middle cerebral, anterior cerebral, or posterior cerebral arteries was impossible with small catheters and guide wires until Serbinenko [1] showed that intravascular navigation was easy with a miniballoon attached to the tip of a minicatheter. With a calibrated leak through the tip of his balloons, he could obtain selective opacification of cerebral cortical branches and inject antimitotic drugs in patients with glioblastomas.

Kerber [2] developed a nondetachable, Silastic, calibrated-leak balloon and was the first to embolize a cerebral arteriovenous malformation (AVM) with isobutyl-2 cyanoacrylate (IBC-2) (Ethicon). Without a calibrated leak balloon, it would be impossible to deliver the tissue adhesive into the malformation itself unless a cortical feeder were exposed at surgery. Pevsner and Doppman [3] also developed a Silastic calibrated-leak balloon and extensively used it to embolize brain AVMs with IBC-2. The development of our research with latex balloons [4] stimulated us to modify our calibrated-leak balloon (which was not attached to the catheter) and to develop two new balloon catheters.

Latex Detachable Calibrated-Leak Balloon with Teflon Catheter

Material

The distal part of a latex balloon is perforated with a 22 gauge needle; then the narrow part of the latex sleeve is tied with three turns of a latex thread to the tip of a Teflon catheter (0.4 mm ID, 0.6 mm OD) so that the tip of the catheter is 2 mm within the balloon. The balloon and its leak are tested by injecting saline and are considered acceptable if on inflation the maximum diameter of the balloon remains identical whatever the force of the injection through the catheter and if the balloon shrinks immediately when the injection is stopped.

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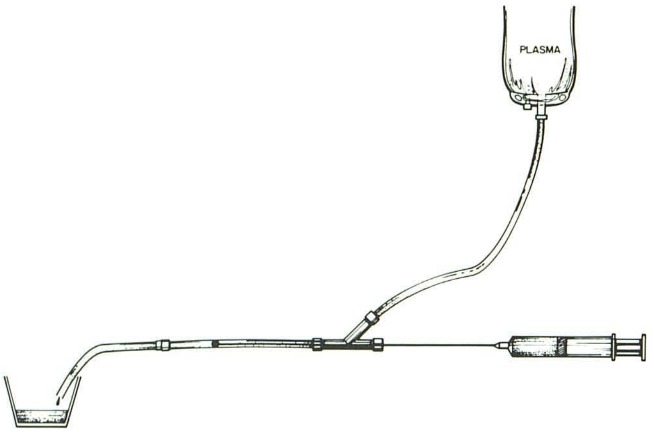

Fig. 1.—Experimental model: calibrated-leak balloon catheter positioned in middle of transparent connecting tube after introduction through straight limb of side arm. Permanent infusion of plasma fills connecting tube through lateral limb of side arm.

The Teflon catheter is inserted into a polyethylene catheter (0.8 mm ID, 1.15 mm OD) curved at its tip so that it is possible to direct the balloon to the selected arterial branch. The polyethylene catheter may be used to detach the balloon, but because the balloon is often glued in position in the artery, this is unnecessary in most cases. The last 5 cm of the Teflon catheter is greased with silicone oil to make withdrawal easier.

A 1.6 mm ID, 2.1 mm OD polyethylene tube is positioned in the trunk of the external carotid artery and the coaxial system is maneuvered from the groin. The whole system is continually flushed with heparinized saline, and systemic heparinization is also administered intravenously to decrease the risk of clot formation inside the coaxial system. A bolus of 2000 U heparin is injected as soon as the introducer is inserted through the femoral artery. Repeated injections of 1000 U heparin are made hourly. Hypocoagulability is reversed at the end of the procedure with protamine sulfate.

Experimental Model

A very simple experimental model (fig. 1) was used to study the easiest and safest way to detach the balloon after injection of IBC-2. It consists of a plastic, transparent connecting tube (3 mm ID) connected to a Cook side arm. The side arm is connected to a permanent infusion of plasma, which simulates blood and is chosen for its property of inducing polymerization of IBC-2. The distal end of the connecting tube is connected to tubing that empties into a bowl.

The Teflon tubing with the latex calibrated-leak balloon is introduced through the straight arm and pushed until the balloon reaches the middle of the connecting tube. Several injections of Conray 60 can be carried out through the balloon to make sure that the injection always occurs distally, with no proximal reflux or leakage of contrast material. The balloon catheter is then flushed with dextrose, and a mixture of IBC-2 (2 ml), tantalum powder (1 g of 1 μm particles) and ethiodan (0.3 ml of Iophendylate) is injected. When the IBC-2 starts to solidify, the balloon is deflated by aspiration. On occasions, minimal reflux of IBC-2 proximally will embed the balloon. If this does not happen, the balloon is slightly reinflated with IBC-2 until a small amount of glue embeds the balloon. A proximal reflux of 1 cm of IBC-2 along the connecting tube is considered optimal. The Teflon tubing and the latex balloon are intentionally embedded within the cast of IBC-2. Strong aspiration empties the tip of the Teflon tubing of the IBC-2. In experiments, a 1 min delay before detaching the balloon seems optimal. The balloon is detached by rapidly withdrawing the Teflon catheter.

Animal Experiments

Experiments in dogs were carried out. A 7 French catheter was introduced through the femoral artery and positioned at the origin of the external carotid artery. Angiography was performed to identify the different branches of the external carotid artery and to determine the branch to be embolized. The balloon was positioned immediately beyond the bifurcation of a main stem into two branches. The goal of the embolization was to obtain distal occlusion of the selected branch with IBC-2, to detach the balloon, and to preserve the bifurcation. After detachment of the balloon, a further angiogram was obtained to demonstrate the results (fig. 2). In figure 2 the balloon is positioned in one of the branches of division of the superior dental artery which is less than 1 mm in internal diameter. After detachment of the balloon, the bifurcation being protected by the inflated balloon is still patent. The tissue adhesive was selectively delivered into the superior dental artery branch.

Human Application

The balloon has been used to embolize lesions supplied by the external carotid artery.

Case Reports

Case 1

A 69-year-old man with a spontaneous left carotid-cavernous fistula had progressive exopthalmos, decreased vision, and diplopia. The fistula was supplied by a cavernous carotid artery branch, a distal network of vessels from the sphenopalatine artery, and the artery of the foramen rotundum. Drainage was into the superior ophthalmic vein. The balloon catheter could easily pass the initial 360° loop of the internal maxillary artery and reach the sphenopalatine artery. Selective angiography through the calibrated-leak balloon (fig. 3) showed that there was no opacification of the internal carotid artery through external carotid–internal carotid channels. An injection of 0.2 ml of radiopaque IBC-2 was followed under fluoroscopy and was stopped as soon as the superior ophthalmic vein was filled with IBC-2. An internal carotid angiogram (with reflux into the external carotid artery) demonstrated complete occlusion of the fistula. Because of the tortuosity of the internal maxillary artery, it would have been probably difficult, or impossible, to reach the sphenopalatine artery with a minicatheter. The detachable calibrated-leak balloon allowed selective deposition of the tissue adhesive with preservation of the normal branches of the internal maxillary artery.

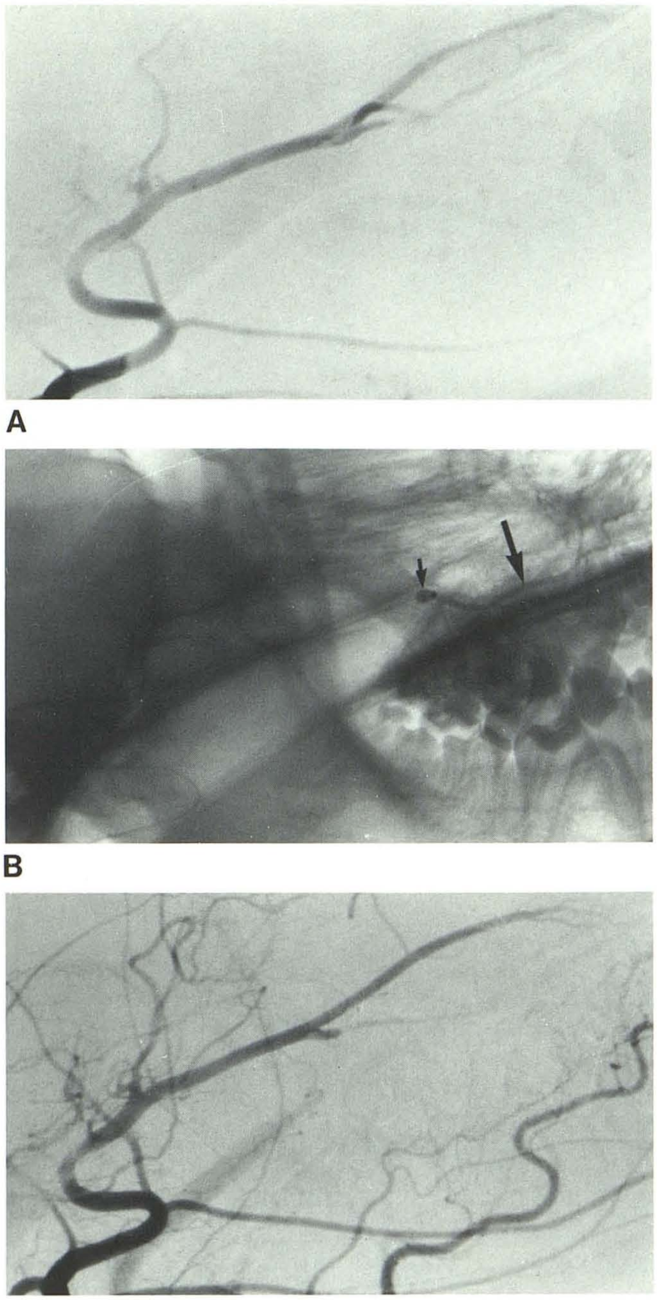

Fig. 2.—Selective embolization of branch of dog's superior dental artery. **A**, Angiogram of external carotid artery. **B**, Selective angiogram of one branch of superior dental artery (*large arrow*). Calibrated-leak balloon (*small arrow*). **C**, After embolization of this branch with IBC-2, balloon has been detached and bifurcation has been preserved.

Case 2

A 16-year-old girl had an intractable tic douloureux on the right side. Complete angiography revealed a right posterior fossa arteriovenous malformation associated with a dural supply from the right middle meningeal artery which was 2.5 mm in diameter. The external carotid artery was tortuous, and it was possible to direct the calibrated-leak balloon into the middle meningeal artery and to position the balloon above the foramen spinosum. Selective angiography (fig. 4) filled the dural part of the AVM. Injection of 0.4 ml of IBC-2 completely obliterated the dural segment of the AVM and occluded the middle meningeal artery. The balloon was detached. Control angiography showed disappearance of the dural part of the AVM and preservation of the internal maxillary artery. The tic douloureux instantaneously disappeared after the embolization.

Latex Nondetachable Calibrated-Leak Balloon with Silastic Catheter

Material

The narrow part of a latex balloon is cut with a razor blade 2 mm below the orifice of the balloon. Through this orifice a 22 gauge needle is introduced and carefully pushed through the balloon until it perforates its tip. Then the needle is removed, and the orifice of the balloon is dilated with a forceps and a blunt needle to facilitate entering the sleeve with a 0.5 mm ID, 0.9 mm OD radiopaque Silastic tube. The narrow part of the sleeve grasps the tubing, but the union is not sufficiently strong to avoid balloon detachment after multiple inflations and deflations. The balloon must be glued to the tip of the Silastic tubing with one drop of IBC-2.

The Silastic tubing is 170 cm long and is introduced coaxially. The catheter needs to be coiled into a plastic chamber (Becton-Dickinson) which has a lateral connection for the injection of saline and to propel the catheter through an outer catheter that has been positioned in the desired artery. A 23 gauge blunt needle is introduced into the proximal end of the Silastic tubing, which is held in the plastic chamber through a Tuohy-Borst adapter (fig. 5).

The Silastic catheter is propelled with 10 ml of saline and the balloon's location is identified by gently injecting contrast material through the Silastic tubing. It is possible to see the Silastic catheter in the neck, but it is difficult to see it through the petrous bone without subtraction fluoroscopy. The catheter is easily identifiable intracranially. Care must be taken to insure that the catheter is not coiled in the internal carotid or the vertebral arteries. The coiling can be corrected by gentle pulling of the Silastic tubing through the plastic chamber or the introducer in the groin. To advance the microcatheter more distally, four different maneuvers may help: (1) rapidly injecting contrast material through the leaking balloon, (2) introducing 5 cm of tubing into the plastic chamber and propelling it with saline through the lateral connector, (3) manipulating the introducer in the neck, and (4) injecting saline or dextrose (both less viscous than contrast material) through the balloon to increase the flow and propel the balloon more easily.

This balloon is flow directed. If it is necessary to catheterize an artery with relatively low flow or sharp angle of origin [1], it is useful to compress the contralateral carotid artery in the neck for a few seconds or occlude an intracranial arterial trunk with a second balloon.

Experimental Model

A similar experimental model to that used to test the first catheter was applied to test the second one. Some technical modifications were performed because the latex calibrated-

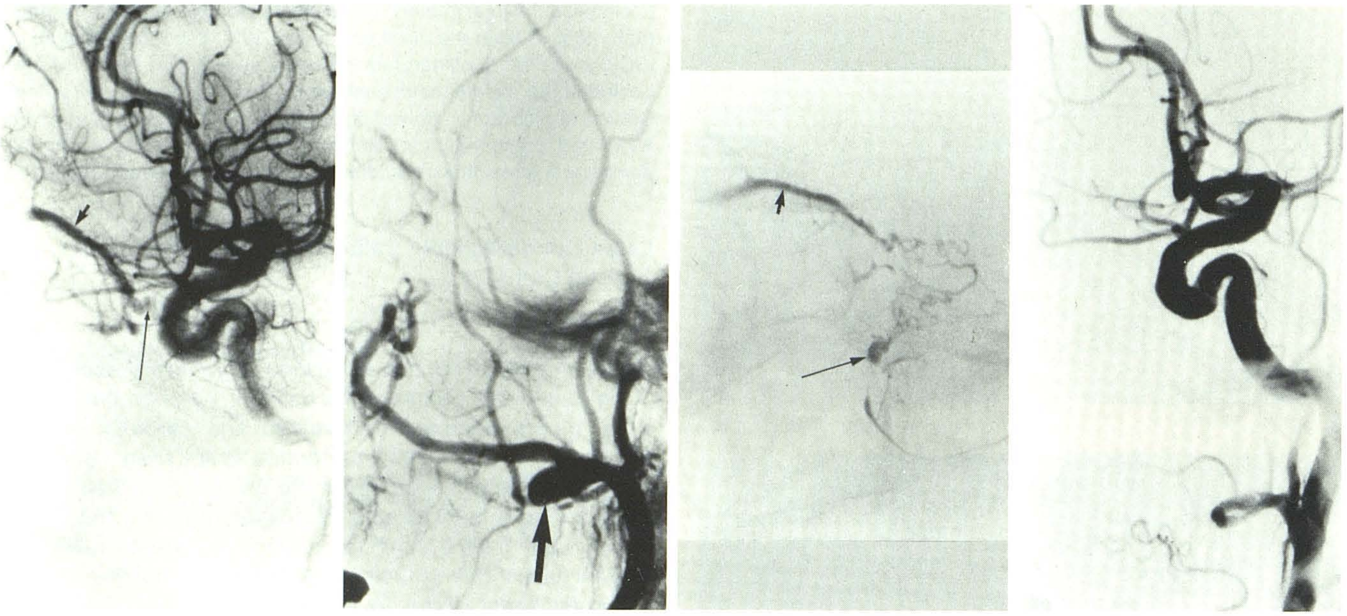

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Fig. 3.—Spontaneous carotid-cavernous fistula. **A**, Selective internal carotid angiogram. Inferolateral cavernous carotid trunk (*long arrow*) fills superior ophthalmic vein (*short arrow*). **B**, Angiogram of external carotid artery. Note 360° loop of internal maxillary artery (*arrow*). **C**, Selective angiogram of distal internal maxillary artery with latex calibrated-leak balloon (*long arrow*). Filing of artery of foramen rotundum and of network of abnormal vessels that fill superior ophthalmic vein (*short arrow*). **D**, Internal carotid angiogram with reflux into external carotid artery. After embolization through balloon with 0.2 ml of IBC-2, there is complete disappearance of fistula.

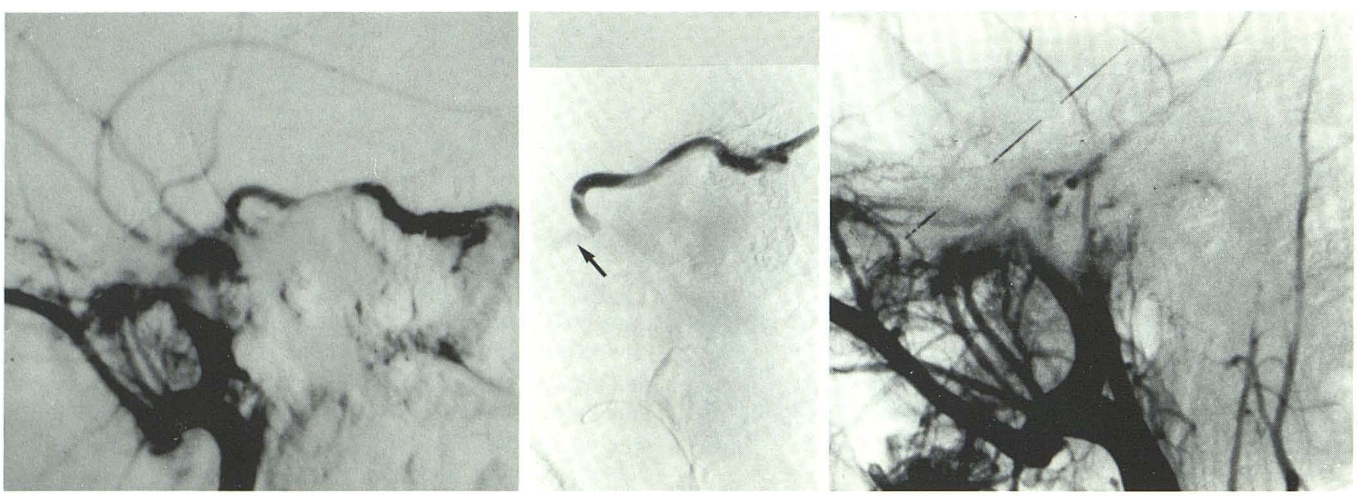

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Fig. 4.—**A**, Lateral subtraction angiogram of distal external carotid artery shows dural part of mixed arteriovenous malformation. **B**, Detachable latex calibrated-leak balloon in posterior division of meningeal artery above foramen spinosum (*arrow*). **C**, Control angiogram of right external carotid artery after embolization with 0.4 ml of IBC-2. No filling of dural part of AVM.

leak balloon is not detachable and must be rapidly withdrawn before the polymerization of the IBC-2 occurs. The injection is about 1 ml in 3–5 sec to both maintain the inflated balloon and deliver the tissue adhesive in a short period of time. The balloon leak is tested several times with contrast material, then flushed with dextrose, and finally with the mixture of IBC-2, tantalum powder, and ethiodan. The injection is continued until the column of IBC-2 stops advancing through the connecting tube. The injection is stopped immediately, the balloon is deflated by aspiration through the 1 ml syringe, and the Silastic tubing is withdrawn.

Embolization is considered successful if (1) the balloon is empty, with no solid particles of IBC-2 attached to its tip; (2)

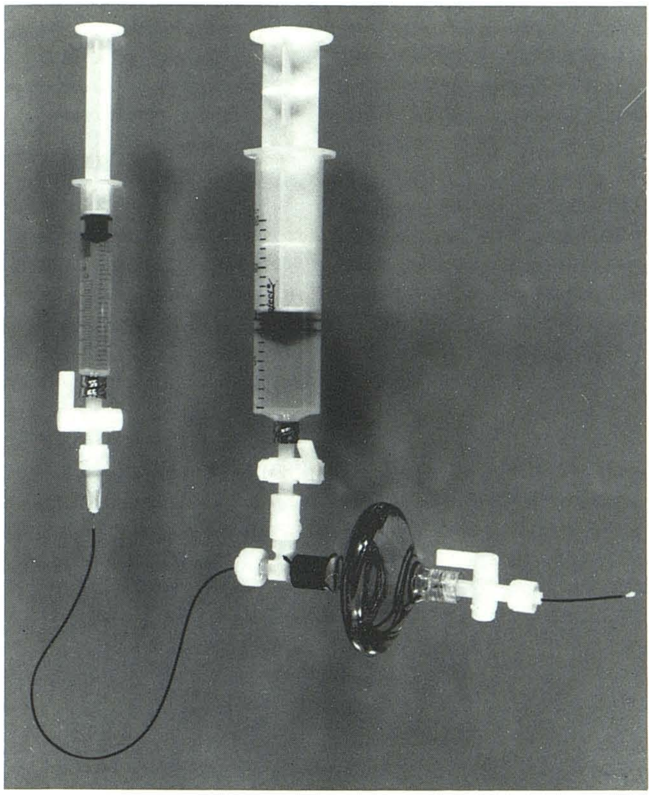

Fig. 5.—Latex nondetachable calibrated-leak balloon. Silastic tubing coiled inside plastic chamber. Blunt needle (23 gauge) attached to tuberculin syringe allows testing of balloon and its leak.

there is no reflux of IBC-2 proximally; and (3) the removal of the balloon is easy. (In practice the Silastic catheter does not slide easily through the introducer, and it is necessary to remove the latter when the silastic balloon catheter is to be removed.)

In experiments this maneuver was repeated 100 times. The balloon was always removed easily if the delay after the end of the glue injection was no longer than 3 sec and if the balloon and distal Silastic catheter were coated with silicone grease. To be sure that the mixture of IBC-2 remains sufficiently fluid not to clot the balloon leak or the proximal needle, it is extremely important to aspirate the overflowing mixture of IBC-2 and tantalum powder through the 25 gauge needle. We avoid aspirating heavy lumps of tantalum powder.

Animal Experiments

The latex, nondetachable, flow-directed calibrated-leak balloon catheter has been used in dogs to selectively embolize branches of the renal artery, of the external carotid artery, and the vertebral artery itself. Embolization with IBC-2 was always done after selective angiography through the calibrated-leak balloon and the goal was to obtain a cast reproducing the identical pattern of vascular branching. Angiography was always performed through the outer catheter immediately after the embolization to check that the main trunk of the renal or external carotid arteries was preserved.

The vertebral artery is a good artery for experiments because the amount of bucrylate that can be injected distally and the solidification time of the glue can be measured more accurately than in smaller arteries.

Human Application

Twelve superselective embolizations in 11 patients have been accomplished. The lesions have all been large cerebral arteriovenous malformations (AVMs) that were difficult or impossible to resect without a high risk of neurologic deficit. Branches of the posterior cerebral artery were embolized in six cases, of the pericallosal artery in two cases, and of the middle cerebral artery in four cases. Quadranopsia occurred in two cases after embolization of the posterior cerebral artery feeder.

In two cases, the balloon catheter was in a distal branch of the posterior cerebral artery. In both, the distal end of the catheter ruptured while attempting to remove it, and the catheter was accidentally glued in position. These patients were not operated on and there were no clinical complications.

In two of the 11 patients, the AVMs did not opacify after embolization. In the other nine patients, the AVM partially opacified; however, there was a significant decrease in their size, and there was improved visualization of normal cortical branches (decrease of the sump effect). Figure 6 shows an example of a right rolandic AVM fed by the right pericallosal artery and right middle cerebral artery. Initially, since the latex calibrated-leak balloon was not available, an intraoperative direct injection of IBC-2 into one of the right middle cerebral arterial feeders was made. IBC-2 was injected after surgical ligation of one feeder and after compression of the left carotid artery in the neck, thereby decreasing the flow through the right pericallosal artery and permitting the adhesive to reach the watershed territory between the middle cerebral artery and anterior cerebral artery. The angiogram obtained 1 month later showed complete disappearance of the feeding arteries arising from the pericallosal artery, but still partial filling of the right middle cerebral artery feeders. At a second procedure, this main feeder was selectively catheterized with the latex calibrated-leak balloon and embolized with IBC-2. The AVM was completely obliterated. The patient had a mild clumsiness of the left arm and face but was neurologically intact at the time of discharge and has since been asymptomatic.

Discussion

The detachable, latex, calibrated-leak balloon catheter is exclusively used to embolize branches of the external carotid artery. It cannot be used for the internal carotid artery because the Teflon tubing necessary for detachment is too stiff to navigate intracranially.

The advantages of this catheter include that of an atraumatic technique with less risk of spasm than during manipulations with a guide wire. The balloon can navigate into

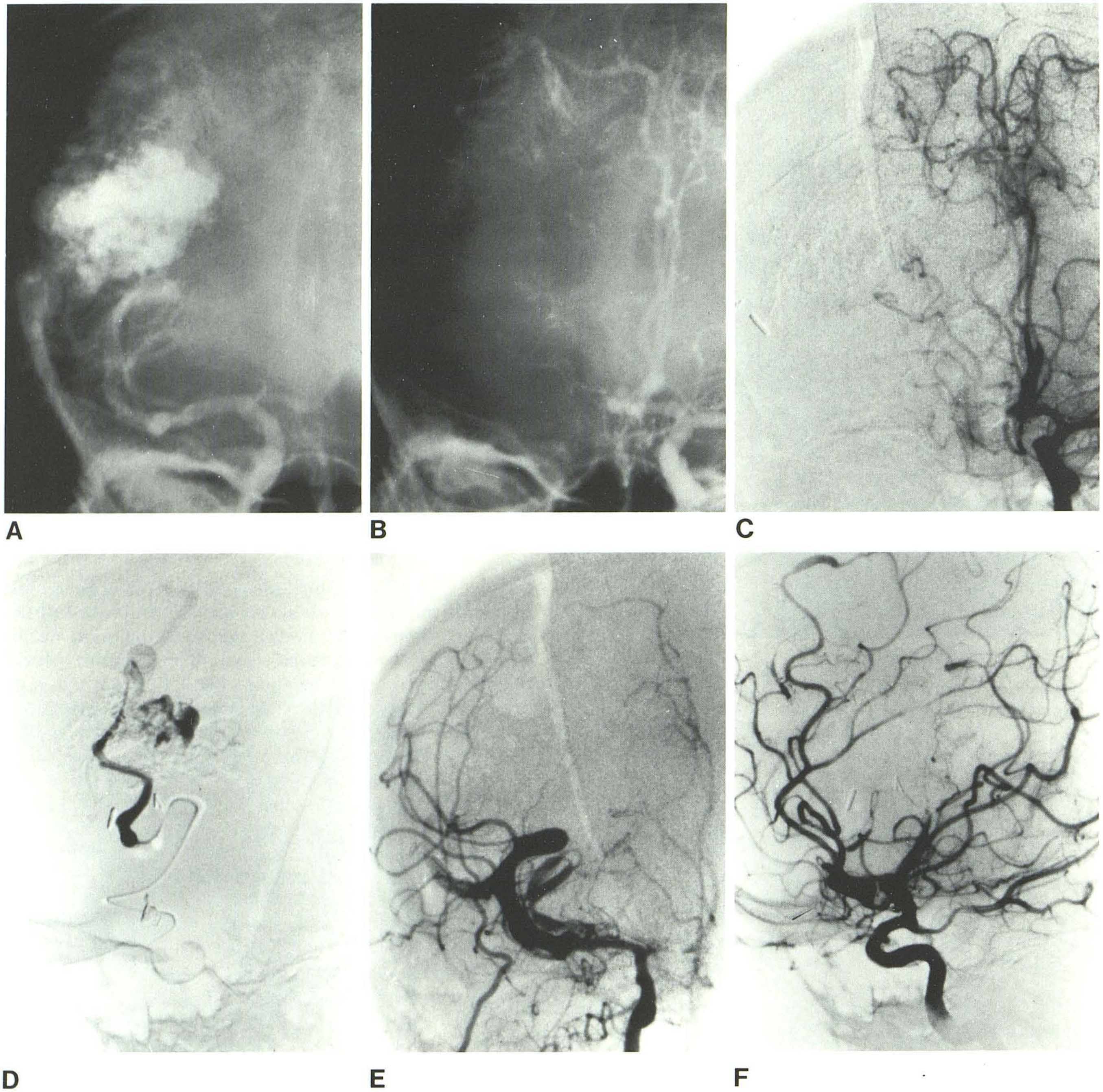

Fig. 6.—**A**, Right rolandic AVM before embolization. Right internal carotid angiogram. **B**, Left internal carotid angiogram shows watershed area between anterior cerebral artery and middle cerebral artery supplying lesion. **C**, After intraoperative embolization with IBC-2 of one right middle cerebral artery feeder while left carotid artery was being occluded in neck, blood supply to AVM from anterior cerebral artery has disappeared. **D**, Selective angiogram of remaining middle cerebral artery feeder. **E** and **F**, After embolization of this middle cerebral artery feeder with IBC-2. Nidus of AVM does not fill. Patient was neurologically intact.

distal arterial branches such as the middle meningeal artery above the foramen spinosum, the occipital artery beyond the anastomosis with the vertebral artery, and the sphenopalatine artery. Deposition with IBC-2 is very selective, sparing normal branches, because inflation of the balloon avoids proximal reflux of the IBC-2. The technique is safely reproducible. Detachment is easy. There is no need to extract the catheter rapidly since the balloon is intentionally imprisoned in the cast of IBC-2.

A major disadvantage of the latex system is that only low-viscosity fluid agents can be injected, therefore limiting this system to the use of IBC-2 or other low-viscosity tissue adhesives.

The detachable catheter is best used in the treatment of

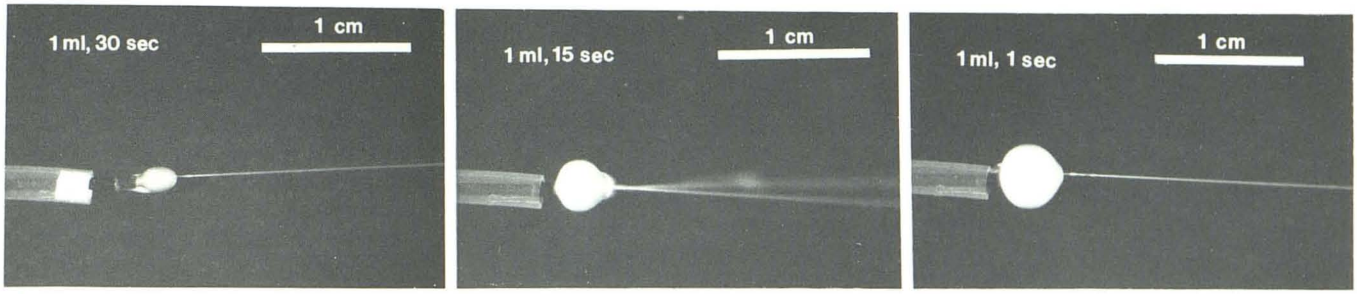

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Fig. 7.—Debrun latex balloon with distal hole. **A**, Balloon barely expands when 1 ml of saline is injected slowly in 30 sec. **B**, Balloon slightly enlarges with injection of 1 ml of saline in 15 sec. **C**, Balloon reaches maximum diameter with injection of 1 ml of saline in 1 sec. Despite rapid injection, balloon does not burst.

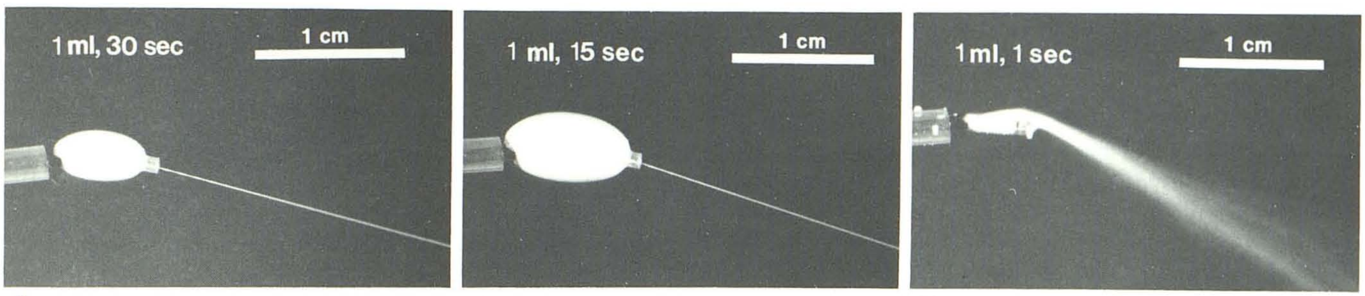

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Fig. 8.—Silastic balloon (Cook). **A**, Balloon remains small when 1 ml of saline is injected slowly in 30 sec. **B**, Balloon enlarges with injection of 1 ml of saline in 15 sec. **C**, Balloon bursts with injection of 1 ml of saline in 1 sec. Balloon will always burst if 1 ml of saline is injected in less than 5 sec.

dural arteriovenous malformations, spontaneous carotid-cavernous fistulas, glomus jugulare tumors and certain facial arteriovenous malformations where the flow is so rapid that solid particles can not be used. This latex balloon provides an alternative method to embolization with particles of Ivalon, dura mater, Gelfoam, or polymerizing substances such as silicone polymers.

The second latex calibrated-leak balloon is nondetachable and is glued to the tip of Silastic tubing which is pliable. The advantages of this balloon over Silastic balloons is that it is possible to inflate and deflate the balloon many times without modifying its compliance. The balloon almost never bursts because the leak increases with the strength of the injection and the size of the balloon does not increase. It is possible to experimentally inject 1 ml of saline through the balloon in 1 sec without bursting the balloon or increasing its maximum diameter, whereas the Silastic balloon always ruptures with the same experiment (fig. 7). This experiment was repeated 100 times without changing the properties of the balloon. These results are only valid with a latex *leaking* balloon. A nonleaking latex balloon would become fatigued and burst. The leaking balloon shrinks spontaneously in 1–3 sec when the injection is interrupted and the leak closes, so there is no retrograde flow of blood into the balloon. However, the spontaneous shrinkage of the balloon in 1–3 sec is generally too long when IBC-2 is injected through the balloon, since it would be glued in the vessel during this period of time. It is therefore necessary to deflate the balloon quickly by aspiration through the syringe as soon as the injection of IBC-2 is completed. There is no reflux of blood into the balloon, and the balloon always shrinks in 1 sec, allowing retraction of the catheter with an empty balloon preventing the risk of injecting IBC-2 into normal cortical branches. The malleability of the latex balloon allows it to assume the size of the vessel that is catheterized with no distension of its wall, making it less likely to rupture a vessel as compared to Silastic balloons. Injection of IBC-2 through the balloon can be very fast and reach more distal parts of the arteriovenous malformation.

If the same experiment is carried out with the Silastic balloon (fig. 8), it is difficult to inflate and deflate it many times without modifying its compliance because the walls become fatigued. The balloon *always* bursts when the strength of the injection is increased; therefore, the injection must be very slow and gentle to avoid bursting the balloon. If overinflation and bursting of the balloon is to be avoided, the injection rate through the balloon has to be 1 ml in 20–30 sec. When the walls of a Silastic balloon are fatigued, the balloon does not shrink spontaneously when the injection is stopped, and it takes a few seconds to deflate it. If the balloon enlarges, it distends the wall of the vessel, increasing the risk of rupture. Rapid injection of liquid causes the balloon to burst immediately.

The disadvantages of the latex and Silastic balloons are that they are glued to the tip of the Silastic tubing so that the balloons are not detachable and there is a risk of permanent gluing of the catheter at the end of the injection of IBC-2. The injection of radiopaque IBC-2 must be carefully monitored and immediately stopped when the tissue adhesive stops flowing into the AVM. We consider it risky to flush the Silastic catheter with dextrose at the end of the injection, because there is a risk of injecting more bucrylate than needed. This maneuver may glue the balloon in place, or it may produce injection of bucrylate proximal to the balloon with embolization of normal cortical branches.

We compared the risks of embolizing intracerebral AVMs in two groups of patients, one using the Silastic leaking balloon and one using the new latex balloon. In the first group of 22 patients with AVMs embolized with the Silastic calibrated-leak balloons, IBC-2 was injected in 14 patients. The main complications in this group were five cases of rupture of a feeder to the AVM when the Silastic balloon enlarged and burst. The patients developed severe headaches, vomiting, and seizures, with extravasation of contrast material into the surrounding sulci, immediately after the balloon and the artery burst. Four of the patients completely recovered, and one died from an intracerebral hemorrhage. This complication may be avoided if one removes the Silastic tubing whenever the size of the balloon becomes larger than the inner diameter of the feeding artery and if inflation is always carried out gently and slowly. A similar complication has been reported by Prager et al. [5]. The death occurred in a patient with a right middle cerebral artery AVM. The balloon ruptured the feeding artery and the patient immediately became comatose. Postembolization computed tomography showed a large subdural hematoma, and the patient died 72 hr later. Berenstein [6], using the Silastic balloon catheter, reported two cases of rupture of a middle cerebral branch with one death.

A second group of 11 patients had embolization with IBC-2 delivered through our new latex calibrated-leak balloon. In none of the patients in this group was there dissection or rupture of the catheterized artery.

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