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Therapeutic Embolization With a Microballoon Catheter System

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Clinical experience with a new embolization and perfusion microballoon catheter system is presented in 34 patients with angiomas, arteriovenous fistulas, and cerebral hemorrhages. The system uses two separate balloon tips, one for detachment as an embolus and one for perfusion of elastomer. The criteria for catheter and perfusate selection are described. One permanent complication, two temporary complications, and one death occurred in this series. The technique represents a primary mode of therapy for treatment of certain vascular lesions, especially in nonsurgical candidates by virtue of their lesion or clinical state. Abdominal and extremity applications in 15 additional patients are also described. No complications occurred in these patients.

In recent years, diagnostic radiology has undertaken a new role in the treatment of vascular and neoplastic disorders. Catheter techniques have evolved for embolization of angiomas, arteriovenous fistulas, tumors, hemorrhage, and perfusion of primary and secondary neoplasms [1-26]. Embolization and perfusion with particulate matter are performed through 1.3-1.6 mm OD polyethylene catheters. The large size of these catheters and the particulate nature of the material limits the selectivity of embolization and perfusion.

A microballoon 0.3-0.6 mm OD catheter system was developed to obviate these problems (Pevsner [17], manufactured under license by Becton-Dickinson, Rutherford, N.J.). It can be introduced with standard percutaneous catheter techniques through the femoral, axillary, or carotid arteries and superselectively placed anywhere in the vascular system in distal vessels of 0.5-1.0 mm ID [19].

Since 1975, 69 patients had microballoon catheterization with detachable and perfusion balloons. Embolization of angiomas, arteriovenous fistulas, gastrointestinal hemorrhage, and presurgical devascularization of neoplasms was performed in 49 patients, and superselective perfusion of primary and secondary neoplasms in 20 patients. The embolization group is discussed in this report, as well as the criteria for patient selection, catheter selection, and response to therapy.

Subjects and Methods

The microballoon catheter system consists of catheters with one of two different distal silicone balloons. One catheter has a balloon for distention with water-soluble contrast medium and detachment, and the second catheter, which has a balloon with a distal hole, is for perfusion of elastomer or chemotherapeutic agents. The balloons are available in different sizes with external, uninflated diameters of 0.3-0.6 mm. They measure 4-8 mm

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in diameter fully inflated. Larger balloons are available. A complete unit consists of the catheter with either a perfusion or detachable balloon tip.

The catheter material can be polyethylene, polyurethane, or silicone, the smallest diameter of the catheter being less than 0.3 mm. Larger catheters are also available. The choice of catheter material is moot. The characteristics of the three materials are similar, but polyurethane and polyethylene are less distensible than silicone. Catheters of polyurethane, which is easy to opacify with heavy metals, were used in this study. In clinical application there is no significant difference among the three materials.

The delivery system is the same as that described previously with the addition of an injection chamber (fig. 1) [18]. The injection chamber allows the microballoon catheter to be coiled within it, while the proximal part of the catheter is held fast by the proximal wing screw. This allows injection of the balloon catheter into the arterial catheter with total control of the proximal end of the balloon catheter. The entire assembly is connected to the proximal vascular catheter. Brisk injection of flush solution through the side arm of the proximal flushing hub will rapidly propel the distal end of the balloon catheter beyond the distal tip of the vascular catheter. The distal balloon is then inflated with 0.05–0.20 ml of radiopaque contrast medium under fluoroscopic control. The exact volume of contrast medium injected into the correctly positioned detachable balloon must be sufficient for the distended balloon to engage the wall of the vessel. Overdistention can result in balloon rupture. While this is not serious, the entire balloon catheter must be removed and replaced with a new unit. The mechanism and technique of balloon detachment were described in a previous report [19].

An isosmolar contrast medium such as metrizamide (Nygaard, Oslo, Norway) is ideal for the detachable balloon, but the osmolality should not exceed $\times 2.5$ –3 that of blood. High osmolality will result in swelling and rupture of the silicone balloon, which is permeable to water.

The distal balloon is advanced in three ways: (1) alternate inflation and deflation, producing a parachute effect in the blood stream; (2) advancement of the entire vascular catheter and delivery unit at the level of the percutaneous arterial puncture; and (3) loosening the wing screw of the proximal flushing hub and advancing the desired length of the proximal balloon catheter through the proximal flushing hub into the injection chamber. The wing screw is then tightened and flush solution injected as described above. If the inflated balloon passes the desired branch orifice, the entire balloon catheter is pulled back just proximal to the orifice, the balloon is slightly deflated, and step 3 is repeated.

Our early experience with this maneuver was rather prolonged, but after the fifth case, sufficient experience was gained to shorten the time of the procedure. No selective arterial catheterization failures occurred in the entire series of 49 patients. The technique is identical for intra- and extracranial vasculature.

Acrylic (isobutyl-2-cyanoacrylate, Ethicon, Inc., Sommerville, N.J.) or silicone (Dow Corning, Midland, Mich.) infusion is performed as follows: (1) the perfusion balloon is correctly positioned in the appropriate feeding vessel; (2) 5 ml of sterile water or 5% glucose in water is used to flush all contrast material out of the balloon catheter; (3) liquid silicone is perfused in the same way; and (4) acrylic (0.6–1 ml) is injected through the perfusion balloon catheter and the catheter is rapidly removed.

Vascular Lesions of the Head and Neck

Before detachment or elastomer infusion, the balloon is inflated for 5 min to unmask signs of ischemia. When intra-

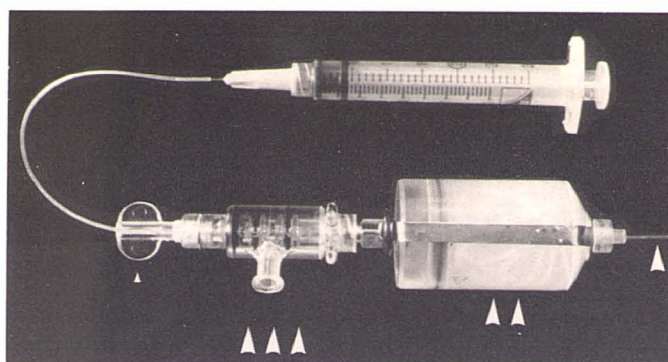


Fig. 1.—Balloon catheter delivery system. Distal balloon catheter (single large arrowhead) protrudes from Luer end of injection chamber (double arrowheads) in which it is coiled. Proximal flushing hub (triple arrowheads). Wing screw (small arrowhead).

cranial lesions are being treated, the patient's neurologic status should be monitored during catheterization. If neurologic deficit is encountered, the balloon is either repositioned or the procedure aborted. It is difficult to monitor children because they usually must be catheterized and embolized under general anesthesia. Three children with intracranial lesions were embolized under light general anesthesia without any complications or neurologic sequelae. Light anesthesia is recommended, so these patients may be rapidly awakened and neurologic testing performed. Antibiotics and steroids were never used and no evidence of clinical infection was observed in the series.

Representative Case Reports

The following seven cases illustrate some of our experiences in embolization in the head and neck in 34 patients 6 months to 67 years old (tables 1 and 2). Perfusion balloon catheters were used in cases 1–6 and a detachable balloon catheter in case 7.

Case 1

A 45-year-old woman, with subarachnoid hemorrhage and a left hemiparesis, had a right parietal angioma fed by the middle cerebral artery. Acrylic (0.6 ml) was injected through the perfusion balloon catheter into a major arterial feeder, and the lesion was reduced by 70% (fig. 2). The patient tolerated the procedure without difficulty. She had no neurologic sequelae and her left hemiparesis cleared.

Case 2

A 24-year-old woman with subarachnoid hemorrhage and cerebellar ataxia had a large right cerebellar hemisphere angioma (figs. 3A and 3B). Surgical excision was attempted after each of two previous episodes of subarachnoid hemorrhage. A perfusion balloon catheter inflated in the proximal right anterior inferior cerebellar artery produced immediate right hearing loss that was relieved with balloon deflation. The procedure was aborted. However, 3 weeks later the catheter was successfully placed in the distal antero-inferior cerebellar artery without hearing loss or other neurologic deficit. Acrylic (0.6 ml) was injected and the angioma was reduced by 70% (fig. 3C). The cerebellar symptoms gradually improved, and there

TABLE 1: Embolizations: Head and Neck

Type and Outcome	No. Patients
Type:	
Perfusion (acrylic)	28
Perfusion (silicone)	4
Detachable balloon	2
Total	34
Morbidity:	
Catheter glued into facial artery	1
Temporary hearing loss with catheter inflated	1
Minor neurologic deficits reversed by catheter tip manipulation	1
Total	3
Mortality	1

TABLE 2: Head and Neck Lesions Treated by Embolization

Type of Lesion	No. Patients
Intracranial angioma	23
Carotidocavernous fistula	2
Vertebral arteriovenous fistula	2
Dural fistula	2
Temporal artery pseudoaneurysm	1
Facial angioma	1
Scalp angioma	1
Angiofibroma	1
Glomus jugulare tumor	1
Total	34

was no recurrent subarachnoid hemorrhage. Arteriography 1 year after embolization revealed a further diminution of the angioma and no growth 2 years after embolization (figs. 3D and 3E).

Case 3

A 67-year-old woman had buzzing in her left ear, a loud postauricular bruit, and palpable thrill. Arteriography revealed a fistula arising from the cervical vertebral artery with a large feeder extending intracranially and immediately draining into the sigmoid sinus (fig. 4A). A perfusion balloon catheter was placed in the major feeding branch of the fistula and acrylic (0.6 ml) was injected, totally obliterating the lesion (figs. 4B and 4C). The patient noted immediate cessation of the bruit and remained symptom-free.

Case 4

A 65-year-old man was admitted with severe occipital headaches, a palpable thrill, and audible bruit over the occiput. Arteriography revealed a large meningeal arteriovenous fistula fed by the left middle meningeal and occipital arteries (fig. 5A). Acrylic (0.6 ml) was injected into the middle meningeal and occipital arteries with 90% occlusion of the fistula (fig. 5B). The other part of the fistula was surgically removed without difficulty.

Case 5

A 27-year-old man who had a facial angioma for 14 years was treated with surgical excision, several ligations of the external carotid arterial branches, and irradiated to 2,400 rad (24 Gy). Arteriography demonstrated a large angioma involving the entire

left face and malar eminence (figs. 6A and 6B). Acrylic (0.6 ml) was injected into the left facial artery, and the balloon catheter was glued into the vessel. It was removed through surgical arteriotomy of the facial artery. The proximal facial artery remained patent postoperatively, and no embolic phenomenon occurred. There was no local skin necrosis or neurologic deficit.

Postembolization arteriography demonstrated almost complete occlusion of the lower part of the angioma (fig. 6C). Since the distal external carotid artery had been ligated, the internal maxillary artery was approached percutaneously with a 21 gauge needle under fluoroscopic control and acrylic (0.6 ml) was injected directly. This produced virtually complete occlusion of the malar part of the angioma (fig. 6D). During the next 12 months, the intraoral and external facial mass progressively diminished. Angiography 2 years after embolization revealed total occlusion of the lower part of the lesion and minimal residual angioma in the malar part.

Case 6

A 23-year-old man had proptotic left eye, bruit, loss of vision, and multiple facial fractures sustained in a high speed automobile accident. Left carotid angiography revealed a large carotid cavernous fistula with cross-filling of the contralateral cavernous sinus and superior orbital vein, and nonfilling of the intracranial branches of the left internal carotid system (figs. 7A and 7B). Large medial and lateral tears in the cavernous carotid artery precluded the use of detachable balloons. Successive perfusion balloon catheters were placed in the medial and lateral aspects of the fistula with several injections of acrylic (0.6 ml).

After the first injection, immediate occlusion of the contralateral superior ophthalmic vein occurred. After the second injection, intracranial filling of the left middle and anterior cerebral arteries was observed. After the third injection, the fistula diminished significantly, but filling defects were noted (from the acrylic) in the supracavernous part of the internal carotid artery (fig. 7C). The patient had no subjective complaints, and no neurologic signs were elicited, but he still complained of the bruit. A fourth injection further reduced the fistula, and the patient immediately noted a cessation of the bruit. This was confirmed on physical examination. The proptosis gradually decreased, and the patient sustained no ill effects from the procedure.

Case 7

A 30-year-old man sustained a laceration of the left preauricular zone, which was sutured primarily. He returned 3 weeks later with a painfully swollen left temporal and preauricular area. Angiography revealed a pseudoaneurysm of the superficial temporal artery (fig. 8A). A detachable balloon catheter was placed in superficial temporal artery and the balloon was released (fig. 8B). Postembolization angiography revealed total occlusion of the superficial temporal artery (fig. 8C). The patient tolerated the procedure without difficulty and obtained a good clinical result without recurrence. The balloon was still inflated 1 year after embolization.

Vascular Lesions in the Abdomen and Extremities

Fifteen patients 11–58 years old with various vascular lesions in the abdomen and extremities were embolized with the perfusion or detachable balloons (table 3). Five patients were treated with acrylic perfusion for spontaneous hemorrhage that was associated with peptic ulcers in two, and esophageal varices, pulmonary hemorrhage from a heman-

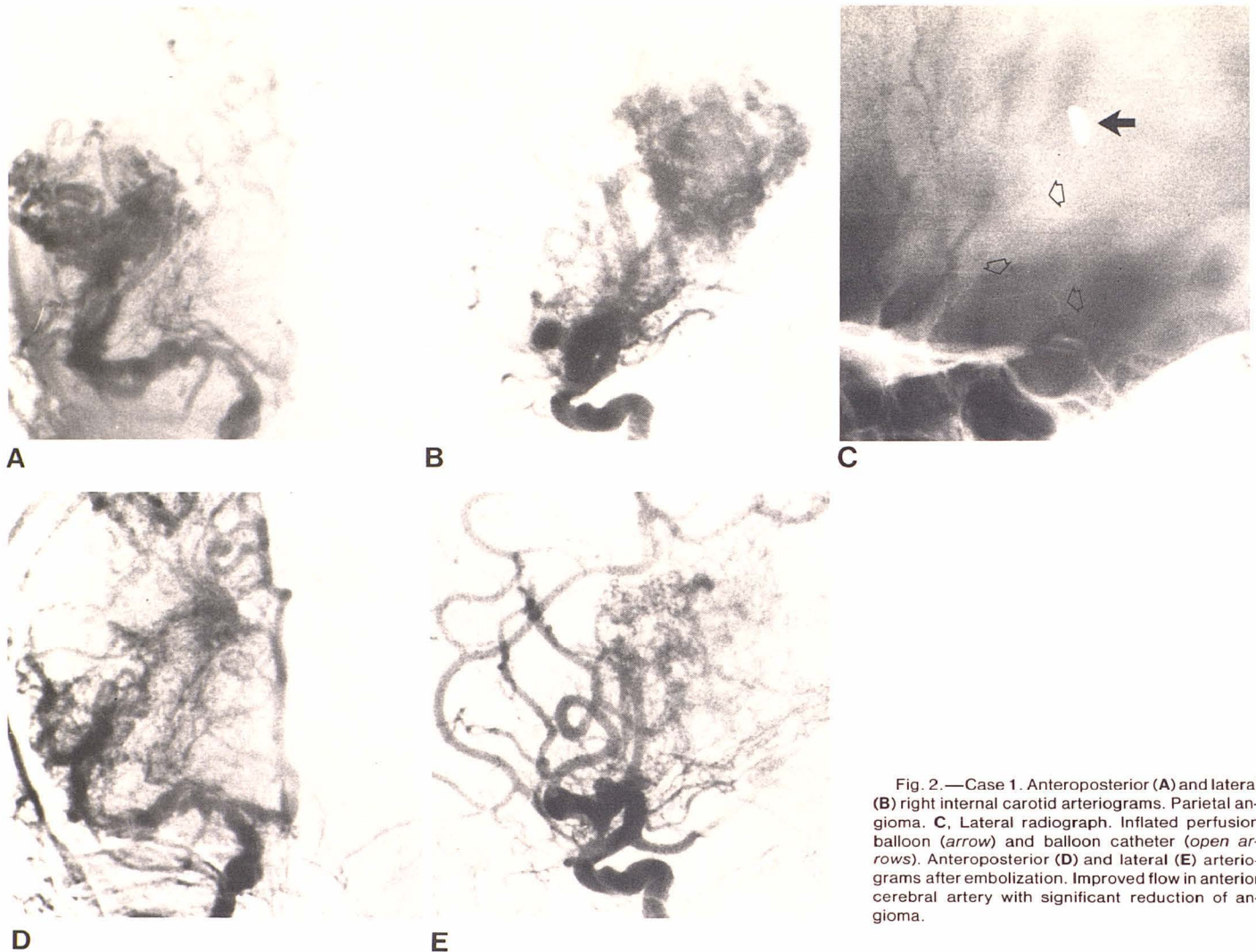


Fig. 2.—Case 1. Anteroposterior (A) and lateral (B) right internal carotid arteriograms. Parietal angioma. C, Lateral radiograph. Inflated perfusion balloon (arrow) and balloon catheter (open arrows). Anteroposterior (D) and lateral (E) arteriograms after embolization. Improved flow in anterior cerebral artery with significant reduction of angioma.

gioma, and hemorrhage from a cervical cancer in one each. In three patients the detachable balloons were used preoperatively to aid in the resection of hypernephroma. Three patients with arteriovenous fistulas (hepatic, femoral, radial) were treated with detachable balloons and one patient with a gluteal arteriovenous malformation was perfused with acrylic. In case 8 both detachable balloons and acrylic were used for the control of an insulinoma. In one patient a sciatic artery aneurysm was occluded with a detachable balloon, and in another patient with hypersplenism, splenic artery occlusion was obtained with a detachable balloon.

The techniques and decisions regarding perfusion or detachable balloon catheters and the advantages over particulate emboli are the same in the body as in the head. No morbidity or mortality was observed in this group of patients. No steroids or antibiotics were used.

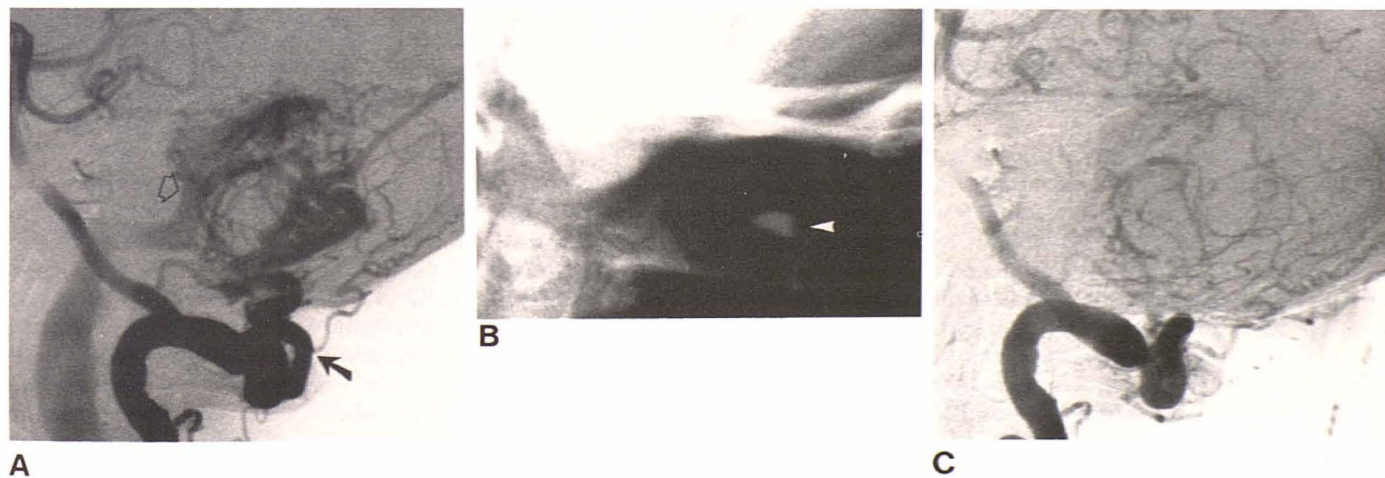
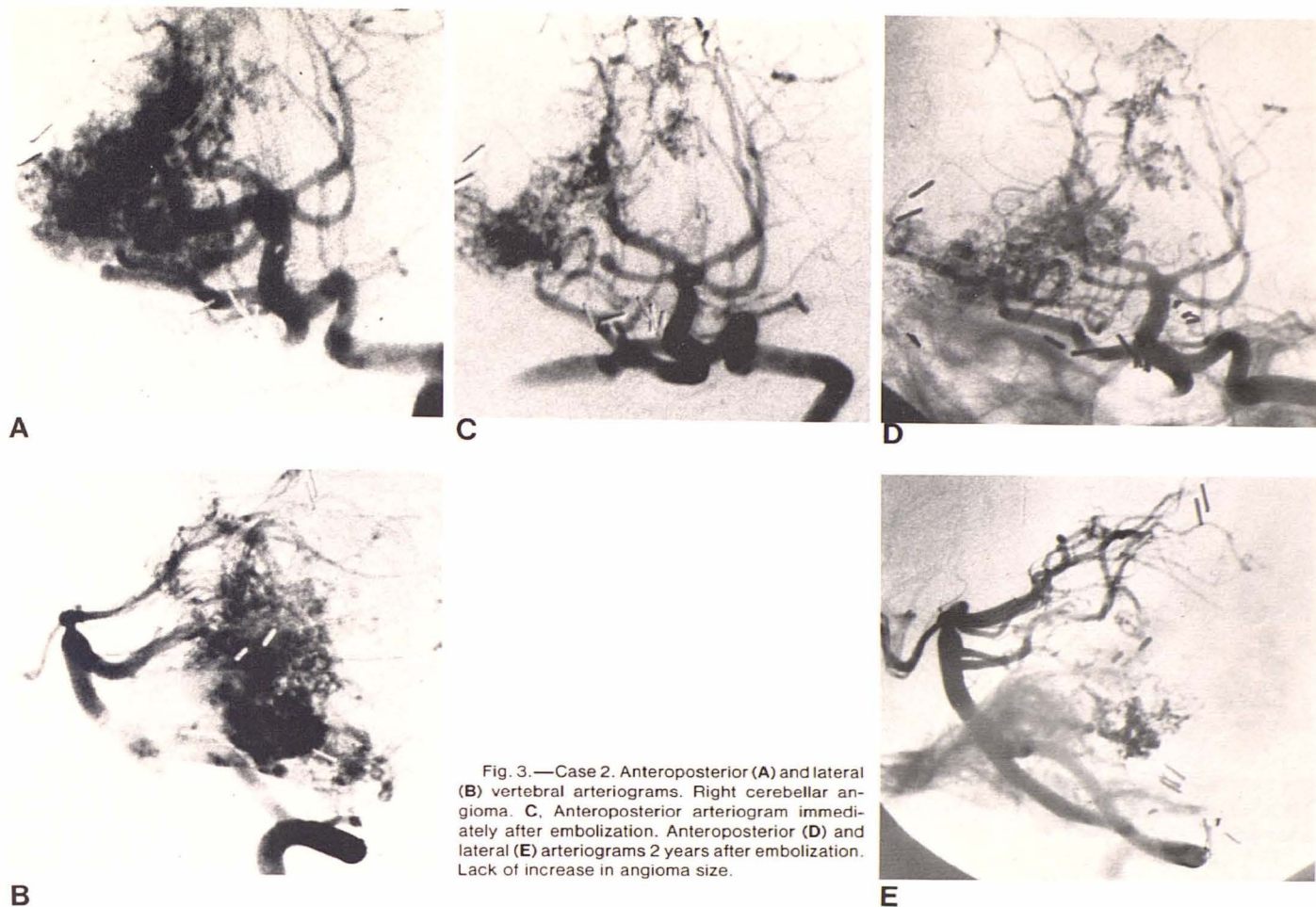
Representative Case Reports

The following reports detail two of the most interesting cases. In case 8, an early case, an overinflated balloon deflated. No subse-

quent balloon deflation occurred. Total occlusion was achieved in eight (90%) of nine cases with the detachable balloon and in six (85%) of seven cases with elastomer perfusion. In the one perfusion case that was not totally occluded, 80% occlusion was obtained. A comparable series of 13 patients using the identical detachable balloon system was recently reported by White et al. [27]. Similar efficacious results were obtained.

Case 8

A 57-year-old man with metastatic insulinoma in the right lobe of the liver and elevated serum insulin levels requiring constant intravenous or oral feedings was referred for therapeutic tumor infarction. The branches of the right hepatic artery were embolized with detachable balloons occluding two of three right branches and narrowing the origin of the third (fig. 9). The patient tolerated the procedure without difficulty, but 24 hr after embolization, one of the balloons deflated, presumably due to overinflation. Serum insulin stayed at the preembolization level. The right hepatic artery was embolized 1 week later with acrylic (0.6 ml). Serum insulin declined to almost normal, and the patient was sent home. However, 3 months later he returned with preembolization serum insulin levels and died on hospital admission.



Case 9

A 52-year-old man with a history of somatostatinoma of the pancreas with liver metastasis was referred after a Whipple proce-

dure for selective arterial perfusion of the liver with chemotherapy. He had a percutaneous liver biopsy before initial surgery and at angiography an arteriovenous fistula was demonstrated (fig. 10A). A detachable balloon was used to occlude the fistula (figs. 10B and

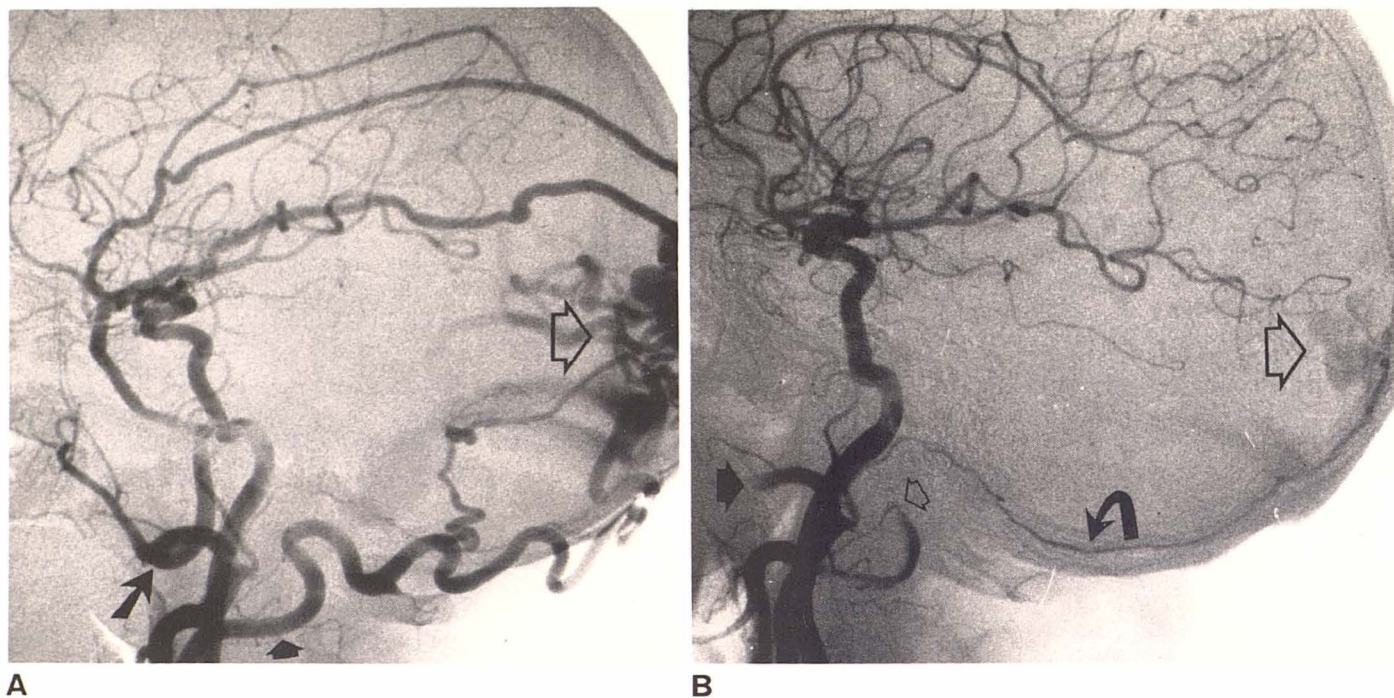


Fig. 5.—Case 4. **A**, Lateral left carotid arteriogram. Meningeal fistula (open arrow). Middle meningeal artery (long arrow). Occipital artery (short solid arrow). **B**, After embolization. Occluded middle meningeal artery (short solid arrow) and occipital artery (small open arrow). Residual meningeal artery (curved arrow) feeds reduced fistula (large open arrow).

10C), which was still occluded with the balloon inflated 6 months after embolization.

Discussion

Three important aspects govern interventional radiology with the microballoon catheter: (1) patient selection, (2) choice of catheter, and (3) patient response.

All patients with angiomas or arteriovenous fistulas are potential candidates for embolization with this technique, but the following considerations should be examined in each case:

1. Is the patient symptomatic; has there been hemorrhage; or have there been seizures? Therapeutic embolization is preferably reserved for symptomatic patients.
2. Are the potential risks of the angioma or arteriovenous fistulas greater than the risks of the procedure? (There was one permanent complication, two temporary complications, and one death in our series of 34 patients.)
3. Is the lesion amenable to embolization techniques (e.g., fine capillary angiomas, especially intracranial, may have no identifiable major arterial feeder)?

Catheter choice of either a detachable balloon or perfusion balloon is dictated by the type of lesion. Arteriovenous fistulas with a single communication (case 9), pseudoaneurysms (case 7) with a single arterial feeder, giant aneurysms with an identifiable neck, and bleeding sites in the lung, gastrointestinal tract, or pelvis with a single or even three or four main feeders are best treated with detachable balloons. On the other hand, angiomas require occlusion of the tissue level shunts (cases 1, 2, and 5). The interstices of these

lesions must be filled to abolish the sump effect that promotes progressive growth and enlargement of the lesion. Occlusion of the arterial feeders is no better than surgical ligation. Elastomer perfusion (acrylic or silastic) using the perfusion catheter is the appropriate therapy. Large arteriovenous fistulas can be treated with perfusion techniques (cases 3, 4, and 6). If there are high level shunts and a rapid flow lesion, acrylic is the perfusate of choice because of its relatively instant polymerization, preventing embolization to the pulmonary circulation. If the lesion is large but has low flow, silicone with its slower rate of polymerization will allow more complete occlusion of these large lower flow lesions.

Embolic particulate matter was and still is a major component of neurologic and peripheral angiography armamentarium. However, such materials cannot be selectively controlled by antegrade methods, although effective retrograde techniques are available [1] to prevent reflux of this material. Lack of antegrade specificity is unimportant in the extracranial extrafacial peripheral vasculature, but can be disastrous intracranially. As the sump effect decreases during embolization with particulate matter, the emboli can then travel to vital areas supplied by vessels close to but not directly involved with the angioma. In 68% of the embolization procedures carried out in one series, the emboli strayed into normal arteries. Temporary neurologic complications occurred in one-half of these instances but only one patient (of 34) had permanent neurological deficit [28].

Over a 5 year period, the microballoon catheter system was used in 34 patients for head and neck embolization. Only one permanent morbidity (gluing the catheter into the

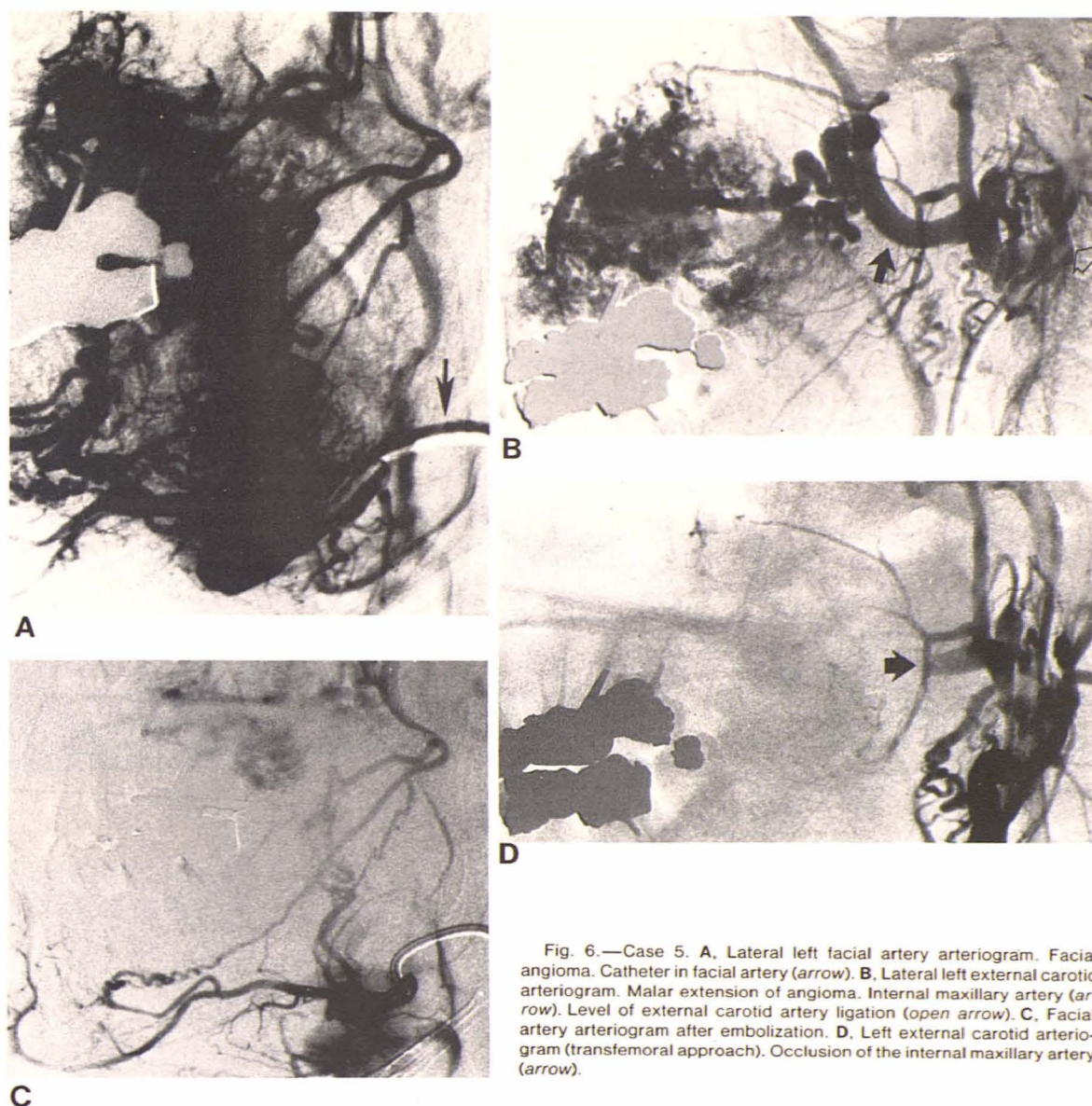


Fig. 6.—Case 5. **A**, Lateral left facial artery arteriogram. Facial angioma. Catheter in facial artery (arrow). **B**, Lateral left external carotid arteriogram. Malar extension of angioma. Internal maxillary artery (arrow). Level of external carotid artery ligation (open arrow). **C**, Facial artery arteriogram after embolization. **D**, Left external carotid arteriogram (transfemoral approach). Occlusion of the internal maxillary artery (arrow).

facial artery with acrylic) and one death occurred; neither was related to uncontrollable catheter position (table 1). Because of its superselective placement, the balloon catheter allows temporary occlusion and evaluation of any neurologic deficit caused by such occlusion. In the one instance in which hearing loss was produced when the balloon was inflated, hearing was immediately restored with deflation of the balloon (case 2), and the procedure was aborted and successfully repeated 3 weeks later. In one other patient (not in this series), the procedure was aborted because of temporary neurologic deficit detected on inflation of the trial detachable balloon [19]. On one other occasion a minor hemiparesis (positive Goldstein sign) was observed, but this was reversed by slight changes in the catheter tip position. Such manipulation is entirely empiric. Thus, the microballoon catheter system offers greater selectivity and control over the particulate emboli systems.

The single death occurred in a 22-year-old woman. She was admitted with a subarachnoid hemorrhage, severe ataxia, and depressed mentation. Angiography revealed a 5 cm thalamic angioma. This was treated with 0.6 ml acrylic without incident with a 50% ablation of the lesion. She was discharged and returned 1 month later for follow-up angiography and further treatment. On physical examination, all signs of ataxia had cleared, and her mentation was significantly improved on psychologic testing (Halsted-Reitan-Battery). Repeat arteriography showed a large thalamoperforate arterial feeder remained. This vessel was easily catheterized with the balloon catheter, and the balloon was inflated. The patient tolerated the temporary occlusion without any neurologic signs. Suddenly, she had an epileptic seizure and respiratory arrest. Resuscitation was successful, but she never regained consciousness and died 48 hr after the procedure. Postmortem examination revealed a large mid-

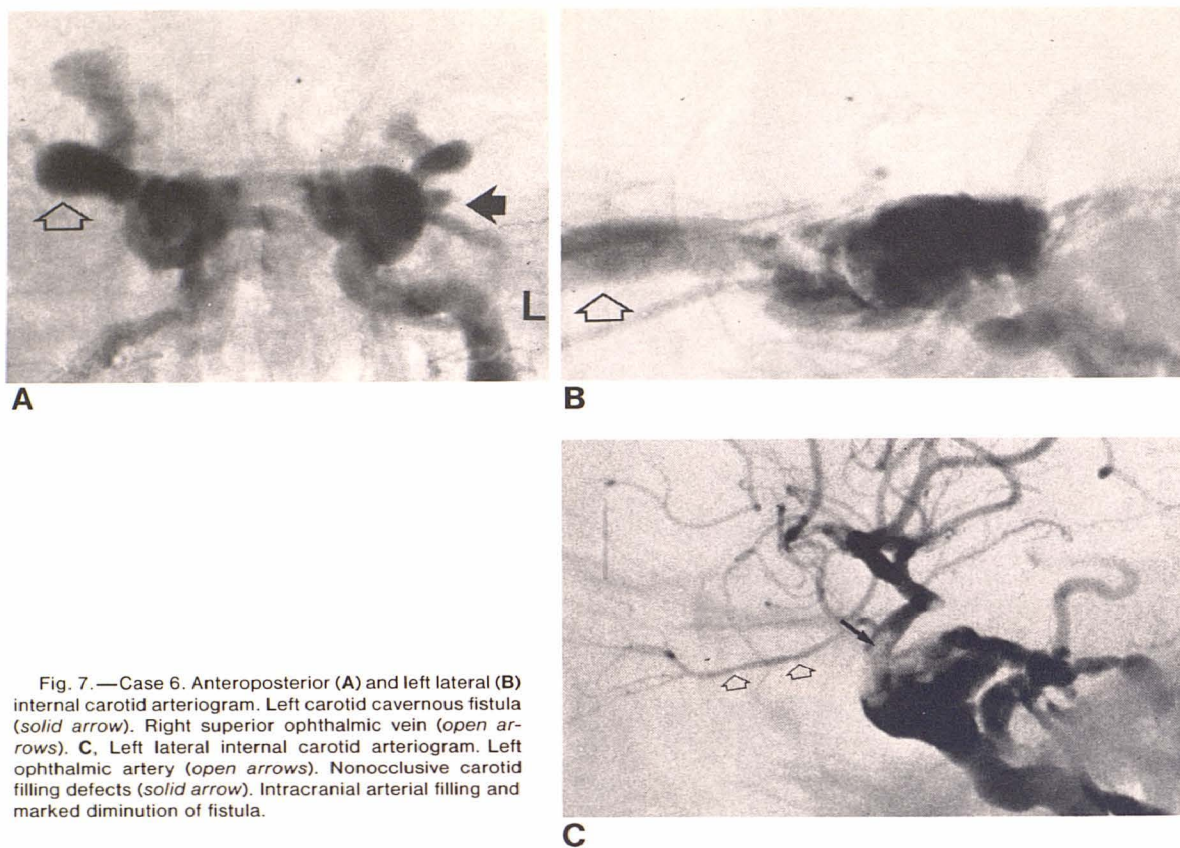


Fig. 7.—Case 6. Anteroposterior (A) and left lateral (B) internal carotid arteriogram. Left carotid cavernous fistula (solid arrow). Right superior ophthalmic vein (open arrows). C, Left lateral internal carotid arteriogram. Left ophthalmic artery (open arrows). Nonocclusive carotid filling defects (solid arrow). Intracranial arterial filling and marked diminution of fistula.

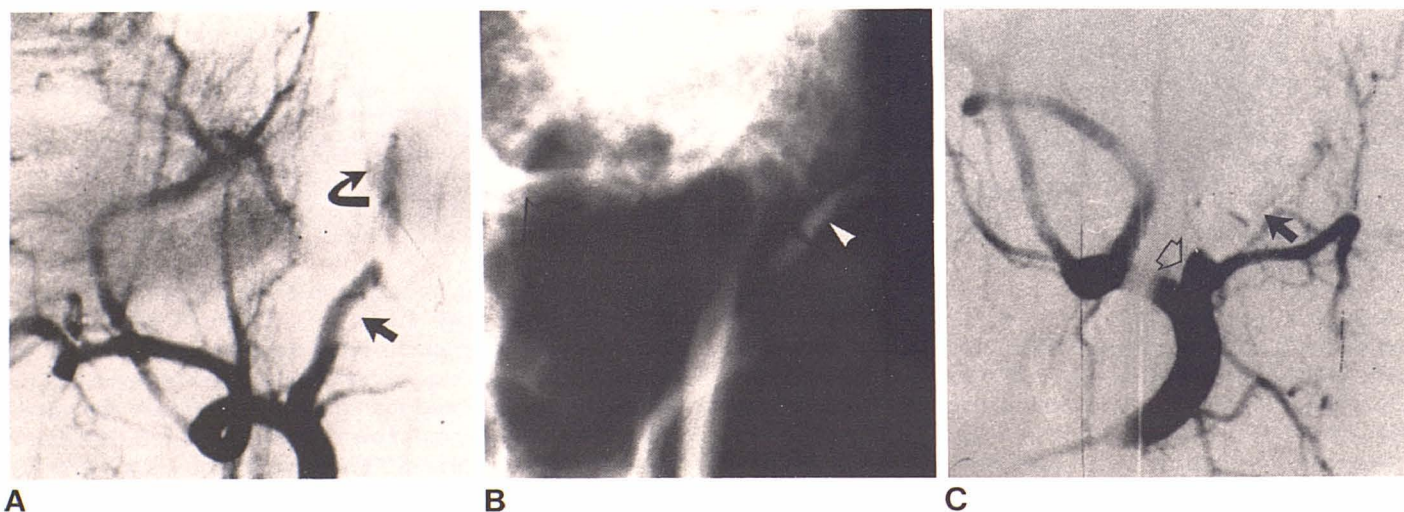


Fig. 8.—Case 7. A, Anteroposterior left external (B) carotid arteriogram. Superficial temporal artery (straight arrow) and pseudoaneurysm (curved arrow). B, Anteroposterior film. Contrast-filled detached balloon (arrowhead). C, After embolization. Obstructed proximal superficial temporal artery (open arrow) and detached balloon (solid arrow).

brain hemorrhage. Careful dissection revealed no vessel tears, and a specific site of vascular rupture could not be demonstrated. The fatal hemorrhage is considered a complication of the procedure, but remains unexplained.

Long term effects are best measured by clinical and

angiographic evaluation, specifically decrease in incidence of seizures, absence of recurrent hemorrhages, permanent fistula occlusion, and progressive decrease in lesion size. Follow-up evaluations have been from 12 to 42 months. A single seizure was the initial presenting sign in nine patients.

After embolization, all patients were treated with anticonvulsants. No patient had a recurrence of seizures. A cerebral hemorrhage was the presenting sign in 14 patients. One patient (case 2) had three hemorrhages and the rest had one. No hemorrhages recurred after embolization.

Greater than 80% occlusion of the lesions was achieved in 13 (40%) of 32 perfusion cases. Greater than 60%

occlusion was achieved in 14 (43%), and no less than 50% occlusion was obtained in the rest. Cases 2 and 5 were studied angiographically at 1 and 2 years after embolization. In case 2 the cerebellar angioma continued to diminish. In case 5, the lower part of the facial angioma remained totally occluded; however, a small residual upper part was unchanged at 2 years. These findings are in contradistinction to the surgical experience where it is found that lesions tend to recur unless they are totally ablated.

Total occlusion was achieved in both head and neck cases with detachable balloons. Because of distention with isosmolar radiopaque contrast media, the balloons remained visible on plain radiographs. Of the total 49 patients, sequential films were obtained in each of the 11 treated with detachable balloons (tables 1 and 3). The last follow-up film was 42 months after balloon detachment (case 7). The balloons remained inflated in all cases except one (case 8).

TABLE 3: Embolizations: Abdomen and Extremities

Type of Embolization	No. Patients (n = 15)
Perfusion (acrylic)	7
Detachable balloon occlusion	9
Total	16*

Note. —No morbidity or mortality was associated with these embolizations.

* Case 9 was treated by both methods.

Fig. 9.—Case 8. **A**, Right hepatic arteriogram. Right hepatic artery (arrow). **B**, After embolization. Detached balloons (arrows) with occlusion of two branches of hepatic artery.

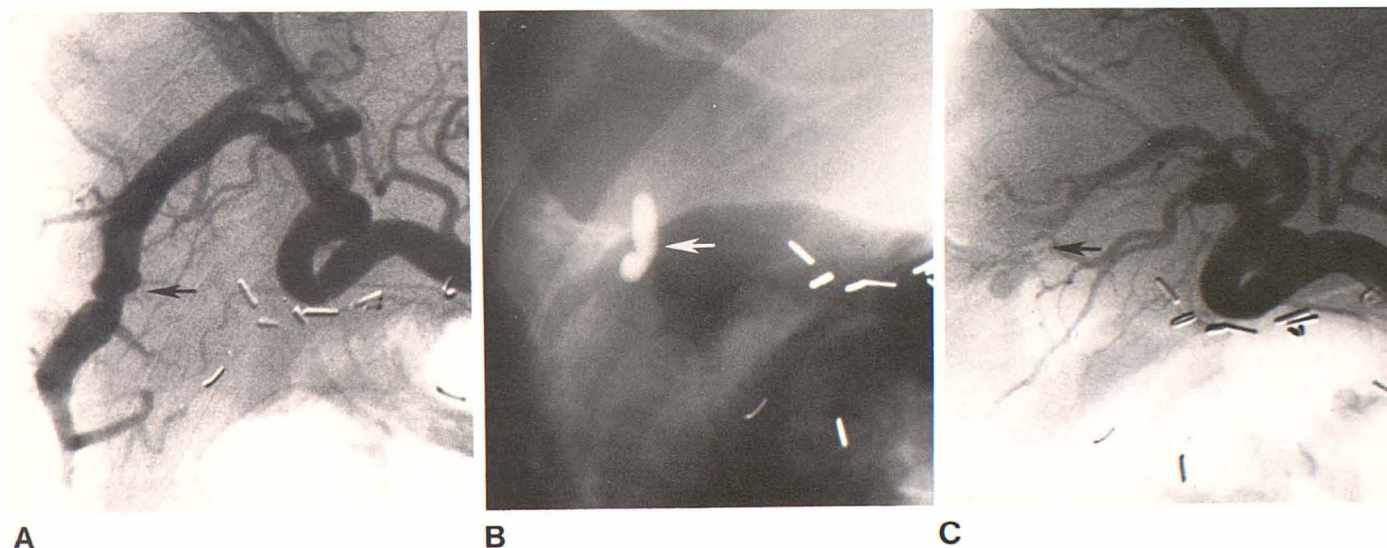
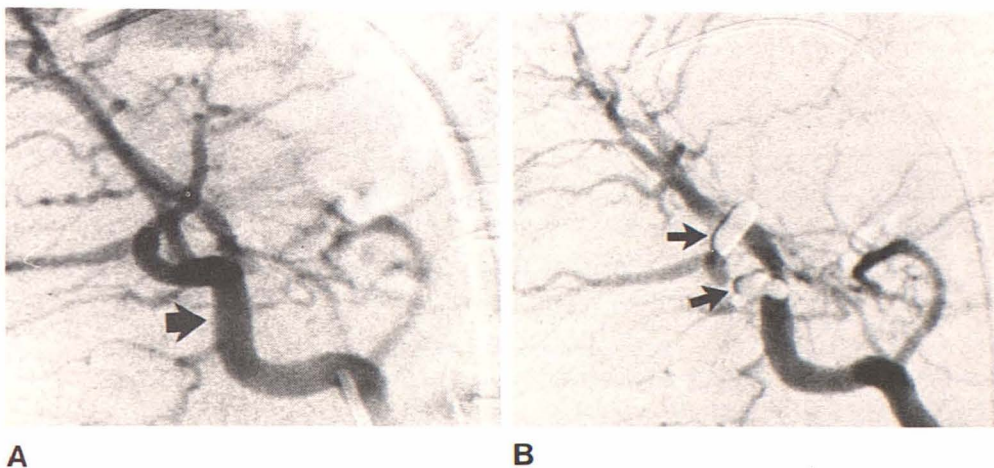


Fig. 10.—Case 9. **A**, Selective right hepatic artery angiogram. Distal arteriovenous fistula (arrow). **B**, Anteroposterior abdominal film. Detached balloon conforms to shape of fistula (arrow). **C**, Angiogram after embolization, right hepatic artery. Occlusion of fistula and detached balloon (arrow).

Three other balloon catheter systems are in current use. The calibrated leak balloon of Kerber [11] is similar to the present system except that only a perfusion tip and no detachable balloon tip is available. It is an excellent system and easy to use. The balloons of Debrun et al. [2] have two problems: (1) a coaxial catheter is necessary for detachment of the balloon tip in one type (which limits catheter use to levels no higher than the carotid siphon) and (2) premature detachment can occur with their other balloon catheter. The balloon catheter of Serbinenko [21], which is similar to the noncoaxial system of Debrun et al. [2], suffers the same problem of premature detachment (P.H.P., personal observation, Burdenko Institute, Moscow, 1975).

Our clinical experience suggests an alternate, relatively safe primary mode of therapy for focal vascular lesions in the head and body, or as an adjunct to surgery.

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