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## Endovascular Arterial Occlusion Accomplished Using Microcoils Deployed with and without Proximal Flow Arrest: Results in 19 Patients

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*AJNR Am J Neuroradiol* 1999, 20 (8) 1452-1456

<http://www.ajnr.org/content/20/8/1452>

This information is current as of August 7, 2025.

## Endovascular Arterial Occlusion Accomplished Using Microcoils Deployed with and without Proximal Flow Arrest: Results in 19 Patients

John D. Barr and Thomas J. Lemley

**BACKGROUND AND PURPOSE:** Prior to their relatively recent FDA approval, detachable balloons for endovascular arterial occlusion had been available on only a limited basis. We evaluated the feasibility of permanent endovascular carotid and vertebral artery occlusion using microcoils deployed with and without proximal flow arrest in 19 patients.

**METHODS:** Permanent endovascular occlusion was performed in 19 arteries of 19 patients. The treated lesions included nine aneurysms, one carotid-cavernous fistula/pseudoaneurysm, seven neoplasms, and two dissections. Nondetachable balloons were used to arrest proximal blood flow during occlusion of only six arteries. Anticoagulation (heparin, 5000 U IV) was used during occlusion of 18 arteries. Three to 88 coils were used per lesion. Complex fibered platinum microcoils were used for all cases, and GDCs were also used in two patients.

**RESULTS:** Sixteen patients had no new neurologic deficits after arterial occlusion. No patient had an acute event that suggested an embolic complication. Coils provided rapid and durable arterial occlusion in 17 patients. In both patients with acute carotid artery rupture, large numbers of coils placed during flow arrest failed to produce complete occlusion, which was accomplished subsequently with detachable balloons. One of these patients incurred a fatal hemispheric infarct after occlusion. One patient treated for a ruptured posterior inferior cerebellar artery aneurysm by vertebral artery occlusion continued to have progressive neurologic deficits. One patient with a cavernous aneurysm had upper extremity weakness and mild dysphasia 24 hours after internal carotid artery occlusion.

**CONCLUSION:** In our small series, microcoils were found to be safe and effective for neurovascular occlusion. When both intravenous heparin (5000 U IV bolus) and heparinized catheter flush solutions (5000 U/L) are used, flow arrest during coil placement is unnecessary to prevent clinically apparent embolic complications.

After Serbinenko published his description of arterial occlusion with the use of detachable latex balloons in 1974 (1), permanent endovascular occlusion of the carotid and vertebral arteries was rapidly adopted for treatment of a variety of vascular disorders. The efficacy of endovascular carotid and vertebral artery occlusion for treatment of aneurysms, pseudoaneurysms, arteriovenous fistu-

las, neoplasms, and traumatic injuries is now widely acknowledged. For over two decades, detachable balloons made from silicone or latex have been considered the appropriate device for endovascular occlusion of the carotid and vertebral arteries. Until May 1998 (subsequent to treatment of the patients described in this report), no detachable balloons had been approved by the Food and Drug Administration, and these devices were available only on a limited basis. Alternative methods for arterial occlusion were used in some cases, and only a few reports had been published concerning the use of coils for cerebrovascular arterial occlusion (2–6). More recently, Graves et al (7) described safe endovascular arterial occlusion using complex platinum microcoils placed during temporary proximal flow arrest in a series of 19 patients. In this report, we describe the use of microcoils for occlusion of 11 vertebral and eight carotid arteries in 19 patients. Unlike the technique reported by Graves et

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Received August 21, 1998; accepted after revision April 5, 1999.

Presented at the annual meeting of the American Society of Neuroradiology, Philadelphia, May 1998.

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TABLE 1: Patient characteristics

Patient	Age (y)/ Sex	Diagnosis	Site of Occlusion	Tempo- rary Flow Arrest Used	Complications
1	68/F	Metastatic renal cell carcinoma	VA	Yes	None
2	23/M	CCF/pseudoaneurysm	ICA	No	None
3	66/M	Aneurysm	VA	No	None
4	50/M	Squamous cell carcinoma/ carotid rupture	ICA, ECA, CCA	Yes	Required detachable balloon
5	41/F	Osteosarcoma	VA	No	None
6	53/F	Aneurysm	VA	No	None
7	72/F	Aneurysm	VA	No	Progressive deficits attributed to vasospasm
8	59/M	Myeloma	VA	No	None
9	82/M	Squamous cell carcinoma/ carotid rupture	ICA, CCA	Yes	Required detachable balloon, fatal infarction
10	72/M	Dissection	VA	No	None
11	35/F	Dissection	VA	Yes	None
12	47/F	Aneurysm	VA	Yes	None
13	79/F	Aneurysm	ICA	No	None
14	64/F	Aneurysm	ICA	No	None
15	53/F	Aneurysm	ICA	No	None
16	65/M	Metastatic renal cell carcinoma	VA	No	None
17	42/F	Aneurysm	ICA	Yes	None
18	68/F	Aneurysm	ICA	No	Mild dysphasia, upper extremity weakness
19	61/F	Lymphoma	VA	No	None

Note.—CCF indicates carotid-cavernous fistula; ICA, internal carotid artery; ECA, external carotid artery; CCA, common carotid artery; VA, vertebral artery.

al, we used temporary proximal flow arrest for only six (32%) of these cases.

## Methods

Nineteen patients, 12 women and seven men, 23 to 82 years old (mean age, 58 years), underwent permanent endovascular occlusion of 19 arteries (Table 1). The occluded vessels included six internal carotid, two common/internal carotid, and 11 vertebral arteries. The treated lesions included nine aneurysms, one carotid-cavernous fistula with a pseudoaneurysm, seven neoplasms, and two arterial dissections. Nondetachable balloons were used to arrest proximal blood flow during occlusion of six (32%) arteries. Anticoagulation was used in 18 (95%) of the cases. All of these patients received intravenous bolus injections of heparin (5000 U) 5 to 10 minutes before microcoil placement. Laboratory analyses of the effects on coagulation profiles were not performed. In all 19 cases, the coaxial catheter systems were perfused continuously with normal saline flush solutions containing heparin (5000 U/L). The additional amount of heparin introduced through the catheter systems was estimated to be approximately 1500 U. To reduce the risk of air emboli, all coil introducers were flushed with an identical heparinized saline solution before coil introduction. The number of coils used in each case ranged from three to 88 (mean, 18). Complex fibered platinum microcoils (Boston Scientific Corp, Watertown, MA, and Cook, Inc, Bloomington, IN) were used for all cases, and Guglielmi detachable coils (GDCs) (Boston Scientific Corp) were also used in two patients. Complete pre- and postocclusion neurologic evaluations were performed in all patients.

These 19 patients do not represent a consecutive series. During the same time period (December 1993 to December 1997), five additional patients underwent carotid artery occlusion for treatment of aneurysms and carotid-cavernous fistulas with detachable silicone balloons under our physician-sponsored in-

vestigational device exemptions (IDEs) for this device. Our IDEs did not cover vertebral artery occlusion with these balloons, which accounts for the relatively higher number of vertebral arteries occluded with microcoils. Patients treated with detachable latex balloons were also excluded. Additional patients in whom temporary arterial balloon test occlusion had failed and who had bypass grafts placed before arterial occlusion were also excluded from this report.

## Internal Carotid Arteries

Proximal flow arrest was used during occlusion of only one (17%) of six internal carotid arteries. Five patients were treated for cavernous carotid aneurysms and one for a residual carotid-cavernous fistula with a large pseudoaneurysm. Balloon test occlusion of the internal carotid artery was performed on and passed by all patients. Our balloon test occlusion protocol consisted of a 30-minute clinical neurologic evaluation combined with  $^{99m}\text{Tc}$ -hexamethylpropyleneamine oxime single-photon emission CT (SPECT) cerebral blood flow evaluation. After completion of the balloon test occlusion procedure, patients were transported from the neuroangiography suite to the nuclear medicine department for SPECT scanning. It is not our usual practice to follow balloon test occlusion immediately with permanent vessel occlusion; thus, all six patients underwent permanent arterial occlusion the day after balloon test occlusion.

In all cases, permanent occlusions were performed with microcoils placed through Rapidtransit (Cordis Endovascular Systems, Miami Lakes, FL) or TurboTracker (Boston Scientific Corp) microcatheters. No proximal flow arrest was used in five patients; instead, 5F or 6F guiding catheters were employed. For patient 2, 11 complex microcoils (Boston Scientific) were used. In the subsequent four patients, three to nine (mean, five) Diamond Vortex coils (Boston Scientific) were used. Systemic anticoagulation with heparin (5000 U IV) was used in all cases.

For patient 17, who had a 40-mm-diameter cavernous aneurysm, a 5.4F Zeppelin balloon occlusion catheter (Medtronic/Micro Interventional Systems, Sunnyvale, CA) was used to arrest proximal blood flow during microcoil placement. Our goal in this case was to trap the giant aneurysm by placing microcoils both distal and proximal to the aneurysm. Because we planned to place coils closely matched to the vessel diameter just distal to the aneurysm, we were concerned about distal coil migration during coil placement. To prevent this, we used the proximal occlusion balloon to arrest blood flow. We were, however, unable to position the microcatheter just distal to the aneurysm, so we occluded the internal carotid artery with 10 Diamond Vortex coils placed proximally to the aneurysm.

#### *Common Carotid Arteries*

Two patients with malignant lesions of the head and neck presented with acute carotid rupture. The source of hemorrhage in patient 4 was a distal common carotid artery pseudoaneurysm. Hemorrhage had been controlled initially by direct manual compression of the pseudoaneurysm through a dehiscent cutaneous wound. Assessment of tolerance for permanent carotid artery occlusion was desired to determine the appropriate therapy—either endovascular arterial sacrifice or surgical bypass graft placement. Balloon test occlusion was complicated by the need to maintain hemostasis during anticoagulation. Isolation of the pseudoaneurysm by simultaneous occlusion of the common, internal, and external carotid arteries was necessary. An 8.4F Zeppelin balloon catheter was inflated in the distal common carotid artery. Two nondetachable Endeavor balloons (Boston Scientific) were advanced through the Zeppelin catheter and inflated within the proximal internal and external carotid arteries. Hemostasis was maintained without manual arterial compression during anticoagulation with heparin (5000 U IV), and a 30-minute clinical neurologic evaluation was performed with no changes detected. Protamine sulfate (50 mg IV) was given to reverse anticoagulation. Proximal flow arrest was maintained while 88 complex microcoils were placed into the external, internal, and common carotid arteries.

Patient 9 had massive hemorrhage from a carotid bifurcation erosion controlled only by firm manual compression, which occluded the carotid artery. The patient was hemodynamically unstable, and balloon test occlusion was not feasible. No anticoagulation was used. An 8.4F Zeppelin balloon catheter was inflated in the distal common carotid artery, and proximal flow arrest was maintained while 32 complex microcoils were placed into the internal and common carotid arteries.

#### *Vertebral Arteries*

Temporary proximal blood flow arrest was not used during occlusion of eight (73%) of 11 vertebral arteries; instead, heparin (5000 U IV) was used for systemic anticoagulation. Three to 27 (mean, 13) microcoils (Boston Scientific and Cook, Inc) were placed through a variety of microcatheters introduced through 4F to 6F guiding catheters. In addition to the complex shaped microcoils used in all cases, GDCs were used in two patients. In one case, a single GDC was selected to allow precise coil placement. In the other case, GDCs were used to gain experience with their thrombogenicity and possible utility for occlusion of large arteries, not because precise coil placement and distal migration were particular concerns.

Patient 7 was being evaluated for vasospasm following subarachnoid hemorrhage and posterior inferior cerebellar artery (PICA) aneurysm clipping. Angiography revealed moderate arterial vasospasm and showed that the aneurysm clip had been mistakenly placed on the anterior inferior cerebellar artery (AICA), leaving the PICA aneurysm patent. A second open surgical procedure was believed to carry excessive risk. The morphology of the aneurysm suggested that sacrifice of the PICA would be unavoidable; endovascular occlusion of the

vertebral artery across the PICA origin was considered to be effective and straightforward. A single GDC was selected to allow precise placement proximal to the vertebrobasilar junction. Nine Tornado coils (Cook, Inc) were then placed across and below the PICA origin.

Patient 6 presented with subarachnoid hemorrhage from a fusiform vertebral artery aneurysm with the right PICA arising at the most distal aspect of the aneurysm. Open surgical treatment was considered to have minimal chance of maintaining patency of both the vertebral artery and the PICA. Endovascular occlusion of the vertebral artery proximal to the aneurysm was planned to allow thrombosis of the aneurysm and possibly to preserve patency of the PICA. Five GDCs were placed into the vertebral artery, followed by six Tornado coils placed proximally to the GDCs.

Proximal flow arrest was used during occlusion of the remaining three vertebral arteries (27%). Patient 11 had a large right PICA distribution infarction caused by an acute vertebral artery dissection. Long-term anticoagulation for prevention of distal emboli was undesirable owing to fear of hemorrhagic transformation of the acute infarction. Because the left vertebral artery was of similar caliber as the right, a temporary right vertebral artery occlusion test was not considered necessary. To prevent distal embolization of fresh thrombus identified at the site of the dissection, a 5.4F Zeppelin dual-lumen balloon catheter allowed temporary proximal flow arrest during placement of 25 microcoils through a coaxially placed Rapidtransit microcatheter. Systemic anticoagulation with heparin (5000 U IV) was used during coil placement but reversed with protamine sulfate (50 mg IV) immediately thereafter.

In two patients (cases 1 and 12), temporary occlusion testing of the dominant vertebral artery had been performed immediately before permanent occlusion. Clinical neurologic evaluations during 15 minutes of arterial occlusion detected no changes in either patient; no cerebral blood flow evaluation or other type of adjunctive testing was used to assess tolerance for arterial occlusion. Dual-lumen balloon occlusion catheters (7F MediTech, 5.4F Zeppelin) had been used in both cases and were not removed before the placement of 15 and 17 microcoils, respectively, through coaxially introduced microcatheters.

## **Results**

Microcoils provided rapid and durable arterial occlusion in 17 (89%) of the 19 patients. Routine follow-up angiograms were not obtained. Arterial recanalization was not evident clinically in any case. The follow-up period ranged from 4 to 36 months (mean, 19 months). No new neurologic deficits developed in 16 (84%) patients after arterial occlusion. No patient had an acute event that suggested an embolic complication.

Patient 7 (treated for a ruptured PICA aneurysm by occlusion of the vertebral artery across the PICA origin) continued to incur slowly progressive neurologic deficits attributed to severe vasospasm and inadvertent surgical ligation of the AICA. No abrupt or significant change in neurologic status was noted on the day of the procedure to suggest an embolic complication.

Patient 18 (with a cavernous aneurysm) had transient upper extremity weakness and mild dysphasia 24 hours after internal carotid artery occlusion. Whether this represented collateral vascular insufficiency or a delayed embolic event could not be determined reliably. This patient's deficits resolved significantly within 1 week.



Four patients died during the follow-up period. One patient (case 9) had a fatal hemispheric infarction after arterial occlusion to treat acute carotid rupture. A near exsanguinating hemorrhage had precluded either temporary occlusion testing or subsequent bypass graft placement. Infarction was most likely related to carotid artery occlusion and severe hypotension, but we cannot exclude the possibility of a procedure-related thromboembolic complication. Three additional patients (cases 1, 4, and 8) died of progressive malignant tumors 2 to 11 months after arterial occlusion. Their deaths were not related to our treatment.

In both patients with acute carotid rupture, even large numbers of densely packed microcoils placed during proximal flow arrest failed to produce complete arterial occlusion. After deflation of the proximal occlusion balloons, evaluation 15 and 20 minutes after placement of the last coils revealed minimal but persistent antegrade flow. The proximal balloons were reinflated and detachable latex balloons (Nycomed, Paris, France) were then placed proximally to the coils to effect complete arterial occlusion.

### Discussion

Detachable balloons have long been considered the appropriate device for endovascular occlusion of the carotid and vertebral arteries (1, 8–10). Balloons had been in use for over a decade before microcoils became available (11). The use of embolization coils to occlude the carotid and vertebral arteries has been considered an inferior technique, primarily because of the theoretical risk of distal embolic complications. In some cases, arterial tortuosity or stenosis may prevent placement of a large-diameter guiding catheter to allow the use of detachable balloons for arterial occlusion. Before their recent approval, detachable balloons were generally unavailable or informed consent for use of investigational or unapproved balloons was often impossible to obtain in emergency circumstances. The use of investigational or unapproved detachable balloons was also undesirable in situations that carried a high risk of litigation.

In 1996, Hughes et al (12) reported that sonographically detectable distal emboli associated with microcoil embolization in a canine model were virtually eliminated when proximal temporary balloon occlusion was used during coil placement. It is important to note that this study was conducted without the use of anticoagulation, which would be expected to reduce or eliminate thromboemboli. The initial clinical experience with the GDC system revealed that thromboembolic complications were relatively frequent unless anticoagulation was used. Anticoagulation is now almost universally employed when using the GDC system, and it markedly reduces thromboembolic complications.

Graves et al (7) subsequently reported satisfactory clinical results of carotid and vertebral artery

occlusion in 19 patients when microcoils were placed during temporary proximal flow arrest. They reported development of neurologic deficits in five patients. Deficits were transient in four patients and permanent in only one. In three of the five patients, hypoperfusion not detected during balloon test occlusion was thought to be the underlying cause of the new deficits. Most important, none of their patients sustained a neurologic deficit suggestive of an acute embolic event related to the use of coils for vessel occlusion. They concluded that microcoils placed during temporary proximal flow arrest were safe and effective for endovascular occlusion of the carotid and vertebral arteries.

None of the three patients in our series who incurred a neurologic deficit had an acute deficit at the time of arterial occlusion. The minor stroke sustained by patient 18 was compatible with either a delayed embolic event or hypoperfusion. The fatal hemispheric infarction suffered by patient 9 was most likely related to carotid artery sacrifice combined with prolonged hypotension. Vasospasm and occlusion of both the AICA and PICA accounted for the progressive deficits in patient 7. As with the experience reported by Graves and colleagues, none of our patients had an acute event consistent with an embolic complication related to the use of microcoils placed for arterial occlusion.

In both our patients with acute carotid artery rupture (cases 4 and 9), arterial occlusion with microcoils alone failed. Complete arterial occlusion required placement of a detachable balloon proximal to the microcoils in both patients. Our results suggest that microcoils will not provide effective vessel occlusion when coagulation has been diminished by aggressive resuscitation of near exsanguinating hemorrhage. Both patients had received extensive blood product transfusions and intravenous fluid administration leading to a hypocoagulable state. Heparin administration did not seem to be a factor. Only one of these two patients had received heparin (5000 U IV) and this had been reversed with protamine (50 mg IV) before microcoil placement. Systemic anticoagulation with heparin did not prevent vessel occlusion in any other patient.

In addition to worry over thromboembolic complications associated with the use of microcoils for large-vessel occlusion, concern for inadvertent distal embolization of the microcoils has also been raised. We did not observe distal migration of a microcoil in any of the 11 patients who underwent arterial occlusion without the use of proximal flow arrest or initial placement of GDC. We prevented inadvertent distal coil embolization by selecting coils that were 33% to 50% larger than the diameter of the artery to be occluded as the first coils placed. Subsequent coils of approximately the same size as the artery were then placed within and proximally to the initial coils. The coils were packed into a dense mass.

The small number of patients in our series is a recognized limitation. In addition, routine follow-

up imaging studies were not obtained to evaluate for possible clinically silent embolic complications. Moreover, laboratory evaluations to quantify the effects of our anticoagulation regimen were not performed.

### Conclusion

Our results, and those reported by Graves and colleagues (7), indicate that microcoils are safe and effective for neurovascular occlusion. When anticoagulation is used as we described, proximal temporary flow arrest during coil placement does not appear to be necessary to prevent clinically apparent embolic complications. The variety of microcoil shapes and sizes, as well as the availability of electrolytically and mechanically detachable coils, allows placement without fear of distal migration. Even with the recent approval of detachable balloons, the ability to place microcoils into tortuous and stenotic arteries makes them an attractive alternative to detachable balloons in selected cases. Nonetheless, when coagulation has been markedly diminished by massive hemorrhage and transfusion, microcoils may not produce complete arterial occlusion even when temporary proximal flow arrest is used. Detachable balloons remain invaluable for such cases.

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