Laboratory experience with a magnetically guided intravascular catheter system

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An improved magnetically-guided intravascular catheter system in dogs is described as safe, requiring little attention, allowing the application of flow surges to aid propulsion of the tip, and providing for angiography of good quality. Current concepts of the relationship of magnetic and flow guidance are discussed. The uses of the system demonstrated include selective angiography, perfusion of isobutyl-2-cyanoacrylate into experimental arteriovenous fistulas, and perfusion of microparticulate iron suspensions into experimental aneurysms. A unique detachable macroballoon that may function as a reversible tethered embolus is reported.

Key Words: intravascular catheterization - magnetic guidance - reversible embolus - isobutyl-2-cyanoacrylate - cerebral aneurysm

Despite advances in the modern surgical management of aneurysms and vascular malformations, there still remains a significant operative morbidity and mortality. In addition, a small number of patients are deemed inoperable. There is a growing interest in the management of aneurysms stereotaxically,1,2,15 and of arteriovenous malformations by embolization.5,6,15

We have developed in dogs a magnetically-guided catheter system that provides direct injection of relatively inaccessible areas of the cerebral vasculature. We are presenting this preliminary report of the intravascular obliteration of experimental aneurysms and arteriovenous fistulas with iron microspheres, isobutyl-2-cyanoacrylate, and macroballoons, and the use of isobutyl-2-cyanoacrylate and detachable macroballoons for selective embolization.

Method

Thirty mongrel dogs, weighing not less than 26 kg each, were anesthetized with sodium pentothal intravenously. Experimental aneurysms were created on the common carotid artery near the internal carotid origin by the vein pouch technique originally described by German and Black.5 Experimental arteriovenous fistulas were fashioned by end-to-side anastomosis of the external jugular vein to the common carotid artery. The catheter tip was introduced into the common carotid artery through a small separate supraclavicular incision.

Catheter System

The catheter system previously created in this laboratory15 has been extensively modified (Fig. 1). Two concentric sheaths around the external portions of the small flexible silicone catheter have facilitated its introduction through the tortuous carotid vasculature. Heparinized saline, under positive pressure generated by a Harvard peristaltic perfusion pump, perfuses both the catheter lu-
Herbert L. Cares, et al.

Fig. 1. Catheter system used. The biologically innocuous, highly flexible, silicone-rubber catheter (F) has an inner diameter of .30 mm, an outer diameter of .64 mm, and a length of 110 cm. It is perfused through a No. 20 G Courand-type needle (A), and is tipped with a platinum-cobalt permanent magnet (G) (30 mm ID, 1.00 mm OD, 2.50 mm long) magnetized longitudinally. Because the silicone rubber catheter is so flexible, a stiffer Teflon introducer sheath (B) (.97 mm ID, 1.28 mm OD, 60 cm long) is required to advance it. This basic assembly is placed inside a 51-cm vinyl water jacket (D), B-D No. 8286. The proximal fitting (C), B-D No. 3106 tubing adaptor, allows continual perfusion of heparinized saline around the silicone rubber catheter and seals the proximal end of the vinyl water jacket. The cardiovascular adaptor (E), B-D No. 03-0047, provides a rotating male Luer-Lok fitting for easy connection with the 16 G catheter needle (shown in the diagram but not photograph) previously inserted in the artery. It has a side-arm connection which also provides for angiography or rapid-flow flushing through the vinyl roentgenography tubing (H), B-D No. 8286, sealed with a stopcock (I). The entire system is mounted on an autoclavable phenolic board (J) and secured to sterile drapes on the animal’s chest. The entire system may be gas-sterilized, or the basic catheter and fittings may be autoclaved and then assembled.

Magnetic Guidance

A recently constructed 5 kW water-cooled electromagnet, 40% stronger than previous models, is now being used for all animal work and initial human studies until a superconducting magnet becomes available. This magnet is mounted on an arm with a universal joint, much like the tube head on a portable x-ray machine, and provides maximum directability. As far as we are aware, it is the strongest magnet for this purpose in existence. The magnetic field generated at 8 cm...
Magnetically guided intravascular catheter system

Fig. 2. Left: Uninflated, undetached macroballoon next to inflated, detached macroballoon. Center and Right: Drawings of uninflated and inflated macroballoons to scale (.025 in. = .65 mm). Note occlusion of tip (right) by coagulated albumen shown with stippling.

The construction of our ferromagnetically-tipped balloon catheter is shown in Fig. 2. A thin-walled latex balloon having an inner diameter (when not inflated) of .75 mm is attached by silicone adhesive to a detachable silicone nipple formed from a very short segment of small (.30 mm × .64 mm) silicone rubber tubing. When the detachable balloon is used it is necessary to substitute a carbon steel tip of the same dimensions as the standard platinum-cobalt tip because carbon steel heats more efficiently in the detaching sequence described below. The silicone nipple is shrunk-fitted with toluene into the slightly larger (.51 mm × .94 mm) silicone rubber catheter. A 3 mm long balloon may be safely inflated to a maximum capacity of 0.3 cc, and a maximum diameter of 7.5 mm. After the tip has been guided to its destination, it is inflated with 25% serum albumen to an appropriate volume, as determined angiographically. The carbon steel tip is then heated by a remote (external) radiofrequency induction coil, operated at a frequency of 380 kilohertz (kHz), using the technique introduced by Walker and Burton. When the temperature of the tip reaches approximately 55°C, the albumen coagulates like egg white, and seals the orifice of the balloon, as shown in Fig. 2 right. The

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Magnetic Tip

The tip, fabricated from platinum-cobalt alloy, is 2.5 mm long, has an outer diameter of 1.0 mm, and a lumen of 0.3 mm. It is initially coated with a molecular layer of silicone, using a water soluble silicone solution. A variety of diagnostic and therapeutic agents have been evaluated for use with this tip, including contrast medium (60% Renografin), iron microspheres, isobutyl-2-cyanoacrylate, and copper wire.

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* An oersted (Oe) is a unit that expresses magnetic intensity, and by definition 1 Oe equals twice the earth's natural magnetic field. Thus, the magnetic intensity acting on a compass needle is 0.5 Oe.
balloon is then detached by the additional infusion of as little as 0.1 cc of albumen into the catheter over a 30-sec interval; this distends the catheter and blows off the inflated balloon assembly. The albumen plug remains in the tip lumen, and thereby keeps the balloon inflated. The lumen of the carbon steel tip is machined with a slight hourglass taper in its center to prevent the albumen plug from being blown either into the balloon or the bloodstream during or after detachment.

Procedure

The magnetic tip with its silicone rubber catheter is easily introduced into the bloodstream, and readily advanced. No thrombus has developed around the catheter or catheter tip; thrombosis both within the catheter and around the site of its entrance into the carotid artery is prevented by the continuous perfusion of heparinized saline through both the catheter lumen and its vinyl water jacket.

The system is continuously and automatically flushed, leaving the operator free to concentrate on guiding the tip to its destination or injecting special materials. We found the use of an infusion pump critical in providing reliable clot-free operation. There is no danger of too rapid an infusion rate, since the fastest pump setting does not rupture the tubing. The pump can be set as slow as 50 cc
Magnetically guided intravascular catheter system

hr; all that is needed to keep the system clot-free is a slight positive pressure. We have found that the standard intravenous tubing assembly serves as a safety valve in that, should there be distal obstruction in the catheter, the joints disconnect before the silicone rubber tubing ruptures.

Results

Magnetic Guidance

The initial concept of “magnetic propulsion” has not proved feasible, and is no longer necessary since the catheter is primarily flow-guided, with the tip magnetically deflected at critical junctions, and magnetically fixed at its destination. The capability of the magnetic system to deflect a magnetic tip against the major direction of flow into a lesser tributary was demonstrated previously in the human vasculature (Fig. 3). Moreover, its capability to guide and hold a tip inside an experimental aneurysm was demonstrated in 25 dogs (Fig. 4).

Selective Angiography

Although a brisk jet could be generated through the tip at the maximum injection rate of approximately 0.5 cc/sec, multiple trials of selective angiography with 60% Renografin in 10 major canine carotid vessels resulted in very poor, if any, visualization of the vessel catheterized due to volume dilution in the large vessels. However, high-quality selective angiograms were obtained with the tip wedged in a small vessel of about 1 mm in diameter (Fig. 5).

Perfusion of Microparticulate Iron

One gram of iron particles suspended in 20 cc of 25% human serum albumen easily passed through this catheter system. We have used both carbonyl iron microspheres (General Aniline and Film Company), which have a diameter of about 4 μ, and pure black iron oxide particles (Pfizer Company) which have an average diameter of 4 μ. After the tip had been magnetically guided and held in the experimental aneurysm, the iron suspension was injected into the aneurysm and held there by the external magnetic field until thrombosis occurred and the catheter had been withdrawn (Fig. 6).
Herbert L. Cares, et al.

The complete data will be the subject of a separate communication.

**Perfusion of Isobutyl-2-Cyanoacrylate Cells**

Isobutyl-2-cyanoacrylate (supplied by Ethicon, Inc.) has many properties which make it suitable for our system. It has a low viscosity, flows easily through the catheter, and polymerizes in less than 1 sec on contact with blood. An example of its use in experimental fistulas is shown in Fig. 7. Data detailing its use in experimental fistulas and aneurysms will be reported separately.

**Copper Wire**

Mullan, et al., have shown that operative needle insertion of copper wire induces delayed aneurysmal thrombosis. We were intrigued with the thought of introducing wire into an aneurysm through our catheter system. However, we were unable to flush 1 to 10 cm segments of .07 mm pure copper wire through the catheter with any reliability, not even when the wire was loaded into the catheter distally through the tip.

**Macroballoons**

A macroballoon could be guided magnetically into an experimental aneurysm; the aneurysm was obliterated when the balloon was inflated (Fig. 8). We were repeatedly able to occlude a vascular conduit as large as the common carotid artery and then detach the balloon in the vessel. Hunter, et al., have shown the long-term safety of latex balloons in major vessels, and that even though the balloon may eventually collapse, the vessel still remains occluded. The use of macroballoons in the treatment of experimental aneurysms and fistulas is currently being investigated.

**Discussion**

The side-arm connection to the cardiovascular adaptor provides a means of introducing fluid into the carotid artery rapidly, thereby allowing high-quality angiography. The location of this connection close to the arterial catheter needle affords a greater flow rate than a more proximal location; this is because at the back fitting there is very little clearance between the lumen of the fitting and the outer wall of the Teflon introducer. We have found that a rapid flush of saline through this side-arm connection is highly effective in introducing and advancing the silicone rubber catheter. One reason that flow is so effective is because the catheter offers significant friction to blood or saline flowing next to its outer wall. There is also significant friction between the catheter surface and vessel intima. We have found that this friction is sometimes great enough to be a hindrance. For example, once the catheter is negotiated around a sharp turn, slight withdrawal is often impossible because the catheter simply stretches until tension over-

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**Fig. 6.** Left: Common carotid angiogram showing catheter tip (arrow) magnetically held in neck of 1-week-old experimental saccular aneurysm while iron microspheres are perfused. Center: Plain film showing microparticulate iron (arrow) held in the fundus of the aneurysm by the external magnetic field. Right: Common carotid angiogram one week later confirmed permanent thrombosis of aneurysm. Arrow shows site of previous aneurysm. M = external electromagnet.
Magnetically guided intravascular catheter system

comes the friction between the catheter and intima. The catheter then suddenly snaps back to a position which is much farther withdrawn than desired. The most effective way of manipulating the catheter, therefore, is to turn on the external magnet slightly before the tip has reached the deflection point; then if the tip overshoots its deflection point, the catheter is withdrawn almost back to the needle hub and the catheterization begun afresh.

Although most of the time we used small silicone rubber tubing, we found no disadvantage in using the next larger size (.51 mm × .94 mm). With the latter we used a 14-gauge catheter needle because, although the tubing fits through a 16- or even 17-gauge needle, the fit is too snug to allow effective flushing or angiography.

This system is designed primarily for carotid catheterization in man and dog. Should posterior circulation catheterization be desired, a longer version of the present system could be used, with a fine tungsten wire as an obturator to facilitate guiding the tip through a brachial or femoral catheter to the orifice of the vertebral artery. A small length of silicone rubber catheter joined to a large length of Teflon tubing ⁴ could also be used, but this would have the theoretical disadvantage of a joint in the tubing, which could separate intravascularly.

The absence of clot formation in and about the catheter no doubt relates to the continuous perfusion of heparinized saline. Should the latter be undesirable, the catheter may be presoaked overnight in pure heparin solution; the heparin will leach out of the saturated catheter to prevent thrombosis.⁵

Due to the short distances involved, the electromagnet we used produced magnetic fields and gradients in the dog of about the

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Fig. 7. Left: Common carotid angiogram showing experimental common carotid-external jugular fistula. Note total steal through the fistula. Right: Common carotid angiogram following selective catheterization of fistula by magnetically tipped catheter and injection of 0.8 cc isobutyl-2-cyanoacrylate. Note obliteration of fistula and visualization of common carotid artery distal to fistula.

J. Neurosurg. / Volume 38 / February, 1973 151
same magnitude as those of the superconducting magnet now under development for use in the human skull. There seems little doubt, therefore, that the magnetic force will be great enough in the human to hold a tip in an aneurysm. In fact, there is some evidence that, under special circumstances, this is possible with the existing electromagnet. We have found less need for an oscillating magnetic field than originally anticipated. However, the vibration imparted to the tip and catheter is useful both in reducing the friction between the catheter wall and intima, and in keeping the tip out of lesser tributaries while negotiating arterial curves.

The fact that the system is basically flow-guided simplifies problems of roentgenographic viewing. An image intensifier can be used to follow the progress of the tip until it reaches a critical junction. Then, since the image intensifier works poorly in a magnetic field, it is turned off and the magnet turned on. Fluoroscopy, although unaffected by magnetic fields, does not have the resolution necessary to delineate the tip in the human head. The correct deflection of the tip is therefore verified by Polaroid or rapid processed x-ray film. This viewing technique is no more than a minor inconvenience, but the problem of continuous, high-resolution radiographic viewing in the presence of a strong magnetic field remains essentially unsolved.

A variety of agents may be perfused selectively through the plain tip. Chemotherapeutic agents may be injected into the major vessel supplying a tumor. Similarly, unusual angiography is possible by wedging the tip into such vessels as the meningeal artery or an arterial tributary to an arteriovenous malformation. Fluids of surprisingly high viscosity such as glycerin will pass through this system.

The thrombosis of a human aneurysm with microparticulate iron is currently done only by stereotaxic injection. The use of a magnetically guided catheter system has been suggested as an alternate to stereotaxic injection, but although we have confirmed its feasibility, there are two associated hazards that have become apparent from our animal work. First, when the magnetic gradient is strong enough to hold both the tip and the injected iron microparticles in the aneurysm, the iron tends to aggregate in the tip and occlude its lumen. This often results in undetected detachment of the tip, or rupture of the tubing; should the infusion of iron particles then be continued, they would pass directly into the bloodstream where they may aggregate and embolize to cause a ma-
Magentically guided intravascular catheter system

jor neurological deficit. Second, some iron particles always adhere to the tip, and may wash off downstream as the catheter is withdrawn from the vessel. Both of these hazards, although decreased by the use of a carbon steel tip instead of a permanent magnet tip, still constitute serious problems. We are currently evaluating a system that should answer both of these objections: the iron microspheres themselves are first packed into the end of the catheter, and then used as the ferromagnetic tip for guidance into the aneurysm. They are then flushed through a one-way valve into the aneurysm and held there by the external magnetic field, and the catheter withdrawn.

The intravascular use of isobutyl-2-cyanoacrylate pioneered by Zanetti has taken advantage of the unique combination of its low viscosity and rapid polymerization to generate large emboli from tiny catheters. Our magnetic guidance should give us the advantages of selective instead of flow-guided embolization for arteriovenous malformations; and intravascular catheterization in place of stereotaxic injection of berry aneurysms.

It is a formidable task to devise and build a system that will inflate and detach a macroballoon and yet not compromise the navigability of the catheter. Previous macroballoons did not detach reliably and, since they were equipped with a one-way valve, could neither be pretested nor reversibly inflated. At present, the best solution is controlled occlusion of the tip. To be successful, the occlusion must occur exactly in the lumen of the ferromagnetic tip. If it occurs proximally, then not only will the balloon fail to detach, but it will not be deflatable. The fluid used to inflate and detach must be physiologically inert, since a few drops will always squirt into the arterial circulation from the proximal catheter following detachment. If two complementary liquids are injected into the balloon, they may harden. But then the additional fluid needed for detaching may merely continue to inflate the balloon and the balloon would be neither detachable nor deflatable.

Two potential limitations to the system of detaching described here (Fig. 2) are the large power source needed for induction-heating a tip when it lies transversely. The use of a slightly larger tip at least partially solves these two limitations. We have shown that the use of fine .025 mm silver wires to carry electrical current to coagulate the albumen in the lumen of the tip is not feasible because it embarrasses the catheter's navigability and necessitates two detachable microconnections at the tip.

The macroballoons described here have the distinct advantage of reversibility. To the best of our knowledge, a system with the capability of a reversible detachable embolus has never been reported. The balloon, for example, could be guided into the fundus of an aneurysm or, as a tethered embolus, into a feeding artery of an arteriovenous malformation. As the balloon is inflated, should the patient develop a neurological deficit or the tip be improperly positioned, the balloon could be quickly deflated. Otherwise the inflated balloon is detached and the catheter withdrawn.

References

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