Endovascular treatment of giant and large intracranial aneurysms by using a combination of stent placement and liquid polymer injection

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Object. The aim of this study was to test the feasibility, safety, and efficacy of a new endovascular method for the treatment of giant intracranial aneurysms. This new method consists of combining a metallic stent with a liquid polymer; the stent is first placed across the neck of the aneurysm to reconstruct a tubular arterial lumen, followed by obliteration of the fundus of the aneurysm with an ethyl vinyl alcohol polymer. During its injection, the liquid polymer is contained within the aneurysm by temporarily inflating an occlusion balloon in the parent artery.

Methods. Eleven patients harboring a giant aneurysm were successfully treated using this procedure. All aneurysms were excluded from the circulation, with preservation of the parent artery. In nine of the 11 patients, the 6-month follow-up angiogram demonstrated no recanalization of the aneurysm. In one patient who had a giant and partially clotted internal carotid artery bifurcation aneurysm, the follow-up angiogram demonstrated minimal recanalization. The complications in this series of patients included one death and one case of transient hemiparesis caused by watershed ischemia.

Conclusions. The initial anatomical results and the clinical outcome in this small series of patients are very encouraging. The mortality and morbidity rates associated with this new endovascular treatment are superior to those associated with surgical clipping of giant aneurysms.

KEY WORDS • unruptured intracranial aneurysm • giant aneurysm • fusiform aneurysm • endovascular occlusion • stent

GIANT aneurysms represent 3 to 5% of all intracranial aneurysms and are often located either extradurally or in the proximal segments of the ICA or VA. The natural history of these lesions is treacherous; they are associated with a high mortality rate. Their surgical treatment is complicated because it requires significant retraction of the brain and occasionally cardiopulmonary arrest. The surgical morbidity and mortality rates are relatively high.

Similarly, the endovascular treatment of giant aneurysms is difficult and is often associated with a high rate of complications. The early attempts to obliterate giant aneurysms with detachable balloons often resulted in regrowth of the aneurysm around the balloon. The balloon tends to act as a solid intraaneurysmal device that transmits the arterial pulsation to the wall of the aneurysm and contributes to its ultimate regrowth. Since the development of the GDC, the endovascular treatment of saccular aneurysms has become more reliable and reasonably safe. The GDC system is most effective in the treatment of small aneurysms, especially those with a small neck. In contrast, large or giant aneurysms with a wide neck, particularly those that are partially clotted, are not well suited to obliteration with GDCs. They tend to recanalize due to compaction of the coils, loose packing of the aneurysm, and incorporation of the coils within the ever-changing, preexisting clot.

Balloon-expandable metallic stents have been used to obliterate the neck of large intracranial aneurysms, with some success. Notwithstanding, both experimental and early clinical results have led to the conclusion that a stent alone is usually insufficient to obliterate an aneurysm. Although a stent placed across the neck of an aneurysm alters the blood flow and redirects the shear stress in such a way that it may lead to partial thrombosis, an additional embolic device is usually needed as a filler to obliterate the lumen of the aneurysm. Most investigators have used GDCs as filler material. Although the early clinical results from this combined method are encouraging, there have been reports of recanalization of aneurysms and even of fatal rupture following their treatment.

We report a novel endovascular procedure for the treatment of large, giant, or otherwise complex and wide-necked aneurysms. The method consists of combining placement of a balloon-expandable stent at the neck of the
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Clinical Material and Methods

We treated 11 patients (10 female and one male), who ranged in age from 9 to 81 years. All 11 patients were symptomatic; the five with large or giant cavernous aneurysms presented with headaches, cranial nerve involvement, or angiographic evidence of aneurysm expansion. The patients' demographics, aneurysm location, and the anatomical and clinical results of the treatment are summarized in Table 1. Three of these patients had been treated previously with liquid polymer alone; their 3-month angiographic follow-up studies had shown recanalization of the aneurysm, prompting retreatment with the combination of stent and liquid polymer. None of these 11 aneurysms were deemed candidates for surgical clipping. The endovascular treatment was undertaken after approval by the local ethics committee, and all patients signed an informed consent before the treatment.

All patients were treated after induction of general anesthesia and full systemic heparinization, which consisted of pretreatment with a combination of clopidogrel or ticlopidine and aspirin for a period ranging from 4 to 7 days before the procedure. Arterial access required two No. 6 French femoral sheaths introduced through bilateral percutaneous femoral artery punctures. Two guide catheters were introduced into the parent artery past the neck of the aneurysm. Alternatively, and when the aneurysm is located in the vertebrobasilar circulation, a guide catheter can be introduced into each VA.

The first technical step of the endovascular procedure consists of passing a braided hydrophilic microcatheter (inner diameter 0.018 in) over an atraumatic guidewire past the neck of the aneurysm and into the distal circulation. This can be difficult to achieve because almost all of these aneurysms have a large and patentulous neck that cannot be easily distinguished from the lumen proper of the parent artery. The tip of the microguidewire has a tendency to enter into the aneurysm or to buckle through the neck into the lesion's fundus. Through this microcatheter, a stiff exchange microguidewire (0.014 in in diameter and 300 cm long) was introduced in the parent artery past the neck of the aneurysm.

Once the exchange guidewire was in place, a balloon-expandable stent was gently advanced over the wire and positioned across the neck of the aneurysm by using road-map guiding (Figs. 1 and 2). The stent was then gently deposited using the recommended inflation pressure necessary to expand the stent fully and to embed it in the wall of the parent artery. We have used one stent exclusively (model S670; Medtronic AVE, Santa Rosa, CA).

The dimensions of the stents that we used in these first 11 patients varied from 3.5 to 4.5 mm in diameter and from 9 to 24 mm in length. The longer the stent, the more difficult it is to navigate in the intracranial vasculature, particularly in tortuous and atherosclerotic arteries. We believe that the addition of the stent confers an advantage over using liquid polymer alone because it allows for reconstruction of the dysplastic arterial wall and helps in the complete obliteration of the aneurysm, thus reducing the chance of recanalization. The first three patients harboring giant aneurysms who were treated with polymer alone did experience recanalization. We often use intraarterially administered papaverine before, during, and after the placement of the stent to prevent and treat vasospasm that may result from trauma incurred during its navigation.

Once the stent was deposited, the inflation balloon (which is compatible with DMSO) used to position the stent was deflated and kept in place across the neck of the lesion. Through the second guide catheter a DMSO-compatible microcatheter (Rebar 14; MicroTherapeutics Corp.) measuring 0.014 in (inside diameter) was navigated over a microguidewire through the metallic mesh of the expanded stent inside the fundus of the aneurysm. The tip of this microcatheter was preferably positioned in the inflow zone and outer third of the aneurysm within a few millimeters of the wall. Once the catheter was well positioned, its dead space was filled with 0.27 ml of the solvent DMSO, which was used to prevent precipitation of the liquid polymer within the lumen of the delivery catheter.

### Table 1

Patient demographics and aneurysm characteristics*

<table>
<thead>
<tr>
<th>Case No.</th>
<th>Age (yrs), Sex</th>
<th>Aneurysm Location</th>
<th>Post-treatment Occlusion (%)</th>
<th>At 3-Mo FU</th>
<th>At 6-Mo FU</th>
<th>Complications</th>
<th>GOS Score At 6 Mos</th>
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<tr>
<td>2</td>
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<td>5</td>
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<tr>
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<td>100</td>
<td>100</td>
<td>none</td>
<td>5</td>
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<tr>
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<td>1</td>
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<td>90</td>
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* FU = follow up; NA = not available; OphA = ophthalmic artery.
Fig. 1. Artist’s rendition detailing the different steps of the endovascular procedure in a giant saccular aneurysm.  
A: The unexpanded stent is advanced over a guidewire and positioned across the neck of the aneurysm.  
B: The stent is placed by inflating the balloon to the recommended nominal pressure.  
C: Once deposited, the stent is embedded in the wall of the artery across the fundus of the aneurysm.  
D: The microcatheter is introduced into the fundus of the aneurysm through the mesh of the expanded stent.  
E: The balloon used to position the stent is inflated temporarily to seal the aneurysm and occlude the parent artery.  
F: With the occlusion balloon inflated, the radiopaque polymer is slowly injected inside the fundus of the aneurysm.  
G: Several small injections of the polymer are made to obliterate the aneurysm completely.  
H: Once the aneurysm is completely obliterated, the microcatheter and occlusion balloon are withdrawn from the parent artery.
After priming the delivery catheter with DMSO, the aneurysm was slowly obliterated with the liquid polymer at a concentration of 20% (20% ethyl vinyl alcohol/80% DMSO). The aneurysm was obliterated slowly and progressively by using small repeated injections of the polymer while simultaneously inflating the balloon inside the stent. The balloon was inflated to seal the aneurysm and to prevent any leakage of the liquid polymer into the lumen of the parent artery. The polymer precipitates and solidifies within an average period of 2 to 3 minutes, during which time the balloon remains inflated. The total inflation time of the balloon (that is, occlusion of the parent artery) did not exceed 5 minutes in one session. Several cycles of balloon inflation, polymer injection, and balloon deflation were repeated as often as necessary to obliterate the aneurysm completely, including its neck. The total amount of polymer that has been required to obliterate these large aneurysms has varied between 3 and 11 ml.

After the last injection of polymer, the catheter was slowly aspirated to eliminate any residual positive pressure and to avoid any possible injection of the polymer that may still be within the lumen of the microcatheter. The catheter was left in place for approximately 10 minutes to allow the polymer to cure completely within the aneurysm. The occlusion balloon was then inflated and the catheter was withdrawn from the aneurysm. Once the catheter was completely withdrawn, the balloon was deflated and removed from the parent artery. A final angiogram was obtained to assess the degree of aneurysm occlusion and the patency of the parent artery. At the end of the procedure, the systemic heparinization was reversed using protamine sulfate, and the femoral sheaths were removed. Hemostasis at the femoral puncture sites was achieved using either manual pressure or a percutaneous arterial closure device. Following the treatment, the patients were maintained on oral ticlopidine or clopidogrel combined with aspirin for a period of 6 weeks. At the end of the 6 weeks, the ticlopidine or the clopidogrel was discontinued and the patient was maintained on orally administered aspirin at a dose of 325 mg per day. We follow this regimen of antiplatelet therapy in all patients who receive CA, VA, or intracranial stents. Follow-up angiograms were scheduled at 3, 6, and 12 months after the endovascular treatment.

Results

All lesions were completely obliterated except for two giant cavernous aneurysms, in which very minimal filling of a residual neck was noticed on the immediate posttreatment angiogram. The 6-month follow-up angiogram in one of these two patients demonstrated complete obliteration of
the aneurysm, and in the second patient, the follow-up angiogram demonstrated no evidence of recanalization. In all patients, the diameter of the lumen of the parent artery was restored to the corresponding diameter of the stent used (3.5–4.5 mm). This includes the two patients in whom the aneurysm was considered to be the posttraumatic dissecting type, and who originally had a stenotic and irregular parent artery. The parent artery was reconstructed to a normal appearance at the level of the aneurysm neck, even in the case of giant fusiform aneurysms. Antegrade flow was preserved in all patients, with no evidence of branch occlusion in the corresponding intracranial arterial territory.

There were two serious procedural complications in this series of 11 patients. In one, overinflation of the balloon resulted in dissection of the parent artery and fatal intracranial bleeding. The second patient, an 81-year-old woman presenting with a dissecting giant cavernous aneurysm, developed watershed ischemia in the ipsilateral cerebral hemisphere, presumably from prolonged balloon occlusion of the parent artery.

In 10 of the 11 patients, a follow-up angiogram was obtained 6 months after the endovascular treatment. In one patient, who has since died from complications of head and neck cancer that was undiagnosed at the time of the endovascular treatment, only a 3-month follow-up angiogram is available. All follow-up angiograms demonstrated a stable appearance and persistent obliteration of the giant aneurysms, including a giant cavernous aneurysm that was partially obliterated at the time of the initial treatment.

The clinical outcome at 3 months was excellent according to the GOS scale (GOS 5) in nine of the 11 patients. One patient with a GOS score of 1 died as a result of procedure-related arterial dissection and intracranial hemorrhage, and another died of complications of cancer. One 81-year-old patient who experienced a mild hemiparesis following the endovascular treatment has recovered significantly from her deficit and is living independently. One patient who presented with partial third cranial nerve palsy from an expanding giant cavernous aneurysm experienced transient worsening of her third nerve palsy that resolved completely over the course of 4 weeks.

Discussion

Giant intracranial aneurysms are relatively rare and represent between 3 and 5% of all cerebral aneurysms. Despite their low incidence, however, they represent a formidable technical challenge for neurosurgeons as well as for endovascular therapists. When left untreated, the natural history of these lesions is dismal because of the high incidence of hemorrhage, mass effect, or thromboembolic events. The mortality rate of untreated giant aneurysms is very high; it approaches 85% in some series.

Several surgical procedures have been developed for better management of these kinds of aneurysms, and good outcomes have been reported in various surgical series. The surgical improvements have focused primarily on better and wider surgical exposure, reliable control of the parent artery both proximal and distal to the aneurysm, reconstruction of the artery with multiple clips, aneurysmorrhaphy, aneurysm excision with end-to-end anastomosis, and revascularization procedures. Despite these technical surgical improvements, direct surgical clipping of giant aneurysms is still associated with a relatively high rate of procedure-related morbidity and mortality.

Similarly, the endovascular treatment of giant aneurysms has heretofore been frustrating and often leads to poor anatomical results and ultimate recanalization. The original endovascular concept of obliterating the aneurysm with detachable balloons has largely been abandoned because of the unacceptable rate of recanalization and aneurysm rupture. The use of GDCs as embolic devices has somewhat improved the results of endovascular treatment in this subgroup of aneurysms, although the GDC system is most effective in obliterating small aneurysms that have a small neck. In large and giant aneurysms, the rate of complete obliteration with GDCs is low and the incidence of recanalization is very high. Platinum or any other metallic coils obliterate only a small portion of the volume of the aneurysm, with significant residual dead space remaining between the interstices of the coils. It is this low volume of metallic coils relative to the overall volume of the aneurysm, coupled with the hemodynamics of giant aneurysms, that leads to their recanalization, particularly in the presence of soft intraluminal clots. The intraluminal thrombus undergoes continuous physiological changes associated with lysis and clot reformation that incorporate the coils and result in recanalization.

Parent artery occlusion in which either detachable balloons or platinum coils are used is an acceptable and effective endovascular method of treating giant aneurysms. If performed properly, it invariably leads to complete thrombosis and ultimate shrinkage of the aneurysm. It requires a successful test occlusion before permanent treatment to determine the adequacy of the collateral circulation and to minimize the risks of subsequent ischemic complications. Surgical revascularization procedures can be performed successfully in those patients who require permanent artery occlusion but do not have adequate collateral circulation. Delayed ischemic insults can still occur following occlusion of the parent artery despite a successful test occlusion. We believe that the parent artery should be preserved whenever possible, provided that the safety guidelines of the endovascular treatment are clearly established and maintained.

The ideal endovascular treatment should, in theory, reconstruct the dysplastic arterial segment involved by the giant aneurysm, maintain antegrade flow distal to the reconstructed arterial segment, and obliterate the lumen of the aneurysm with a filler material that does not recanalize with time.

With our method, we have used endoluminal metallic stents to reconstruct an arterial wall along the expected flow trajectory of the parent artery. The stent is positioned across the neck of the giant aneurysm and bridges the dysplastic arterial gap between the otherwise healthy segments of the parent artery. In giant saccular aneurysms, the stent is deposited in an eccentric fashion along the wall of the artery and opposite the fundus of the aneurysm. In contrast, in giant fusiform aneurysms, the stent is placed so as to traverse the entire length of the lesion and to connect the proximal end with the distal one (Figs. 3 and 4). In these cases, in contrast with the treatment of saccular aneurysms, the stent is not juxtaposed to any arterial wall but rather tra-
Aneurysm treatment combining stent placement and liquid polymer injection

Fig. 3. Artist’s rendition detailing the different steps of the endovascular procedure in a giant fusiform aneurysm. A: The unexpanded stent is advanced over a guidewire and positioned within the fusiform aneurysm along the expected trajectory of the artery. B: The stent is deposited by inflating the balloon to the recommended nominal pressure. C: The microcatheter is then introduced into the fundus of the aneurysm through the mesh of the expanded stent. D: With the balloon temporarily inflated, the polymer is slowly injected into the fundus of the aneurysm. E: The aneurysm is gradually obliterated using several small injections of the polymer. As more polymer is injected, it circumferentially surrounds the stent and obliterates the entire aneurysm. F: Once the polymer has cured completely, the microcatheter and then the occlusion balloon are withdrawn from the parent artery.
verses freely the entire length of the giant aneurysm. A new tubular lumen is created for the artery with the stent, which follows the virtual trajectory of the parent artery between the proximal and distal ends of the aneurysm.

Endoluminal stents have previously been used to treat intracranial aneurysms, either alone or in combination with platinum coils. To our knowledge, ours is the first report of the successful use of the combination of a stent and liquid polymer to obliterate giant intracranial aneurysms. When stents are used alone to obliterate aneurysms, they can disrupt the blood flow and modify the hemodynamics so as to induce partial or complete thrombosis of the aneurysm. The early experience with using stents alone is not entirely satisfactory, however, because of a high rate of failed obliteration; a large percentage of aneurysms treated with stents alone remain patent due to persistent flow.

To improve the obliteration rate of aneurysms, new clinical protocols have been initiated to combine metallic stents with platinum coils. The stent is used to secure the neck of the aneurysm and the coils are used as a filler material to obliterate its fundus. Although the initial clinical results of combining stents with platinum coils are encouraging, the method is expensive, requires a rather long procedure time, and can still result in poor filling of the aneurysm because of the dead space between the coils. In combination with metallic stents, the use of a liquid polymer as a filler material has several advantages over using platinum coils. The polymer conforms better to the size and shape of the aneurysm; a large percentage of aneurysms treated with stents alone remain patent due to persistent flow.

Fig. 4. Giant fusiform aneurysm of the cavernous CA treated with a combination of stent placement and liquid polymer injection. A: Frontal view of an ICA angiogram revealing a giant fusiform aneurysm of the cavernous segment of the CA. B: The corresponding lateral view demonstrating the fusiform nature of the aneurysm, which has no discernible neck. C: The unexpanded stent is advanced over a guidewire and positioned within the fusiform aneurysm along the expected trajectory of the artery. D: The stent is placed by inflating the balloon to the recommended nominal pressure. E: Once deposited, the stent is anchored in the proximal and distal ends of the aneurysm. F: The microcatheter is introduced into the fundus of the aneurysm through the mesh of the expanded stent. The balloon is then temporarily inflated to seal the aneurysm and preserve the inner lumen of the stent. G: With the occlusion balloon inflated, the radiopaque polymer is slowly injected into the aneurysm around the inflated balloon. H: Frontal view of the skull, obtained at the end of the treatment demonstrating the radiopaque cast of the polymer surrounding the stent. I: Frontal view of the post-treatment CA angiogram demonstrating complete obliteration of the aneurysm and preservation of the parent artery. J: Lateral view of the posttreatment angiogram demonstrating complete obliteration of the aneurysm and reconstruction of a normal appearing parent artery. K and L: Frontal (K) and lateral (L) views of the angiogram obtained 6 months post-treatment, demonstrating persistent and complete obliteration of the aneurysm.
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rsym, thus eliminating any residual dead space. It is faster to use, thus shortening the procedure time, and is potentially less expensive.

Currently, the major technical challenge involved in using liquid polymer alone to obliterate aneurysms (including any potential small residual neck) is to control the injection of the polymer safely without risking the migration of the embolic material into the parent artery. In this study we accomplished this objective by temporarily inflating an occlusion balloon across the neck of the aneurysm during the injection of the polymer in an effort to seal the aneurysm and to confine the polymer to the fundus. The risk of polymer leakage within the parent artery is always present but has been significantly reduced using a combination of procedural measures as follows: 1) using the stent to trap the embolic material that may leak between the device and the wall of the artery; 2) judicious maximal inflation of a compliant balloon to ensure proper seal of the aneurysm; 3) increasing the viscosity of the polymer; and 4) using a small catheter (0.01 in) to deliver the polymer.

Positioning the stent across the neck of the aneurysm, coupled with the temporary inflation of the balloon, creates an effective barrier against any potential encroachment on the main lumen of the parent artery. Any liquid polymer that may leak around the inflated balloon laminates between the stent and the arterial wall, effectively creating a de novo covered stent in situ and resulting in reconstruction of the parent artery. We hope that such a solid reconstruction of the artery diminishes or eliminates the risk of recanalization, particularly in these giant aneurysms in which the entire arterial wall is diseased and dysplastic. Inflation of a compliant balloon within the stent positioned in the parent vessel offers a good seal of the aneurysm during injection of the polymer. Utmost care must be exercised, however, not to overinflate the balloon, which can lead to catastrophic dissection or rupture of the parent artery or to aneurysm rupture.

The concentration of ethyl vinyl alcohol in the polymer mixture can also be adjusted. A lower concentration (6%) is very fluid, and is currently being used for the endovascular obliteration of arteriovenous malformations and hypervascular tumors. As the concentration of ethyl vinyl alcohol increases, the embolic mixture becomes more viscous, polymerizes faster, and has a better chance of being trapped inside the aneurysm, thus minimizing the risk of leakage into the parent artery. In the original animal studies that we conducted, we used a concentration of 14%, which has progressively increased to 16, 20, 25, and 30%. All the aneurysms reported in this series were treated with a 20% concentration of ethyl vinyl alcohol. The technical challenge of using the relatively safe high-concentration mixture is to be able to inject it through microcatheters and to overcome its viscosity. The viscosity of the mixture increases at a much higher rate than the increase in its concentration. Also, the increase in the concentration of ethyl vinyl alcohol has the theoretical advantage of eliminating or minimizing any potential toxicity of the solvent DMSO. To date, we have not seen any noticeable toxic effect of DMSO in our patients.

Conclusions

Treatment of giant intracranial aneurysms represents a formidable technical challenge both for neurosurgeons and endovascular therapists. Although new surgical approaches and technical measures have improved the surgical results in this subgroup of intracranial aneurysms, the surgical morbidity and mortality rates remain relatively high. The endovascular treatment of giant aneurysms with GDCs is relatively safe but is often associated with poor anatomical results because of the unacceptably high rate of recanalization. We report a new endovascular procedure for treating these aneurysms that combines a metallic stent with which to reconstruct the parent artery and a liquid polymer with which to obliterate the aneurysm. Our early clinical experience has yielded excellent anatomical results and very favorable morbidity and mortality rates.

Disclosure

Dr. Mawad has a financial interest in MicroTherapeutics Corporation.

References


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