Evaluation of the TriSpan Neck Bridge Device for the Treatment of Wide-Necked Aneurysms
An Experimental Study in Canines

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Background and Purpose—Many wide-necked aneurysms are difficult or impossible to treat with the Guglielmi detachable coil (GDC). The purpose of this study was to evaluate the use of a neck bridging device, the TriSpan coil, in combination with standard GDCs for the treatment of wide-necked aneurysms in an experimental canine aneurysm model.

Methods—Of 24 experimental aneurysms in 12 animals, 19 (7 lateral and 12 terminal) were treated with the TriSpan coil in conjunction with standard GDCs. Digital subtraction angiography (DSA) was performed on all animals immediately after treatment. In 6 animals, follow-up DSA and histological evaluation were performed 4 weeks after treatment. In the remaining 6, DSA was done at both 90 and 180 days after treatment. Histological evaluation was done immediately after the 180-day angiographic evaluation.

Results—The TriSpan was easy to use in conjunction with the standard GDC. Because of their geometry, some lateral aneurysms were difficult or impossible to treat with this device. Greater than 90% aneurysm occlusion was obtained in all 19 aneurysms. In no instance was there evidence of coil migration, herniation, or aneurysm recanalization. Histological evaluation of the tissue surrounding the TriSpan coil showed tissue responses similar to that seen with standard GDCs.

Conclusions—These results show that the TriSpan coil in conjunction with standard GDCs can be used safely and effectively for the treatment of wide-necked aneurysms in this canine model. Positioning and deployment of the neck bridge in aneurysms having an acute angle with the long axis of their parent artery are difficult or impossible. It is likely that this device, used in conjunction with the standard GDC, will allow treatment of some wide-necked aneurysms that are not treatable with the GDC alone. (Stroke. 2001;32:492-497.)

Key Words: aneurysm ■ stents ■ therapeutic embolization ■ dogs

Regardless of their size, aneurysms with wide necks are often difficult to treat properly and safely with traditional endovascular techniques. Even when wide-necked aneurysms are treated with standard Guglielmi detachable coil (GDC) techniques, they are associated with higher incidences of incomplete obliteration, thromboembolic events, and parent artery occlusions than are aneurysms with small necks. Recently, a variety of techniques aimed at improving the ability to treat these difficult aneurysms with endovascular methods have been described. Whether these methods use multiple catheters, balloons, or stents, they are all aimed at allowing coils to be positioned and detached in the aneurysm lumen with reduced risk of their herniation into the parent artery.

It was our hypothesis that placement of a TriSpan coil in the ostium of a wide-necked aneurysm would assist in the subsequent placement and detachment of standard GDCs. Our aims were to test the stability of the device and its effect on coil compaction and to examine the histological response to its presence.

Materials and Methods

TriSpan Construction
The TriSpan coil (Figure 1) is a neck bridge device consisting of 3 nitinol loops or “petals”; the proximal ends of these petals are bound together by coiled platinum wire to form a “stem.” This stem is then attached to a stainless steel GDC pusher wire measuring 0.014 in. in diameter. A portion of each petal is wrapped with a platinum wire to enhance its radiopacity. During introduction, the TriSpan coil is compressed in a 0.018-in. tracker 18 catheter. As it is deployed, the loops of the device open like petals on a flower to form a scaffold.
Aneurysm Creation

All aneurysms were made under an institutionally approved animal protocol by use of variations of a technique originally described by German and Black\(^2\) and then further defined in our laboratory.\(^22,23\) Single lateral and bifurcation vein pouch aneurysms were surgically created in the carotid arteries of 12 mongrel dogs. The arteriotomy for the lateral aneurysm onto which these vein patch aneurysms were attached was standardized by use of a 5-mm circular Hancock vascular punch. For the construction of the bifurcation aneurysm, an attempt was made to standardize the arteriotomy onto which the vein graft was attached so that its greatest diameter was \(\approx 6\) mm. Because the average diameter of the parent artery onto which these vein patch aneurysms were attached is between 5 and 6 mm, it is impossible to create an aneurysm ostium that exceeds this measurement in \(\approx 1\) of its dimensions, ie, length or width.

Aneurysm Treatment

We allowed \(\approx 3\) weeks between the time of aneurysm creation and treatment to allow for wound healing. Endotracheal halothane anesthesia was used in all instances. Vascular access was obtained by sterile technique through an 8F sheath placed by surgical cutdown on 1 or both of the common femoral arteries. Fluoroscopy and digital subtraction angiography (DSA) were performed with a portable C-arm. Seven lateral and 12 bifurcation aneurysms were treated in this study. Treatment was not completed for 5 of the lateral aneurysms because of an inability to properly position the TriSpan device in the aneurysm.

An 8F guiding catheter was positioned in the common carotid artery several centimeters below the level of the bifurcation aneurysm. Angiograms were obtained in \(\approx 2\) projections, with efforts made to optimize visualization of the aneurysm neck. Intravascular ultrasound was used to directly measure the ostium of all bifurcation aneurysms; DSA was used to assess the relationship of the coil mass and TriSpan coil stem to the parent artery.

Size Selection of the TriSpan Neck Bridge Device

In the early phase of the study, a neck bridge measuring \(\approx 2\) mm greater in diameter than the largest diameter of the aneurysm neck was selected. Experience showed that for optimal placement, positioning, and fit, it was better to increase the size of the TriSpan coil so that its diameter was on average \(\approx 4\) mm larger than the largest neck diameter. To ensure that the loops or petals of the TriSpan coil are securely engaged in the aneurysm dome, it is also important to consider the height of the aneurysm when a neck bridge is selected. When 1 dimension of an aneurysm neck is larger than the height of the aneurysm from its base to its dome, it may be difficult for the device to be positioned securely in the aneurysm.

In 6 dogs (9 aneurysms: 3 lateral and 6 bifurcation), final evaluation was done 28 days after treatment. After DSA, the dogs were euthanized with an intravenous injection of Euthasol (1 mL/10 kg). In the remaining 6 dogs (10 aneurysms: 4 lateral and 6 bifurcation), follow-up angiograms were performed at both 90 and 180 days. These dogs were then euthanized as previously described.

Histology

In a nonrandomized selection, 9 of the aneurysms were processed for scanning electron microscopy (SEM) and the remaining 10 for histological analysis. Of the 9 aneurysms explanted 28 days after embolization, 5 were sent for histological analysis and 4 for SEM. Ten aneurysms were explanted at 180 days after embolization; 5 were sent for histology and 5 for SEM. After the dogs were euthanized, the aneurysms were fixated in situ with 10% buffered formalin, explanted, photographed, and then placed in 10% buffered formalin solution. The aneurysms selected for histology were then embedded in glycol methacrylate plastic and cut with a diamond band saw into 3 sections perpendicular to the long axis of the parent artery. The sections were then ground to 30 to 50 \(\mu\)m with the Exakt system and stained with hematoxylin and eosin. A pathologist then evaluated the slides. The remaining aneurysms were processed for SEM through standard laboratory procedures.

Results

Seven lateral and 12 bifurcation aneurysms were treated. Of the 12 lateral aneurysms, 5 were not treated because of an inability to properly position the GDC TriSpan coil in the aneurysm. This occurred when the proximal angle formed by lines drawn though the long axis of the parent artery and the long axis of the aneurysm was \(\leq 90^\circ\). There was no difference in the degree of aneurysm obliteration in the lateral and bifurcation aneurysms. In 1 case, a small residual aneurysm neck remained after \(\approx 90\%\) aneurysm occlusion. This remnant did not change at the final 28-day evaluation.

Parent Artery Occlusion

In 1 bifurcation aneurysm (1 of 19, 5%), inadvertent movement of the guide catheter by the operator after deployment of the TriSpan coil and during placement of the standard GDCs caused the neck bridge to be displaced into the parent artery. Repositioning or removal of the TriSpan device was not
possible. At the time of the 28-day follow-up DSA examination, this parent artery was occluded. This event was attributable to operator error and was not felt to be device related.

Aneurysm Recurrence
No aneurysm recurrences were noted. In 1 lateral aneurysm, there was evidence of a small new residual aneurysm at the time of the 90-day follow-up. There was no change in its size or shape between the 90- and 180-day angiograms.

Thromboembolism
Of the 19 aneurysms, 3 (16%) demonstrated a small amount of thrombus adjacent to the aneurysm on the immediate posttreatment DSA. This all had resolved by the time of next observation. All dogs survived without gross adverse affects.

TriSpan Coil Herniation/Migration
Some portion of the TriSpan coil was visible apart from the GDC mass at the aneurysm ostium in 14 of the 19 aneurysms (74%). In only 1 of these (7%) was this associated with compromise of the parent artery. As previously discussed, this was thought to be due to operator error rather than device malfunction. In 4 instances, a TriSpan coil loop was visible outside the GDC mass on the follow-up DSA. Two of these occurred in lateral aneurysms in which the relationship between the axis of the aneurysm and the parent artery made it difficult to optimally position the TriSpan coil. The other 2 occurred in aneurysms treated early in the study. In retrospect, the TriSpan coil used in these 2 aneurysms was sized too small for the aneurysm ostium. The stem coil of the TriSpan coil was visualized outside the GDC mass in the remaining 9 aneurysms. This did not in any instance protrude significantly into the parent artery. There was no instance of GDC migration causing parent artery compromise.

Histology
Histological evaluation of the tissue surrounding the TriSpan coil showed a similar tissue response to that seen with standard GDCs. In the 28-day postembolization group, the aneurysms demonstrated well-organized fibromuscular tissue in the periphery and a central core of fibrin. Lymphohistio-
cytic and giant cell reactions were observed adjacent to the GDCs and TriSpan coil (Figure 2). On SEM, the GDCs and TriSpan coil were easily seen in all cases and were covered with a layer of endothelial cells. In the 180-day postimplantation group, a highly vascularized, organizing granulation tissue response was seen histologically. Mild to moderate lymphohistiocytic infiltration was present around some of the GDCs. Others were surrounded by fibrointimal tissue consisting of smooth muscle cells in a proteoglycan and collagenous matrix. Much less inflammatory reaction was seen around the TriSpan coil loops at 180 days. SEM in the 180-day postimplantation group clearly identified the TriSpan in 3 of the 5 specimens. In all but 1 of the specimens in this group, the surfaces of the TriSpan were covered with endothelium, and all aneurysm necks were well sealed (Figure 3).

Discussion
Over the last decade, endovascular techniques have assumed a major role in the management of intracranial aneurysms. The GDC provides a safe and effective technique for the treatment of those aneurysms that have a small neck (<4 mm).1,2 Regardless of their size, aneurysms with large necks continue to be technically challenging and difficult to treat effectively with the GDC.1,2

In an effort to enhance the ability to treat wide-necked aneurysms with the GDC, techniques using balloons and stents or other techniques have recently been described.3–20 All are aimed at providing a means to prevent the coils from herniating out of the aneurysm and into the parent artery. The use of nondetachable balloons for this purpose (“neck protection”) was pioneered by Moret and colleagues,16 who described the technique in 1994. This approach has expanded the ability to treat some aneurysms not otherwise treatable with conventional GDCs. The 2 largest neck protection series reported to date have described an incidence of complications similar to that observed when GDCs alone are used.6,19 A recent report has suggested that a wide aneurysm neck could be an independent indicator of increased risk from thromboembolic events.3

Dramatic improvements in the flexibility of stents have now made it possible to deliver and deploy these devices in the intracranial circulation. Although early reports concerning the use of stents in conjunction with GDCs to treat wide-necked aneurysms are encouraging, the experience is still small. Inability to reliably and accurately place and deploy a stent in tortuous vascular anatomy, issues of long-term patency when placed into arteries <3 mm in diameter (ie, thromboresistance), and an inability to use stents for treatment of aneurysms having a bifurcation or terminal geometry limit widespread use of currently available stents for this purpose.

In our study, a neck bridge designed to be used in conjunction with GDCs for the treatment of wide-necked aneurysms was evaluated. The TriSpan coil is an electrically detachable neck bridge that is designed to provide a lattice across the ostium of an aneurysm. It has 3 loops that are shaped like the petals of a flower when fully deployed (Figure 1). We were able to adequately occlude 19 (7 lateral, 12 bifurcation) of 24 wide-necked aneurysms in 12 dogs. All bifurcation-type aneurysms were successfully treated with ≥90% occlusion; this remained stable on follow-up studies. Of the 12 lateral aneurysms, 5 could not be treated because of an inability to properly position and deploy the device within the aneurysm. Positioning and deployment are difficult or impossible when the proximal angle formed by a line drawn though the long axis of the parent artery and the long axis of the aneurysm is <90°. In this canine model, this angle is variable, depending largely on the amount of scarring that occurs after creation of the aneurysm. In 7 of the 12 lateral aneurysms, the angle described was obtuse, and successful treatment was possible in all of these cases. Treatment remained stable on follow-up studies. Determination of neck size and aneurysm height is important in the selection of the proper size of TriSpan coil. The coil should be oversized by ≈4 mm to fit properly across an ostium; ie, an aneurysm with a 10-mm ostium requires a 14-mm TriSpan coil. When the greatest dimension of the aneurysm neck is larger than the maximum height of the aneurysm as measured from its base to its dome, the TriSpan coil may not always be securely placed in an aneurysm.

Preparation, deployment, and detachment of the TriSpan coil are similar to the standard GDC. Use of this device requires that 2 Tracker catheters be used because the neck bridge is not detached until placement of the standard GDCs has been completed. For treatment, the TriSpan coil is placed and deployed in an aneurysm; then the second Tracker catheter is introduced, and standard coils are deposited and detached (Figure 1). After removal of this second Tracker catheter, the neck bridge is detached. We encountered no difficulty in performing these manipulations.

Parent artery compromise secondary to coil impingement from endovascular treatment of wide-necked aneurysms has been well documented.2,4,5,19 Vinuela et al,2 in prospective study of 403 patients, reported unintentional parent artery occlusion in 12 of 403 aneurysms (3%). In the present study, we encountered only 1 instance of parent artery occlusion (5%). This occurred in a bifurcation aneurysm after inadvertent movement of the guide catheter and was thought not to be device related. In this case, 1 of the TriSpan coil loops became dislodged and protruded into the parent artery, compromising flow to the left common carotid artery. The
TriSpan coil could not be withdrawn or repositioned because several GDCs had already been deployed. To avoid such an occurrence, special care should be used to ensure that the position of the TriSpan device is not changed during placement or detachment of coils into an aneurysm. In 9 of the 19 aneurysms, a small portion of the TriSpan coil stem was seen separate from the coil mass at the base of the aneurysm. This did not compromise the lumen of the parent artery. In 4 aneurysms, 1 of the TriSpan coils loops was visible outside the coil mass on the follow-up DSA. These were all due to suboptimal device placement in a lateral aneurysm or operator error in determining appropriate device size; ie, the TriSpan coil chosen was too small, so the petals were not securely engaged in the aneurysm dome.

Aneurysm recurrence was seen in 1 of 19 treated aneurysms (5%). This was discovered on the 90-day follow-up and was stable at 180 days. This recurrence was thought to be due to development of a false aneurysm as a result of a breakdown in the suture line where the vein patch was sewn to the parent artery in the outflow region of the aneurysm.

Thromboembolism has been reported as the most frequent complication encountered during coil embolization, with Pelz et al10 reporting a rate of 28%. It has been suggested that using the double catheter or balloon technique may further increase this risk.4,5,19 We observed thrombus formation in 3 of the 19 aneurysms (16%) treated with the TriSpan coil and standard GDCs. In 1 instance, no heparin was administered, and subtherapeutic doses were administered in the other 2 cases. In each case, the thrombus occurred at the time of embolization and had resolved by the time of the follow-up.

Histological and SEM evaluations of the aneurysms at 28 and 180 days after implantation revealed that the TriSpan coil elicits a similar if not suppressed inflammatory response as standard GDCs. At 28 days after implantation, organized thrombus formation was identified that had progressed to a highly vascularized granulation tissue by 180 days. Furthermore, by 180 days after implantation, all TriSpan surfaces were covered with endothelium, and the aneurysm neck was well sealed. Future projects with the TriSpan coil coated with a biologically active substrate may enhance the healing response and allow earlier aneurysm isolation from the arterial circulation.

Conclusions

The TriSpan neck bridge device is a novel intravascular device designed to enhance the ability to treat wide-necked aneurysms with the GDC. In this study, it provided a stable lattice at the aneurysm ostium, which prevented significant coil herniation, migration, or aneurysm recanalization. We think that the use of this device will enhance the ability to treat wide-necked aneurysms with an endovascular approach.

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References

Endovascular coil occlusion has become established as a safe and effective means of preventing recurrent bleeding from ruptured intracranial aneurysms. However, the permanency of aneurysm occlusion with coils is not easy to predict. Regular (usually annual) follow-up imaging is required to evaluate the appearance of the coil mass. Sometimes aneurysms will reopen, particularly if the aneurysm neck is wide (>4 mm) or if the original coil packing was less than 100% complete. The reopening may occur early because of compaction of the coils or later on because of growth of new aneurysm from a residual open neck.

Thus, the primary objective for the endovascular operator is to obtain a dense packing of the aneurysm with coils down to and including the neck. In aneurysms with narrow necks, this goal can be easy: the risk of acute coil herniation into the parent artery is low, and many coils can be safely deposited in the aneurysm. But wide-necked aneurysms pose a distinctly greater challenge. Coils are not so easily restrained and may herniate or later migrate out to cause local or downstream thrombosis and stroke. Operators are wary of this and often reluctant to aggressively pack these types of aneurysms.

Numerous tactics have been developed to address this problem. Coil manufacturers have modified the spiral shape of the coils to include a tighter initial coil helix (so-called 2-dimensional coils) to help keep coil loops inside the aneurysm sac. Coils are now also made with complex helix geometry (3-D coils), or no memory geometry at all (J coils). These have had variable success but have probably improved the capability of treatment. French investigators have pioneered the “balloon protection” technique, in which a balloon is temporarily inflated in the parent artery across the aneurysm neck to ensure that coils are deposited properly. Others have used 2 microcatheters simultaneously to deposit 2 separate coils and brace them across the aneurysm neck. Most recently, cylindrical wire coronary stents have been placed across the aneurysm neck to set up a preliminary lattice against which coils can be restrained and prevented from herniating.

In this issue of *Stroke*, Turk and colleagues present the latest technical advance in the attack on wide-necked aneurysms. The Trispan neck bridge device is a 3-pronged wire that is introduced like an inverted umbrella, braced internally against the aneurysm neck by its shape. Acting as an internal aneurysm stent, the Trispan permits coils to be placed via a second microcatheter without fear of herniation. Using their established canine aneurysm model, the authors’ angiographic and histopathologic results appear promising. All aneurysm necks were well sealed, and 4 of 5 Trispan surfaces were covered with endothelium at 180-day follow-up. Unfortunately, a control group was lacking, but the degree of aneurysm occlusion suggests that human clinical trials should be considered. Indeed, a few centers have already utilized the Trispan on compassionate grounds, with some degree of success, in patients with aneurysms considered impossible for microneurosurgical clipping. Only longer term follow-up will determine whether the Trispan improves the permanency of coil occlusion for wide-necked aneurysms. Neck width may be an independent predictor for late aneurysm regrowth, separate from the density of coil packing alone.

Equally important in this study, the authors were able to define certain vascular geometric parameters in their aneurysm model that predicted technical failure of the Trispan device. These parameters should be extended to human trials and serve as an important reminder of the importance of new device assessment in animal models before use in humans.

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