Multicenter study of the feasibility and safety of using the Memotherm carotid arterial stent for extracranial carotid artery stenosis

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Object. Carotid artery (CA) angioplasty with stent placement has been proposed as an alternative technique for revascularization in cases of CA stenosis. In this report the authors review the results of a multicenter Phase I study in which they evaluated the safety and feasibility of using a new self-expanding nitinol stent, the Bard Memotherm, to treat CA stenosis.

Methods. Enrollment was limited to patients in whom there was either 50% or greater symptomatic or 70% or greater asymptomatic stenosis of the internal CA. The primary endpoint was a technically successful implantation procedure (delivery of the stent to the target site and retrieval of the delivery device), resulting in less than 30% residual stenosis demonstrated on immediate postprocedure (control) angiograms, and no incidence of mortality, ipsilateral stroke, Q-wave myocardial infarction, or other major cardiovascular events immediately after or within 30 days following the procedure.

Stent placement was attempted for 73 lesions in 71 patients (mean age 71.3 ± 8.5 years), 43 (61%) of whom were men. The mean degree of stenosis was 82.6 ± 9%. The stenosis was symptomatic in 27 (37%) and asymptomatic in 46 (63%) of 73 lesions. In four procedures the stent could not be delivered or released. The mean residual stenosis observed on angiograms was 3.8 ± 6.9% in the 69 lesions treated with the Bard Memotherm stent; residual stenosis was greater than 30% in one of the 69 procedures. The primary endpoint was achieved in 65 (89%) of the 73 procedures. One patient experienced a major ischemic stroke and another patient died of intracerebral hemorrhage. The overall 1-month stroke rate was 2.7% for 73 attempted procedures. One patient died of pneumonia and acute respiratory distress syndrome, which occurred 3 weeks after the stent procedure and was unrelated to the procedure.

Conclusions. The Memotherm stent can be used to treat patients with CA stenosis and is associated with a low periprocedure complication rate. Long-term follow-up studies are underway to determine the impact of stent placement on the risk of ipsilateral ischemic events.

Key Words • carotid stenosis • ischemic stroke • myocardial infarction • platelet inhibitors • angioplasty • stent

C AROTID endarterectomy has been shown to reduce the risk of stroke in patients with CA stenosis. In the NASCET, CEA was compared with medical treatment in 659 patients in whom there was 70 to 99% stenosis who had experienced ipsilateral retinal or hemispheric TIAs or nondisabling strokes.16 The cumulative risk of an ipsilateral stroke 2 years posttreatment was 26% in 331 medically treated patients and 9% in 328 surgically treated patients. The risk reduction for all ipsilateral strokes in the surgically treated group was 26% for patients with 90 to 99% stenosis, 18% for those with 80 to 89% stenosis, and 12% for those with 70 to 79% stenosis. In another randomized trial, the European Carotid Surgery Trial, CEA was compared with medical treatment in 778 patients with 70 to 99% stenosis, each of whom had experienced ipsilateral retinal or hemispheric TIA or nondisabling stroke.19 The risk of ipsilateral stroke during the next 3 years was 2.8% for surgical patients, compared with 16.8% for medically treated patients. Although CEA is one of the most common surgical procedures performed in the United States,3,20 many patients cannot safely undergo such an extensive operation because of anatomical factors, such as lesions located in the upper cervical region, or concomitant severe medical illnesses, such as coronary artery disease and cardiac failure.7,8 Angioplasty of the CA involving stent placement has been introduced as an alternative treatment for revascularization of CA stenosis.17 Carotid artery angioplasty with stent placement can be performed without inducing general anesthesia in the patient and may prove to be the proce-
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dure of choice, particularly for high-risk surgical patients. At present, no large, multicenter, randomized trial has been conducted to compare CA angioplasty and stent placement with CEA. Presently, several angioplasty techniques and stent devices are being examined in Phase I trials of feasibility and safety before a large-scale multicenter trial is undertaken.

Although treatment of CA disease is a relatively new indication, the Memotherm stent (C. R. Bard, Inc., Murray Hill, NJ) has been used extensively to treat occlusive artery disease. In a report covering the period from 1994 to 1997, Nawaz and colleagues concluded that use of the Memotherm stent for aortoiliac occlusive disease resulted in good short- and long-term clinical success, with low incidences of morbidity and mortality. The Memotherm self-expanding nitinol stent was also found to be effective in the bilateral iliac “kissing stent” approach to aortic bifurcation reconstruction. Using intravascular ultrasonography, Kuribayashi, et al. confirmed the excellent stent-expansion characteristics of the Memotherm, when used for stent placement in the iliac artery. The stent was granted the approval of the European Commission and has been marketed overseas since December 1998. Londero and associates evaluated the Bard CA stent and commented that nitinol self-expanding stents are a good choice for treatment of extracranial obstructive CA disease.

We recently conducted a Phase I investigation to assess the feasibility and safety of the Memotherm CA stent for nonsurgical management of extracranial CA stenosis in patients with either symptomatic or asymptomatic stenosis of the CA. Our findings on feasibility, technical success, and 1-month postprocedure outcomes are reported here.

Clinical Material and Methods

The study was conducted as a prospective feasibility and safety study without comparative controls at six centers in the United States. Enrollment was limited to 75 patients. Patients exhibiting symptoms with 50% or greater ICA stenosis or asymptomatic patients with 70% or greater ICA stenosis were eligible for participation. The United States Food and Drug Administration reviewed the protocol and approval (IDE# BHQ9801) was given after the following criteria were met: 1) the risks were not considered sufficient to outweigh the anticipated benefits to the patient and the importance of the knowledge gained; 2) the investigational plan was scientifically sound; 3) there was no evidence to suggest that the device as used would be ineffective; 4) no evidence of inadequacy was documented in the reports of prior investigations; and 5) an adequate plan for monitoring and review of the investigation was implemented. The institutional review board at each participating center approved the study.

Patient Selection

Patients were enrolled in the study only after they were screened for eligibility and found to have met inclusion and exclusion criteria. The screening process consisted of a review of ultrasound images and/or CA angiograms by the study site investigator. Baseline angiographic findings were the final determinants of eligibility. The severity of stenosis was measured using NASCET criteria. Study patients underwent computerized tomography scanning or magnetic resonance imaging before the endovascular procedure.

Inclusion Criteria. To be included in the study, the patient had to meet the following inclusion criteria: 1) extracranial CA disease with 50% or greater symptomatic stenosis or 70% or greater asymptomatic stenosis; 2) age 45 years or older; 3) written consent to participate in the study (provided by the patient or the patient’s legal guardian); and 4) ability and willingness to comply with all study procedures, including scheduled follow-up visits and diagnostic tests at the study site.

Exclusion Criteria. Patients with any of the following conditions identified during the screening process were not eligible for enrollment: 1) an intracranial tumor or arteriovenous malformation; 2) dementia or previous stroke (a previous stroke was defined as a neurological event corresponding to an NIHSS score of >5 within the preceding 7 days: dementia was determined at the discretion of the screening physician); 3) CA angiography–demonstrated thrombus at the lesion site (the angiographic definition of thrombus was evidence on multiple projections of a defect or lucency with intraluminal filling, surrounded by contrast material, and without evidence of calcification); 4) a CA aneurysm; 5) a lesion length longer than 40 mm; 6) intracranial hemorrhage; 7) a coagulation disorder or contraindication to antiplatelet or anticoagulant therapy; 8) uncontrolled hypertension (defined as diastolic blood pressure >100 mm Hg); 9) concurrent enrollment in any other study; 10) kidney, liver, heart, or lung failure, or cancer likely to cause death within 5 years; 11) severe tortuosity or angulation of the CA vessel that might prevent access; 12) contraindication or allergy to contrast media; and 13) evolving myocardial infarction or unstable angina.

Procedural Management

Three days before the procedure, patients received aspirin (325 mg daily) and clopidogrel (150 mg daily) or ticlopidine (250 mg twice daily). Aspirin-sensitive patients were only required to take the clopidogrel. Each patient underwent neurological assessment, graded by the NIHSS, modified Rankin Scale, and Barthel index before the procedure. Preoperative medications and intraoperative anesthetic agents were administered using standard hospital procedures and monitoring techniques. Percutaneous vascular access was secured via standard sterile techniques. Systemic anticoagulation was achieved by administering 5000 IU of heparin; additional doses were administered during the procedure to maintain the ACT within the range of 200 to 250 seconds. A guide sheath was placed in the common CA at the site of the ICA stenosis. Carotid artery angioplasty was performed using standard angioplasty techniques and equipment. The CA was imaged using high-definition digital angiographic techniques. The investigator measured the vessel size and lesion severity to determine which stent size should be used. The stent was selected to be 1 to 1.2 times the diameter of the proximal reference vessel. In the initial part of the study, a first-generation Bard Memotherm stent was used. Due to technical difficulties, the design of the stent and its delivery device were modified and a second-generation Memotherm stent was used in the latter part of the study.

A detailed account of adjunctive surgical or medical
treatments (such as balloon dilation or expansion, or repair of arterial dissection), or associated procedures (any additional procedure used to treat the patient’s vascular disease, such as peripheral or iliac angioplasty, thrombectomies of existing peripheral grafts, or other stent placements) was maintained. Any blood products or medications that were administered, duration of the procedure, fluoroscopic imaging, stent implantation, and the amount and type of contrast media used were noted.

Postprocedural Management
The patient was returned to the recovery area or the intensive care unit according to local hospital policies; CA Doppler ultrasound imaging and a neurological examination, which included the NIHSS, modified Rankin Scale, and Barthel index, were performed before discharge. Cranial magnetic resonance imaging or computerized tomography examination was performed only if a new deficit, such as a TIA or minor or major stroke, developed.

An evaluation was performed 30 days after the procedure, which included a complete neurological assessment using the aforementioned grading systems. Doppler ultrasound imaging of the CA was performed as well. According to the study protocol, 6- and 12-month follow-up evaluations were scheduled.

Outcomes Analysis
Analysis of the feasibility and safety of the Memotherm stent was performed in the intent-to-treat patient population. Therefore, the analysis included all patients with lesions for which stenting with the Memotherm CA stent was attempted. The primary endpoint was a technically successful implantation procedure resulting in less than 30% residual stenosis demonstrated on postprocedure (control) angiograms and no incidence of mortality, ipsilateral stroke, Q-wave MI, or other major cardiovascular events immediately after or within 30 days following the procedure. For the purpose of this study, a successful implantation procedure was considered to be delivery of the stent to the intended location and retrieval of the delivery device.

The following are definitions of outcomes that were collected and analyzed.

**Transient Ischemic Attack.** This outcome was defined as symptoms lasting less than 24 hours that resulted from ischemia of insufficient duration to cause permanent damage related either to embolization or thrombosis. The TIAs included, but were not limited to transient monocular blindness and transient hemispheric attacks most often affecting the middle cerebral artery.

**Stroke.** This was defined as the sudden development of neurological deficits affecting one side of the body as a consequence of interruption of cerebral blood flow initiated by thrombosis, embolization, or arterial wall rupture. The stroke was classified as minor (nondisabling) when the neurological event lasted for at least 24 hours, but did not result in decreased functional independence relative to the ipsilateral hemisphere, or reduction in usual activities after 30 days (modified Rankin Scale Score 0 or 1). The stroke was classified as major (disabling) when the neurological event produced some level of dependence or disability after 30 days (modified Rankin Scale Score 2–4).

**Myocardial Infarction.** This represented the death of a segment of heart muscle subsequent to interruption of its blood supply. A Q-wave MI was defined as an MI in which new Q-waves develop in two or more leads and the creatine kinase MB fraction ratio exceeds 1. A non-Q-wave MI was defined as an elevation in creatine kinase that was at least two times the upper limit of the normal value, with an elevated creatine kinase MB isoenzyme and without new Q waves on the electrocardiogram.

**Vascular Access Complications.** These included arteriovenous fistula, pseudoaneurysm, retroperitoneal bleeding, and surgical repair of the percutaneous insertion site. Classification of a vascular access complication involved ultrasound evidence of the lesion, signs of peripheral ischemia, or an operative report from the study site documenting surgical repair of the site or retroperitoneal bleeding requiring transfusion or prolonged hospital stay.

**Recording of Adverse Events and Mechanical Failure**
An adverse event was defined as any undesirable clinical occurrence, sign, symptom, or illness, abnormal laboratory value, or other medical event appearing or worsening during the study that required medical treatment or intervention regardless of whether it was considered to be related to the device. All adverse effects that occurred during or 1

<table>
<thead>
<tr>
<th>TABLE 1</th>
<th>Demographic and baseline clinical characteristics of 71 patients with CA stenosis treated with the Memotherm stent*</th>
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<tbody>
<tr>
<td>Characteristic</td>
<td>Value</td>
</tr>
<tr>
<td>age (yrs)</td>
<td>71.3 ± 8.5†</td>
</tr>
<tr>
<td>male sex (no. of patients)</td>
<td>43 (61%)</td>
</tr>
<tr>
<td>coronary artery disease or angina (no. of patients)</td>
<td>6 (8%)</td>
</tr>
<tr>
<td>congestive heart failure (no. of patients w/ NYHA score &gt;II)</td>
<td>1 (1%)</td>
</tr>
<tr>
<td>poorly controlled diabetes mellitus (no. of patients)</td>
<td>1 (1%)</td>
</tr>
<tr>
<td>systolic hypertension (no. of patients w/ systolic blood pressure &gt;180 mm Hg)</td>
<td>1 (1%)</td>
</tr>
<tr>
<td>renal insufficiency (no. of patients w/ serum creatinine level &gt;2 mg/dl)</td>
<td>1 (1%)</td>
</tr>
<tr>
<td>peripheral vascular disease (no. of patients)</td>
<td>9 (13%)</td>
</tr>
<tr>
<td>baseline NIHSS score</td>
<td>0.4 ± 1.2†</td>
</tr>
<tr>
<td>baseline Barthel index</td>
<td>19.6 ± 4.2†</td>
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<tr>
<td>baseline modified Rankin Scale score</td>
<td>0.2 ± 0.5†</td>
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* NYHA = New York Heart Association.
† Mean ± SD.

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<tr>
<th>TABLE 2</th>
<th>Characteristics of the 73 lesions included in the Memotherm study</th>
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<tbody>
<tr>
<td>Characteristic</td>
<td>No. of Lesions (%)</td>
</tr>
<tr>
<td>preprocedure stenosis (mean ± SD)</td>
<td>82.6 ± 9.0%</td>
</tr>
<tr>
<td>symptomatic lesion</td>
<td>27 (37)</td>
</tr>
<tr>
<td>asymptomatic lesion</td>
<td>46 (63)</td>
</tr>
<tr>
<td>previous ipsilateral CEA</td>
<td>5 (7)</td>
</tr>
<tr>
<td>location of lesion</td>
<td></td>
</tr>
<tr>
<td>ICA</td>
<td>70 (96)</td>
</tr>
<tr>
<td>common CA</td>
<td>2 (3)</td>
</tr>
<tr>
<td>common CA bifurcation</td>
<td>1 (1)</td>
</tr>
<tr>
<td>contralateral stenosis &gt;70%</td>
<td>11 (15)</td>
</tr>
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**TABLE 3**

<table>
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<th>Experience with use of the Memotherm stent</th>
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Results

Seventy-eight Memotherm stent placements were attempted for 73 lesions in 71 patients. The mean age of the patients was 71.3 ± 8.5 years and 43 (61%) of the patients were men (Table 1). Twenty-seven (37%) of the 73 lesions were symptomatic and 46 (63%) were asymptomatic. Four patients (6%) had experienced one or more TIAIs within the week before the procedure. Five patients (7%) had previously undergone CEA of the affected vessel. In 11 patients (15%) contralateral stenosis was greater than 70% and in two patients (3%) there was contralateral occlusion. Nine patients (13%) suffered from peripheral vascular disease. Among the 71 patients, unstable angina or MI (appearing within 1 month postprocedure), congestive heart failure (New York Heart Association grade > II), and renal insufficiency (serum creatinine level > 2 mg/dl) were observed in one patient each. At baseline the NIHSS score (mean ± SD) was 0.4 ± 1.2, the Barthel index was 19.6 ± 4.2, and the modified Rankin Scale score was 0.2 ± 0.5. The mean degree of stenosis was 82.6 ± 9% (Table 2).

The mean duration of the 73 procedures was 62 ± 38 minutes. Intravenous abciximab or eptifibatide was used as adjunctive therapy in addition to heparin during procedures in 18 patients (25%) to prevent thromboembolic events. The mean ACT recorded during the procedure was 281 ± 79 seconds. Atropine was intravenously administered during 33 procedures (45%) to prevent or treat bradycardia at the discretion of the treating physician. Predilation angioplasty (mean diameter of inflated balloon 4 ± 0.4 mm) was performed in 71 procedures (97%). Angiographic dissection following angioplasty was observed in one procedure. A total of 78 stent devices were used for 73 lesions. Overall stent placement difficulties were encountered in six procedures (seven stent placements) (Table 3). The stent could not be delivered or placed in four procedures. In two procedures, the stent could not be delivered to the stenotic segment due to the tortuosity of the vessel (“failure to deploy” [Fig. 1]). In one procedure, the stent was placed across the lesion but could not be delivered due to mechanical failure of the delivery system (“failure to deploy” [Fig. 1]). In one procedure, the guide catheter could not be placed in the proximal vessel to attempt delivery or placement (“introducer failure” [Fig. 1]). Memotherm stents were placed in 69 lesions (Fig. 1). In two procedures, the stent was placed either proximal or distal to the site initially intended for placement (“imperfect deployment”); however, the stenotic segments were covered and no postprocedure residual stenosis was detected in either procedure. Stent sizes (diameter × length) were 6 × 20 mm (12 cases), 6 × 30 mm (six cases), 8 × 20 mm (five cases), 8 × 40 mm (11 cases), and 8 × 30 mm (35 cases). Difficulties with placement related to the stent system (four cases) occurred only when the original design of the stent was used in patients with tortuous anatomy. In the second part of the series, after improvement of the stent system design, there were three additional procedure failures that were unrelated to the stent system. Postdilation angioplasty (mean balloon diameter 4.9 ± 0.6 mm) was performed in 70 procedures (96%). The mean residual stenosis observed on angiograms was 3.8 ± 0.6

month after attempted or actual use of the Memotherm device were recorded. Adverse effects related to the procedure or the device were recorded on case reporting forms and included complications related to mechanical failure such as misplacement or migration of a delivered or implanted stent or failure to deliver or implant the stent.

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**Fig. 1.** A schematic representation of results of the multicenter feasibility and safety study of the Memotherm CA stent for extracranial CA stenosis. Technical success is defined by a successful implantation procedure resulting in less than 30% residual stenosis on postprocedure (control) angiograms. Clinical success is defined by a technically successful procedure that does not result in death, ipsilateral stroke, Q-wave MI, or other major cardiovascular events immediately after or within 30 days after the procedure. ARDS = acute respiratory distress syndrome.
TABLE 4
One-month adverse outcomes in patients with CA stenosis who were treated with the Memotherm CA stent

<table>
<thead>
<tr>
<th>Negative Outcome</th>
<th>No. of Patients (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>major ischemic stroke</td>
<td>1 (1)</td>
</tr>
<tr>
<td>ICH</td>
<td>1 (1)</td>
</tr>
<tr>
<td>total stroke rate</td>
<td>2 (3)</td>
</tr>
<tr>
<td>death</td>
<td>2 (3)*</td>
</tr>
<tr>
<td>postprocedure stenosis &gt;30%</td>
<td>1 (1)</td>
</tr>
</tbody>
</table>

* Includes patient with ICH.

terward—was achieved in 65 (89%) of 73 procedures (63 of 71 patients). The mean postprocedure hospital stay was 1.8 ± 3 days. Table 4 shows 1-month adverse outcomes of patients observed in the study. One patient experienced a major ipsilateral stroke during the procedure. Intracranial angiographic images did not reveal distal vessel embolization. The patient’s poststroke NIHSS score was 11 and the modified Rankin Scale score was 4 at discharge, 19 days after the procedure. Further follow-up data were not available because the patient withdrew from the study. Another patient experienced a TIA, but there was complete resolution of deficits within the immediate periprocedure period. One patient experienced a fatal ICH during the immediate postoperative period, which may be related to the use of intravenous abciximab and heparin. Another patient died of pneumonia and adult respiratory distress syndrome 3 weeks after the procedure. Bradycardia occurred in five patients during or after the procedure. One patient experienced CA dissection, pseudoaneurysm, and iliac artery dissection caused by intravenous catheter placement, lower-extremity claudication, pseudoaneurysm, and iliac artery dissection, which occurred in one patient each. Two patients suffered an episode of non-Q-wave MI or unstable angina 12 and 20 days after the procedure, respectively. One patient experienced pneumonia requiring hospital admission. In two other patients a blood transfusion was required for a decreased hemoglobin level, which was related to gastrointestinal bleeding in one of these patients. Other adverse events included fever of unknown cause in one case and contrast nephropathy in two cases.

**Discussion**

**Salient Results of the Study**

This study represents one of the few prospective multicenter studies that has focused on the feasibility and technical success rate of CA angioplasty and stent placement. We observed that Memotherm stent placement is feasible and can be performed with a low risk of major disabling stroke or death. Successful stent placement resulting in less than 30% residual stenosis and no major periprocedure complications was possible in 65 (89%) of the 73 procedures (71 patients). The stent could not be delivered or placed in four of the eight procedures in which the primary endpoint could not achieved. After one procedure, residual stenosis was greater than 30%. Three other procedures were complicated by stroke and/or death within 1 month after the procedure. Two strokes, one fatal ICH, and one major ischemic stroke were observed during two (2.7%) of the 73 procedures. A second death was unrelated to the CA stent procedure and occurred 3 weeks after the procedure; causes of death in that case were pneumonia and acute respiratory distress syndrome.

**Design of the Memotherm Stent**

The Bard Memotherm CA stent was derived from the first nitinol stent, introduced by Angiomed GmbH (Karlruhe, Germany) to Europe in 1993 for a variety of vascular and nonvascular indications. Nitinol is the name given to a series of paramagnetic nickel–titanium compounds characterized by outstanding properties including shape memory, superelasticity, excellent fatigue strength, and biocompatibility. Shape memory refers to the ability of a device to regain a programmed shape when subjected to the appropriate thermal procedure. Generally shape memory alloys such as nitinol can be deformed (or constrained) at a low temperature and will return to their previous shapes on exposure to a higher temperature (for example, body temperature). The superelastic property refers to the strongly enhanced ability of nitinol to be deformed without irreversible change in shape. Accordingly, the elastic strain tolerance of nitinol is more than 20 times that of stainless steel. Both superelasticity and the shape memory are due to a reversible crystal-phase transformation between martensite and austenite that is driven by force and temperature.

The Memotherm CA stent is a flexible prosthesis constructed of a tight mesh, which self-expands because of the material properties of nitinol described earlier. The stent geometry is a repeating mesh pattern of rhomboids, which provide a scaffold for the vasculature and recanalize the lumen. The majority of the stent rhomboids are symmetrical; however, those located at the proximal and distal ends of the stent are slightly elongated in shape with respect to the longitudinal axis of the stent. The outer diameter of the stent is slightly larger at each end than at the center. On implantation, the stent apposes the vascular wall at the stated diameter on each end. The Memotherm CA stent was available during the study in nominal diameters of 6 and 8 mm with 20-, 30-, and 40-mm lengths for each diameter. The stent is delivered with the aid of a No. 7 French delivery device, and is advanced through a No. 7 French guide sheath or a No. 9 French guide catheter. The delivery device can be advanced on guidewires ranging in diameter from 0.014 to 0.035 in. The major limitation of the Memotherm stent system appears to be the size of the delivery device.

In response to stent placement difficulties observed early in this investigation, Bard introduced an improved second-generation stent delivery catheter. The stent is captured between a fixed, inner catheter and a sliding, outer catheter. The stent is exposed and placement occurs as the outer catheter is pulled back against the inner catheter. In cases in which there is severe vessel tortuosity, the frictional force between the inner and outer catheters increased when the
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First-generation stents were used, causing difficulty in stent placement. The second-generation stent delivery catheter improvements included a new outer catheter, constructed of polytetrafluorethylene, which is considerably more flexible and lubricious. These attributes provided improved access to the target lesion in cases in which there was tortuous anatomy and reduced catheter system friction, which resulted in improved ease and accuracy of stent placement. Development efforts are underway to reduce the system profile of the delivery device and to expand the available stent sizes. The stent will be available in nominal diameters equal to 4, 5, 6, 7, and 8 mm with lengths for each diameter available from 20 to 40 mm in 10-mm increments.

Periprocedure Morbidity and Mortality in Cases of CA Revascularization

Three major strokes or deaths were observed in the 73 CA angioplasty and stent placement procedures performed in this Phase I study. These included one major ischemic stroke and one fatal ICH. Another patient died of pneumonia and acute respiratory distress syndrome. This provides an overall 1-month rate of 4% for major stroke or death and a 2.7% stroke rate per procedure. All three complications were observed during the 27 procedures for symptomatic CA stenosis. No stroke or death was observed during the 46 procedures performed for asymptomatic stenosis. The rate of perioperative complications is an important determinant of overall benefit derived from any CA revascularization procedure. In the report from NASCET investigators, a rate of 6.5% for perioperative (30-day) stroke and death was observed in all 1415 patients who underwent CEA.24,26 The rate of permanently disabling stroke and death associated with surgery was 2%. Hemispheric ischemic events, left-sided procedures, contralateral CA occlusion, ipsilateral ischemic lesion observed on CT scan, and irregular or ulcerated plaque were all associated with an increased surgical risk.2 A direct comparison between the complications reported in our study and those of the NASCET study is not possible due to differences in definitions of complications and their severity.

Among patients with 60% or greater stenosis in the Asymptomatic Carotid Atherosclerosis Study, the absolute risk reduction over 5 years conferred by CEA was modest (5.9%), compared with that associated with medical treatment.3 The surgically treated group incurred a 2.3% perioperative risk of stroke or death (19 of 825 patients). On the basis of these results, the American Heart Association recommended CEA for symptomatic CA stenosis if the surgical risk is lower than 6% and for asymptomatic CA stenosis if the surgical risk is lower than 5% and life expectancy longer than 5 years.13 Our rates of periprocedure morbidity and mortality in patients with asymptomatic stenosis compare favorably with those required to derive a benefit from revascularization.

Previous Studies of CA Angioplasty and Stent Placement

The rate of periprocedure neurological complications in the present report compares favorably with rates cited in previous studies of CA angioplasty and stent placement. A cumulative analysis of previous studies of the results of CA angioplasty and stent placement in 834 patients was recently published.18 Periprocedural neurological complications, consisting of 26 TIAs and 47 ischemic strokes, were reported in 73 patients (8.8%) and the overall rate of ischemic strokes leading to either poor or no recovery or death was 1.4% (12 patients). In a global survey of 5210 CA angioplasty and stent procedures involving 4757 patients, a technical success rate of 98.4% with 5219 arteries was observed.21 The rates of occurrence of TIs, minor strokes, and major strokes were 2.8%, 2.7%, and 1.5%, respectively; the overall mortality rate was 0.9%.

Few reports exist in which CA angioplasty with stent placement is compared with CEA. A prospective consecutive randomized trial of CEA compared with CA angioplasty with stent placement for symptomatic severe ICA disease was conducted at a university teaching hospital.15 All patients were assessed before and after surgery by a neurologist. The study consisted of 23 patients with focal CA territory symptoms and severe (> 70%) ICA stenosis, who were randomized to groups undergoing either CEA with patch grafting or CA angioplasty with stent placement. Only 17 patients received their allocated treatment before the trial was suspended. The main outcome measures were death or disabling or nondisabling stroke within 30 days postprocedure. All 10 endarterectomies proceeded without complication; however, five of seven patients who underwent CA angioplasty with stent placement suffered a stroke, three of whom were disabled at 30 days. After review, the data monitoring committee invoked the stopping rule, and the trial was suspended. The results of our study suggest that angioplasty with stent placement can be performed with low incidences of morbidity and mortality at this point, justifying the initiation of other studies in which the two CA revascularization techniques are compared.

Conclusions

Memotherm stent placement is feasible in patients in whom there is symptomatic or asymptomatic extracranial ICA stenosis. Stent placement combined with angioplasty resulted in a high degree of reduction in the severity of the stenosis. The procedure can be performed with a low perioperative complication rate. Further studies are required to determine whether Memotherm stent placement leads to a reduced occurrence of ischemic stroke and associated morbidity and mortality over time.

Appendix

Sites and Investigators Participating in the Bard Memotherm Carotid Stent Clinical Study (BHV 9801)

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