

The CReATe Registry

The accuracy and acute clinical outcome of the Acculink Carotid Stent were evaluated in this multicenter European study.

BY JOS C. VAN DEN BERG, MD, PHD, ON BEHALF OF THE CReATe INVESTIGATORS

The Carotid Registry for Accuracy and Taperings of the Acculink carotid artery stent system (Guidant Corporation, Indianapolis, IN) (CReATe) is a multicenter, prospective, single-arm study in which the primary objective was to evaluate the acute performance of the Acculink stent (Figure 1) in patients with symptomatic and asymptomatic carotid artery atherosclerotic disease. The secondary objective was to register any adverse event related to carotid stenting during the procedure and prior to discharge of the patient. In the CReATe registry, 100 patients were recruited in 15 centers (Table 1). Patients were enrolled between April 4, 2002, and September 23, 2002.

DEMOGRAPHICS AND LESION CHARACTERISTICS

Overall patient age ranged from 50 to 89 years; the average age of all patients was 70.8 years, with symptomatic patients being slightly older on average than asymptomatic patients (71.4 vs 69.9 years). The majority of patients were of male gender (71 male vs 29 female).

Sixty-four of 100 patients were symptomatic (64%), and 36 were asymptomatic (36%). Fifty patients (50 of 91; 55.6%) were reported to have a high cardiovascular risk profile; 41 patients (41 of 91; 44.4%) were considered to have a normal risk. Data were lacking in the remaining nine patients.

No patients with a reported stenosis rate <60% were included. Eighty-one of 97 patients (83.5%) had a stenosis between 60% and 90%, and 16 of 97 patients (16.5%) had a stenosis >90%. Information on stenosis grade was not available in three patients. In the symptomatic population, 53 of 62 patients had a stenosis between 60% and 90%, whereas nine of 62 had a stenosis >90%; data were missing in two cases. Twenty-eight of 35 asymptomatic patients had a stenosis between 60% and 90%, and seven of 35 patients had a stenosis >90%; the data were missing for one patient. The average lesion length was 16 mm (range, 0.5-100 mm). In the patient with a 100-mm lesion, three Acculink stents were used with excellent stent performance and no clinical or technical complications. This patient had severe four-vessel disease and was symptomatic. He had a history of carotid endarterectomy and presented with restenosis with-

in the endarterectomized segment as well as lesions distally in the common carotid artery and proximally in the internal carotid artery.

Tapered stents were used in the majority of cases (91% of cases). This can be explained by the distribution of the lesions (Table 2): the majority was found at the level of the carotid bifurcation or proximal internal carotid artery. To completely cover the target lesion, the stent must be placed from the (wide) common carotid artery, across the external carotid artery, into the (narrow) internal carotid artery. This step down in diameter can best be handled using a tapered stent.

Embolic protection devices were used in 58 of 100 patients, and no difference in the rate of use of an embolic protection device was noticed between symptomatic and asymptomatic patients. An embolic protection device was used in 37 of 64 symptomatic patients, versus 17 of 36 asymptomatic patients (57.8% of symptomatic patients, 58.3% of asymptomatic patients).

STENT PERFORMANCE

Accuracy of placement was rated excellent in 55 of 100 patients (55%), good in 38 of 100 patients (38%), satisfactory in five of 100 patients (5%), and poor in two of 100 patients (2%). Conformability of the stent to the patient's

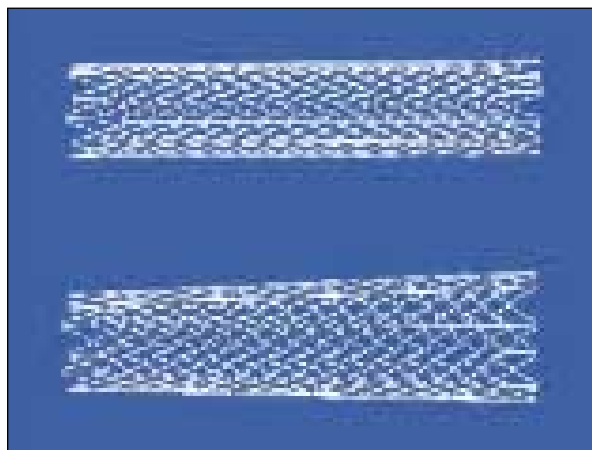


Figure 1. The nontapered and tapered Acculink stents.

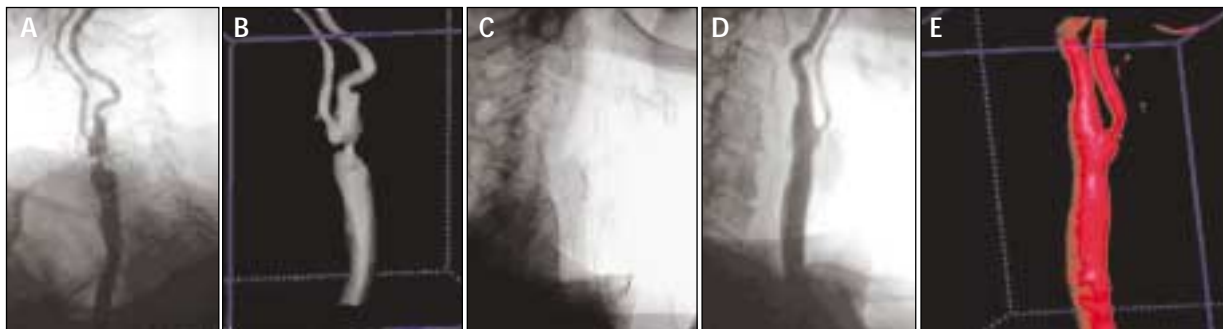


Figure 2. Stenosis of the distal part of the common carotid artery as demonstrated on angiography (A), and 3-D rotational angiography (B). The appearance after stenting using the Acculink stent, with clear depiction of the conformability of the stent (C-E).

anatomy (Figures 2 and 3) was perceived as excellent in 56 of 100 patients (56%), good in 39 of 100 patients (39%), and satisfactory in five of 100 patients (5%). No distortion (in 79 of 100 patients) or little distortion (in 17 of 100 patients) of the vessel was seen in most patients after stent deployment and tailoring/postdilatation. In 4% of patients, however, a significant distortion of the target vessel was observed.

In the 58 cases during which an embolic protection device was used, no serious tracking problems were encountered, with smooth passage of the stent over the embolic protection device wire in 45 of 55, and some minor resistance in 10 of 55 cases; data were missing in three cases. In all cases during which the external carotid artery was patent prior to the procedure (86 of 100 cases), the external carotid artery remained patent after stent placement, indicating that, as with other target vessels and other stents, overstenting of side branches can be performed without sequelae.

COMPLICATIONS

Procedural complications were encountered in five cases (5%). In one patient, the stent was too short to cover the lesion, requiring the placement of a second Acculink stent. One stent became displaced during positioning, and another stent was placed successfully. In one patient, there was some difficulty in retracting the nose cone of the stent delivery system due to insufficient deployment of the stent in a very tight lesion. In another case, there was entrapment of the embolic protection device by the delivery system of the stent as the filter slid down. Finally, only one patient experienced a residual stenosis within the stent; this was seen on control Duplex scanning the day

after the procedure. In all other patients, no residual stenosis was found, indicating that radial force is appropriate.

CLINICAL OUTCOME

Immediate clinical outcome was good (97 of 100) or satisfactory (two of 100) in 99% of cases. Clinical outcome was rated poor in one patient (1 hour after the procedure, there was a clonic spasm and an epileptic fit). Clinical complications at stent deployment were seen in five of 100 patients, consisting of hypotension in four patients and one patient who had syncope.

Neurological complications were seen in 2% of cases:

- Minor stroke: 1% (a symptomatic patient who had a minor stroke 1 day after the procedure that completely resolved after 1 week).
- Major stroke and death: 1% (an asymptomatic patient who had hyperperfusion syndrome occurring 6 hours after the intervention with hemorrhagic stroke and death).

TABLE 1. PARTICIPATING CENTERS AND THEIR RECRUITMENT RATE

Site	Location	No. of Cases
Elisabethinen Hospital Linz	Linz, Austria	12
Hospital San Ambrogio	Milan, Italy	11
Hospital Virgen Rocio	Seville, Spain	10
Hospital San Gerardo	Monza, Italy	9
Allgemeines Krankenhaus	Vienna, Austria	8
Puerta de Hierro	Madrid, Spain	7
St Vincent-Krankenhaus	Essen, Germany	7
Krankenhaus Güstrow GmbH	Güstrow, Germany	7
UZ Gasthuisberg	Leuven, Belgium	7
St. Antonius Hospital	Nieuwegein, Netherlands	5
Klinikum Nürnberg Süd	Bad Krozingen, Germany	5
Univ. Hospital Graz	Graz, Austria	4
Hospital Cardarelli	Naples, Italy	3
Städtisches Kliniken Dortmund	Dortmund, Germany	3
Northern General Hospital	Sheffield, UK	2

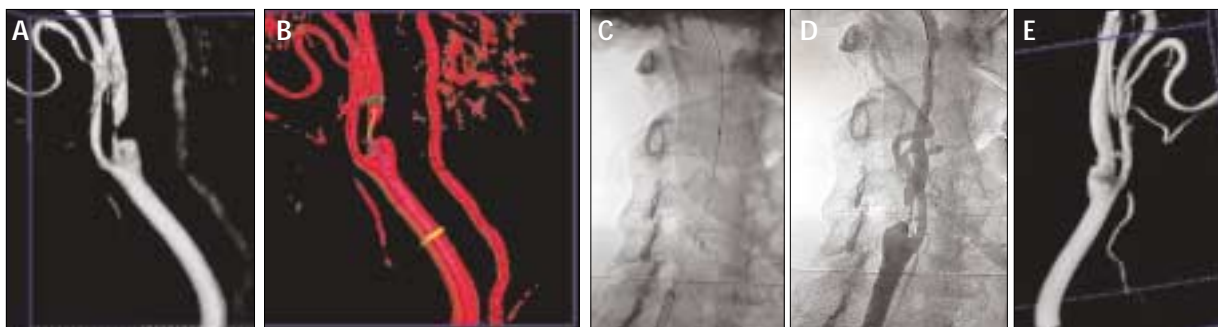


Figure 3. Severe stenosis of the internal carotid artery as demonstrated on 3-D rotational angiography (A,B). The appearance after primary passage, without predilation, of an embolic protection system, maintaining antegrade flow (C,D). Completion 3-D rotational angiography after stenting using the Acculink stent (E).

TABLE 2. DISTRIBUTION OF THE LESIONS BY LOCATION

	CCA	Bifurcation	Proximal ICA	Distal ICA	Missing Data
No. of Cases	4	40	51	3	2
% Tapered Stent Used	50% (2/4)	100% (40/40)	90.2% (46/51)	33% (1/3)	N/A

TABLE 3. OUTCOME AS RELATED TO SYMPTOMATOLOGY AND USE OF EMBOLIC PROTECTION DEVICE

CLINICAL OUTCOME	SYMPTOMATIC (n=64)		ASYMPTOMATIC (n=36)	
	With Embolic Protection Device n=37	Without Embolic Protection Device n=27	With Embolic Protection Device n=21	Without Embolic Protection Device n=15
Uncomplicated	37	26	21	14
TIA	0	0	0	0
Minor Stroke	0	1	0	0
Major Stroke	0	0	0	1
Death	0	0	0	0

In addition, one patient (symptomatic) had some problems with disorientation, but no focal neurological deficits. Comparison of short-term clinical outcome of the patients treated without an embolic protection device versus those treated with an embolic protection device, and comparison of short-term clinical outcome of the asymptomatic patients versus those with symptoms, show that the several groups are comparable in their complication rates. In both patients who had neurological complications, no embolic protection device was used. A full comparison of the clinical outcome in the various subsets is listed in Table 3.

SUMMARY

Accuracy of placement of the Acculink stent is more than satisfactory, and conformability of the stent is perceived as high. Neurological complications were seen in 2% of cases (minor stroke, 1%; major stroke and death, 1%.) In both

cases no embolic protection device was used.

In this acute study, the Acculink carotid stent seems to be a stent system with an excellent accuracy of placement and good clinical and neurological outcome. The radial force of the Acculink is appropriate, and the tapered stent has a high physician preference. ■

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