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PERIPHERAL

A Prospective, Multicenter Study of a Novel Mesh-Covered Carotid Stent

The CGuard CARENET Trial (Carotid Embolic Protection Using MicroNet)

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ABSTRACT

OBJECTIVES This study sought to evaluate the feasibility of the CGuard Carotid Embolic Protective Stent system—a novel thin strut nitinol stent combined with a polyethylene terephthalate mesh covering designed to prevent embolic events from the target lesion in the treatment of carotid artery lesions in consecutive patients suitable for carotid artery stenting.

BACKGROUND The risk of cerebral embolization persists throughout the carotid artery stenting procedure and remains during the stent healing period.

METHODS A total of 30 consecutive patients (age 71.6 ± 7.6 years, 63% male) meeting the conventional carotid artery stenting inclusion criteria were enrolled in 4 centers in Germany and Poland.

RESULTS The primary combined endpoint was the procedure success of the CGuard system and the number and volume of new lesions on the ipsilateral side assessed by diffusion-weighted magnetic resonance imaging at 48 h post-procedure and at 30 days. The secondary endpoint was 30-day major adverse cardiac or cerebrovascular events (death, stroke, or myocardial infarction). Protection devices were used in all procedures. Procedure success was 100%, with 0% procedural complications. The 30-day major adverse cardiac or cerebrovascular events rate was 0%. New ipsilateral ischemic lesions at 48 h occurred in 37.0% of patients and the average lesion volume was 0.039 ± 0.08 cm^3. The 30-day diffusion-weighted magnetic resonance imaging showed complete resolution of all but 1 periprocedural lesion and only 1 new minor (0.116 cm^3) lesion in relation to the 48-h scan.

CONCLUSIONS The use of the CGuard system in patients undergoing carotid artery stenting is feasible. In addition, the benefit of using CGuard may extend throughout the stent healing period. (J Am Coll Cardiol Intv 2015;8:1229–34)

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ABBREVIATIONS AND ACRONYMS

CAS = carotid artery stenting

DW-MRI = diffusion-weighted magnetic resonance imaging

MACCE = major adverse cardiac or cerebrovascular event(s)

TIMI = Thrombolysis In Myocardial Infarction

Carotid artery stenting (CAS) is associated with a stroke risk mainly due to dislodgement of debris from the target lesion during the procedure. The CGuard Embolic Protection Stent (InspireMD Inc., Boston, Maryland) is a novel thin strut nitinol stent combined with a polyethylene terephthalate mesh covering designed to trap and exclude thrombus and friable atheromatous debris to prevent acute and late embolic events from the target lesion. The CARENET (Carotid Embolic Protection Using MicroNet) trial was the first multicenter study of CGuard following the CE Mark of this device in March 2014. The trial was designed to evaluate the feasibility of the CGuard system in the treatment of carotid lesions and the number and volume of new lesions on the ipsilateral side assessed by diffusion-weighted magnetic resonance imaging (DW-MRI) at 48 h post-procedure and at 30 days in consecutive patients suitable for CAS in a multioperator, real-life setting.

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METHODS

STUDY DESIGN AND PATIENTS. The prospective multicenter single arm clinical trial included 30 consecutive eligible patients enrolled in 4 centers in Germany and Poland. The principal inclusion criteria were age of at least 18 years, written informed consent, de novo atherosclerotic target lesion. Symptomatic patients had to have transient ischemic attack, stroke, or amaurosis fugax within the last 6 months on the ipsilateral side with carotid stenosis ≥50% as diagnosed by angiography using NASCET (North American Symptomatic Carotid Endarterectomy Trial) criteria. Asymptomatic subjects had to have carotid stenosis ≥80% that qualified for revascularization in the opinion of a vascular specialist and an independent neurologist. The principal exclusion criteria were stage III renal insufficiency, acute stroke within 30 days, myocardial infarct within 72 h, atrial fibrillation, or any other than carotid stenosis known reason for stroke, total occlusion of the index carotid artery, a pre-existing stent that extended into the aortic arch, severe circular calcification of the target lesion, and lesion length exceeding 30 mm.

CAS PROCEDURE. The CAS procedure was to follow the operator's routine except for the use of CGuard in place of a conventional noncovered carotid stent. In particular, the vascular access and the type of embolic protection during CAS were left to the discretion of the operator. Because CAS-related embolization is not limited to the stent deployment and post-dilation phase (1), use of an embolic protection device was recommended.

DEVICE DESCRIPTION. The CGuard System is a carotid stent wrapped with a MicroNet mesh, mounted on a self-expandable delivery system compatible with a 6-F (2.0-mm) catheter (**Figure 1**). The pore size of the mesh when the stent is fully expanded is 150 to 180 μm. Prior to carotid application, this particular mesh type was evaluated in the coronary balloon-expandable stents where it demonstrated a substantial benefit in myocardial perfusion, indicating its impact on reducing thrombotic lesion embolization (2). The CGuard System is available in an array of diameters (6 to 10 mm) and lengths (20 to 60 mm), and is CE-marked for this indication.

STUDY ENDPOINTS AND DEFINITIONS. The primary combined endpoint was the procedure success of the CGuard system and the number and volume of new lesions on the ipsilateral side assessed by DW-MRI at 48 h post-procedure and at 30 days. Procedure success was defined as device delivered to the target lesion, deployed in the target lesion, and delivery system retrieved. Secondary endpoints were 30-day major adverse cardiac or cerebrovascular events (MACCE) (death, stroke, or myocardial infarction), in-hospital MACCE, and any procedural complications. Per-protocol analysis also includes 12-month MACCE; ipsilateral stroke from 31 days to 1 year; peak systolic velocity and end-diastolic velocity assessment at 30 days, 6 months, and 12 months. Diameter stenosis was determined angiographically according to the NASCET criteria (3). The flow in the external carotid artery was determined according to modified TIMI (Thrombolysis In Myocardial Infarction) criteria (4).

Perfusion was defined as follows: TIMI flow grade 0 = no flow; TIMI flow grade 1 = penetration without perfusion; TIMI flow grade 2 = partial perfusion; TIMI flow grade 3 = complete perfusion.

Detailed evaluation of the patient status at baseline, 24 h after CAS, and at 30 days was by a consultant neurologist independent of the study team. Angiographic and DW-MRI analysis were performed by external core labs, independent of the study sponsor or investigators.

DW-MRI ANALYSIS. MR images available for analysis included T1, T2, fluid attenuated inversion recovery, DW-MRI, and apparent diffusion coefficient sequences. The images were evaluated by a core lab neuroradiologist without the knowledge of the patient's age, sex, or symptoms. Images were analyzed