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Original Research Article

Midterm Clinical Outcomes and Hemodynamic Patency of Standalone Cguard Micronet-Covered Carotid Stenting in Symptomatic Carotid Artery Stenosis: A Prospective Single-Center Study

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ABSTRACT
Background: Carotid artery stenting (CAS) is an established alternative to carotid endarterectomy for selected patients with symptomatic carotid artery stenosis. Conventional CAS commonly incorporates embolic protection devices to reduce procedural cerebral embolization; however, these devices may increase procedural complexity and are associated with device-related limitations. The CGuard MicroNET-covered carotid stent was developed to provide continuous plaque coverage and may reduce embolic complications without the routine use of adjunctive embolic protection devices. This study evaluated the safety and midterm efficacy of the CGuard MicroNET-covered stent when used as a standalone embolic protection strategy.
Methods: This prospective single-center observational study included 117 consecutive patients with symptomatic carotid artery stenosis who underwent CAS using the CGuard MicroNET-covered stent between January 2018 and December 2023 without distal filter or proximal flow-reversal protection. The primary safety endpoint was stroke within 30 days. The primary efficacy endpoint was primary stent patency at 12 months. All patients underwent diffusion-weighted magnetic resonance imaging within 48 hours after the procedure and standardized clinical and imaging follow-up for 12 months.
Results: Technical success was achieved in all 117 procedures (100%). No patient experienced periprocedural stroke, myocardial infarction, or death within 30 days. One patient (0.85%) demonstrated a new asymptomatic diffusion-weighted imaging lesion. Twelve-month follow-up was available for 110 patients (94.0%). Primary patency was maintained in 108 patients (98.4%), and no patient experienced ipsilateral stroke or required target lesion revascularization during follow-up. Adherence to the prescribed dual antiplatelet therapy regimen was significantly associated with maintained primary patency (OR 8.41, 95% CI 4.12–15.68; $p < 0.001$).
Conclusions: The CGuard MicroNET-covered carotid stent demonstrated a high technical success rate, low periprocedural complication rate, and durable midterm patency when used without adjunctive embolic protection devices in this prospective cohort. These findings support the feasibility of standalone mesh-covered carotid stenting in selected patients with symptomatic carotid artery stenosis. Larger multicenter comparative studies with longer follow-up are required to confirm these findings.

Keywords: Carotid Artery Stenting, Cguard Micronet-Covered Stent, Symptomatic Carotid Stenosis, Embolic Protection, In-Stent Restenosis.

INTRODUCTION

Ischemic stroke remains one of the leading causes of mortality and long-term disability worldwide, with extracranial internal carotid artery (ICA) stenosis accounting for a substantial proportion of ischemic cerebrovascular events.[1,2] Carotid endarterectomy (CEA) has historically been

regarded as the standard treatment for significant carotid artery stenosis; however, improvements in endovascular techniques, device technology, and operator experience have established carotid artery stenting (CAS) as an effective alternative for appropriately selected patients and those considered to be at increased surgical risk.[3,4]

Despite these advances, symptomatic carotid stenosis continues to present a therapeutic challenge because patients derive the greatest benefit from revascularization while simultaneously carrying the highest risk of periprocedural cerebral embolization.[2,5] Vulnerable carotid plaques are characterized by lipid-rich necrotic cores, intraplaque hemorrhage, and thin fibrous caps, making them susceptible to plaque disruption during angioplasty and stent deployment.[6,7] Conventional single-layer carotid stents may permit plaque prolapse through their relatively large cell architecture, increasing the risk of distal embolization during and after the procedure.[8]

To reduce embolic complications, contemporary CAS commonly incorporates distal filter or proximal flow-reversal embolic protection devices (EPDs). Although these devices have improved procedural safety, they may increase technical complexity and remain associated with limitations such as incomplete embolic capture, arterial spasm, vessel injury, and embolization during device deployment or retrieval.[5,9] Consequently, there is growing interest in device technologies capable of providing continuous embolic protection without the routine use of adjunctive EPDs.[9]

The CGuard MicroNET-covered stent was developed to address these limitations by combining a self-expanding nitinol framework with an external polyethylene terephthalate (PET) MicroNET mesh designed to minimize plaque prolapse while maintaining vessel patency.[10] The present prospective study evaluated the safety and midterm efficacy of the CGuard MicroNET-covered stent when used as a standalone embolic protection strategy in patients with symptomatic carotid artery stenosis undergoing carotid artery stenting.

MATERIALS AND METHODS

Study Design

This prospective, single-center, single-arm observational study was conducted at a high-volume tertiary neurovascular referral center between January 2018 and December 2023. The primary objective was to evaluate the periprocedural safety and midterm efficacy of the CGuard MicroNET-covered carotid stent when used as the sole embolic protection strategy during carotid artery stenting (CAS) in patients with symptomatic carotid artery stenosis. The primary safety endpoint was the occurrence of stroke within 30 days after the procedure, whereas the primary efficacy endpoint was primary stent patency at 12 months. Secondary endpoints included freedom from ipsilateral cerebrovascular events and target lesion revascularization during follow-up. The study protocol was reviewed and approved by the Institutional Ethics Committee, and written informed consent was obtained from all participants before enrollment.

Patient Selection

Eligible participants were adults aged 18 years or older with symptomatic extracranial internal carotid artery (ICA) stenosis who had experienced an ipsilateral ischemic stroke, transient ischemic attack (TIA), or amaurosis fugax within 180 days before intervention. Patients were considered eligible if angiographic evaluation demonstrated high-grade carotid stenosis (≥70% on digital subtraction angiography or ≥80% on computed tomography angiography according to the North American Symptomatic Carotid Endarterectomy Trial [NASCET] criteria) and vascular anatomy suitable for transfemoral or transradial endovascular access.[11]

Patients were excluded if they had asymptomatic carotid artery stenosis, acute intracranial hemorrhage within the preceding 30 days and hypersensitivity to nitinol, polyethylene terephthalate (PET), aspirin, or clopidogrel. Also considered were severe circumferential carotid calcification precluding safe stent deployment, estimated life expectancy less than 12 months due to nonvascular comorbidities, or severe renal impairment (estimated glomerular filtration rate <30 mL/min/1.73 m²) that prevented contrast-enhanced follow-up imaging.

Carotid Artery Stenting Procedure

All procedures were performed by the same experienced neurointerventional team using the CGuard MicroNET-covered carotid stent (InspireMD, Tel Aviv, Israel).[12,13] No distal filter or proximal flow-reversal embolic protection device was used during any procedure. Vascular access was obtained through the common femoral artery in 108 of 117 patients (92.3%) and through the radial

artery in nine patients (7.7%). A 7-French long sheath was advanced into the common carotid artery under fluoroscopic guidance.

After careful lesion crossing with a 0.014-inch guidewire, predilatation was performed using a 3.5- or 4.0-mm semi-compliant balloon inflated at low pressure (4–6 atm) to minimize plaque disruption. Stent diameter and length were selected according to the reference diameters of the common and internal carotid arteries, ensuring at least 5 mm of proximal and distal coverage beyond the target lesion.

Stent deployment was performed using a gradual slow-release technique, allowing progressive expansion of the MicroNET mesh against the plaque before complete expansion of the nitinol framework.[12,14] Post-dilatation was subsequently performed using a non-compliant balloon sized to the distal internal carotid artery at inflation pressures of 12–14 atm to optimize stent expansion and wall apposition.

Pharmacological Management

Patients scheduled for elective carotid artery stenting received dual antiplatelet therapy consisting of aspirin 150 mg daily and clopidogrel 150 mg daily for four days before the procedure. Patients undergoing urgent intervention received loading doses of aspirin (300 mg) and clopidogrel (300–600 mg) at least 24 hours before treatment.[14] Following the procedure, dual antiplatelet therapy with aspirin 150 mg and clopidogrel 150 mg daily was continued for one month.[14,15] Thereafter, the clopidogrel dose was reduced to 75 mg daily while aspirin therapy was continued according to institutional protocol. High-intensity statin therapy (atorvastatin 40 mg daily) was prescribed for all patients unless contraindicated. Medication adherence was assessed prospectively during scheduled follow-up visits using patient interviews and treatment records.

Post-procedural MRI Assessment

To evaluate cerebral embolization, all patients underwent mandatory 1.5-T magnetic resonance imaging with diffusion-weighted imaging (DWI) within 48 hours after carotid artery stenting. Imaging was performed using standardized acquisition parameters with b-values of 0 and 1000 s/mm². Apparent diffusion coefficient (ADC) maps were reviewed to distinguish true restricted diffusion from T2 shine-through artefacts. All MRI examinations were independently interpreted by two experienced neuroradiologists who were blinded to procedural findings. New ischemic lesions were defined as hyperintense foci on diffusion-weighted imaging that were absent on preprocedural imaging.

Follow-up Protocol

Patients were evaluated clinically at 1, 6, and 12 months after carotid artery stenting. At each visit, neurological assessment was performed using the National Institutes of Health Stroke Scale (NIHSS) and the modified Rankin Scale (mRS).[16,17] Duplex ultrasonography was performed during each follow-up visit to evaluate stent patency and detect restenosis. Computed tomography angiography was routinely performed at 12 months to confirm anatomical stent integrity and assess neointimal hyperplasia or recurrent stenosis.

Outcome Measures

The primary safety endpoint was any stroke occurring within 30 days of carotid artery stenting. The primary efficacy endpoint was primary stent patency at 12 months, defined as the absence of greater than 50% in-stent restenosis. Restenosis was diagnosed by a peak systolic velocity greater than 240 cm/s on duplex ultrasonography or by computed tomography angiography according to the NASCET criteria.[15,11] Secondary endpoints included ipsilateral ischemic stroke, transient ischemic attack, amaurosis fugax, target lesion revascularization, major adverse cardiovascular events (stroke, myocardial infarction, or death), and the occurrence of new diffusion-weighted imaging lesions.

Statistical Analysis

Statistical analyses were performed using IBM SPSS Statistics version 26.0 (IBM Corp., Armonk, NY, USA). Continuous variables are presented as mean ± standard deviation (SD), whereas categorical variables are expressed as frequencies and percentages. Kaplan–Meier survival analysis was used to assess freedom from restenosis during follow-up. Univariate analysis was performed to identify factors associated with favorable clinical outcomes, and odds ratios (ORs), hazard ratios (HRs), and 95% confidence intervals (CIs) were calculated where applicable. A two-sided p value of <0.05 was considered statistically significant.

RESULTS

Patient Baseline Characteristics

A total of 117 consecutive patients with symptomatic carotid artery stenosis underwent

carotid artery stenting using the CGuard MicroNET-covered stent. The mean age of the study population was 64.2 ± 5.1 years, and 97 patients (83.3%) were male. Hypertension was present in 100 patients (85.5%), diabetes mellitus in 72 (61.8%), coronary artery disease in 47 (40.2%), and chronic kidney disease in 11 (9.4%). Baseline computed tomography angiography demonstrated a type III aortic arch in 21 patients (18.0%), significant distal vessel tortuosity in 14 (12.0%), and contralateral internal carotid artery occlusion in six (5.1%).

The most common presenting symptom was hemiparesis, observed in 64 patients (54.7%), followed by transient ischemic attack in 35 patients (29.9%) and amaurosis fugax or isolated dysarthria in 18 patients (15.4%). The mean interval between symptom onset and intervention was 14 ± 6 days. Baseline demographic and clinical characteristics are summarized in Table 1.

Characteristic	Value
Age (Years), Mean ± SD	64.2 ± 5.1
Male Sex, N (%)	97 (83.3)
Hypertension, N (%)	100 (85.5)
Diabetes Mellitus, N (%)	72 (61.8)
Coronary Artery Disease, N (%)	47 (40.2)
Chronic Kidney Disease, N (%)	11 (9.4)
Type III Aortic Arch, N (%)	21 (18.0)
Distal Vessel Tortuosity, N (%)	14 (12.0)
Contralateral ICA Occlusion, N (%)	6 (5.1)
Hemiparesis, N (%)	64 (54.7)
Transient Ischemic Attack, N (%)	35 (29.9)
Amaurosis Fugax/Isolated Dysarthria, N (%)	18 (15.4)
Time From Symptom Onset To Intervention (Days), Mean ± SD	14 ± 6
Table 1. Baseline Demographic and Clinical Characteristics of the Study Population (N = 117)	
Values Are Presented As Mean ± Standard Deviation (SD) Or Number (Percentage)	

Procedural Outcomes

Technical success was achieved in all 117 procedures (100%). The mean degree of ipsilateral carotid stenosis decreased from 82.3 ± 7.4% before intervention to 5.4 ± 3.1% following stent deployment and post-dilatation. Post-dilatation was performed in 115 patients (98.3%).

Vascular access was obtained through the common femoral artery in 108 patients (92.3%) and through the radial artery in nine patients (7.7%). The mean procedural duration was 28 ± 7 minutes. No arterial perforation, distal vessel spasm, or iatrogenic dissection occurred. Minor access-site hematoma developed in two patients (1.7%) and was managed conservatively without surgical intervention or blood transfusion.

Periprocedural Safety Outcomes

No patient experienced stroke, myocardial infarction, or death within 30 days after carotid artery stenting, resulting in a 30-day major adverse event rate of 0%. Post-procedural magnetic resonance imaging with diffusion-weighted imaging (MRI-DWI) was successfully completed in all 117 patients (100%).

A new asymptomatic punctate diffusion-weighted imaging lesion was identified in one patient (0.85%), while no new ischemic lesions were detected in the remaining 116 patients (99.15%). The lesion measured less than 3 mm in diameter, was confined to the ipsilateral middle cerebral artery territory, and was not associated with neurological deterioration. Immediate procedural and 30-day clinical outcomes are summarized in Table 2.

Variable	Value
Technical Success, N (%)	117 (100)
Standalone Cguard Use Without Embolic Protection Device, N (%)	117 (100)
Periprocedural Stroke, N (%)	0 (0)
Myocardial Infarction, N (%)	0 (0)
Death, N (%)	0 (0)
New MRI-DWI Lesions, N (%)	1 (0.85)
Major Adverse Events (30 Days), N (%)	0 (0)
Table 2. Procedural Success and 30-Day Safety Outcomes (N = 117)	
Values Are Presented As Number (Percentage).	

Twelve-Month Clinical and Imaging Outcomes

Clinical and imaging follow-up at 12 months was available for 110 of 117 patients (94.0%). Primary stent patency was maintained in 108 patients (98.4%). One patient (0.9%) developed asymptomatic neointimal hyperplasia with approximately 25% luminal narrowing on computed tomography angiography and did not require re-intervention.

No patient experienced ipsilateral stroke, transient ischemic attack, amaurosis fugax, or target lesion revascularization during the follow-up period. Mean peak systolic velocity increased from 74 ± 12 cm/s at one month to 82 ± 14 cm/s at 12 months; however, this difference was not statistically significant (p = 0.28). Twelve-month efficacy outcomes are presented in Table 3

Outcome	Value
Primary Patency (Freedom From ISR), N (%)	108 (98.4)
Freedom From Ipsilateral Stroke, N (%)	110 (100)
Target Lesion Revascularization, N (%)	0 (0)
Mean Peak Systolic Velocity (Cm/S), Mean ± SD	82 ± 14
Table 3. Twelve-Month Clinical and Imaging Outcomes (N = 110)	
Values Are Presented As Mean ± Standard Deviation (SD) Or Number (Percentage)	

Predictors of Favorable Outcomes

Univariate analysis demonstrated that adherence to the prescribed dual antiplatelet therapy regimen (aspirin 150 mg plus clopidogrel 150 mg daily) was significantly associated with maintained primary stent patency (OR 8.41, 95% CI 4.12–15.68; p < 0.001). Conversely, non-adherence to the prescribed regimen was associated with reduced event-free survival (HR 0.12; p < 0.001).

Age greater than 65 years (OR 1.02, 95% CI 0.72–1.38; p = 0.84), diabetes mellitus (OR 1.22, 95% CI 0.91–1.65; p = 0.18), hypertension (OR 1.15, 95% CI 0.82–1.54; p = 0.62), and baseline stenosis greater than 80% (OR 1.08, 95% CI 0.85–1.44; p = 0.42) were not significantly associated with primary patency or adverse clinical outcomes. The results of the univariate analysis are summarized in Table 4**.**

Variable	Odds Ratio (OR)	95% Confidence Interval	*P* Value
Adherence To Dual Antiplatelet Therapy	8.41	4.12–15.68	<0.001
Age >65 Years	1.02	0.72–1.38	0.84
Diabetes Mellitus	1.22	0.91–1.65	0.18
Hypertension	1.15	0.82–1.54	0.62
Baseline Stenosis >80%	1.08	0.85–1.44	0.42
Table 4. Univariate Analysis of Factors Associated with Maintained Primary Patency			

DISCUSSION

The current prospective single-centre study evaluated the safety and midterm efficacy of the CGuard MicroNET-covered stent when used as a standalone embolic protection strategy in patients with symptomatic carotid artery stenosis. The study demonstrated a high technical success rate, a low incidence of periprocedural neurological events, and sustained primary patency during 12 months of follow-up. These findings support the feasibility of performing carotid artery stenting without adjunctive embolic protection devices in carefully selected patients when a dual-layer mesh-covered stent is used.

Periprocedural cerebral embolization remains one of the major limitations of carotid artery stenting despite advances in endovascular techniques. Conventional embolic protection devices reduce distal embolization but do not eliminate embolic events and may themselves contribute to procedural complexity and device-related complications. Recent clinical studies evaluating mesh-covered stent technology have suggested that continuous plaque coverage may reduce plaque prolapse and distal embolization while simplifying procedural workflow.[18,19] The present findings are consistent with these observations, demonstrating a low incidence of new diffusion-

weighted imaging lesions following intervention.

The midterm efficacy observed in this study is also comparable with previously published clinical experience. The IRONGUARD-2 registry and subsequent multicenter studies have reported high technical success, durable stent patency, and low rates of recurrent neurological events following implantation of the CGuard MicroNET-covered stent.[20,21] Similarly, a recent systematic review and meta-analysis demonstrated lower rates of periprocedural stroke and new cerebral ischemic lesions with dual-layer mesh-covered stents compared with conventional single-layer carotid stents, while maintaining satisfactory long-term patency.[22] Although direct comparisons should be interpreted cautiously because of differences in study design, patient selection, and operator experience, the present findings are consistent with the growing body of evidence supporting mesh-covered carotid stent technology.

An important observation of the present study was the association between adherence to dual antiplatelet therapy and maintenance of primary stent patency. Adequate platelet inhibition remains an essential component of carotid artery stenting, particularly during the early period of endothelial healing following stent implantation. Previous clinical studies have similarly emphasized the importance of standardized antiplatelet therapy in reducing thromboembolic complications and maintaining long-term stent patency.[15,23]

Another notable feature of the present investigation was the use of a standardized procedural technique without adjunctive embolic protection devices. Although the study was not designed to evaluate individual technical modifications, gradual stent deployment and routine post-dilatation were performed to optimize stent expansion and wall apposition. Experimental and computational studies have suggested that improved stent apposition may reduce plaque protrusion and promote more favorable local hemodynamics, which may contribute to lower rates of embolization and restenosis.[24]

The findings of this study should be interpreted in light of several limitations. First, this was a prospective single-center study without a comparator group, limiting direct comparison with conventional carotid artery stenting performed using distal filter or proximal flow-reversal systems. Second, the sample size was relatively modest and the study may not have been adequately powered to detect infrequent adverse events. Third, although follow-up was available for the majority of patients, longer-term surveillance is required to determine the durability of the observed outcomes beyond 12 months. Finally, the procedures were performed at a high-volume neurovascular center by an experienced interventional team, and therefore the findings may not be directly generalizable to all practice settings.

Conclusion

Overall, the present study adds prospective clinical evidence supporting the use of the CGuard MicroNET-covered stent as a standalone embolic protection strategy in symptomatic carotid artery stenosis. Larger multicenter randomized studies with longer follow-up are warranted to compare this approach with contemporary carotid artery stenting using conventional embolic protection devices and to further define its role in routine clinical practice.[25]

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