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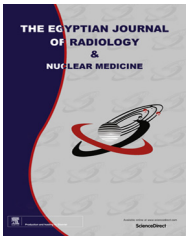

ORIGINAL ARTICLE

Efficacy and safety of carotid artery stenting for stroke prevention

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KEYWORDS

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Abstract *Background:* Extracranial carotid artery stenosis is a leading cause of ischemic stroke. Carotid endarterectomy (CEA) is the gold-standard management for secondary stroke prevention yet carotid artery stenting (CAS) has emerged in the last decade as an alternative for high surgical risk patients.
Purpose: To assess the effectiveness, safety and outcomes of CAS in extra-cranial carotid artery stenosis patients in terms of stroke prevention.
Methodology: Twenty patients with symptomatic and asymptomatic carotid artery stenosis were enrolled between 2012 and 2014. Symptomatic patients were eligible for CAS if the internal carotid artery stenosis was $\geqslant$50%, while 80% was the threshold in asymptomatic patients.
Results: Symptomatic patients enrolled were fifteen (75%) and asymptomatic patients were five (25%). Two patients (10%) were excluded owing to target vessel occlusion. One patient (5%) underwent bilateral CAS. The procedure was successful in eighteen patients (90%) one of them complicated by distal embolization (5%). One patient died secondary to associated chronic liver disease (5%), otherwise no stroke or death was recorded along the follow-up period.
Conclusion: Careful patient selection and technique optimization are crucial to improve clinical outcome which make it a safe alternative for surgical revascularization in stroke prevention.

1. Introduction

Stroke is the third most common cause of death in industrialized nations, after myocardial infarction and cancer. It is the single most common reason for permanent disability. Approximately 1 in 4 people die within 1 year after having an initial stroke (1). Moreover, 30–50% of stroke survivors do not regain functional independence and 15–30% of all stroke survivors are permanently disabled (i.e., not able to walk, talk clearly, or feed themselves with a favored hand). Thus stroke demands a massive financial and personal burden on our society (2). Approximately 25% of ischemic strokes are secondary to extracranial carotid artery occlusive disease. Carotid artery

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Table 1 Study group clinical presentation and associated comorbidities.

Age (range, mean ± SD)	45–75 years & mean age 60.8 ± 7.8
Men	17 (85%)
Smoking – current or past	12 (60%)
Symptomatic ICA/CCA stenosis	15 (75%)
Previous stroke	10 (50%)
TIA	4 (20%)
Amaurosis fugax	1 (5%)
Diabetes mellitus	8 (40%)
Arterial hypertension	12 (60%)
Peripheral arterial disease	4 (20%)
History of myocardial infarction	5 (25%)
Significant bilateral ICA disease	3 (15%)
High risk lesion	14 (70%) (Near total 'string-sign' stenoses; 9 (45%) & ulcerated plaque; 5 (25%))
Others	1 (5%) with hepatocellular carcinoma

stenosis is quite common, with 2–8% of the population having asymptomatic stenosis of >50% (3), with a higher prevalence among patients with heart disease (18.2%) or concomitant hypertension and heart disease (22.1%). The prevalence is even higher among patients with acute strokes, with up to 60% having carotid stenosis on duplex ultrasonography (4). The carotid stenosis related stroke risk is dependent on the stenosis severity, patient symptom, and specific lesion characteristics. Symptomatic patients who have had stroke or transient ischemic attack within the previous 6 months, have a much higher stroke risk than do asymptomatic individuals (5).

Antiplatelet therapy of carotid disease reduces the incidence of stroke (6), yet several studies have demonstrated that carotid endarterectomy (CEA) is more effective than medical therapy alone for both symptomatic and asymptomatic carotid atherosclerotic disease (including the North American Symptomatic Carotid Endarterectomy Trial (NASCET) (7), Asymptomatic Carotid Atherosclerosis Study (ACAS) (8), and Asymptomatic Carotid Surgery Trial (ACST) (9)). Endarterectomy has several limitations as the operation carries a significant risk of complications, particularly in patients with multiple comorbidities, and is highly operator dependent (10).

Kerber et al. published the first report of carotid artery balloon angioplasty in 1980 (11). In 1987, Theron et al. published a larger series including 48 patients with 94% technical success rate and 4.1% major stroke morbidity (12). By 1995, a worldwide experience review among 523 patients claimed favorable results with 96.2% technical success, 2.1% morbidity, 6.3% transient minor complications, and no deaths (13). Over the past decade, the intraprocedural use of cerebral protection devices to guard against micro- or macroembolism has further improved these outcomes (14) making carotid artery stenting (CAS) an accepted alternative to CEA for patients at high surgical risk (15).

This study was constructed to assess the effectiveness and safety as well as the short- and long-term clinical outcomes of CAS in management of extra-cranial carotid artery stenosis including patients with no high surgical risk in terms of stroke prevention.

2. Patient and methods

2.1. Study group

Twenty patients were enrolled in this study between 2012 and 2014 for carotid artery stenting (Fourteen men and two women with age range from 45 to 75 years and mean age 60.8 ± SD 7.8) each of them gave informed written consent to participate. Symptomatic patients were eligible for CAS if the ICA stenosis was 50%, while 80% was the stenosis threshold in asymptomatic patients. Lesions were classified as "high risk" by morphology (Near total "string-sign" stenoses were nine patients (45%) and five patients (25%) have ulcerated plaques). The clinical presentation and associated comorbidities are demonstrated in Table 1.

2.2. Imaging

All patients underwent Duplex ultrasound performed with a linear 7- to 10-MHz probe to evaluate lesion severity (area and diameter stenosis) and morphology (echogenicity, the presence and degree of calcification, or ulceration). Extra- and intracranial CTA (biplanar, 3-dimensional reconstructions with smart vascular analysis) or contrast enhanced MRA was performed in selected patients to characterize the target lesion, aortic arch type, and supra-aortic vessel anatomy and to exclude significant intracranial pathology as well as evaluation of the collateral circulation. Morphological (semiquantitative) lesion assessment included fatty, fibrous, and calcium content was depicted.

2.3. CAS procedure

Patients received a dual antiplatelet regimen consisting of aspirin (100 mg daily) and clopidogrel (75 mg daily) at least 3 days before the stenting. A loading dose of clopidogrel (300–600 mg) administered early on the day of the procedure was an alternative for patients who are already taking aspirin. The patient receives an intravenous loading dose of heparin (50–70 U/kg) with activated clotting time of 250–300 s is maintained throughout the procedure. During the procedure patient was under ECG monitoring due to potential bradycardia and blood pressure monitoring for possible hypotension related to carotid sinus stimulation by balloon inflation.

Procedures were done under the image guiding of (Artis zee Flat Detector Biplane-Angiosuite, Siemens, Forchheim, Germany). The vascular access via the femoral artery was the approach that was employed. Femoral artery was punctured using a Seldinger needle and then 6–8 F sheath was placed under local anesthesia.

Angiography of the aortic arch was often performed prior to selective carotid angiography in order to identify possible

difficult anatomic conditions that might make it necessary to exchange the typically employed diagnostic catheters for an alternative one. After engaging the common carotid artery, standard angiographic projections for demonstrating the carotid bifurcation (anteroposterior, lateral and ipsilateral anterior oblique (30–45°) projection) were obtained. Four-vessel angiography was conducted to visualize the intracranial vessels and show the status of collateral arteries.

Once the anatomy of the target vessel has been identified, an exchange-length 0.035-in. wire was inserted under road mapping into the ECA. The diagnostic catheter was exchanged over the wire for a 90-cm, 6-to 8-Fr guiding catheter that is then advanced into the common carotid artery (CCA) below the bifurcation.

Predilatation of the stenosis was needed in selected patients to provide better passage of protection devices and positioning of the stent. An exchange length 0.014-in. microguidewire (Transcend 300 Floppy microwire; Boston Scientific, Fremont, CA, USA) was used for navigation and dilatation was done by using a small angioplasty balloon 3 mm (Fairway Balloon-IHT, Barcelona, Spain) with short inflation time of 5–10 s. The procedures were done under the cerebral protection of distal filter (SpideRx™-EV3, Plymouth, MN, USA) which was introduced into the vascular segment distal to the stenosis. The stent was selected according to the ICA course: a closed-cell stent (Wallstent-Monorail, Boston Scientific, Fremont, CA, USA) was used in a straight course, and an open-cell stent (Protégé RX-EV3, Plymouth, MN, USA) was used in a tortuous course. Post-dilation of the stent was performed after stent deployment using a 4–6-mm balloon in selected patients with slow and gradual inflations (each 10–60 s at 6–20 atmospheres).

Following post-dilation of the stent, angiography of the carotid arteries and intracranial vessels was carried out to rule out cerebral embolism. Patients who underwent CAS were monitored in the intensive care unit for 24 h with continuous blood pressure, oxygen saturation, and electrocardiographic monitoring and underwent a neurological examination hourly. Antihypertensive agents were used as needed to maintain systolic blood pressure 140 mmHg after CAS. Patients who show no additional neurological deficits after CAS were discharged within 3 days after CAS with 75 mg/day clopidogrel and 100 mg/day aspirin continued for 6 months after CAS.

2.4. Follow-up

A follow-up color duplex ultrasound scan and neurological examination were conducted for all patients at 1 month after the intervention to verify the acute result of the procedure, and at 3, 6 and 12 months to rule out ischemic insults.

3. Results

3.1. Interventional results

Symptomatic patients enrolled in the study were fifteen (75%) and asymptomatic patients were five (25%). Two patients (10%) were excluded owing to target vessel occlusion. One patient (5%) underwent bilateral carotid artery stenting. Stents were successfully inserted in 18 of 20 patients (90%). Distal cerebral protection was used in all patients using distal filter (SpideRx™-EV3, Plymouth, MN, USA.). Four patients (20%) needed pre-dilation to pass the distal filter. No additional pre-dilation of the stenosis was needed for stent deployment after installing the filter. Closed cell stents (Wallstent-Monorail, Boston Scientific, Fremont, CA, USA) were implanted in 15 patients (75%) (Fig. 1), and an open-cell stents (Protégé RX-EV3, Plymouth, MN, USA) were implanted in 3 patients (15%) presented with curved ICA (Fig. 2). Additionally, 8 patients (40%) required post-dilation after placing the stent. The results are summarized in Table 2.

The criteria for carotid artery near occlusion were used (16): Obvious reduced diameter of the ICA compared with the opposite ICA or the ipsilateral ECA and delayed cranial arrival of ICA contrast compared with that of the external carotid artery (ECA). Bilateral CAS was done for bilateral tight stenosis in one patient (5%) with one week interval.

Transient hemodynamic alterations such as hypotension and bradycardia were observed in three patients (15%) during and/or after balloon inflation which were recovered by intravenous 1 mg atropine administration. No major vascular access site complications were recorded.

Intra-procedural vascular events occurred in one patient (5%) who was presented by sensory aphasia and right hemiparesis secondary to ischemic infarction affecting the left frontoparietal watershed zone and tight left ICA stenosis. After implantation of the stent, thromboembolism occluding the left MCA was encountered (Fig. 3). It was managed by self expanding stent (Solitaire FR, EV3, Plymouth, MN, USA) and angioplasty balloon 2 mm (Fairway Balloon-IHT, Barcelona, Spain). The patient shows full recovery with no superadded neurological deficits.

3.2. Follow-up results

All patients received regular clinical follow-up of at least 6 months. Among these, only one patient died (5%) secondary to associated liver cell failure and hepatocellular carcinoma. All other patients didn't develop any new neurological symptoms. No significant intimal hyperplasia by follow-up color Doppler scan was detected. No cases developed myocardial infarction along the follow-up period.

4. Discussion

Carotid artery stenting (CAS) has steadily developed during the past decade as an alternative to CEA for patients who would benefit from surgical treatment. Percutaneous CAS offers several potential advantages, including the avoidance of general anesthesia, neck incision, and the risk of cranial or cutaneous nerve damage from the surgical incision (17). Large randomized trials in the 1980s and 1990s for CEA as management of carotid artery stenosis contained strict eligibility criteria and excluded many patients commonly found in clinical practice. These exclusion criteria include anatomic and physiologic "high-risk" criteria, such as age, previous surgery, uncontrolled diabetes or hypertension, kidney or liver failure, and heart valve or rhythm disturbance. The presence of such comorbidities has a significant negative effect on outcome after CEA, and they have served as the basis for subsequent implementation of CAS as an alternative treatment to CEA in clinical practice (18–20).

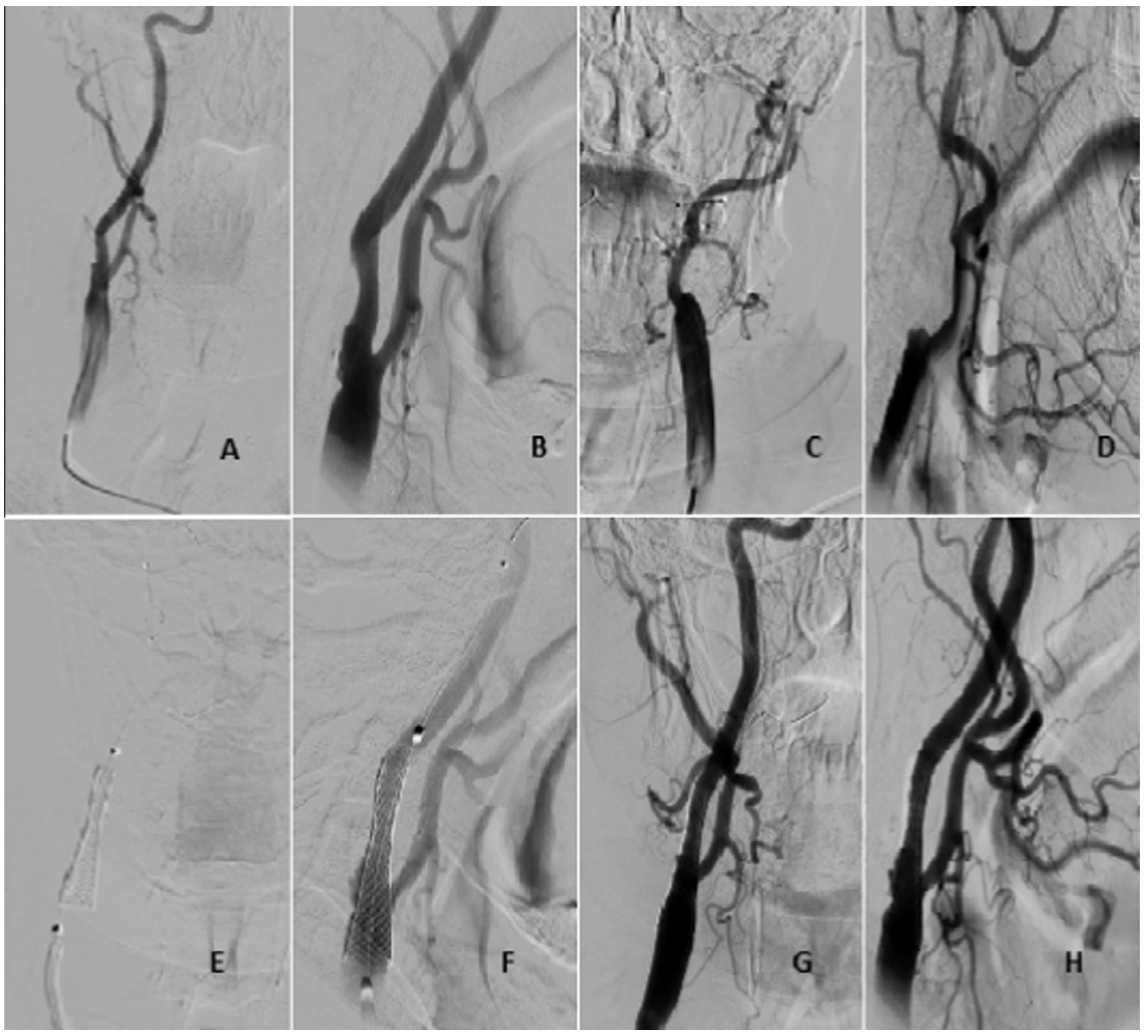

Fig. 1 67 years old male patient with history of right side hemiplegia. Digital subtraction angiograms. (A & B) Right common carotid artery (CCA) injection, AP & lateral views show internal carotid artery stenosis (50%) with ulcerating thrombus. (C & D) Left common carotid artery (CCA) injection, AP & lateral views show totally occluded left internal carotid artery. (E & F) After deployment of the stent (Wallstent-Monorail, Boston Scientific, Fremont, CA, USA) under the cerebral protection of the distal filter (SpideRx™-EV3, Plymouth, MN, USA). (G & H) Final angiographic result after implantation of the stent.

Many studies analyzed the associated risks of the CAE and CAS including stroke, myocardial infarction and death. The overall perioperative carotid endarterectomy stroke risk and death was 5.8% in NASCET, 2.3% in ACAS and 3.1% in ACST (21). However, these trials were conducted using highly screened surgeons, low-risk patients and high-volume surgical centers (22), limiting the application of these results to smaller institutions with wider patient demographics. Combined carotid endarterectomy related stroke and death rates are up to 12.6% have been reported for less highly selected patients (23), with certain prognostic features imposing an even poorer outcome (age >75 years, coronary artery disease or contralateral internal carotid artery occlusion) (24).

Over the past decade, carotid artery stenting (CAS) has become an accepted alternative to CEA for patients at high surgical risk, and more recently has shown similar outcomes for patients at standard risk. Multiple carotid registries summarized in Table 3 have been done to improve the outcome and optimize the indication.

The Carotid Revascularization Endarterectomy versus Stenting Trial (CREST) is the largest trial comparing the CAS and CAE results. It is a multicenter, prospective randomized clinical trial initially designed to compare CEA with CAS in only symptomatic patients. Target enrollment was powered at 2500–3000 patients, but trial was revised to include patients with asymptomatic carotid stenosis. The trial eventually enrolled 1321 symptomatic and 1181 asymptomatic patients. The primary endpoint included periprocedural (30 days) death/stroke/MI, as well as any subsequent stroke ipsilateral to the carotid intervention during a 4-year follow-up window. The summary findings of this trial, published in 2010 in the New England Journal of Medicine (31), demonstrated no difference between CEA and CAS in the composite endpoint of death/stroke/MI (CAS 7.2% versus CAE 6.8%). However, stroke occurred more frequently following CAS (CAS 4.1% versus CAE 2.3%) and MI occurred more frequently following CEA (CAS 1.1% versus CAE 2.3%). Late ipsilateral stroke rates were slightly higher following CAE (CAS 2% versus

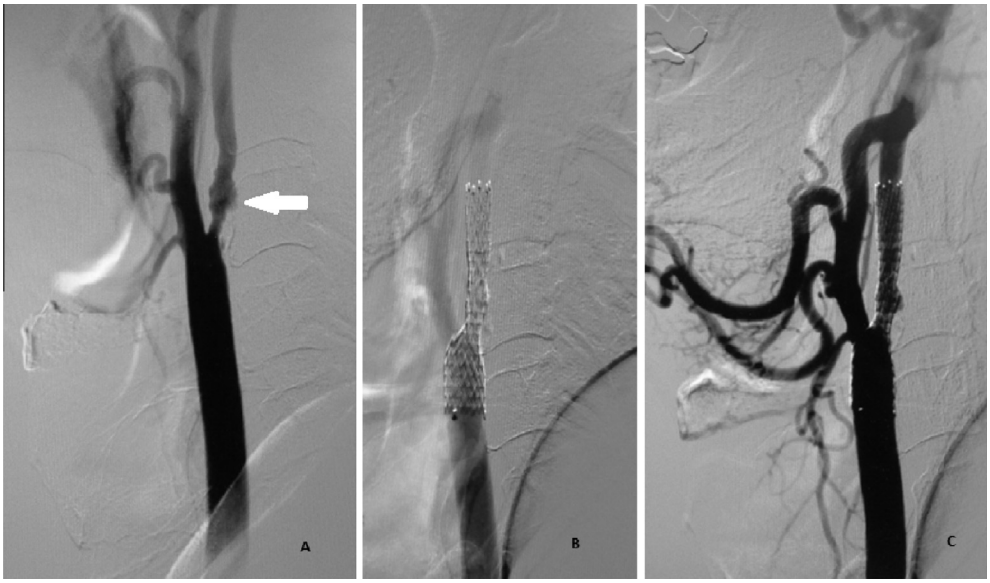

Fig. 2 60 years male patient with history of recurrent transient ischemic attacks. Digital subtraction angiogram. (A) Left common carotid artery (CCA) injection, lateral views, shows internal carotid artery stenosis (70%) with ulcerating thrombus (arrow). (B) After deployment of the stent (Protégé RX-EV3, Plymouth, MN, USA). (C) Final angiographic result after implantation of the stent.

Table 2 Summary of the results.

Failed procedure	2 (10%)
Stent type	Closed cell design: 15 (75%)
	Open cell design: 3 (15%)
Predilatation	4 (20%)
Postdilatation	8 (40%)
Distal embolization	1 (5%)
Sustained hypotension and bradycardia	3 (15%)
Follow-up stroke or MI	0 (0%)
Follow-up death rate	1 (5%)

CAE 2.4%) and there was no substantive difference in periprocedural death rates (CAS 0.7% versus CAE 0.3%). In addition, associated complication like periprocedural cranial nerve palsies were less frequent with CAS (0.3%) versus (4.7%) with CEA (32). Subsequently, guidelines based on the CREST were published, suggesting that CAS was equivalent to CEA for the symptomatic patient (33) and an alternative for CAE with selected high-risk patients because of anatomic or physiologic factors (34).

We tried in our experience to optimize the technique, minimize the associated complication and improve the outcome. All procedures were done under cerebral protection of distal filters which preserve the flow and have the advantage to perform angiogram during the procedure; no filter drawbacks such as missing small particles, filter thrombosis or ICA spasm (32) were encountered. Stent selection was depending on stenosis severity, angulation in the perilesional carotid segments, calcification and plaque characteristics; open cell design has larger free cell area between the stent cell lattices and more malleable, flexible, and less prone to kinking (35) so it was preserved to handle tortuous anatomy while closed cell design is more rigid and prone to kinking with greater outward radial force and more effective support to labile plaques (35) which made it the perfect choice for tight stenosis with straight course.

Symptomatic distal embolization is the most frequent and important complication of CAS. It is caused by the release of material (thrombotic, necrotic, or atherosclerotic) from the site of the lesion during the intervention (36). Intraprocedural distal embolization occurs in one patient in our study which was treated properly with no residual neurological deficits. The contributing risk factors for distal embolization can be classified into three groups: the first group related to the carotid lesion itself which may be soft plaque or fresh thrombus, the second group related to the medical therapy including poor pretreatment with double antiplatelet agents or insufficient heparin during procedure, and the third one related to the procedure which are aggressive manipulation of the guide wire, aggressive balloon dilatation prior to or after stent deployment or unprotected procedure (37). The inventory of the cathlab should be equipped for such complications by lytic agents, intracranial retrieval devices (e.g., Phenox Clot Retriever, Merci Retrieval Device, Penumbra) or intracranial stents (e.g., Wingspan, Solitaire, Enterprise, Neuroform).

Sustained hypotension and bradycardia have been reported to occur following 4–11% of carotid stenting procedures and were not usually associated with any adverse clinical events in the hospital or during the 30-day follow-up period (38). Sustained hypotension and bradycardia were avoided in our study by atropine administration at the time of balloon inflation. Preserved blood pressure at 140 mm/hg was important as a prophylaxis against intracranial hemorrhage and hyperperfusion syndrome. The long-term follow-up results of CAS in our study were outstanding with no stroke recurrence and no cardiovascular complications related to the procedure. The single cause of death in our study was secondary to associated liver disease and hepatocellular carcinoma.

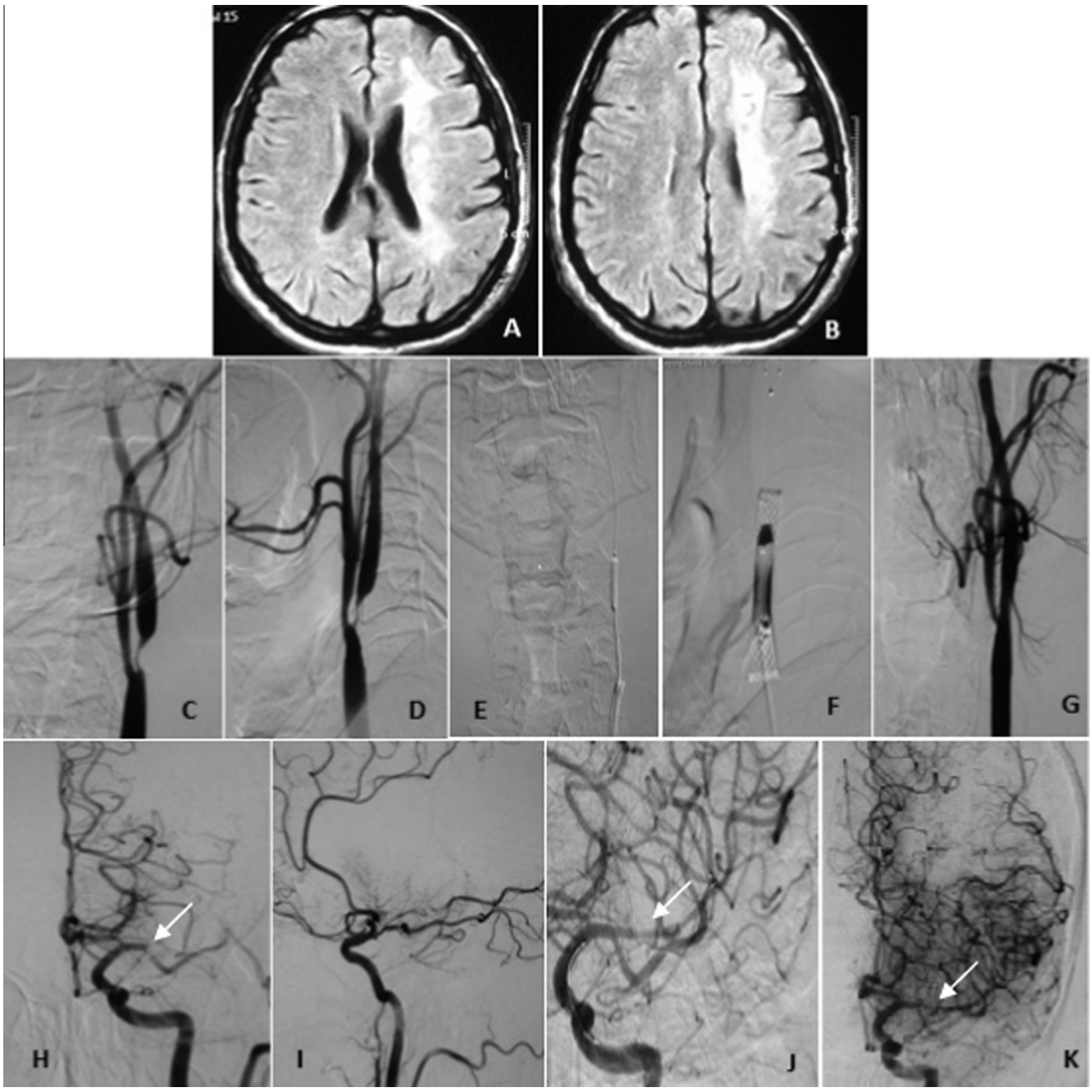

Fig. 3 65 year old male patient with history of right side hemiparesis and sensory aphasia. (A & B): axial FLAIR images show ischemic infarction in the left frontoparietal watershed zone. (C & D) Left common carotid artery DSA, (A-P & lateral) views show tight stenosis at the proximal ICA. (E) Anteroposterior DSA demonstrates the predilatation balloon (Fairway Balloon-IHT, Barcelona, Spain (3 mm)). (F) Lateral DSA After deployment of the stent (Wallstent-Monorail, Boston Scientific, Fremont, CA, USA) and inflation of the balloon (Fairway Balloon-IHT, Barcelona, Spain (4.5 mm)). (G) Final angiographic result after implantation of the stent. (H & I) Left MCA angiogram (A-P & lateral) views show filling defect at the bifurcation of M2 segment with occluded superior division. (J & K): Angiographic results after deployment of (Solitaire FR, EV3, Plymouth, MN, USA) stent and inflation of angioplasty balloon 2 mm (Fairway Balloon-IHT, Barcelona, Spain).

Our study has major limitations, including small number of patients, absence of a control group and relatively short follow-up period. But we confirmed CAS results in symptomatic and asymptomatic patients with a carotid artery disease and identified CAS as a technically feasible and effective method for preventing stroke, not necessarily limited to high risk patients by displaying our results and some others in the previous literature.

Table 3 30 day complication rates in carotid artery stenting registries enrolling more than 1000 patients.

Name	Year	No	EPD (%)	Sympt. patient %	Surgical high risk	D/S/MI (%)	S (%)
CAPTURE (25)	2007	3500	100	14	Yes	6.3	5.7
CASES PMS (26)	2007	1493	100	22	Yes	5.0	4.5
PRO-CAS (27)	2008	5341	75	55	No	NA	3.6
SAPPHIRE (28)	2009	2001	100	28	Yes	4.4	4.0
SVS (29)	2009	1450	95	45	Yes	5.7	NA
EXACT (30)	2009	2145	100	10	Yes	NA	4.1
CAPTURE 2 (30)	2009	175	100	13	Yes	NA	3.4

CAPTURE; Carotid ACCULINK/ACCUNET Post Approval Trial to Uncover Rare Events. CASES–PMS (Carotid Artery Stenting With Emboli Protection Surveillance–Post-Marketing Study). Pro-CAS, Prospective Registry of Carotid Artery Stenting. SAPPHIRE: Stenting and angioplasty with protection in patients at high-risk for endarterectomy. EXACT; Emboshield and Xact Post Approval Carotid Stent Trial (EXACT).
EPDs, emboli protection devices; sympt, symptomatic; D, death; S, stroke; MI, myocardial infraction.

5. Conclusion

CAS is a safe alternative for surgical revascularization by CEA in management of extracranial carotid artery disease and stroke prevention which should not be limited to high risk patients only. Careful patient selection and optimization of the technique are crucial to avoid the complication of CAS and improve clinical outcome.

Conflict of interest

We have no conflict of interest to declare.

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