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ORIGINAL ARTICLE

Incidence of Postprocedural Microembolic Events Following Carotid Artery Stenting Without Protection Devices

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Abstract

Background: **There is debate about the efficacy and complications of The utilization of carotid artery stenting (CAS) in the management of carotid artery stenosis, in the absence of embolic protective devices.**

Objective: **To estimate the incidence of microembolic events in CAS procedures without a protection device.**

Patients and methods: **Fifty-three patients with carotid artery stenosis attended The Neurology Clinic of Kobri El-Koba Military and Al-Hussien University Hospitals, Egypt from July 2022 to March 2023. Undergoing carotid artery stenting without protection devices. Outcome was assessed clinically with the National Institutes of Health Stroke Scale and modified Rankin Scale and radiologically with Diffusion-weighted magnetic resonance imaging 24 h before and after the procedure and follow-up after 30 days.**

Results: **There was a low complication rate as only 4 (7.547%) cases showed mild deterioration in NIHSS and 3 (5.66%) other cases showed that novel instances of acute cerebral microemboli were identified through the use of brain diffusion-weighted magnetic resonance imaging (DW-MRI), without any accompanying clinical deficits.**

Conclusion: **CAS without the use of embolic protection devices can be considered a safe and reliable method of treating carotid artery stenosis.**

Keywords: Artery stenosis, Artery stenting, Postprocedural microembolic events

1. Introduction

Previous extensive randomized trials have indicated that Carotid Endarterectomy (CEA) and Carotid Artery Stenting (CAS) had comparable long-term outcomes about stroke, mortality, and myocardial infarction rates. In comparison with CEA, CAS is a less-invasive method to prevent stroke, in favour of shorter hospitalization and recovery period in the treatment of carotid artery disease.[1]

Given that the majority of strokes are caused by emboli, the primary goal of CAS is to stabilize the plaque in the carotid artery rather than only focusing on restoring blood flow. Pre-procedural balloon angioplasty, known as predilatation, is performed to prepare a narrowed blood artery for the subsequent placement of a stent. On the other hand, postprocedural balloon angioplasty, referred to as postdilatation, is employed to address any remaining stenosis following the deployment of a stent.[2]

The primary concern related to CAS is the potential occurrence of embolism in the cerebral circulation. To mitigate this risk, the utilization of protective devices is crucial. Nevertheless, prior research has indicated that the utilization of these devices is associated with potential safety concerns,

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including the occurrence of adverse consequences such as vascular spasm and dissection. Furthermore, the exorbitant expense associated with these gadgets.[3]

There is a great debate about the efficacy of embolic protection devices (EPDs) in decreasing the rate of ipsilateral stroke. Several reviews showed the benefit of EPDs in decrease that rate.[4,5]

On the other hand, many uncontrolled studies showed marvelous outcomes of procedures done without the use of EPDs.[6,7]

Recently, the implementation of advanced methodologies and a diverse array of equipment, such as atraumatic catheters, cell stents with diverse configurations, embolic protection devices, and specialized wires, has resulted in a notable decrease in the occurrence of periprocedural embolic events.[8]

2. Patients and methodology

A retrospective analysis was conducted on the data registry of carotid stenting July 2022 to March 2023. Following Egyptian legislation, informed consent was obtained from all participants involved in the study. Fifty-three patients (11 females and 42 males) with ages between 56 and 74 years old with a mean 65.44 ± 10 The participants in this study were selected from individuals who visited the neurology clinic at Kobri El-Koba Military Hospital and Al-Hussien University Hospital. Specifically, individuals with moderate and severe internal carotid artery stenosis were included in the study. These participants then received a total of 53 CAS procedures, all of which were performed without the utilization of EPDs.

The criteria for considering CAS included the existence of symptomatic carotid stenosis with a degree greater than 50% and asymptomatic carotid stenosis with a degree greater than 70%. The selection of patients was based on the results of carotid duplex, Computed Tomography Angiography (CTA), and Magnetic Resonance Angiography (MRA). The degree of stenosis was confirmed during the diagnostic phase of digital subtraction angiography, ensuring it exceeded 50% before proceeding with the stenting procedure. The assessment of the extent of angiographic carotid stenosis was conducted utilizing the North American Symptomatic Carotid Endarterectomy trial (NASCET) technique. The exclusion criteria encompassed renal impairment, hypersensitivity to contrast agents, prior heart failure, emergency catheterization history, complete occlusion of the target vessel, substantial hypotension or severe anemia, contraindication to anticoagulation or antiplatelet therapy, presence of an ongoing infection or history of cancer, and ineligibility for magnetic resonance imaging (MRI) among patients.

A comprehensive neurological evaluation was conducted by a proficient neurologist utilizing the National Institutes of Health Stroke Scale (NIHSS) and modified Rankin Scale (mRS) at four distinct time points: prior to the procedure, immediately following the procedure, 24 h prior to discharge, and after a 30-day period. All procedures involving coronary angiography and angioplasty were conducted using local anesthesia administered through the common femoral artery. The patients were administered either Acetylsalicylic Acid (ASA) 81 mg and clopidogrel 300 mg 12 h before CAS, or they received ASA 81 mg and clopidogrel 75 mg daily for a duration of 1 week prior to CAS.The recommended postprocedure regimen includes a daily dose of 150 mg of aspirin for lifelong use, along with a daily dose of 75 mg of clopidogrel for a duration of 3 months. Additionally, the administration of Enoxaparin at a subcutaneous dose of 40 units every 12 h for a period of 7 days may be considered. The entirety of the procedures were executed with utmost proficiency by a highly skilled interventional neurologist at the interventional neurology unit of Kobry El-Kobba military Hospital and Al-Hussien University Hospital, utilizing a monoplane neurovascular machine manufactured by (Siemens in Germany). The initial dilation procedure involved the utilization of low-profile balloons, specifically those with a diameter ranging from 2 to 3 inches and compatibility with 0.014-inch wires. Following the implantation of a stent, post-dilatation was performed utilizing balloons with diameters ranging from 3.5 to 6 mm. Subsequently, a plain film of the neck was acquired from several oblique projections in order to record and verify the expansion of the stent. Technical success is defined as the achievement of successful treatment of stenosis, wherein residual stenosis of 30% is observed in at least two matched views on angiography.

Brain diffusion-weighted magnetic resonance imaging (DW-MRI) was acquired using conventional head coils on 1.5-T scanners (Achieva and Ingenia, Philips medical system, Eindhoven, Netherlands) for all patients, both 24 h prior to and following the surgeries. The identification of acute cerebral ischemia lesions involved the recognition of hyper-intense areas exhibiting diffusion restriction signals. These areas were further verified through the utilization of apparent diffusion coefficient mapping, which served to eliminate any potential artefacts. The DW-MRI scans were evaluated by radiologists who were unaware of the clinical condition and prognosis of the patients.

Table 1. Description of carotid stenosis of the studied group.

Morphology of stenosis	($n = 53$)
Degree of stenosis	
Range Mean ± SD	60-99 85.86 ± 12.489
50–74%	11 (20.755%)
75–90%	34 (64.151%)
≥91%	8 (15.094%)
Length of stenosis	
Range Mean ± SD	6-25 15.357 ± 6.134
<10	8 (15.094%)
10–20	34 (64.151%)
>20	11 (20.755%)
Shape of stenosis	
Eccentric	27 (50.943%)
Concentric	26 (49.057%)
Surface	
Smooth	8 (15.094%)
Irregular	45 (84.906%)
Ulceration	
Not ulcerated	15 (28.302%)
Ulcerated	38 (71.698%)
Calcification	
Not Calcified	30 (56.604%)
Calcified	23 (43.396%)
Side of the stenosis	
Right	34 (64.151%)
Left	19 (35.849%)
Laterality of the stenosis	
Unilateral	30 (56.604%)
Bilateral	19 (35.849%)
Unilateral + contralateral occlusion	4 (7.547%)

Table 2. Type of used stent and their relation to 24 h Postprocedural post diffusion-weighted magnetic resonance imaging lesions.

	($n = 53$)		*P* value
	− ($n = 50$)	+ ($n = 3$)	
Casper	14	0	1.000
Wallstent	31	1	0.971
Portege	8	2	0.588

The collected data was, tabulated, and statistically analyzed using SPSS program (Statistical Package for Social Sciences) software version 25.0.Descriptive statistics were done for numerical parametric data as mean ± SD (standard deviation) and minimum and maximum of the range and for numerical nonparametric data as median and range.

3. Results

Over a period of 6 months, 53 patients fulfilled the inclusion criteria and accepted to participate in the study and CAS procedures without the use of EPDs were performed to them.

Age of patients ranged from 56 to 74 years old with a mean 65.44 ± 10.42 patients were males and 11 were female. According to vascular risk factors 34 (64.15%) patients had diabetes mellitus, 34 (64.15%) patients had hypertension, 30 (56.6%) patients had dyslipidemia, 11 (20.75%) patients had coronary heart disease, four (7.54%) patients had peripheral vascular disease and 15 (28.3%) patients were smokers.

Before the procedure, all patients were classified into symptomatic and asymptomatic and they were evaluated using NIHSS and mRS. Twenty-three (43.396%) patients had asymptomatic carotid lesions and 30 (56.604%) patients had symptomatic carotid lesions.

All studied patients were assessed by carotid duplex while CTA of carotid arteries was done in fifteen patients. Thirty-four (64.151%) patients had right ICA stenosis and the other 19 (35.849%) had left side ICA stenosis. As regard laterality of the stenosis, 30 (56.604%) patients had unilateral ICA stenosis, 19 (35.849%) patients had bilateral ICA

Table 3. Neurological Evaluation of the studied group 24 h Preprocedural, and 30 days Postprocedural.

Neurological Evaluation	24 h Preprocedural ($n = 53$)	24 h Postprocedural ($n = 53$)	30 days Postprocedural ($n = 53$)	χ^2
NIHSS				
No clinical Deficit (NIHSS = 0)	51 (96.226%)	49 (92.453%)	47 (88.679%)	0.146
TIA	0	4 (7.547%)	6 (11.32%)	0.264
Minor Stroke (NIHSS ≤4	2 (3.773%)	0	0	0.381
Moderate Stroke (NIHSS 5–15)	0	0	0	
Major Stroke (NIHSS ≥16)	0	0	0	
mRS				
mRS 0	51 (96.226%)	49 (92.453%)	49 (92.453%)	0.135
mRS 1	2 (3.773%)	4 (7.547%)	6 (11.32%)	0.262
mRS 2	0	0	0	
mRS 3	0	0	0	
mRS 4	0	0	0	
mRS 5	0	0	0	

Table 4. Description of 24 h postprocedure diffusion-weighted magnetic resonance imaging findings.

24hrs Postprocedure diffusion-weighted magnetic resonance imaging findings	($n = 53$)
Number of cases with no new MRI-DWI lesions	50 (94.339%)
Number of cases with new MRI-DWI lesions	3 (5.66%)
Number of new MRI- DWI lesions	
Range	0–2
Mean ± SD	0.5 ± 0.76

stenosis and the degree of stenosis in the other side ranged from 50 to 90%. Four patients had unilateral ICA stenosis with contralateral ICA occlusion. Degree of the carotid stenosis ranged from 50% to subtotal occlusion 99%. Eleven (20.755%) patients had stenosis ranged from 60 to 74%, 34 (64.151%) patients had stenosis range from 75 to 90% and eight (15.094%) patients had stenosis of more than (90%).The length of the stenosis was less than 10 mm in eight (15.094%) patients, from 10 to 20 mm in 34 (64.151%) and Eleven (20.755%) had a stenosis length more than 20 mm. Twenty-seven (50.943%) patients had eccentric stenosis while the other 26 (49.057%) had concentric stenosis regarding the surface of the stenosis, eight (15.094%) had smooth surface and 45 (84.906%) had irregular surfaces. Thirty-eight (71.698%) patients had ulcerated atheromatous plaques. Calcifications within the atheromatous plaque were present in 23 (43.396%) patients (Table 1).

According to the interventional details, Pre-dilatation was done in 11 (20.755%) patients. CASPER stent was used in 14 (26.415%) patients, 31 (58.491%) patients and eight (15.094%) patients had PORTEGE stent. As regard number of stents used to treat a single lesion, one stent was used in

Table 5. Relation of age, sex, characteristics of stenosis and vascular risk factors 24 h postprocedural clinical ischemic event.

			No postprocedural Clinical ischemic insults ($n = 49$)	Presence of postprocedural Clinical ischemic insults lesions ($n = 3$)	χ^2test
Stenosis description	Side of the stenosis	Right (n 34)	32	2	$P = 0.444$
		Left (n 19)	17	2	
	Other side stenosis or occlusion	Unilateral stenosis (n.30)	27	3	$P = 0.221$
		Bilateral Stenosis (n.19)	18	1	
		Unilateral stenosis + contralateral occlusion (n.4)	4	0	
	Degree of stenosis	**60–74% (n.11)**	11	0	$P = 0.260$
		75–90% (n.34)	31	3	
		≥ 91% (n.8)	7	1	
	Length of stenosis	**<10 mm (n.8)**	8	0	$P = 0.741$
		10–20 mm (n.34)	32	2	
		>20 mm (n.11)	9	2	
	Shape of stenosis	**Eccentric (n.27)**	25	2	$P = 0.299$
		Concentric (n.26)	24	2	
	Surface	**Smooth (n.8)**	7	1	$P = 0.672$
		Irregular (45)	42	3	
	Ulceration	**No ulceration(n.15)**	14	1	$P = 0.512$
		Ulceration(n.38)	35	3	
	Calcification	**No calcifications(n.30)**	27	3	$P = 0.231$
		Calcification(n.23)	22	1	
Vascular Risk Factors	Diabetes		31	3	0.571
	Hypertension		31	3	0.145
	Dyslipidemia		28	2	0.145
	CHD		10	1	0.707
	PVD		4	0	0.308
	Smoking		13	2	0.588
Age			63.46 years ± 9.854 ($n = 49$)	69 years± ($n = 4$)	0.355
Sex			Male 39/42 Female 10/11	Male 3/42 Female 1/11	0.571

CHD, coronary heart disease.

treatment of each lesion of 42 (79.2452%) patients. Eleven (20.754%) patients had 2 stents due to presence of a long stenotic segment (Table 2), Fig. 2.

Preprocedural neurological evaluation of the patients using NIHSS showed that 51 (96.226%) patients had no clinical deficit (NIHSS = 0), Two (3.773%) had minor strokes with NIHSS between 1 and 4 (see Fig. 3). Using mRS showed 51 (96.226%) patients had mRS 0 and two (3.773%) patients had mRS1. The clinical assessment of all cases was conducted using the (NIHSS) the National Institutes of Health Stroke Scale and mRS immediately following the intervention, 49 (92.453%) had no change in their initial NIHSS and four (7.547%) cases (7.547%) showed mild deterioration of the NIHSS which improved completely within 1 h and defined as transient ischemic attack Using mRS, 49 (92.453%) patients had mRS 0 and four (7.547%) patients had mRS1 (Table 3).

Regarding to radiological outcome, all patients of the studied group had MRI incorporating DWI within 24 h of the procedure. All MRI-DWI ischemic events were subcortical or cortical a few minor infractions. Three (5.66%) patients and 50 (94.339%) patients, respectively, exhibited new MRI-DWI lesions. The number of MRI-DWI lesions ranged from 0 to 2, with a mean of 0.0.5 (±0.76) (Table 4), Fig. 4.

In our study, there was no statistically significant association between age, sex, vascular risk factors, characteristics of the stenosis or stent type and clinical outcome or the development of post-

Table 6. Relation of age, sex, features of stenosis and vascular risk variables to diffusion-weighted magnetic resonance imaging lesions 24 h after procedure.

			No postprocedural diffusion-weighted magnetic resonance imaging lesions (n = 49)	Presence of postprocedural diffusion-weighted magnetic resonance imaging lesions lesions (n = 3)	Chi Square test
	Side of the stenosis	**Right (n 34)**	32	2	0.078
		Left(n 19)	18	1	
	Other side stenosis or occlusion	**Unilateral stenosis (n.30)**	28	2	1.000
		Bilateral Stenosis(n.19)	18	1	
		Unilateral stenosis + contralateral occlusion(n.4)	4	0	
Stenosis description	Degree of stenosis	**60–74% (n.11)**	10	1	0.971
		75–90%(n.34)	33	1	
		≥91%(n.8)	7	1	
	Length of stenosis	**<10 mm(n.8)**	8	0	0.781
		10–20 mm(n.34)	31	3	
		>20 mm(n.11)	11	0	
	Shape of stenosis	**Eccentric(n.27)**	25	2	0.237
		Concentric(n.26)	25	1	
	Surface	**Smooth(n.8)**	7	1	0.469
		Irregular(45)	43	2	
	Ulceration	**No ulceration(n.15)**	14	1	0.852
		Ulceration(n.38)	36	2	
	Calcification	**No calcifications (n.30)**	28	2	0.733
		Calcification (n.23)	22	1	
	Diabetes		32	2	0.052
	Hypertension		32	2	0.480
Vascular risk factors	Dyslipidemia		28	2	0.733
	CHD		10	1	0.837
	PVD		4	0	0.512
	Smoking		13	2	0.533
Age			**68.666 ± 10.507 (n = 50)**	**68.666 ± 11.758 (n = 3)**	0.523
Sex			**Male 42 Female 11**	**Male 2 Female 1**	0.670

CHD, coronary heart disease.

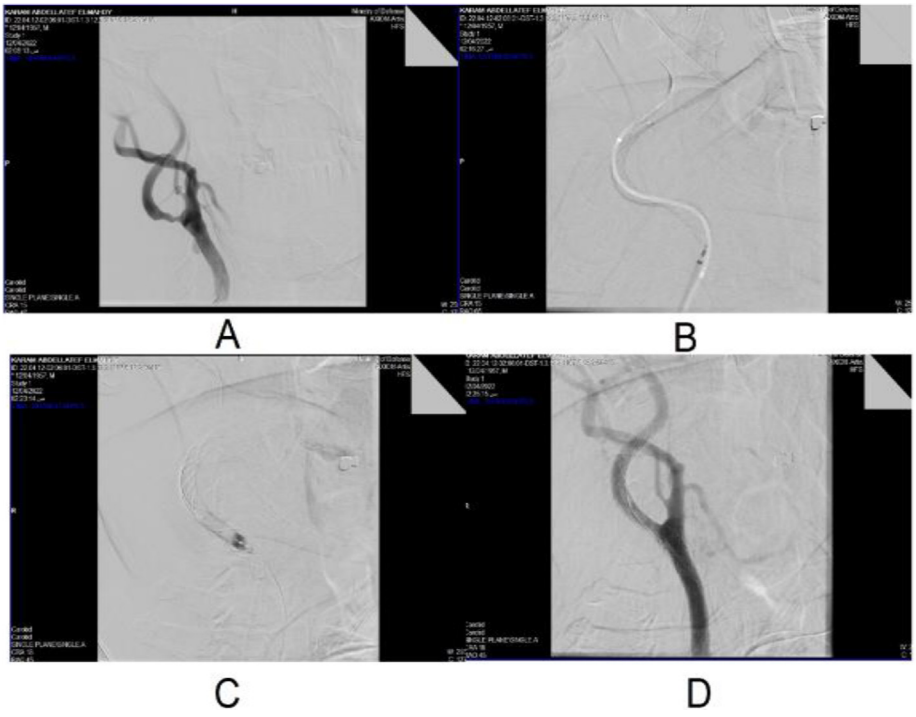

Fig. 1. A) Rt ICA DSA, lateral view. Severe atherosclerotic stenosis of the proximal ICA, B) Deployment of Casper stent C) Post-dilaltion using (3.5-6mm in diameter) balloon, D) plain film of the neck oblique projections to document the expansion of the stent.

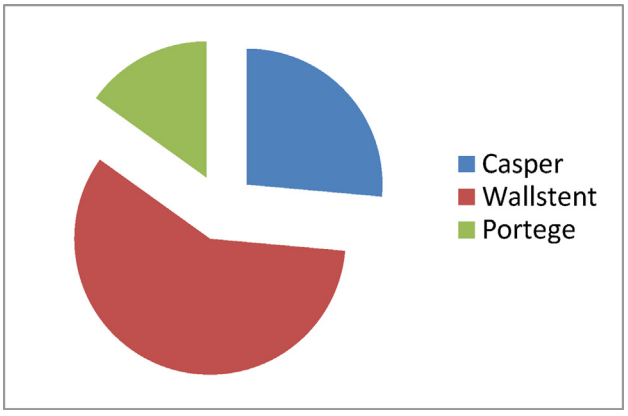

Fig. 2. Distribution of stent type usage.

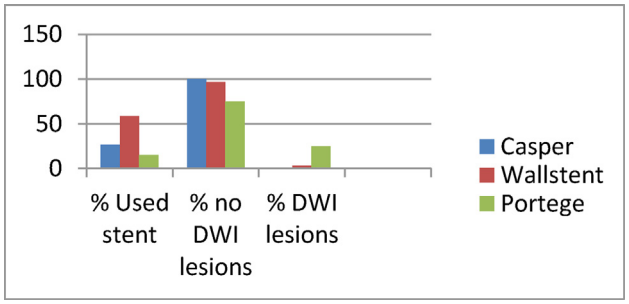

Fig. 4. Diagram illustrates % of stent type usage and associations with diffusion-weighted magnetic resonance imaging lesions.

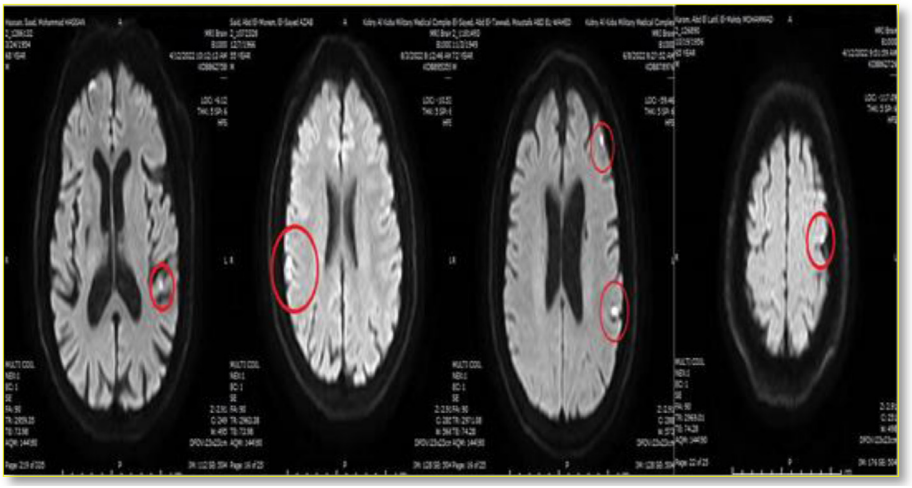

Fig. 3. Postprocedure diffusion-weighted magnetic resonance imaging findings.

procedural MRI-DWI lesions as illustrated in (Table 1), (Tables 3 and 4)

30 days postprocedural follow-up revealed that only six (11.32%) patients developed transient ischemic attack which improved completely within minutes to 1 h with no statistically significant association between age, sex, vascular risk factors or characteristics of the stenosis (Tables 5 and 6), Fig. 4.

(−) = No post-procedural MRI-DWI lesions.

(+) = Post-procedural MRI-DWI lesions were present.

4. Discussion

The role of EPDs in limiting distal cerebral embolic events still debatable. EPDs were advised to be used in the Endarterectomy versus Angioplasty in patients with Symptomatic Severe Carotid Stenosis (EVA-3S) experiment in CAS procedure to minimize the risk of distal embolization. However, The average age of patients without cerebral protection was found to be 8 years older. Additionally, it was observed that the majority of strokes did not occur during the stenting process itself, but rather at a later stage in the clinical course. These findings suggest that the absence of EPDs cannot be solely attributed as the cause of embolic events. Also, The limited sample size of patients in the non-EPDs group resulted in a statistically insignificant difference.[9,10]

In a recent study authored by Cho YD *et al*., a comprehensive analysis was conducted on a total of 539 symptomatic CAS procedures derived from four distinct investigations. Among these procedures, 345 were performed utilizing EPDs, while the remaining 194 were carried out without the implementation of any protective device. The incidence of stroke was 1.7% (n = 6) in the protected CAS group and 5.7% (n = 11) in the unprotected CAS group. However, this difference was not statistically significant ($P = 0.160$), indicating that the use of EPDs did not result in a substantial reduction in the occurrence of stroke following CAS.[11]

A randomized trial states that the use of EPDs was connected to a nonsignificant rise in new lesions on DWI and a considerably greater TCD-detected microembolic burden than unprotected CAS that makes the use of EPD to decrease the occurrence of microembolic events debatable.[12]

The observed lesion load in our investigation was rather minimal, as new instances of cerebral ischemia lesions were identified in only three cases. This finding is consistent with prior research as.[13,14]

This phenomenon can be elucidated by several factors. Firstly, advancements in materials used in the exchange system have contributed to improved outcomes. These materials include self-expandable stent devices that are less traumatic and more resistant to friction, as well as introducer catheters that are better equipped to handle the exchange process. Additionally, flexible guiding catheters have been employed instead of long sheaths, further enhancing the efficiency of the procedure. Secondly, there has been a reduction in the number of device manipulations performed across the lesion prior to stent placement. This is achieved by avoiding the use of filters and limiting the use of pre-stenting balloon dilatation. In specific cases involving tight stenotic lesions, selective pre-stenting balloon dilatation was performed to facilitate the passage of the stent across the lesion. Lastly, the majority of cases involved the use of stents with a closed-cell design, which were placed before angioplasty balloon dilatation. This approach has been found to be beneficial in optimizing the placement and effectiveness of the stent. Closed-cell stents with their unique.[15,16]

Two prior investigations have demonstrated a consistent pattern indicating improved outcomes associated with the utilization of closed cell stents.[17,18]

There are other factors that could represent a protective concept during CAS other than usage of distal protection devices that may have been important co-factors in preventing cerebral embolism during the recent era of CAS studies, In light of current advancements in technology, such as the accompanying learning curve of active interventionists, as well as the enhanced peri-procedural anticoagulation and antiplatelet regimens, there has been a notable improvement in supplementary measures.[19]

Other studies advise assessing the influence of anatomical traits on outcomes following CAS at any age. Abnormal arch architecture, vascular tortuosity, lengthy stenotic lesions (>15 mm), and plaque echolucency are a few factors that have been linked to an elevated risk of severe effects.[20]

4.1. Conclusion

Regarding to our clinical and radiological outcome, it seems that carotid artery stenting without the use of,embolic protection devices can be considered as a safe and reliable method in treating the carotid artery stenosis with small rate of clinical and radiological complications.

4.2. Recommendations

Although being safe procedure CAS without the use of EPDs is not complication free and requires proper technical development and material

improvement for better clinical and radiological outcome. It would be useful to perform a prospective study to evaluate the long term outcome of the procedure Fig. 1.

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Conflicts of interest

No conflict of interest: yes.

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