



2023

Section: Neurosurgery

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### How to Cite This Article

Ali, Mostafa Y.; Albialy, Mohammed Abdulaziz; and Hawary, Magdy A. El (2023) "Endovascular Management for Carotid Artery Stenosis with or without using of Distal Protection Device," *Al-Azhar International Medical Journal*: Vol. 4: Iss. 9, Article 35.

DOI: <https://doi.org/10.58675/2682-339X.2015>

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# Endovascular Management of Carotid Artery Stenosis With or Without a Distal Protection Device

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## Abstract

**Background:** Transient ischemic episodes and ischemic strokes are frequently brought on by internal carotid artery atherosclerotic stenosis. Carotid artery stenosis can be treated with medicine, surgery, endovascular therapy, stenting, or a combination of these methods.

**Aim of the work:** Analyzing the various endovascular treatment options for carotid artery stenosis with and without filters.

**Patients and methods:** This is a prospective and retrospective study, which was conducted on 30 patients with carotid artery stenosis; 13 with filters and 17 without filters undergoing different endovascular techniques.

**Results:** In this study, we found that in group A, the mean age of patients was 65.85 ( $\pm 7.29$ ) while in group B, the mean age of patients was 64.29 ( $\pm 9.68$ ). Eleven patients in group A were males and two were females. In group B, there were 15 male patients and two female patients in which there is a significant difference between both studied groups as regards age. There was no statistically significant association between characteristics of the stenosis and postprocedural clinical ischemic insults in groups A and B.

**Conclusion:** The frequent use of distal filter devices during carotid artery stenting cannot be justified by any discernible advantage. It is still important to conduct prospective, randomized, and controlled studies including sizable patient cohorts to compare the utilization of protected carotid artery stenting with non-protected carotid artery stenting. To accurately determine the various modalities of endovascular approach for the management of carotid artery stenosis, more patients, longer follow-up, and multicenter experience are all required. Undoubtedly, there is a need for larger studies and additional research into CP alternatives.

**Keywords:** Cerebrovascular, Embolic protection devices, Stenosis

## 1. Introduction

The FDA and Centers for Medicare and Medicaid Services' approval of carotid artery stenting (CAS) for patients at high risk of carotid endarterectomy serve as the main foundation for the procedure's current indications (CEA). The North American Symptomatic Carotid Endarterectomy Trial (NASCET) and other CEA trials are the main sources of inspiration for these recommendations.<sup>1</sup>

As a result, CAS is now approved for individuals who have high-risk diseases and carotid stenosis greater than 70 %.<sup>2</sup>

Based on the patient's anatomical features and comorbidities as well as the surgeon's preference and experience, CEA or CAS was selected as the procedure for revascularization.<sup>3</sup>

Proximal occlusion (P-EPD) and distal filtering are two techniques that are frequently utilized during CAS to protect the brain (D-EPD).<sup>4</sup>

To catch any atheroembolic particles released during catheter manipulation, the D-EPD uses a filter that is passed through the lesion in a closed position into the internal carotid artery (ICA), and then opened distal to the lesion. P-EPD uses common carotid/external carotid occlusion to stop the

Accepted 27 February 2023.  
Available online 22 January 2024

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<https://doi.org/10.58675/2682-339X.2015>

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ipsilateral circulatory system without crossing the lesion and induce retrograde flow.<sup>5</sup>

## 2. Methods

Between May 2021 and November 2022, this prospective and retrospective study was conducted at Nasr City Health Insurance Hospital and the Faculty of Medicine at Al Azhar University's Al Hussein Hospital.

All study participants were introduced to the researcher, who then requested their participation after briefly outlining the study's objectives.

All of the chosen participants were given thorough explanations of the study's goal and anticipated advantages. Every ethical factor was taken into account during the entire project.

### 2.1. Inclusion criteria

All patients with carotid artery stenosis between the ages of 18 and 80 years, of both sexes, with either 70 % or 50 % symptomatic extracranial internal carotid artery stenosis were included in the study.

### 2.2. Exclusion criteria

Patients who could not receive radiation or dye injections and those who could not access endovascular procedures because of severely convoluted vessels were excluded.

All patients were subjected to the following:

### 2.3. Complete medical history

Any of the risk factors listed below have been present in a patient's medical history in the past: arterial hypertension, diabetes mellitus, smoking, heart disease, dyslipidemia, peripheral vascular disease, prior stroke, transient ischemic attack, and/or reversible ischemic neurological impairment.

### 2.4. Neurological examination

Patients who had a clinical and neurological examination were evaluated using the National Institutes of Health Stroke Scale (NIHSS), and were then assigned to one of the following categories: Minor stroke: new neurological deficit with NIHSS scores of 8 or lower; moderate stroke: new neurological defect with NIHSS scores of 9–15; and major stroke: new neurological deficit with NIHSS scores of 16 or higher.

### 2.5. Imaging

Carotid artery imaging: Duplex ultrasonography and, in some situations, high-frequency probes were used to assess all carotid abnormalities at first. In some instances, magnetic resonance angiography (MRA) and computed tomography angiography (CTA) were used. When necessary, brain diffusion MRIs or CT scans were performed before the surgery. According to the North American Symptomatic Carotid Endarterectomy Trial (NASCET) guidelines, the stenosis was measured angiographically.

### 2.6. Endovascular intervention

Patients underwent endovascular catheterization. There were documented issues and difficulties throughout the operation.

### 2.7. Postoperative assessment

All patients underwent postoperative evaluations with an emphasis on postoperative complications or neurological abnormalities. When necessary, brain imaging tests including CT angiography and brain MRI and MRA were performed.

### 2.8. Statistical analysis

Version 20 of the Statistical Program for Social Sciences was used for data analysis (SPSS Inc., Chicago, IL, USA).

### 2.9. Administrative design

#### 2.9.1. Approvals

All participants were verbally consented after being fully informed, and information confidentiality was guaranteed. From the Al-Azhar University's Dean of the College of Medicine, the Head of the Department of Neurology there, and the management of Al Hussein Hospital, a formal written administrative authorization letter was acquired. To secure their cooperation, the study's title and goals were explained to them.

#### 2.9.2. Ethics committee

In addition, authorization from the Faculty of Medicine's Ethics Committee and Institutional Review Board permission were acquired.

## 3. Results

Tables 1–5.

Table 1. Demographic data descriptive in each group.

Demographic data	Group A with filter (n = 13) Number (%)	Group B without filter (n = 17) Number (%)	Total (n = 30) Number (%)
<b>Sex</b>			
Female	2 (15.4 %)	2 (11.8 %)	4 (13.3 %)
Male	11 (84.6 %)	15 (88.2 %)	26 (86.7 %)
<b>Age (years)</b>			
<60 years	2 (15.4 %)	4 (23.5 %)	6 (20.0 %)
60–70 years	7 (53.8 %)	9 (52.9 %)	16 (53.3 %)
>70 years	4 (30.8 %)	4 (23.5 %)	8 (26.7 %)
Mean ± SD	65.85 ± 7.29	64.29 ± 9.68	64.97 ± 8.62
Range	54–78	45–79	45–79

Table 2. Relation between all parameters in Group A with filter and development of postprocedural clinical ischemic insults.

Group A with filter	No postprocedural clinical ischemic insults (n = 11)	Presence of postprocedural clinical ischemic insults (n = 2)	Total (n = 13)	$\chi^2$	P value
<b>Sex</b>					
Female	2	0	2	0.430	0.512
Male	9	2	11		
<b>HTN</b>					
No	5	0	5	1.477	0.224
Yes	6	2	8		
<b>DM</b>					
No	5	1	6	0.014	0.906
Yes	6	1	7		
<b>Mode of Presentation</b>					
Asymptomatic	6	1	7	0.654	0.721
Stroke	3	1	4		
TIA	2	0	2		
<b>Pre NIHSS</b>					
NIHSS ≤ 8	3	1	4	0.410	0.522
NIHSS = 0	8	1	9		
<b>Degree of stenosis</b>					
<70	2	1	3		
70–89	5	1	6	1.477	0.478
>90	4	0	4		
<b>Level of Length of stenosis</b>					
<10	2	1	3		
10–20	6	1	7	1.294	0.524
>20	3	0	3		
<b>Ulceration</b>					
Not ulcerated	4	0	4	1.051	0.305
Ulcerated	7	2	9		
<b>Calcification</b>					
Calcified	4	2	6	2.758	0.097
Not Calcified	7	0	7		
<b>Pre-dilatation</b>					
Done	9	1	10	0.000	1.000
Not done	2	1	3		
<b>Type of stent</b>					
Protege	2	0	2	0.430	0.512
WallStent	9	2	11		
<b>Postprocedure NIHSS</b>					
NIHSS ≤ 8	1	1	2	6.017	0.049*
NIHSS = 0	10	1	11		
<b>MRIDWI and flair (TIA or NORMAL) lesions</b>					
No	5	1	6	0.014	0.906
Yes	6	1	7		
<b>Post-Procedure MRIDWI findings</b>					
No MRI-DWI lesions	5	0	5	0.181	0.671
MRI-DWI lesions	6	2	8		

Table 3. Relation between all parameters in Group B without filter and development of post-procedural clinical ischemic insults.

Group B without filter	No postprocedural clinical ischemic insults (n = 14)	Presence of postprocedural clinical ischemic insults (n = 3)	Total (n = 17)	$\chi^2$	P value
Sex					
Female	1	1	2	1.633	0.201
Male	13	2	15		
HTN					
No	7	2	9	0.275	0.600
Yes	7	1	8		
DM					
No	10	2	12	0.027	0.870
Yes	4	1	5		
Mode of Presentation					
Asymptomatic	4	1	5	0.486	0.784
Stroke	8	2	10		
TIA	2	0	2		
Pre NIHS					
NIHSS 9-15	1	1	2	1.862	0.394
NIHSS $\leq$ 8	7	1	8		
NIHSS = 0	6	1	7		
Degree of stenosis					
<70	1	2	3	3.220	0.060
70–89	9	1	10		
>90	4	0	4		
Level of Length of stenosis					
<10	1	0	1	2.611	0.105
10–20	12	2	14		
>20	1	1	2		
Ulceration					
Not ulcerated	7	1	8	0.275	0.600
Ulcerated	7	2	9		
Calcification					
Calcified	6	1	7	2.204	0.225
Not Calcified	8	2	10		
Pre-dilatation					
Done	11	3	14	0.781	0.377
Not Done	3	0	3		
Type of stent					
WallStent	14	3	17	0.000	1.000
Protege	0	0	0		
Postprocedure NIHS					
NIHSS $\leq$ 8	4	0	4	4.679	0.062
NIHSS 9-15	1	1	2		
NIHSS = 0	9	2	11		
MRIDWI and flair (TIA or normal) lesions					
No	4	1	5	0.617	0.432
Yes	10	2	12		
Post-Procedure MRIDWI findings					
No MRI-DWI lesions	3	0	3	0.002	0.961
MRI-DWI lesions	11	3	14		

Table 4. Comparison between pre and post according to NIHS in group A with filter (n = 13).

NIHS	Pre NIHS (n = 13) Number (%)	Post NIHS (n = 13) Number (%)	Chi-square test	
			$\chi^2$	P value
NIHSS = 0	9 (69.2 %)	11 (84.6 %)	0.217	0.642
NIHSS $\leq$ 8	4 (30.8 %)	2 (15.4 %)		
NIHSS 9-15	0 (0.0 %)	0 (0.0 %)		

Table 5. Comparison between pre and post according to NIHSS in group B without filter ( $n = 17$ ).

NIHSS	Pre NIHSS ( $n = 13$ ) Number (%)	Post NIHSS ( $n = 13$ ) Number (%)	Chi-square test	
			$\chi^2$	P value
NIHSS = 0	7 (41.2 %)	11 (64.7 %)	2.222	0.329
NIHSS $\leq$ 8	8 (47.1 %)	4 (23.5 %)		
NIHSS 9-15	2 (11.8 %)	2 (11.8 %)		

#### 4. Discussion

In a study comparing carotid stenting of asymptomatic and symptomatic carotid artery stenoses with and without the use of distal embolic protection, it was shown that there was a significant difference in age and gender (86 % vs 100 % male;  $P = 0.015$ ) between the EPD group and non-EPD group.<sup>6</sup>

The mean age was found to be 78.6 7.0 in the CP group against 74.1 8.7 in the non-embolic protection group in a randomized experiment comparing carotid artery stenting with and without cerebral protection ( $P = 0.92$ ). Although the median ages of the two groups were comparable, more patients in their 80 s were found in the embolic protection group (61.1 % vs. 22.2 %;  $P = 0.04$ ).<sup>7</sup>

In the study to evaluate the use and value of PDs in contrast to no PD during carotid artery Stenting, there was no appreciable difference between the protection devices group and the no protection devices group in terms of age or sex (CAS).<sup>8</sup>

It was demonstrated in a study to evaluate embolic protection for carotid artery stenting that there was no age or sex difference between the two study groups.<sup>9</sup>

In this thesis, we present evidence that eight patients in group A had hypertension and seven patients in group A had diabetes mellitus. Five patients in group B had diabetes mellitus, and eight had hypertension.

Smokers (73.6 %) vs. (76.4 %),  $P = 6.3$ , and hypertension (90.9 %) vs. (90.4 %) showed no statistically significant difference. Dyslipidemia (87.9 %) vs. (84.9 %),  $P = 1.7$   $P = 8.9$ , peripheral artery disease (43.3 %) vs. (42.9 %)  $P = 0.9$ , diabetes mellitus (38.3 %) vs. (36.5 %)  $P = 3.7$ , and chronic lung disease (28.3 %) vs. (28.3 %)  $P = 0.0$ , respectively, were found between the EPD group and the non-EPD group.<sup>9</sup>

Those receiving PDs exhibited higher rates of arterial hypertension (89.9 % against 78.6 %,  $P = 0.007$ ) and previous myocardial infarction (34 % vs. 27.4 %,  $P = 0.007$ ) than patients receiving no PDs.<sup>8</sup>

In this investigation, we discovered that six patients in group A and seven patients in group A both had symptomatic carotid lesions. Twelve patients in group B had symptomatic carotid lesions compared with five individuals with asymptomatic lesions.

In the non-EPD group, there were 42.9 % symptomatic carotid lesions compared with 50.0 % in the

EPD group. However, there was no clinical presentation statistically different between the two groups ( $P = 0.651$ ).<sup>6</sup>

In terms of clinical manifestations, it was discovered that there was no statistically significant difference between the non-EPD group and the EPD group (46.4 % vs. 44.8 %, respectively).<sup>8</sup>

In the study in our hands, in group B, seven patients had no clinical deficit (NIHSS = 0), eight had minor strokes, and two patients had moderate strokes with NIHSS between 9 and 15.

It was discovered that the no-EPD group had worse pre-procedure neurologic risk factors than the F-EPD group did. These risk factors included higher rates of acute evolving stroke (16.1 % vs. 2.1 %, SD = 50.5), history of ischemic stroke before the procedure (24.4 % vs. 15.5 %, SD = 22.4), symptomatic lesion status (52.8 % vs. 40.2 %, SD = 25.5), and spontaneous carotid artery dissection.<sup>9</sup>

Neurological qualifying events did not differ noticeably between the two stenting groups.<sup>10</sup>

In their study to assess patients following carotid stenting with or without a distal protection device, they found that there were substantial differences between CAS without PD and CAS with PD as regards the side and the laterality of the carotid stenosis.<sup>11</sup>

Before surgery, there were no differences between the two groups' carotid lesions in terms of their location or degree of stenosis. The rate of thrombus visibility was higher in those receiving distal protection (16.5 % vs. 8 %,  $p 0.001$ ) however.<sup>8</sup>

In this study, we found that in group A, nine patients had ulcerated atheromatous plaques but in group B nine patients had ulcerations in their carotid lesions. Calcifications within the atheromatous plaque were present in six patients in group A while in group B, seven patients had calcifications.

Lesions in patients treated with EPD were found to be more problematic because they had more ulcers ( $P = 0.035$ ), severe calcification ( $P = 0.039$ ), a longer lesion length ( $P = 0.025$ ), and a higher pre-interventional grade of stenosis ( $p 0.001$ ).<sup>8</sup>

In this thesis, we present evidence that pre dilatation was carried out in 10 patients in group A and in 14 patients in group B. Except for two patients in group A all of the stents utilized in the study were WallStents. All instances in group B involved WallSten.



Interventional characteristics of individuals treated with and without PDs barely varied. Patients receiving PD had slightly higher median post intervention residual stenosis (median 10 % against median 5 % residual stenosis) and prior carotid artery dilatation (3.5 % versus 1 %,  $p$  0.001); 9.8 % of patients who received a PD predilated before doing so. When a PD was used, the intervention's time was increased by 10 min (median 45 vs median 35 min,  $P$  0.001).<sup>8</sup>

In the study we discovered a substantial difference between the postprocedure NIHSS scores of the two groups. Eleven patients in group A had NIHSS 0 compared with 11 in group B, no patients in group A had NIHSS 9–15 compared with 2, and two instances in group A had NIHSS 8 compared with 4 in group B.

The rate of any ipsilateral ischemic event during the hospital stay was found to be lower in patients who received PDs (4.4 % vs 7.4 %,  $P$  = 0.016, OR = 0.57, 95 % CI: 0.36–0.91) as well as the combined endpoint of all nonfatal strokes and all deaths (2.1 % versus 4.9 %,  $P$  = 0.004, OR = 0.41, 95 % CI: 0.22–0.77). These variations are the result of individuals receiving PDs having a significantly decreased rate of ipsilateral stroke (1.7 % vs. 4.1 %,  $P$  = 0.007, OR = 0.40, 95 % CI: 0.20–0.79). The rates for all nonfatal strokes and all deaths in patients with symptomatic stenoses were 3.7 % versus 6.0 %,  $P$  = 0.137, and the comparable rates in patients with asymptomatic stenoses were 0.3 % against 3.7 %,  $P$  = 0.003, favoring the use of a PD.<sup>8</sup>

Data from 2357 patients who got CAS treatment without a PD and 839 patients who received CAS treatment under distal protection were analyzed. The combined rate of mortality or stroke after 30 days after the surgery was 1.8 % in the group with PD versus 5.5 % in the group without a PD ( $p$  0.001).<sup>12</sup>

Strokes were observed to have occurred 2 (2.0 %) in protected CAS and 4 (5 %), respectively. After CAS, stroke was considerably reduced when a cerebral protective device was used (OR 0.633, 95 % CI 0.479–0.837,  $P$  = 0.001).<sup>13</sup>

In total, 539 symptomatic CAS procedures from four studies were reviewed; 345 of these procedures used CPD, while 194 did not. The number of strokes was six (1.7 %) in protected CAS and 11 (5.7 %) in unprotected CAS, which was statistically nonsignificant ( $P$  = 0.160), indicating that the use of CPD did not significantly reduce the incidences of stroke following CAS.<sup>14</sup>

The capacity to maintain flow throughout CAS procedures and protect the brain from embolization are the advantages of using CPDs with filters. The drawbacks of these devices include the potential for material dislodgement during deployment due to the large crossing profile, low flexibility, and

torquability of the device, as well as the risk of cerebral microembolization following deployment due to flow around and through the filter, pore size, and poor apposition in tortuous vessels, as well as during retrieval.<sup>15</sup>

In this study, we illustrated that there was a significant difference between postprocedure MRI-DWI findings of both groups. Eight cases in group A had MRI-DWI lesions versus cases in group B.

Microembolic lesions that were detectable with DWI were detected in 26 % of patients in the EPD group, with a mean lesion load of 0.53 per patient, whereas they were found in 36 % of patients in the non-EPD group, with a mean lesion load of 2.22/patient. DWI lesions in the EPD group (16 lesions) were lower than in the non-EPD group (49 lesions). In the EPD group (2 lesions), consistent lesions were substantially lower ( $P$  = 0.03) than in the non-EPD group (29 lesions).<sup>16</sup>

It was demonstrated that the application of filter devices did not significantly lower the occurrence of new DWI lesions (15.4 % EPD vs. 18 non-EPD;  $P$  > 0.05).<sup>6</sup>

There was no difference in the post-procedure diffusion-weighted MRI (DW-MRI) evidence of cerebral embolization in the 36 patients, who were randomized to undergo distal filter embolic protection versus no embolic protection.<sup>7</sup>

In this thesis, we discovered that neither group A nor group B nor the entire study revealed any statistically significant correlation between the stenosis features and the postprocedural clinical ischemia insults.

There was no statistically significant association between any patient's stenosis characteristics and their likelihood of hospital death or stroke.<sup>8</sup>

Future prospective trials comparing the characteristics of protective devices and stent designs are still required. The study does have certain restrictions. The traits of plaques that were discovered using the filter devices were not assessed. The modest number of neurological problems following the procedure also prevents any useful interpretations of the safety and viability of the distal filter device used in our current investigation. Last but not least, we did not assess the size of the new DWI lesions. In addition, several studies did not clearly explain what a stroke was, how many people died, or how many people died overall. Since severe strokes can be fatal, total occurrences may be exaggerated even though in a prior study they were calculated as the total of all strokes and deaths. Therefore, more thorough information on perioperative complications based on symptomatology and risk stratification, as well as adverse events

under long-term observation, is needed in randomized controlled research.

The findings of this retrospective investigation show that there are no observable advantages to using distal filter devices during CAS that can support routine use. The frequency of post-procedural DWI lesions or neurological sequelae has significantly decreased. It is still necessary to conduct prospective randomized controlled trials comparing the use of protected CAS versus non-protected CAS in large patient populations.

#### 4.1. Conclusion

The frequent use of distal filter devices during carotid artery stenting cannot be justified by any discernible advantage. It is still important to conduct prospective, randomized, and controlled studies including sizable patient cohorts to compare the utilization of protected carotid artery stenting with nonprotected carotid artery stenting. To accurately determine the various modalities of endovascular approach for the management of carotid artery stenosis, more patients, longer follow-up, and multicenter experience are all required. Larger studies and additional research into alternate CP technologies are unquestionably necessary.

#### Authorship

All authors have a substantial contribution to the article.

#### Sources of funding

This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

#### Disclosure

The authors have no financial interest to declare in relation to the content of this article.

The authors thank Al-Azhar University and the patients recruited in the study.

#### Ethical approval

The study was approved by the Institutional Ethics Committee.

#### Conflicts of interest

The authors declared that there were no conflicts of interest.

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