Cardiology and Cardiovascular Research
2022; 6(2): 75-80
http://www.sciencepublishinggroup.com/j/ccr
doi: 10.11648/j.ccr.20220602.14
ISSN: 2578-8906 (Print); ISSN: 2578-8914 (Online)

Feasibility and Outcome of Endovascular Management of Carotid Artery Stenosis, Egyptian Multicentric Experience

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To cite this article:

Mohammed Alsagheer Alhewy, Mahmoud Galal, Abdelaziz Ahmed Abdelhafez. Feasibility and Outcome of Endovascular Management of Carotid Artery Stenosis, Egyptian Multicentric Experience. *Cardiology and Cardiovascular Research*. Vol. 6, No. 2, 2022, pp. 75-80.
doi: 10.11648/j.ccr.20220602.14

Received: May 2, 2022; **Accepted**: May 20, 2022; **Published**: May 26, 2022

Abstract: *Background:* Internal carotid artery atherosclerotic stenosis is a common cause of transient ischemic attacks (TIAs) and ischemic strokes. The advance of percutaneous, endovascular therapies for vascular disease has been unremitting. Over the last several decades, but recently Endovascular management and stenting is considered one of the lines of treatment for carotid artery stenosis. *Objectives:* To report the outcome and follow up of internal carotid artery stenting. *Patients and methods:* 131 internal carotid artery stenting procedures were done for 131 patients with significant internal carotid artery stenosis at multiple centres, including neurovascular intervention units at Al-Azhar university hospitals (Al-Hussein and Assiut), Mostafa Mahmoud, and Kobbri Elkobba hospitals, Egypt, from February 2019 to March 2021, Patients were followed for 12 months after stenting. *Results:* Early post-interventional complications included stroke (3.8%), TIA (6.1%), transient bradycardia (3.8%) and local groin hematoma (2.3%). One month later, no new neurological deficits developed and carotid artery duplex showed no restenosis. At the end of follow-up, three patients developed stroke and three patients died (one from acute myocardial infarction and two patients died without known aetiology). The carotid artery duplex showed no cases of restenosis. *Conclusion:* Carotid artery stenting is a safe, feasible, and efficacious procedure with a low periprocedural risk of stroke or death. Furthermore, the risk of future stroke and rate of significant restenosis during mid-term follow-up appears to be low and carotid stenting can be considered an alternative to carotid endarterectomy, especially in high-risk patients.

Keywords: Atherosclerosis, Endovascular Stenting, Stroke, TIAs

1. Introduction

Atherosclerotic carotid artery stenosis may be diagnosed in 20–30% of patients with cerebrovascular strokes [1]. Medical treatment includes antiplatelets, statins, and control of risk factors. Medical treatment is advocated for patients with mild-to-moderate stenosis [2]. Carotid revascularization is indicated for patients with persistent symptoms of ischemia despite adequate antiplatelet therapy. Carotid revascularization is an effective intervention to prevent recurrent stroke or death in both symptomatic and asymptomatic patients with carotid artery stenosis [3]. The two available options for revascularization are angioplasty with stent placement and endarterectomy. The Carotid Revascularization Endarterectomy versus Stenting Trial (CREST) did not show significant differences in the risk of the composite primary outcome of stroke, myocardial infarction (MI), or death between the two procedures. However, in the periprocedural period, CAS had a higher risk of stroke, whereas CEA had a higher risk of MI [4, 5]. With continuous improvements in training and technique, perioperative medication, embolic protection, stent design, and better patient selection, stroke risk following CAS decreases. [4-6] Meanwhile, MI and cardiovascular mortality remain important adverse outcomes that favor the use of CAS. [7, 8] So, in asymptomatic patients, some researchers suggest that surgical intervention may be the

preferred option in spite of the fact that other studies concluded that both interventions are comparable in terms of the risk of death. [9-11]

The present study aimed to report Egyptian multicentric experience with carotid artery stenting in patients with carotid artery stenosis.

2. Patients and Methods

An interventional, prospective study was carried out on one hundred and thirty-one patients. the study was carried out at multiple centers, including neurovascular intervention units at Al-Azhar university hospitals (Al-Hussein and Assiut), Mostafa Mahmoud, and Kobbri Elkobba hospitals, Egypt, from February 2019 to March 2021. Patients gave informed consent before the intervention, and the local ethical committee approved the study protocol in agreement with the declaration of Helsinki on clinical research involving human subjects. The study included 131 patients who submitted to 132 internal carotid artery endovascular stenting procedures.

2.1. Inclusion/Exclusion Criteria

Patients were included if they had symptomatic carotid artery stenosis with 50-69% degree of stenosis or asymptomatic carotid artery stenosis with 70-99% degree of stenosis discovered accidentally during a routine checkup or prior to coronary artery bypass graft, if they were high-risk surgical patients for carotid endarterectomy [12], or if they refused surgery. Participants were excluded if they had major functional impairment (Modified Rankin Scale (MRS) $\geq$ 3), Subject had a known hypersensitivity or contraindication to anticoagulants and\or anti-platelet, or contrast media, which is not amenable to pre-treatment, severe renal impairment precluding safe contrast medium administration, or inability to achieve safe vascular access.

2.2. Diagnostic Procedures

All patients had full medical and neurological assessment before stenting, immediately after stenting, one month after stenting 6 and 12 months after stenting. Assessment watched for any neurological disorder (headache, delirium, altered mental state, TIA, or stroke), NIHSS score, and functional disability determined by MRS. The degree of carotid stenosis was assessed using carotid artery duplex ultrasound according to North American Symptomatic Carotid Endarterectomy Trial (NASCET) criteria. MRA and CTA on the arch and supra-aortic vessels were used in some cases to confirm the stenosis and anatomy of the carotid vessels' origins.

2.3. Study Methods

Preoperatively All patients were actually on aspirin 75-100mg/day, three days before the procedure, a loading dose of 320 mg aspirin and 75 mg clopidogrel was administered daily [13]. CAS was performed according to the procedural instructions described by Ahn et al. [14] this dual therapy continues for three months after the procedure, and then aspirin continues with a dose of 75-100 mg/day for life. A nephron-protection protocol was used in all non-dialyzed patients encompassing maximizing urine outflow by infusing saline intravenously with the following regimen of 1.5ml/kg/hr. Every 12hr before and continued 4-6 hours after the procedure, with 3-5ml/kg as a bolus immediately before the procedure. In patients with an ejection fraction < 40%, 20 mg of furosemide were injected intravenously at the beginning and the end of the daily hydration.

All interventions were performed in the C-Arm room, dedicated to percutaneous endovascular intervention. OR was equipped with a C-arm "Philps Pulsera". moveable radiolucent surgical table and accurate monitors for the patient's vital signs with provision for systemic arterial monitoring and continuous electrocardiographic surveillance during the procedure.

Operative technique: Percutaneous transluminal balloon angioplasty (PTA) procedures are usually carried out in our angiography suite with blood pressure and cardiac monitoring and under local anaesthesia (10 ml of Lidocaine 2%) with intravenous antibiotic prophylaxis. In our study, we use general anaesthesia in 12 patients. A retrograde puncture of the common femoral artery was performed with the insertion of an 11-cm 6-F sheath that is usually used to perform initial diagnostic arteriography using nonionic iodinated contrast media. After systemic Heparinization (80 IU/kg; 3000–5000 IU), Using digital subtraction angiography (DSA), the intraoperative angiograms were used to confirm the level of ischemia and target artery. The navigation of the vessels to be treated was conducted via the roadmap technique and with a0.018 - or 0.035-inch guidewire with the support of a suitable curved catheter or low-profile balloon. In all cases, At the end of the procedure, we used the axillary approach in one case only. hemostasis isalways achieved in all cases by Manual compression. Technical success was defined as the opening of the lesion or residual stenosis of less than 30% and the absence of flow-limiting dissections on the final angiogram.

After the endovascular intervention, dual antiplatelet therapy was maintained (Aspirin 81 mg/day and Clopidogrel 75 mg/day) for three months, and then Aspirin alone indefinitely.

3. Results

The present study included 131 patients with ICA stenosis who underwent 132 carotid artery stenting procedures. Patients had an age of 64.6 ± 7.6 years and comprised 79 males (60.3%). The reported risk factors are shown in table 1. Characteristics of the performed procedures are illustrated in table 2. Procedural success was achieved in all patients. The reported complications included stroke in three patients (3.8%) and TIA in 8 patients (6.1%), as shown in Figure 1. Among the various risk factors for procedural complications, prestenting balloon dilatation was the only significant risk factor Table 3.

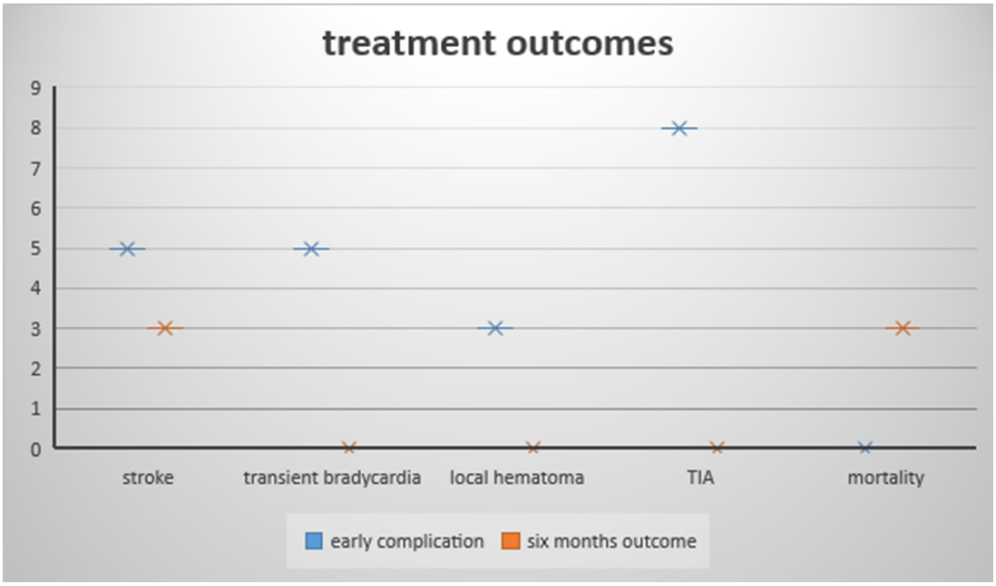

Figure 1. *Treatment outcomes, TIA: transient ischemic attack.*

Case presentation

A 53-year-old hypertensive, diabetic, and smoker complaining of recurrent transient ischemic attack in the form of right-side weakness and carotid duplex shows 70% stenosis in the left carotid; however, in the diagnostic angiography, left internal carotid arteries show sub-total occlusion figure 2, stenting was done using closed cells wallstent 9×40ml and post stenting angioplasty figure 3. No residual stenosis after angioplasty, good restoration of flow in the intracranial circulation after stenting figure 4.

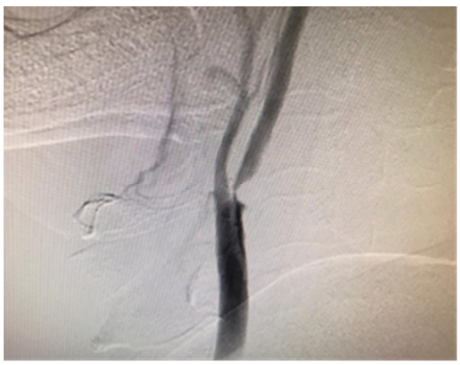

Figure 2. *Left internal carotid arteries show sub-total occlusion.*

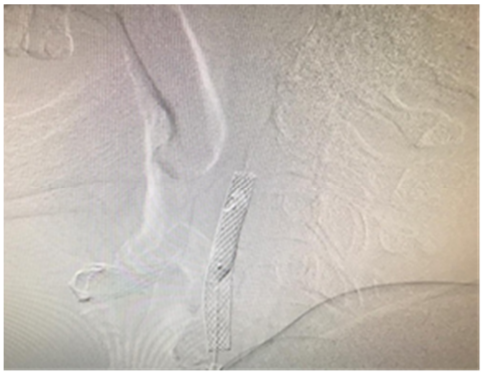

Figure 3. *Post stenting angioplasty.*

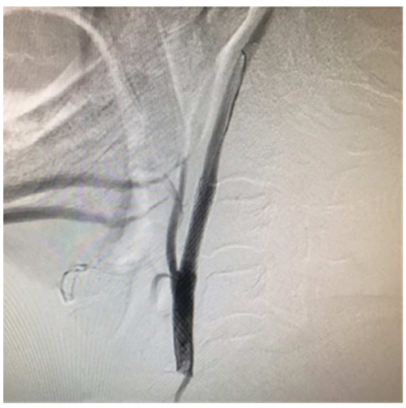

Figure 4. *Good restoration of flow in the intracranial circulation after stenting.*

Another case with bilateral carotid artery stenting follow-up with plain x-ray on the neck after 6 months shows bilateral patent stents with no residual stenosis, as shown in figure 5.

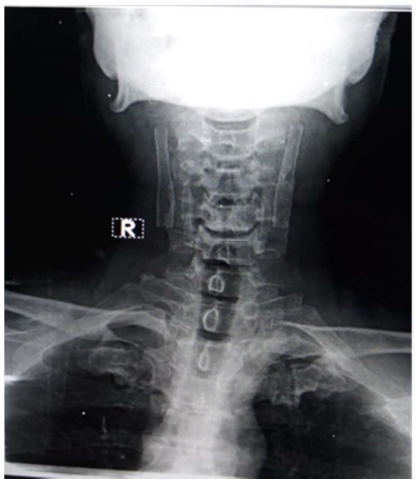

Figure 5. *Plain x-ray on the neck after 6 months shows bilateral patent stents with no residual stenosis.*

Table 1. *Basic data of the studied patients (N=131).*

variable	N (%)
Age, mean ± SD	64.6±7.6
Male	79 (60.3%)
Female	52 (39.7%)
Symptomatic patients	86 (65.6%)
Asymptomatic patients	45 (34.35%)
Risk factors n (%)	
Diabetes	57 (44%)
Hypertension	76 (58%)
Hyperlipidemia	60 (46%)
Coronary artery disease	40 (30%)
AF	5 (3.8%)
History of open-heart surgery	3 (2.2%)
HF	5 (3.8%)
History of myocardial infarction	4 (3%)
Severe bronchopulmonary disease	3 (2.2%)
Multi-vessel disease	10 (7.6%)

HF, heart failure; AF, atrial flutter.

Table 2. *Procedural Characteristics.*

variable	N (%)
Stent side	
Right side	56 (42.7%)
Left side	70 (53.4%)
Bilateral stent	5 (3.8%)
Anaesthesia	
Local anaesthesia	119 (90.8%)
General anaesthesia	12 (9.2%)
Approach	
Transfemoral	130 (99.2%)
Axillary	1 (0.8%)
Stent type	
Closed-cell stents	81 (61.8%)
1) Wall stent	59 (45%)
2) Leo stent	12 (9.2%)
3) RoadSaver stent	10 (7.6%)
Open-cell stent	50 (38.2%)
Stenting site	
Origin of ICA	119 (90.8%)
Petrous part	10 (7.6%)
Cavernous part	2 (1.6%)
Additional procedures	
Use of CPD	20 (15.3%)
Prestenting dilatation	21 (16%)
Post stenting dilatation	70 (53.3%)

ICA, internal carotid artery; CPD, cerebral protection device.

Table 3. *Risk factors for early complications.*

		Strokes	P value	TIA	P value
Symptoms	Symptomatic (76)	4 (80.0)	0.38	6 (75.0)	0.4
	Asymptomatic (55)	1 (20.0)		2 (25.0)	
Prestenting balloon dilatation	+ve (21)	3 (60.0)	0.006	5 (62.5)	< 0.001
	-ve (110)	2 (40.0)		3 (37.5)	
Stent type	Open (81)	3 (60.0)	0.93	4 (50.0)	0.48
	Closed (50)	2 (40.0)		4 (50.0)	
Use of CPD	+ve (20)	2 (40.0)	0.12	3 (37.5)	0.07
	-ve (111)	3 (60.0)		5 (62.5)	

4. Discussion

Carotid artery stenting (CAS) has become an alternative to carotid endarterectomy (CEA) in revascularization therapy of carotid artery stenosis, especially in some high-risk patients for surgical intervention [15]. In our study, the procedural success rate was 100.0%, equal to that reported by a recent

large Japanese study [16]. The reported early complications included stroke (3.8%) and TIA (6.1%). This rate is similar to that reported by the study of Wieker et al. [17], where stroke and TIA were reported in 3.3% and 5.9% of patients. Likewise, the rate of early post-procedural stroke was (4.4%) in the study of DakourAridi et al., [18] In the present study, the frequency of strokes and TIAs occurred more among patients with symptomatic carotid artery stenosis. This finding was similar to Qureshi et al., [19] who noted that the 30-days stroke rate in symptomatic patients was 8.3% compared to 6.0% in asymptomatic patients. The higher rate of ischemic events among symptomatic patients may be due to plaque characteristics [20]. Moreover, we found that periprocedural strokes and TIAs occurred more frequently in patients with pre-stenting balloon dilatation. This finding is consistent with the carotid acculink/accunet post-approval trial (CAPTURE Gray et al.,) [21] that found pre-stenting balloon without the use of (CPD) was associated with higher stroke rates in the first 30-days of stenting. In addition, in the current study, the frequency of periprocedural vascular events was higher with open-cell design than closed-cell design, in agreement with a multicenter study reporting higher 30-day stroke rates in open-cell versus closed-cell design (1.3% versus 3.4%) [22]. However, Jim and his colleagues found that there was no significant difference in outcomes after CAS using open or closed stent cell design [23]. In addition, a randomized controlled trial including 40 patients with CAS using either closed-cell design or open-cell design stents found no significant difference in embolization events detected by DWI-MRI and TCD [24]. This may be due to the free cell area in the closed-cell design stent being less than the open-cell [25]. The present study is limited by the relatively short follow-up period. Another point to be considered is whether the presence of diabetes affects the result? So more research to evaluate the effect of diabetes is needed.

5. Conclusions

In conclusion, this study recognizes endovascular management as a feasible, effective and safe process in the treatment of CAS in symptomatic and asymptomatic patients, with a low periprocedural risk of stroke or death. Furthermore, the risk of future stroke and rate of significant restenosis during mid-term follow-up appears to be low, suggesting that ICA stenting is useful in carotid revascularization and stroke prevention.

Declaration of Conflicting Interests

All the authors do not have any possible conflicts of interest.

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