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Carotid Artery Stenting: A Single-Center Experience of a Tertiary Care Hospital

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Abstract

Background: Carotid artery stenting (CASt) is a method of carotid revascularization, which has developed rapidly over the last 3 decades. CASt now used as an alternative to endarterectomise. Although excellent results from centres with high-volume experience seem to demonstrate CASt as technically feasible and safe, there is an on-going debate about the complications in terms of early outcomes in patients.

Methods: This study was a retrospective study on patients diagnosed with carotid artery stenosis (CASs). The data collected from Jan 2011 to Dec 2019. The patient data screened for inclusion in the study based on findings from contrast angiography. Primary complications to be assessed were major or minor embolic stroke, cardiac arrest, and death within 30 days of the procedure. Minor stroke, myocardial infarction, acute hypotension and bradycardia, no cerebral bleeding, access-site bleeding was considered secondary outcomes.

Results: A total of 77 patients were included in the study with a mean age of 74.4 ± 11.3 years. The technical procedure of CASt was 100% successful for all the patients. Overall post-procedural stroke rate at 30 days was 7.7% (six out of 77). One (1.3%) patient died due to cardiac arrest. There were two cases (2.6%) of acute hypotension and Bradycardiac and one case (1.3%) of Access-site bleeding within 30 days of stent implantation. Comorbid conditions were not significantly ($p>0.05$) associated with the post- procedural complications in CASt.

Conclusion: In this study, we found that CASt is the most reliable technique for CASs and appears feasible and comparatively safe with least post-procedural complications.

However, advanced techniques are required to further reduce the death/stroke rate within 30 days of stent implantation.

Keywords: Carotid Artery Diseases, Carotid stenosis, Stroke, Risk factor, Atherosclerosis

Abbreviations: CVDs: Cerebrovascular Diseases; CASt: Carotid Artery Stenting; CASs: Carotid Artery Stenosis; IHD: Ischemic Heart Diseases

Introduction

Cerebrovascular diseases (CVDs) are the primary cause of neurological and physical impairment and death in adults. The USA alone reported that cerebrovascular diseases are the fifth most common cause of death with a stroke rate of ≈ 795,000/year. CVD is also the third prominent cause of death in Korea; 48.2 persons per 100,000 die from CVDs every year [1]. Ischemic strokes are the most common strokes, occurring from atherosclerotic CASs. CASs observed is about 0.5% in 60–79 years old, whereas 10% in 80 years old and over. [2]. In the CVDs the morbidity and mortality of stroke remain high worldwide. Stroke is the fourth leading cause of death and the number one cause of long-term disability. Ischemic strokes are mostly caused by carotid stenosis, which accounts for 20 to 25% cases [3].

Effective treatment strategies targeting stenosis of the carotid artery is of importance for prohibiting the progression of cognitive dysfunction in patients with ischemic cerebrovascular disease [4]. During the past decade, the rapid improvement in interventional technology and materials has transformed a technique initially developed as a palliative treatment in inoperable patients into an alternative therapeutic option to surgery [5]. Nowadays, CASt has become an option for treatment with fewer invasions. Furthermore, CASt has been regarded as a reliable approach with lower risks of myocardial infarction, cranial nerve palsy, and access site hematoma [6].

Despite significant improvement in equipment and the techniques used during CASt, as well as improved operator experience, complications still occur. A significant proportion of these events are peri-procedural complications that result in catastrophic Events such as stroke or death [7]. Rapid evaluation of these complications are crucial for good patient outcomes. Thus, in our study, we investigated the potential risk factors and complications following stenting treatment.

Methodology

Patient selection

This study was a retrospective study on patients diagnosed with CASs at Prince Sultan Military Medical City, a tertiary care hospital in Riyadh, Saudi Arabia. The data was collected from Jan 2011 and up to Dec 2019. The study was reviewed and approved by the IRB/REC of Prince Sultan Military Medical City. The patient data were screened for inclusion in the study based on findings from contrast angiography. The cases to be included in this study were of CASs, which can be defined as >50% occlusion of the carotid artery detected at any stage during the screening or follow-up. Therefore, stenosis of more than 50% on digital subtraction angiography and more than 70% on computed tomographic

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angiography was considered as the inclusion criteria. In contrast, the presence of comorbid conditions like myocardial infarction within 30 days, chronic atrial fibrillation, paroxysmal atrial fibrillation within six months, and unstable angina within six months were considered as the exclusion criteria for the study.

Procedure for carotid artery stenting

The experts examined the neck and brain vessels for all the patients through computed tomographic angiography, and magnetic resonance angiography imaging before conducting the CASt. The magnitude of vessel stenosis was assessed with its Length as well as location. The stenting process was carried out by an expert neuroradiology intervention list with an ideal catheter sheath, which was inserted through Salinger puncture of the right femoral artery. Afterward, the contrast medium was repeatedly injected via the catheter to evaluate carotid artery stenosis. Additionally, a guiding catheter was advanced towards the common carotid artery. The stent implantation was facilitated by the formation of a protective umbrella and later released following a pre-expanded balloon positioned at the desired site. Hereafter, the carotid stent was implanted and released at the carotid artery's stenosis segment. Immediate angiography was conducted following the removal of safety devices to ensure no extravasation of the contrast agent and no remaining stenosis of the artery.

Follow-up events and complications

Primary complications to be assessed were major embolic stroke, cardiac arrest, and death within 30 days of the procedure. Minor stroke, myocardial infarction, acute hypotension and bradycardia, non-cerebral bleeding, access-site bleeding were considered secondary outcomes. Here, stroke can be defined as an acute neurologic event lasting for more than one day with a diagnosis of focal cerebral ischemia. Myocardial infarction can be defined as an increase of a troponin or creatinine kinase level in addition to symptoms that are consistent with electrocardiographic evidence of ischemia. Mainly computed tomographic angiography was analysed for postoperative complications.

Statistical analysis

All data were analysed using SPSS Statistics software (IBM Corp., NY, and USA). All missing variables coded and omitted from the final analysis. Baseline variables summarized with the use of descriptive statistics. Categorical variables summarized as counts, percentages, and assessed with Chi-square and Fischer's exact analysis.

Results

Based on the inclusion and exclusion criteria of the study, the data of 77 patients with internal CASs were selected for further analysis. The CASt for these patients was performed between Jan 2011 to Dec 2019 by using an embolic protection device. The presence of CASs in all the patients was confirmed by the CTA, or angiography of magnetic resonance. All the patients underwent clinical pre-procedural tests, conducted by a neurologist and they had given written informed consent for the procedure and routine follow-up examinations. The study population consisted of 58 men (75.3%) and 19 women (24.7%) with a mean age of 74.37 ± 11.3 years with a range of 47-101 years. To determine the prevalence of CASt in different age groups, we divided the patient into five subgroups (Table 1). Maximum number of CASt procedures were performed in the patients with an age group of 70-80 years i.e. 27 (35.1%) followed by the group with more than 80 years of age with slightly lowercases as 25 (32.5%) of total cases. The lowest number of cases were observed in the 40-50 and 50-60 years category with four cases in each group, which was the lowest in all groups with a portion of 10.2% of total cases. However, the group with 60-70 years of age was observed to be having 22.1% prevalence, with an overall 17 cases of CASt.

Most of the study subjects were having risk factors like diabetes, hypertension, and ischemic heart diseases (IHD). Twenty-six (33.7%) patients reported being suffering from diabetes and hypertension. Whereas, 20 subjects (25.9%) were having all three risk factors including diabetes, hypertension and ischemic heart disease. Amongst all the study subjects, 25 (32.5%) were >80 years of age and were at high surgical risk; 12 (15.6%) suffered from diabetes and IHD; seven (9.1%) had hypertension and six (7.8%) patients had hypertension altogether with IHD. Whereas, the rest of the five (6.5) subjects were without any comorbid medical condition (Table 1).

In our centre, we achieved successful CASt implantation in each patient. The observed mean duration of the stenting procedure was found to be 30.2 ± 8.4 minutes. The mean duration from the recent event to the treatment was found to be 14.3 ± 5.2 days, whereas, average in-hospital stay was 6.2 days. Length of the lesion and Stenosis was assessed intraoperatively utilizing angiography. Patients were followed for 30 days from the date of procedure for any kind of clinical manifestations and these are summarized in (Table 2).

Over the follow-up period of 30 days, six patients (7.7%) demonstrated major stroke after the procedure, which was successfully managed by the expert team. One patient Died after the procedure due to cardiac

Age (years)	
Mean (±SD)	74.4 (11.3)
Range	47-101
Gender	
Male	58 (75.3)
Female	19 (24.7)
Age groups	4 (5.1)
40-50	4 (5.1)
51-60	17 (22.1)
61-70	27 (35.1)
71-80	
>80	25 (32.5)
Medical history	(1.3)
Diabetes 1	
Diabetes and hypertension	26 (33.7)
Diabetes, hypertension and IHD	20 (25.9)
Diabetes, IHD	12 (15.6)
Hypertension	7 (9.1)
Hypertension, IHD	6 (7.8)
Medically free (No comorbid conditions)	5 (6.5)
Values presented as n (%) IHD, Ischemic heart diseases	

Table 1: Baseline demographics and clinical characteristics of the study population.

Major stroke	6 (7.7)
Minor stroke	0
Myocardial infarction	0
Cardiac arrest and death	1 (1.3)
Acute hypotension and bradycardia	2 (2.6)
Noncerebral bleeding	0
Access-site bleeding	1 (1.3)
Other complications	0
Values presented as n	(%)

Table 2: Post procedural complications/follow up events within 30 days in study population.

arrest, so the overall mortality rate was 1.3%. There were two cases of acute hypotension and bradycardia but they recovered completely. None of the patients experienced minor stroke, myocardial infarction and non-cerebral bleeding. Whereas, one patient (1.3%) experienced access site bleeding, which was absolutely manageable? Upon statistical calculations, no significant association was found between the risk factors and 30 days follow-up outcomes as the value of $p>0.05$ for age, gender and pre-existing risk factors.

Discussion

Carotid stenosis primarily caused by carotid atherosclerosis, and in recent reports, several risk factors identified for carotid atherosclerosis. [8] CASt has gain popularity as an alternative treatment to the other invasive techniques and provides long-term relief and patient satisfaction. Inclusive scrutiny of the literature demonstrates that the risk of stroke or death following CASt amplified in patients with symptomatic stenosis [4]. In our study, the technical success rate was found to be 100%, which was in agreement with the previously published reports [9]. Although the patient included in the study were having many comorbidities. However, there was only one death reported during the follow-up period of 30 days due to cardiac arrest. None of the subjects in our study were excluded due to comorbid conditions, although 32.5% of patients had an age of >80 years, which is considered high risk for surgery.

Out of 77 procedures, the overall intra and post-procedural complications rate for major stroke and death was only 9%. The 49.4% patient population involved in the study had IHD, even though we did not observe any case of myocardial infarction and Positively, we had a lower percentage of stroke/death. Our results are in agreement with the study done by Meng et al. (2019) [4], where they studied the CASt in patients with high-risk factors like old age and stroke history. During the post-procedural 30 days follow-up period, they reported a lower procedure-related complication and a stroke rate of 6.1% in the study population, which was a little lower in comparison to our study. The reason we observed the higher stroke rate might be due to the around 50% of the patients were in the high-risk category for surgery. However, they reported no death due to cardiac arrest but myocardial infarction at a rate of 3%. In another study by Kessler et al. (2013) [10], they reported the data of CASt of 55 patients with symptomatic CASs for death or stroke within 30 days of the procedure. They demonstrated a peri-procedural stroke/death rate of 5.4% at 30 days. Our results are more comparable with the most discussed trial in this regard; the EVA-3S randomized trial, which showed a CASt stroke/death rate of 9.6% at 30 days [2].

Furthermore, our result showed a little higher percentage of death/stroke in comparison to SAPPHIER trial [11], which was performed on 156 patients with CASt by using cerebral protection devices. Patients treated with CASt demonstrated a death/stroke rate of 4.5%. The lower prevalence of death/stroke rate in SAPPHIER trial may be explained based on the fact that these studies excluded the patients with contralateral carotid occlusions, age >80 years, or the presence of cardiovascular comorbidities. In our study, we found little higher adverse events/follow-up events (13%) due to the number of reasons including; 32.5% of patients with an age of >80 years, 49.4% with IHD/CVS. It is evident from the literature that the age of >70 years, cardiovascular diseases, plaque ulceration, type-C lesion are the independent predictors of follow-up Complications after CASt [9]. The patients with the contralateral involvements are considered high-risk patients, and therefore, utmost precaution should be taken when dealing with these patients.

In addition to this, the operator's experience also plays a role in procedural success and follow-up complications resulting from CASt. Published reports demonstrate that canters with less number of interventions reported higher stroke/death rate as a follow- up complications. Whereas, canters with a higher number of interventions reported lower stroke/death rate [12]. In our study, we observed the mean duration of the stenting procedure as 30.2 ± 8.4 minutes, which was in agreement with other published studies. The duration of stenting procedure significantly related to the operator's experience as a randomized trial showed a significant reduction in procedure time and contrast volume with an increase in the operator's experience.

Antiplatelet therapy is peri procedural requirement for CASt, even though we observed only one case (1.3%) of access site bleeding, which is significantly lower from other published reports [4]. Patients of diabetes considered high-risk patients for any kind of surgery and in the case of CASt; diabetic neuropathy is a very common per procedural complication [13]. However, in this study, we had almost more than 50% of the patient with diabetes, but we observed an acceptable incidence of diabetic neuropathy. Previous studies suggested that post-procedural complications are generally associated with patient's risk factors/comorbid conditions like male sex, smoking, and hyperlipidaemia [4]. Whereas, hypertension diabetes mellitus and peripheral vascular disease are not having a significant association with post-procedural complications. We also observed the same finding that pre-existing risk factors like diabetes, Hypertension and IHD were not significantly ($p>0.05$) associated with the 30 days post- procedural outcomes. However, we cannot draw a significant conclusion by this study as it is having limitations of small size, single cantered population, and thus have low statistical power. More extensive and prospective studies warranted to draw some conclusions.

Conclusion

In this study, the CASt was performed in 77 patients and our center achieved good technical success and relatively acceptable post-procedural complications. Despite performing CASt in high-risk groups, the overall stroke rate was 7.7%, while the death rate was 1.3%. There was no significant association between risk factors and post-procedural complications, which may be due to small sample size and single-centre experience. The data from this study may help medical professionals to plan and carry out CASt in target patients.

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