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Short-Term Outcome of Tapered Carotid Stent for Carotid Stenosis: A Single-Center Experience

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Abstract

Objectives— The aim of this study is to report a single-center experience on the use of the tapered carotid stent in patients undergoing the carotid artery stenting.

Methodology— Carotid artery stenting was performed in 82 patients (male: 84.1%; age: 73.7±11.3 years) using tapered carotid stent in Taiwan. Data on demographic and procedural characteristics, postoperative complications, and patency were analyzed. The result in terms of 30-day mortality served as the primary endpoint, whereas the patency of the tapered carotid stent served as secondary.

Results— A 30-day mortality was observed in 2.4% of the patients while a stroke within a year after the procedure was experienced by 3.6%. One-year patency of the tapered carotid stent was observed in all 82 patients (100%) and at 3-years in all 65 patients who were followed up. In addition, the mean stroke-free survival time after CAS was estimated to be approximately 3.61 years. The 95% confidence interval (CI) for the mean survival time ranged from 7.835 to 8.691 years. The probabilities of stroke-free survival at 1, 3, 5, and 8 years were 94.8% (95% CI: 89.9–99.9%), 91.1% (95% CI: 84.5–98.3%), 88.5% (95% CI: 80.5–90.3%), and 88.5% (95% CI: 80.5–90.3%), respectively.

Conclusion— The tapered carotid stent provides optimal patency at 1 and 3 years. The mortality rate at 30days, 1-year, and the post-operative stroke rate at the 1-year follow-up were minimal. However, further long-term investigations are required on the patency, mortality, and stroke rate after the CAS procedure with the tapered carotid stent.

Keywords— Carotid stenosis, mortality, stents, stroke, vascular patency.

Key messages —

- Tapered carotid stents like the XACT™, provide accurate sizing and crush resistance. However, real-world data on its effectiveness, durability, and patency for the management of carotid artery stenosis is limited.
- This single center retrospective study found that the tapered carotid stent resulted in 100% 1-year and 3-year patency in patients who were followed up, low 30-day mortality (2.4%), and low 1-year stroke incidence (3.6%).
- This study supports the use of tapered carotid stents for the management of CAS, due to their optimal patency and minimal incidence of 30-day and 1-year mortality. The findings warrant further multicenter, comparative, and longer-duration studies to validate these results.

INTRODUCTION

Stroke is the second leading cause of death and accounts for 11% of the total deaths worldwide.[1] A recent comprehensive study on ischemic stroke (IS) reported that the global number of IS-related deaths increased from 2.04 million to 3.29 million between 1990 and 2019 and is expected to increase further to 4.90 million by 2030.[2] In Taiwan, the prevalence of stroke ranges from 2.3% to 3%. Male gender and older age groups are associated with a higher prevalence rate compared to females and younger age groups.[3] A systematic analysis of the global burden of diseases reported a disability-adjusted life years (DALY) of 0.35 million in 2019 with a change of 65.3% in the age-standardized DALY from 1990 to 2019.[4] This situation is of concern as it causes a significant burden due to the associated disability and post-stroke depression,

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thereby hampering the quality of life (QoL) of the patients and their caregivers.[5]

Lifestyle modification with adequate exercise, a Mediterranean diet, and cessation of adverse habits; pharmacotherapy for controlling blood pressure, glucose, and lowering lipid level; and surgical reconstruction and endovascular interventions are the management options for patients with carotid artery stenosis.[6,7] However, a high stroke rate has been reported for patients with near occlusion/stenosis of the carotid artery who were treated only with the best medication for carotid stenosis.[8] Carotid endarterectomy (CEA) and carotid artery stenting (CAS) are established treatments that reduce the risk of reoccurrence of stroke.[9] While CEA is a surgical procedure for the removal of plaque from the carotid arteries, CAS is a minimally invasive technique that uses a stent for carotid revascularization.[10,11] CAS, which is generally performed using a stent, is considered effective and is associated with a lower risk of hematoma (odds ratio (OR) of 0.32), myocardial infarction (OR of 0.47), and cranial nerve palsy (OR of 0.09) as compared to CEA.[12] Further investigation is required to determine the long-term efficacy of carotid stents with respect to stent occlusion and patency. XACTTM carotid stent is a nitinol construction available in straight and tapered designs to provide accurate sizing and exceptional crush resistance. The stent has a unique variable cell size that provides improved stent coverage and minimizes plaque extrusion.[13] However, there is limited data on the efficacy, durability, and patency of the use of the tapered carotid stent in the management of carotid artery stenosis. Thus, investigations considering real-world patient information about the outcomes of post procedural mortality and patency of the tapered carotid stent can contribute to the knowledge base of its safety and effectiveness. In this view, the present study aims at providing a single-center experience of retrospectively investigated data on mortality at 30 days and patency at 3 years with the use of the tapered carotid stent (XACTTM) among patients with carotid stenosis.

METHODOLOGY

Study design and patient selection

This was a single-center retrospective study conducted among 82 patients after obtaining approval from the Taipei Veterans General Hospital Institutional Review Board (IRB). The study was conducted in the Division of Cardiovascular Surgery, Department of Surgery, Taipei Veterans General Hospital, Taiwan, from January 2014 to September 2020, for 6 years and 8 months. During this period, all patients who underwent the CAS procedure and received tapered carotid stent of the Abbott XACTTM Carotid Stent System, Park IL, United States.[13] for the management of carotid stenosis were included in the study while patients with restenosis, radiation-induced stenosis, aneurysms, isolated common carotid artery stenosis, tandem stenosis proximal to the carotid bifurcation, and those who received carotid stents other than the tapered type were excluded from the study. Patients with restenosis were excluded to minimize the chances of any biases in the assessment of the effectiveness of the XACT stent treatment.

Data Collection

Data regarding demographic and clinical characteristics such as age, gender, medical history, risk factors; surgical characteristics; postoperative complications (mortality rate); patency up to 3 years; and follow-up data regarding carotid sonogram, computed tomography angiography of the head and neck, or magnetic resonance angiography of the brain were collected and reviewed for the included patients.

Outcome parameters

Postoperative complications such as 30-day mortality and its causes were the primary endpoints whereas evaluation of the patency of the tapered carotid stent at 1 and 3 years of follow-up after the CAS procedure were the secondary endpoints.

Statistical analysis

A descriptive statistical analysis was performed using MedCalc statistical software. The data was presented in the form of frequencies and percentages for all the categorical variables. The stroke-free survival analysis was carried out using Kaplan-Meier statistics.

RESULTS

All 82 patients successfully underwent the CAS procedure using a tapered carotid stent. The demographic characteristics of patients are presented in Table 1. Of the total patients, there were 69 patients (84.1%). The mean age and body mass index (BMI) of the study participants were 73.7±11.3 years and 22.7±4.3, respectively. The medical history of the patients revealed that the study population comprised 29 (35.3%) patients with stroke of which 11 (37.9%) patients had a disabling stroke, and 18 (62.1%) patients had a non-disabling stroke.

Analysis of the clinical parameters revealed that the majority of the study population (81%) was clinically diagnosed with hypertension. A total of 18 patients (22%) were suffering from end-stage renal disease (ESRD). In addition to hypertension and ESRD, patients also presented with other comorbidities such as hyperlipidemia, type 2 diabetes, coronary artery disease (CAD), and peripheral artery disease (PAD) and had an adverse habit of smoking.

The surgical characteristics of the patients (n=82) are represented in Table 2. Pre-dilation was performed among 21 (26%) patients whereas post-dilation was performed in 63 (77%) patients. Intraoperative bradycardia was reported in 24 (29%) patients whereas 32 (39%) patients had undergone concomitant surgical procedures, including thoracic aortic aneurysm (TAA), abdominal aortic aneurysm (AAA), peripheral arterial occlusive disease percutaneous transluminal angioplasty (PAOD PTA), and coronary artery bypass graft (CABG) surgeries. Dual antiplatelet therapy with clopidogrel and aspirin was prescribed within 24 hours of stent implantation and patients were instructed to take the daily medications lifelong.

Details of the postoperative complications and patency are presented in Table 3. The average number of hospitalization days was 17, whereas days in the ICU were 1.63 days. Exposure to the dopamine pump was given for 0.2 days. Four patients experienced postoperative stroke within 3 year of CAS. No interventions were performed in the acute and

TABLE 1: Patient demographics and clinical characteristics of the study population (n=82)

DEMOGRAPHICS	
Male, n (%)	69 (84.1%)
Age in years (mean±SD)	73.7±11.3
BMI (mean±SD)	22.7±4.3
CLINICAL CHARACTERISTICS / MEDICAL HISTORY	n (%)
Stroke (disabling)	11 (13)
Stroke (non-disabling)	18 (22)
Smoking	51 (62)
Hypertension	67 (81)
Hyperlipidemia	21 (26)
Type 2 diabetes mellitus	45 (54)
CAD	57 (69)
PAD	39 (47)
ESRD	18 (22)

BMI: Body mass index; CAD: Coronary artery disease; PAD: Peripheral artery disease; ESRD: End-stage renal disease.

TABLE 2: Surgical characteristics of the study population (n=82)

SURGICAL CHARACTERISTICS	N (%)
Pre-dilatation	21 (26)
Post-dilatation	63 (77)
Stent type	XACT™
Bradycardia	24 (29)
Concomitant procedure (TAA, AAA, PAOD PTA, CABG)	32 (39)

AAA: Abdominal aortic aneurysm; CABG: Coronary artery bypass graft; PAOD PTA: Peripheral arterial occlusive disease percutaneous transluminal angioplasty; TAA: Thoracic aortic aneurysm.

TABLE 3: Postoperative complications and patency (1 year and 3 years)

DETAILS	Average (Min–Max, %)
Hospitalization (days)	17 (3–132)
ICU (days)	1.63(1–16)
Dopamine pump (days)	0.2
Stroke*	3 (3.6)
Disabling	2 (2.4)
Non-disabling	1 (1.25)
30-day mortality (MI, SAH)	2 (2.4)
Total mortality*	8 (9.75)
Acute limb ischemia	3 (3.6)
Pneumonia	2 (2.4)
Cancer	1 (1.25)
MI	1 (1.25)
SAH	1 (1.25)
PATENCY	
1-year patency	82/82
3-year patency#	65/65

17 patients lost to follow-up

*Occurrence within 1 year after the patients received the tapered carotid stent

MI: Myocardial infarction; SAH: Subarachnoid hemorrhage.

subacute stroke period; interventions were only performed in the chronic stroke period (>6months). Of these, two patients suffered a disabling stroke and one suffered a non-disabling stroke (details provided in supplementary information 1). The mean stroke-free survival time after CAS was estimated to be approximately 3.61 years (Figure 1). The 95% confidence interval for the mean survival time ranged from 7.835 to 8.691 years. The probabilities of stroke-free survival at 1, 3, 5, and 8 years were 94.8% (95% Confidence Interval [CI]: 89.9–99.9%), 91.1% (95% CI: 84.5–98.3%), 88.5% (95% CI: 80.5–90.3%), and 88.5% (95% CI: 80.5–90.3%), respectively.

Mortality within one year was observed in 8 (9.75%) study patients. However, 30-day mortality was observed in 2 (2.4%) patients due to myocardial infarction (MI) (n=1) and subarachnoid hemorrhage (SAH) (n=1). The majority of the cases with mortality within 1 year were due to acute limb ischemia (n=3), followed by pneumonia (n=2). The remaining three causes of death were due to cancer (n=1), MI (n=1), and SAH (n=1). One-year patency of the tapered carotid stent was observed in all 82 (100%) study patients. By three years, 17 patients were lost to follow-up, leaving 65 patients for analysis. The 3-year patency of the tapered carotid stent was observed in all 65 (100%) patients who could be followed up.

DISCUSSION

Coronary artery diseases cause a significant economic and healthcare burden. The rupture or the erosion of plaque in the blood vessel leads to a cascade of hemodynamic events, such as the activation of the coagulation cascade and platelets, thereby causing thrombotic occlusion.[14] The estimated prevalence of carotid artery stenosis in ischemic stroke patients ranges from 15% to 20%.[15] The CAS and CEA are established procedures for the prevention of stroke associated with carotid artery stenosis.[9,16] The CAS procedure was highlighted as an alternative to CEA in 1994 and has now gained parity in the field of carotid surgery.[17] The mortality rate and the occurrence of recurrent neurological events such as stroke are the two key indicators of the short-term success of CAS procedures.[18] The present single-center retrospective study with a short follow-up highlights three major successful findings on the CAS procedure using the tapered carotid stent. Firstly, the tapered carotid stent had a patency of 3 years. Secondly, it was observed that 30-day mortality in patients was minimal at 2.4% and thirdly, the occurrence of stroke within 1 year of the CAS procedure was minimal at 3.6%.

The findings on patency from this study report that a 1-year patency was observed in all the patients (100%) and a 3-year patency was observed in all 65 patients who could be successfully followed up. The results of this study are in accordance with the study by Allard J et al. wherein vessel patency at 24 hours after the CAS procedure was observed in 79.1% of patients and 1 in every 5 patients presented with stent occlusion.[19] A cumulative incidence of >70% in-stent restenosis after the CAS procedure was reported to be 7.39%, whereas >50% restenosis at 1 year was reported to be 18.21%.[20] Similarly, the CAS procedure also presented a significantly lower risk of carotid artery restenosis (considered if >60% or >70% stenosis was present) at a 28-month follow-up following CEA.[21] Loss of patency or restenosis plays a major role in determining the long-term efficacy of the CAS procedure. The presence of residual stenosis (influenced by the morphology of the atherosclerotic plaque and type of carotid stent used) and the deployment of multiple stents during CAS are independent predictors of restenosis, whereas the presence of comorbidities such as diabetes or cancer are the suggestive predictors of restenosis.[22,23]

Furthermore, 30-day mortality was observed in only 2.4% of the study population after receiving the tapered carotid stent; cardio-cerebrovascular-related death accounted for both cases. One-year mortality was observed in a total of 8 patients (9.75%), of which non-cardiac death accounted for 75% of the mortality. Stroke severity and mortality have previously been shown to be significantly associated with MI and SAH.[24] The mortality rate observed in this study is in line with the reported all-cause mortality rate at 30 days after the CAS procedure, which ranged between 0% and 1.3%.[18] Despite being a real-world study in which the presence of diverse patient characteristics (presence of multiple comorbidities) may lead to a higher mortality rate,[25,26] the rate observed in this study was lower than the rates of 5.1% reported at 1 year, 17.5% at 4 years, and 31.4% reported at a median follow-up of 7.6 years.[27] Similarly, 5.3 deaths per 100 patient-years and 7.8 deaths per 100 patient-years were reported for CAS of single and double vessels, respectively, at a long-term follow-up of 6.1 years, indicating the worst survival after the procedure.[25] However, the findings on mortality contrast with the findings of a study that compared CAS and CEA procedures in a population of 314 patients and reported that no mortality was observed with either of the procedures.[9]

The occurrence of stroke within 1 year of the CAS procedure was observed in 3 patients (3.6%) of this study population. A study reported an association between carotid stenosis and a high risk of ischemic stroke among patients with carotid stenosis of ≥50%.[28] The results of the occurrence of stroke in this study with the use of the tapered carotid stent are in line with the literature reporting a stroke rate at 30 days after CAS, which ranges between 0% and 9.8%.[18] Freedom from stroke for any reason at 5 years after the CAS procedure was estimated to be 93.2% in patients above 80 years of age.[29] Various predictors of the occurrence of stroke after the CAS procedure are reported in the literature. Age (above 80 years), sex (females), indication (symptomatic patients), time of conducting CAS procedure, and the presence of chronic kidney disease are the clinical predictors; the ostial location and lesion location (stenosis in left carotid artery), aortic arch type (type III), lesion length (longer lesions), calcification at the site, carotid stenosis severity, hemodynamic instability are the anatomical and physiological predictors, whereas stent type (open cell), number of stents (multiple stents), absence of embolic protection devices, amount of residual stenosis (≥30% stenosis), use of medications (IIb and IIIa glycoprotein inhibitors), and surgeon's experience are the technical predictors of stroke post-CAS procedure.[30] The probabilities of stroke-free survival at 1 and 5 years were 94.8% and 88.5%, respectively, which are similar to, but higher than those reported in a study by Hajiyev et al.[31] (91.6% at 1 year and 77.1% at 5 years), which examined the long-term outcomes (up to 12 years) of carotid artery stenting. One reason for this could be that the current study only included 82 patients, whereas the study by Hajiyev et al. included

FIGURE 1: Kaplan-meier curve showing the mean stroke-free survival of patients after cas

1158 patients.[31] Another study on the use of tapered and non-tapered stents in managing carotid artery stenosis reported the probability of stroke-free survival at 6 years as 99.2% and 96.2%, indicating that tapered stents may be slightly better at reducing stroke recurrence than straight stents.[32]

A lower rate of stroke in this study can be attributed to the fact that a majority of the patients had single stents, the study population was predominantly male (84%), and the mean age of the patients was less than 80 years. This observation on patient demographics is consistent with earlier research, in which the majority of the participants were men of a comparable age range.[9] It should be noted that patients who require CAS are usually around the age of 70 years.[9,33,34] It is estimated that the life expectancy (the remaining number of years a person is expected to live before death) at this age is between 13.59 years to 15.82 years.[35] This indicates that information on the patency of stents for long follow-up periods is important to determine the success of the CAS procedure to cover these years of life expectancy. Though studies on other carotid stents have been reported with longer follow-up,[27,29] the studies specific to tapered carotid stents reported so far include follow-up periods of 24 hours, 30 days, and 6 months.[19,36] Consequently, longer follow-up studies are needed to better estimate the patency of CAS procedures.[33] Thus, the strength of this study is the three-year follow-up period. This study provides information on the patency of the carotid artery stent for up to 3 years in the real world in patients with a medical history of comorbidities and concomitant procedures performed.

Bradycardia, a hemodynamic instability, is reported as the most common minor complication after a CAS procedure, with the rate of incidence ranging from 5% to 75%.[37,38] This phenomenon is attributed to the baroreceptor reflex that is caused by direct compression of the carotid bulb during the process of stenting and balloon angioplasty. Although it is a self-limiting and transient condition, a few cases may present with a severe response, leading to neurological and cardiopulmonary events, an increased risk of hospital complications, and mortality in the long term.[37] Among the 82 patients in this study, bradycardia was observed in 29% of the study population, which is within the range reported by Choi J et al. Additionally, a study reported bradycardia as a minor complication in 9.2% of patients after the CAS procedure.[38]

The duration of hospital stay is associated with the post procedural complications of the CAS procedure.[39] The findings from this study indicate that the number of hospitalization days was a minimum of three days with an average of 17 days after the CAS procedure, whereas ICU days lasted for an average of 1.63 days. Liu et al, in their comparison study of tapered CAS vs. straight CAS, reported that patients undergoing tapered CAS experienced fewer postoperative complications such as hemodynamic depression, which resulted in a shorter hospital stay, compared to the patients operated with straight CAS.[36] It should be noted that the higher hospital stay days in this study can be attributed to patient characteristics. Apart from carotid artery stenosis, patients also had comorbidities such as hypertension, type 2 diabetes, hyperlipidemia, and end-stage renal disease, in addition to which, 32 out of 82 patients underwent concomitant procedures for lower limb peripheral arterial occlusive disease, abdominal aorta stent graft surgery, thoracic aorta stent graft surgery, coronary artery bypass surgery, and other interventions for peripheral arterial occlusive disease.

This study has a few limitations. Firstly, this was a single-center experience study with a retrospective approach. Thus, a multicenter study conducted across diverse patient populations of different ethnicities and countries with a larger sample size can contribute towards improved and more accurate results on the associated mortality and patency of the CAS procedure using the tapered carotid stent. Secondly, the follow-up period of the study was 3 years. A study with a longer follow-up could effectively estimate the patency of the tapered carotid stent. Thirdly, there was a loss in follow-up that could have affected the results of this study. Fourthly, there was no comparator group, therefore, a study design with the inclusion of a comparison of the tapered carotid stent with other stent designs for the CAS procedure may provide additional information on the effectiveness of the tapered carotid stent.

CONCLUSION

The tapered carotid stent has optimal patency at 1 year and 3 years following the CAS procedure. The 30-day and 1-year mortality of the patients after the CAS procedure using a tapered carotid stent was minimal at 2.4% and 9.75%, respectively. The post-operative complications observed were also minimal, indicating a low stroke risk with the use of a tapered carotid stent. However, further investigation on durability, patency, mortality, and post-operative complications with CAS procedures using tapered carotid stents with a larger sample and a longer follow-up period beyond 3 years is warranted. Additionally, comparative studies are required to ascertain the beneficial outcomes of tapered carotid stents over other carotid stents.

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SUPPLEMENTARY FILE 1:

Details of the three patients who suffered post operative stroke within one year (2 cases of disabling stroke, 1 case of non-disabling stroke):

Case 1: disabling stroke

The patient was a 74-year-old male with right internal carotid artery stenosis and right vertebral artery stenosis. Right carotid artery stent and right vertebral artery stent were implanted in the same surgery. His consciousness was clear after IVGA, however, there was a sudden change in consciousness 2 hours after surgery. Emergency CT scan showed diffuse SAH and IVH with midline shift. Extraventricular drainage and ICP monitor were inserted immediately. Angiography was suggested, however, the family refused. The patient passed away 12 days after the surgery.

Case 2: disabling stroke, left occipital artery

The patient was a 70-year-old male with right internal carotid artery stenosis. Right carotid artery stent was implanted. He went through surgery smoothly. Coronary artery bypass (CABG) and aortic valve replacement were performed on the next day. However general tonic clonic seizure attacked twice after CABG. Emergency CT showed left occipital area infarction. The patient recovered well after anti-convulsive medication treatment.

Case 3: non-disabling stroke, RMCA

The patient was a 73-year-old male with right internal carotid artery stenosis and peripheral arterial occlusive disease in the left leg. Right carotid artery stent implantation and percutaneous transluminal angioplasty of the left leg were performed during the same operation. He underwent bilateral below-knee amputation one month later and was discharged smoothly. However, he experienced acute left-side weakness four months later, and a CT scan revealed an acute right frontoparietal stroke.