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Research

Evaluating the Efficacy and Safety of Carotid Artery Stenting: A Retrospective Analysis

Karotis Arter Stentlemenin Etkinliği ve Güvenliğinin Değerlendirilmesi: Retrospektif Bir Analiz

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ABSTRACT

Objective: Stroke is the second leading cause of death and the third leading cause of disability globally, with carotid artery stenosis contributing to approximately 20% of cases. Carotid artery stenting (CAS) and carotid endarterectomy (CEA) are effective treatments to reduce stroke risk. While some studies report higher complication rates for CAS compared to CEA, others demonstrate comparable outcomes, emphasizing the importance of patient selection and procedural optimization. This study evaluates the real-world safety and effectiveness of CAS in 52 patients at a single institution.

Methods: This retrospective analysis included 52 patients who underwent CAS between 2020 and 2024. Inclusion criteria were ≥50% stenosis for symptomatic patients and >60% stenosis for asymptomatic ones. Dual antiplatelet therapy was initiated preoperatively, and distal filter embolic protection was used in all procedures. Neurological assessments and radiological imaging were performed pre- and post-procedure. Complications were categorized as periprocedural or post-procedural, and follow-ups were conducted at three, six, and twelve months.

Results: The cohort included 52 patients (78.8% symptomatic, mean stenosis rate: 80.3%±12.5%). Periprocedural ischemic stroke occurred in 5.8% of patients, and asymptomatic diffusion-restricted areas were detected in 34.6% of patients. One patient (2.2%) experienced symptomatic intracerebral hemorrhage. The overall periprocedural stroke and death rate was 7.7%.

Conclusion: CAS is a minimally invasive, effective option for treating carotid artery stenosis when patient selection and procedural protocols are optimized. Ongoing advancements in techniques and devices are anticipated to reduce complications further, supporting CAS as a safe alternative to CEA in selected patients.

Keywords: Carotid stenosis, carotid endarterectomy, stents, stroke

ÖZ

Amaç: İnme, dünya genelinde ölüm nedenleri arasında ikinci, sakatlık nedenleri arasında üçüncü sırada yer almakta olup, inme olgularının yaklaşık %20'sinden karotis arter darlığı sorumludur. Karotis arter stentleme (KAS) ve karotis endarterektomi (KEA), inme riskini azaltmada etkili tedavi yöntemleridir. Bazı çalışmalar, KAS'nin KEA'ya kıyasla daha yüksek komplikasyon oranlarına sahip olduğunu belirtirken, diğerleri benzer sonuçlar sunmakta ve hasta seçimi ile işlem optimizasyonunun önemini vurgulamaktadır. Bu çalışma, tek bir merkezde 52 hastada KAS'nin gerçek yaşam koşullarındaki güvenliği ve etkinliğini değerlendirmektedir.

Gereç ve Yöntem: Bu retrospektif analizde, 2020-2024 yılları arasında KAS uygulanan 52 hasta incelenmiştir. Dahil edilme kriterleri, semptomatik hastalar için ≥%50, asemptomatik hastalar için >%60 darlık olarak belirlenmiştir. İşlem öncesinde çift antiplatelet tedavi başlatılmış ve tüm işlemlerde distal filtre emboli koruma cihazı kullanılmıştır. İşlem öncesi ve sonrası nörolojik değerlendirmeler ve radyolojik görüntülemeler gerçekleştirilmiştir. Komplikasyonlar işlem sırasında ve erken dönemde ortaya çıkan ve işlem sonrası geç dönemde ortaya çıkan olarak sınıflandırılmış, takipler üçüncü, altıncı ve on ikinci aylarda yapılmıştır.

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ÖZ

Bulgular: Çalışmaya 52 hasta (%78,8 semptomatik, ortalama darlık oranı: %80,3±%12,5) dahil edilmiştir. İşlem sırasında ve erken dönemde iskemik inme %5,8 hastada görülmüş, asemptomatik difüzyon kısıtlı alanlar %34,6 hastada tespit edilmiştir. Bir hastada (%2,2) semptomatik intrakraniyal hemoraji meydana gelmiştir. Toplam işlem sırasında ve erken dönemde inme ve ölüm oranı %7,7 olarak bulunmuştur.

Sonuç: KAS, hasta seçimi ve protokoller optimize edildiğinde karotis arter darlığı tedavisinde minimal invaziv ve etkili bir seçenektir. Teknikler ve cihazlarda devam eden ilerlemelerle komplikasyon oranlarının daha da azalması beklenmekte, KAS'ın seçilmiş hastalarda KEA'ya güvenli bir alternatif olarak desteklenmesi gerektiği düşünülmektedir.

Anahtar Kelimeler: Karotis darlığı, karotis endarterektomi, stentler, inme

INTRODUCTION

Stroke is the second leading cause of death and the third leading cause of disability worldwide (1). Carotid artery stenosis is responsible for approximately 20% of all strokes (2). Carotid artery stenting (CAS) and carotid endarterectomy (CEA) are treatment modalities that have been shown to reduce the risk of stroke in both asymptomatic and symptomatic patients with carotid artery stenosis. Although several prospective studies, such as SPACE, EVA-3S, and ICSS (3-5), have reported higher complication rates for CAS compared with CEA, other studies, including SAPPHIRE, CREST, ACT I, and ACST-II (6-9), have demonstrated the non-inferiority of CAS with respect to composite primary outcomes, including stroke, myocardial infarction, and death. Case series from various regions of the world continue to be published, demonstrating the efficacy and low-risk profile of CAS (10-14).

There is still no clear consensus on the optimal treatment, primarily due to the variability in results among these studies. Differing outcomes are likely due to a lack of standardization in patient selection, procedural methods, and physician experience. Given these discrepancies, we believe that CAS is a valuable treatment option when patient selection is carefully individualized. To further assess the real-world outcomes of CAS, we performed CAS on 52 carefully selected patients at a single institution. This was done to evaluate the effectiveness and safety of CAS in a clinical setting.

METHODS

Study Design

We retrospectively analyzed the outcomes of CAS performed on 52 patients between 2020 and 2024 at a single institution. Written informed consent was obtained from all patients. The study was conducted in accordance with the rules of the Declaration of Helsinki and was approved by the Pamukkale University Non-Interventional Clinical Research Ethics Committee (approval no: E-60116787-020-617909, date: 02.12.2024).

Patient Selection

The study included both symptomatic and asymptomatic patients. Inclusion criteria were set at ≥50% stenosis for symptomatic cases and >60% stenosis for asymptomatic ones. Additionally, two patients who had prior unsuccessful CEA attempts were included. Symptomatic carotid artery stenosis was defined as the occurrence of a cerebrovascular event—such as stroke, transient ischemic attack, or amaurosis fugax—within 180 days prior to the procedure.

Procedural Details

Three neurosurgeons, each with at least five years' experience in carotid stenting and angioplasty, performed the procedures. For lesion evaluation, we used combinations of Doppler ultrasonography, magnetic resonance angiography (MRA), computed tomography (CT) angiography, and digital subtraction angiography (DSA).

Pre-procedural Preparation

Dual antiplatelet therapy with aspirin plus clopidogrel or ticagrelor was initiated at least five days before the procedure in all patients. The CAS procedures were performed using a transfemoral approach under local anesthesia.

Intra-procedural Management

After arterial sheath insertion, intravenous heparin was administered, and the activated clotting time was monitored. A minimum activated clotting time of 300 seconds was required to proceed with the intervention. Distal filter protection devices were used as the standard embolic protection method in all cases. Open-cell stents were deployed in 36 cases, and closed-cell stents were deployed in 16 cases.

Complications and Outcomes

Documented complications included retinal stroke, ischemic stroke, asymptomatic hyperintense lesions on diffusion-weighted imaging (DWI), in-stent plaque protrusion, hyperperfusion syndrome, symptomatic intracerebral hemorrhage, morbidity, and mortality. Periprocedural outcomes were defined as complications occurring during the procedure or within 30 days post-intervention, while

post-procedural outcomes were defined as complications occurring beyond 30 days.

Assessment Protocols

A comprehensive neurological examination was performed before the procedure, immediately after the intervention, and daily until discharge. The modified Rankin scale (mRS) was used to assess functional prognosis. Additionally, magnetic resonance imaging (including DWI, apparent diffusion coefficient, and fluid-attenuated inversion recovery sequences) and CT scans were conducted within 12-24 hours post-procedure to evaluate outcomes. All patients underwent MRA at three months and DSA at six months, with annual outpatient MRA follow-ups thereafter.

Definitions

Stroke was defined as a neurological deficit persisting for more than 24 hours, accompanied by corresponding hyperintensity on DWI. Minor morbidity was classified as a 1-point increase in the mRS score, while major morbidity was classified as a 2-point or greater increase. High-risk criteria, as defined in the SAPPHIRE study, include clinically significant cardiac disease, severe pulmonary disease, contralateral carotid occlusion, contralateral laryngeal nerve palsy, previous radical neck surgery or radiation therapy to the neck, recurrent stenosis after endarterectomy, and age over 80 years.

Statistical Analysis

All data were processed with SPSS Statistics, version 26 (IBM Corp., Armonk, NY, USA). Continuous variables are presented as mean±standard deviation when normally distributed (Shapiro-Wilk $p>0.05$) and as median with interquartile range when non-parametric. Categorical variables are summarised as counts and percentages.

The primary end-point was any stroke or death occurring during the procedure or within 30 days after the procedure. Secondary end-points were clinically silent DWI lesions, symptomatic intracerebral haemorrhage, hyperperfusion syndrome, and restenosis of greater than 50% on follow-up angiography.

Exploratory univariable logistic regression was applied to screen potential predictors of the primary end-point. Variables with $p<0.10$ were considered for inclusion in a forward stepwise multivariable model; however, only four primary events occurred and none reached statistical significance, so multivariable analysis was not feasible. Restenosis-free survival was illustrated with Kaplan-Meier curves. Two-sided $p<0.05$ was considered statistically significant for all planned analyses.

Owing to the modest sample size and low event rate, the statistical evaluation remains chiefly descriptive; effect estimates are reported with 95% confidence intervals when calculable, and results should be interpreted with caution.

RESULTS

The characteristics of the study populations and lesion details are summarized in Table 1. A total of 52 patients were included in the study, with 40 males and 12 females. Among these patients, 41 (78.8%) had symptomatic lesions. According to the SAPPHIRE study (6) criteria, 48% of the patients had at least one high-risk factor for CEA and the majority of these factors were related to clinically significant cardiac disease. The mean stenosis rate was 80.3%±12.5%. Five (9.6%) patients had stenosis in the contralateral internal carotid artery (ICA), and five (9.6%) had occlusion of the contralateral ICA.

Asymptomatic high-intensity areas on DWI were detected in 18 patients (34.6%). Symptomatic ischemic stroke occurred in three patients (5.8%). All three patients had symptomatic carotid stenosis, and one had a high-risk factor for CEA. In the first patient, plaque protrusion into the distal filter was observed during the procedure (Figure 1A). Following filter retrieval, the patient developed dysphasia, left-sided facial paralysis, and weakness of the left extremities. Occlusion of the superior trunk of the M2 segment of the right middle cerebral artery was identified (Figure 1B). Thrombectomy was performed using a stent retriever, resulting in successful vessel recanalization (Figure 1C). The patient achieved full recovery and was discharged asymptomatic.

The second patient presented with right-sided paresis affecting the upper and lower extremities prior to the procedure. Dysphasia occurred during the procedure. No significant vascular occlusion was observed on DSA. Post-procedural DWI revealed small, multifocal diffusion-restricted areas. The patient returned to their baseline neurological status within a two-week follow-up period.

The third patient developed dysphasia during the procedure. No significant vascular occlusion was observed on DSA. DWI demonstrated a diffusion-restricted area in the perfusion territory supplied by the distal branches of the callosomarginal artery. The patient was managed medically; the symptoms resolved completely within one week of follow-up.

One patient (2.2%) developed post-procedural confusion and left-sided hemiparesis. Brain CT revealed an intraparenchymal hematoma in the frontoparietal region. The patient was treated medically and discharged with an

mRS score of 2 after two weeks' follow-up. This patient had 99% carotid stenosis and multiple high-risk factors for CEA. Periprocedural complications are summarized in Table 2.

DISCUSSION

Carotid artery stenosis is one of the major risk factors for stroke. CEA is a well-established treatment method for carotid artery stenosis and has been performed since the 1950s (15). The surgical techniques for CEA are highly standardized, and their effectiveness and complication rates are well documented. In contrast, CAS is a relatively recent treatment that was first performed in the early 1990s. Its popularity has grown since the CAVATAS trial, the first large prospective, randomized trial published in 2001, which reported similar major complication rates but lower minor complication rates for CAS than for CEA (16). The results of CAVATAS were further supported by the SAPPHIRE trial (6,16) in 2004.

Since then, numerous studies have been conducted to compare these two treatment modalities and assess the effectiveness and complication rates of CAS. However, the results have been conflicting due to non-standardised techniques, evolving devices, variations in patient populations, and differences in physician's experience.

Historically, CEA was associated with high periprocedural complication rates, with early series reporting stroke and death rates approaching 20% (17). In contrast, contemporary studies have demonstrated significant improvements, with recent trials reporting 30-day stroke and death rates between 3% and 5.7% (18-20). By comparison, recent literature reports periprocedural stroke and death rates for CAS ranging from 2.1% to 8.2% (10-14).

In our study, we carefully selected patients based on their vascular-anatomical suitability for endovascular treatment, surgical risk profile, and patient preference. The periprocedural rate of stroke and death was 7.7%, which is at the higher end of the range reported in larger CAS studies. Although this rate exceeds the average reported for contemporary CEA, the limited sample size in our study may have contributed to reduced statistical reliability.

Table 1. Demographic data of the patients in the series

Age (years)	70.1±9
Gender (n, %)	
Male	40 (77)
Female	12 (23)
Symptomatic lesion (%, in 180 days)	41 (78.8)
Risk factors (n, %)	
Hypertension	36 (69.2)
Diabetes	27 (51.9)
Dyslipidemia	7 (13.5)
Smoker	3 (5.8)
Previous ischemic heart disease (n, %)	23 (44.2)
Previous peripheral artery disease (n, %)	2 (3.8)
High-risk factor for CEA-related complications (described in SAPPHIRE study) (n, %)	25 (48)
Clinically significant cardiac disease	23 (44.2)
Severe pulmonary disease	0 (0)
Contralateral carotid occlusion	5 (9.6)
Contralateral laryngeal-nerve palsy	0 (0)
Previous radical neck surgery or radiation therapy	1 (1.9)
Recurrent stenosis after endarterectomy	3 (5.8)
Age >80 years old	6 (11.5)
Previous CEA (n, %)	3 (5.8)
Contralateral stenosis (n, %)	5 (9.6)
Contralateral occlusion (n, %)	5 (9.6)
Stenosis rate in DSA (n, %) (NASCET)	80.3 (50-99)
Antiplatelet regimen (n, %)	
ASA+clopidogrel	39 (75)
ASA+ticagrelor	13 (25)
Pre-stent PTA (n, %)	24 (46.2)
Post-stent PTA (n, %)	33 (63.5)
Stent brand (n, %)	
Boston Scientific Wallstent™ (closed-cell)	16 (30.8)
Medtronic Protégé™ RX Stent (open-cell)	36 (69.2)

CEA: Carotid endarterectomy, PTA: Percutaneous transluminal angioplasty, ASA: Acetylsalicylic acid (aspirin), DSA: Digital subtraction angiography, NASCET: North American Symptomatic Carotid Endarterectomy Trial

Table 2. Periprocedural complications of patients

Periprocedural complications	**(n, %)**
Asymptomatic DWI high spot	18 (34.6)
Stroke symptomatic group	3 (5.8)
Retinal stroke	0
In-stent plaque protrusion	1
Hyperperfusion syndrome	0
Symptomatic ICH	1 (1.9)
Minor morbidity (mRS score of 1)	0
Major morbidity (mRS score of ≥2)	1 (1.9)
Restenosis or occlusion	0
Reintervention PTA	0
Reintervention restenting	0

The patient with symptomatic ICH was managed conservatively. Among the three patients with stroke, two were treated conservatively, while one underwent thrombectomy.
DWI: Diffusion-weighted imaging, ICH: Intracerebral hemorrhage, mRS: Modified Rankin scale, PTA: Percutaneous transluminal angioplasty

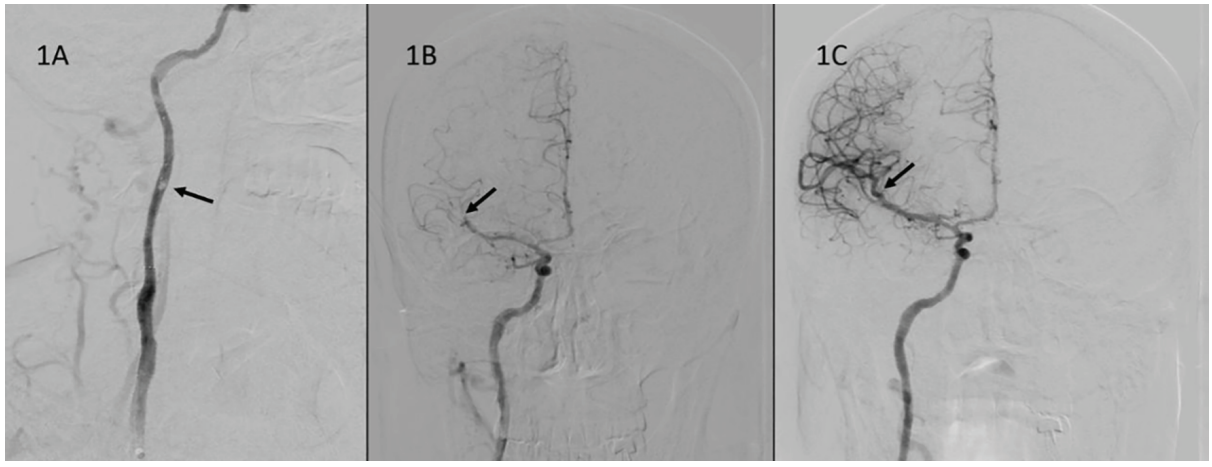

Figure 1. **1A)** Plaque protrusion is seen in distal filter after stent placement. **1B)** An occlusion of the superior trunk of the M2 segment. **1C)** Complete recanalization after successful thrombectomy. The patient achieved full recovery and was discharged asymptomatic

Notably, asymptomatic high-intensity areas on DWI were detected in 18 patients (34.6%). Although such diffusion-restricted lesions have been associated in the literature with an increased risk of future cerebrovascular events or cognitive impairment (21,22), we did not observe any related clinical manifestations in our cohort. This may be attributed to the relatively short follow-up period, which could have been insufficient to capture delayed or subtle effects.

Two major variables related to CAS devices are stent design and cerebral protection device design. Several studies have compared open-cell and closed-cell stents, but the findings remain controversial. In 2007, Bosiers et al. (23) reported that open-cell stents were associated with higher complication rates, particularly among symptomatic patients. However, a year later, Schillinger et al. (24) reported no significant difference in complication rates between open- and closed-cell stents. More recently, Faateh et al. (25) reported that closed-cell stents were associated with an increased risk of in-hospital stroke and death, especially for lesions located at the carotid bifurcation. They suggested that this might be due to the relatively low conformability of closed-cell stents in tortuous, diameter-mismatched bifurcation anatomy (25). In this study, we used open-cell stents in 36 procedures and closed-cell stents in 16 procedures.

The use of cerebral protection devices during CAS is strongly recommended, as CAS without these devices has been shown to be significantly associated with higher rates of periprocedural stroke and death (26,27). Although some studies suggest that proximal balloon occlusion is associated with lower complication rates than distal filter protection (28,29), larger studies have found that neither method is superior for periprocedural stroke and death rates (30,31). We did not perform balloon occlusion, but used distal filter protection in all cases.

Compared with CEA, CAS is less invasive and is typically performed under local anesthesia. Although concerns and debates remain about the complication rates of CAS compared with CEA, its minimally invasive nature makes it a preferable option, particularly for patients at high surgical risk. We believe that with careful patient selection and the appropriate choice of devices, CAS represents an effective and safe treatment option for stroke prevention.

It is important to recognize that CAS is still evolving, and as newer devices are developed, anatomical and technical challenges will likely be addressed, resulting in greater efficacy and reduced complication rates.

Study Limitations

This study is limited by a small patient cohort, which reduces statistical power and the precision of effect estimates. The limited number of events (n=4) precluded multivariable analysis, which should be considered a limitation in interpreting the results. The six- to twelve-month follow-up period is relatively brief, precluding evaluation of late restenosis and longer-term clinical outcomes. Its retrospective nature imposes inherent selection bias and reduces control over data completeness and uniformity. Outcomes cannot be directly compared with CEA because no contemporaneous surgical control group was included. Finally, all procedures were performed by a small, highly experienced team of physicians; therefore, the results may not be generalisable to centres with differing levels of expertise.

CONCLUSION

Our study highlights the viability of CAS as a safe and effective treatment for carotid artery stenosis, provided appropriate patient selection and procedural methods are employed. While ongoing advances and standardization are necessary to further enhance outcomes, CAS demonstrates promise comparable to that of CEA, with a favorable balance between efficacy and complication rates. As techniques and devices continue evolving, CAS is poised to become an increasingly integral component of stroke prevention, warranting its consideration alongside traditional methods in clinical practice.

ETHICS

Ethics Committee Approval: The study was conducted in accordance with the rules of the Declaration of Helsinki and was approved by the Pamukkale University Non-Interventional Clinical Research Ethics Committee (approval no: E-60116787-020-617909, date: 02.12.2024).

Informed Consent: Written informed consent was obtained from all patients.

FOOTNOTES

Authorship Contributions

Surgical and Medical Practices: S.C., N.D.E., I.T., M.A., E.K., H.P., F.Y., Concept: S.C., I.T., Design: S.C., N.D.E., Data Collection or Processing: S.C., N.D.E., I.T., M.A., E.K., R.A., H.P., F.Y., Analysis or Interpretation: S.C., N.D.E., I.T., Literature Search: S.C., N.D.E., I.T., Writing: S.C., N.D.E., I.T.

Conflict of Interest: No conflict of interest was declared by the authors.

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