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RESEARCH ARTICLE **ÖZGÜN ARAŞTIRMA**

EVALUATION OF DEMOGRAPHIC CHARACTERISTICS AND POSSIBLE RISK FACTORS OF PATIENTS WHO DEVELOPED HYPOTENSION AFTER CAROTID ARTERY STENTING

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ABSTRACT

INTRODUCTION: The aim was to determine possible risk factors in patients who developed hypotension after carotid artery stenting (CAS) in this study.
METHODS: 104 patients who underwent CAS were included in the study. Patients with systolic blood pressure lower than 90 mmHg after CAS or a decrease in systolic blood pressure more than 40 mmHg compared to baseline were defined as the hypotensive group and the other patients as the normotensive group. These two groups were analyzed regarding the following parameters: sociodemographic characteristics, comorbidity diseases, percentage of stented side stenosis, percentage of contralateral side stenosis, history of angioplasty, duration of the procedure, the width of the femoral sheath, antihypertensive medical history, glomerular filtration rate, hemoglobin and hematocrit levels before/after the procedure, length of hospital stay, and the frequency of complications after the procedure.
RESULTS: Hypotension was observed in 21 patients after CAS. The ratio of female patients, the degree of stenosis on the stented side, the diameter of the femoral sheath, the glomerular filtration rate value, and the antihypertensive medical history were significantly higher in the hypotensive group.
DISCUSSION AND CONCLUSION: Especially female gender, a high degree of stenosis on the stented side and antihypertensive medical history should be followed more carefully for the development of hypotension after CAS.
Keywords: Carotid stenosis, balloon angioplasty, systolic blood pressure, femoral sheath.

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KAROTİS ARTER STENTLEME SONRASI HİPOTANSİYON GELİŞEN HASTALARIN DEMOGRAFİK ÖZELLİKLERİNİN VE OLASI RİSK FAKTÖRLERİNİN DEĞERLENDİRİLMESİ

ÖZ

GİRİŞ ve AMAÇ: Bu çalışmada karotis arter stentleme (KAS) sonrasında hipotansiyon gelişen hastalarda olası risk faktörlerinin belirlenmesi amaçlandı.
YÖNTEM ve GEREÇLER: Çalışmaya KAS yapılan 104 hasta dahil edildi. KAS sonrasında sistolik kan basıncı 90 mmHg'den düşük olan ya da sistolik kan basıncında bazale göre 40 mmHg'den daha fazla düşüş yaşayan hastalar hipotansif grup, diğer hastalar ise normotansif grup olarak belirlendi. Bu iki grubun sosyodemografik özellikleri, ek hastalıkları, stent takılan taraf darlık yüzdesi, kontralateral taraf darlık yüzdesi, anjioplasti öyküsü, işlem süresi, femoral kılıf genişliği, işlem öncesinde antihipertansif ilaç kullanımı ve glomerüler filtrasyon hızı, işlem öncesi/sonrası hemoglobin ve hematokrit düzeyleri, hastanede kalış süresi, işlem sonrası komplikasyon sıklığı karşılaştırıldı.
BULGULAR: KAS sonrası 21 hastada hipotansiyon gözlendi. Hipotansif grupta kadın hasta oranı, stent takılan taraf darlık derecesi, femoral kılıf çapı, işlem öncesi glomerüler filtrasyon hızı düşüklüğü ve antihipertansif ilaç kullanımı istatistiksel olarak anlamlı bulundu.
TARTIŞMA ve SONUÇ: Kadın cinsiyet, stent tarafı darlık derecesi yüksekliği ve işlem öncesi antihipertansif ilaç kullanımı KAS sonrası hipotansiyon gelişmesi açısından daha dikkatli takip edilmelidir.

Anahtar Sözcükler: Karotis darlığı, balon anjioplasti, sistolik kan basıncı, femoral kılıf.

INTRODUCTION

Cerebrovascular disease (CVD) is the leading cause of death after cardiovascular disease and cancer-related deaths. The majority of cerebrovascular disease is ischemic, and carotid artery stenosis accounts for approximately one-fourth of cases (1). In particular, when the degree of internal carotid artery (ICA) stenosis increases, the risk of ischemic stroke increases significantly (2). With the developments in endovascular treatment, mortality and morbidity of stroke decrease, and secondary prevention can be successfully performed. The main goal of secondary prevention is to reduce the risk of transient ischemic attack (TIA) and stroke. Endovascular treatment modalities include carotid endarterectomy, carotid artery stenting (CAS), and percutaneous transluminal balloon angioplasty (3).

CAS is the treatment of choice for most patients because it is less invasive than carotid endarterectomy. However, hemodynamic instability (hypotension, bradycardia) occurs relatively frequently after CAS (4). The rates of postoperative hypotension and bradycardia reported in previous studies vary widely, ranging from 5% to 76% (4). This situation is thought to be caused by stimulation of the baroreceptors of the carotid sinus, resulting in hypotension (baroreflex response) (5). Moreover, this reflex response, which is often activated during balloon dilatation, can cause profound vasodilation and severe hypotension (6). These episodes of hypotension and bradycardia are generally harmless but may prolong hospitalization. However, in cases of severe hypotension, vasopressor or inotropic therapy and, in some cases, implantation of a pacemaker may be required (6). Furthermore, hemodynamic instability after CAS may cause additional complications such as acute stroke or myocardial infarction (4,7-9).

Although hypotension occurring after CAS is ultimately related to the baroreflex response, it is believed that there are many factors related to both the patient and the procedure (before, during, and after the procedure). This study aimed to identify possible risk factors in patients who developed hypotension after CAS.

METHODS

Our study was a cross-sectional observational study conducted in line with the ethical standards of the Declaration of Helsinki. It was approved by Kahramanmaraş Sütçü İmam University Non-interventional Clinical Research Ethics Committee (Date: 05.04.2021, Number: 18). This study was conducted retrospectively. Therefore, no signed informed consent was obtained from the subjects included in the study. In the study, data of consecutive patients who underwent CAS in the neurology clinic of our hospital were obtained

from the records and archives of the automation system. The study was conducted with data from patients older than 18 years.

Groups: Blood pressures of patients undergoing CAS were routinely monitored for up to 24 hours after the procedure in terms of hypotension monitoring. In this study, a systolic blood pressure of less than 90 mmHg after the procedure or a drop in systolic blood pressure of more than 40 mmHg from baseline, commonly accepted values in the literature, were accepted as hypotensive. The remaining patients were classified as the normotensive group. Subsequently, these two groups were compared according to age, sex, hypertension, diabetes mellitus, hyperlipidemia, coronary artery disease, atrial fibrillation, smoking history, type of aortic arch, percentage of stenosis on the side of the stent, percentage of stenosis on the contralateral side, percutaneous transluminal balloon angioplasty (PTA), the procedure course, femoral sheath width, pre-procedure antihypertensive medication use, pre-procedure glomerular filtration rate (GFR; ml/min), pre-procedure and post-procedure hemoglobin-hematocrit levels, hospital stay, and complications (TIA, stroke) within 24 hours after the procedure. In our study, the percentage of carotid stenosis was calculated using the CC (Common Carotid) criteria (Figure 1) (2,10,11).

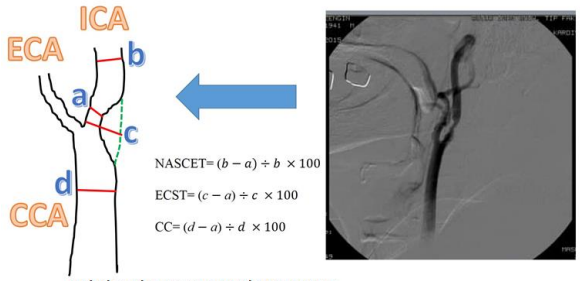


Figure. Methods used to measure carotid artery stenosis.

Perioperative preparation and patient follow-up: All patients who underwent CAS were given detailed information about the procedure. Informed consent was obtained from the patients and/or their relatives. Before the procedure, patients' blood counts and routine biochemical tests were completed. Before the CAS procedure, patients received a dual aggregation inhibitor treatment protocol that included ASA (100-300 mg/day) and clopidogrel 75 mg/day for at least five days. During the procedure, all patients received intravenous (iv) heparin at a dose of 70 mg/kg. Patients with a pulse of < 40 beats/min after the procedure were administered 1 mg iv atropine. After the procedure, all patients underwent close vital and neurological monitoring for 24 hours, and depending on the situation; patients were also hydrated with serum isolyte. During the first 24 hours after the procedure, patients' blood pressure was measured at the brachial artery with a sphygmomanometer every 15 minutes for the first hour, every half hour for the second hour, and hourly after that.

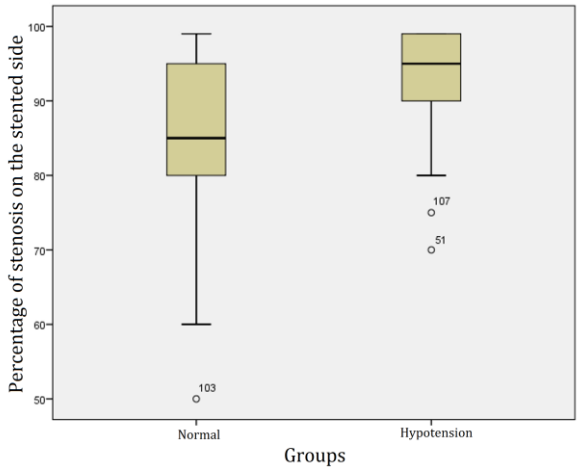
Statistical analysis: Data were analyzed with the IBM SPSS (Statistical Package for Social Sciences) 20 program. The Mann-Whitney U test was used for continuous variables, the chi-square test for categorical variables, and Spearman's rho test for correlations. The Wilcoxon signed ranks test was used as a pre-post test. A binary logistic regression test was used as the method of regression analysis. A $p< 0.05$ value was considered significant in all analyses.

RESULTS

It was found that 118 consecutive CAS were performed by the start of this study (June 2016-August 2021). Fourteen patients with insufficient data were excluded from the study. The study was completed with data from 104 patients. Among these patients, 21 patients with hypotension and 83 patients with normal blood pressure were identified. 57.1% of the hypotensive group were female patients (n=12), 75.9% of the normotensive group were male patients (n=63), and there was a significant difference between the groups (X2; p= 0.003). There was no significant difference between the mean age of the hypotensive group (67.24 ± 6.03 years) and the mean age of the normotensive group (69.10 ± 10.27 years) (Mann-Whitney U test; p= 0.321).

There was no significant difference between these two groups in diabetes mellitus, hypertension, hyperlipidemia, coronary artery disease, atrial fibrillation, smoking, and type of aortic arch (X2; p> 0.05). The procedure duration was 60.71 ± 21.64 minutes in the hypotension group and 58.61 ± 17.26 minutes in the standard blood pressure group, and no significant difference

was found between the groups (Mann-Whitney U test; p= 0.882). The percentage of stented lateral stenosis in the hypotension group (91.33 ± 8.38) was significantly higher than the percentage of stented lateral stenosis (84.82% ± 11.56%) in the standard blood pressure group (Mann-Whitney U test; p= 0.013) (Graph 1). There was no significant difference in the percentage of contralateral stenosis between these two groups (Mann-Whitney U test; p= 0.680).



Graph 1. The percentage of stenosis on the stented side of the hypotensive and normotensive groups.

Six patients with pre-dilatation, three with post-dilatation, and five with pre/post-dilatation were identified in the hypotension group (n=14). Seven patients who developed hypotension without PTA were identified (n=7). There was no significant difference between the hypotension and the normotensive groups in terms of the PTA method (X2; p=0.083). There was no significant difference between these two groups in terms of stent diameter, length, and side of stent insertion (p>0.05). The 8F-9F femoral sheath was used more frequently (61.9%/38.1%) in the hypotension group and the 6F-7F femoral sheath (67.5%/32.5%) in the normal blood pressure group (X2; p=0.013). In addition, 76.2% (n=16) of the hypotensive group had a history of antihypertensive medication use prior to the procedure, while 41% (n=34) of the normotensive group had a history of antihypertensive medication use (X2; p=0.004). The comparison of the hypotensive and normotensive groups concerning potential risk factors is summarized in Table 1.

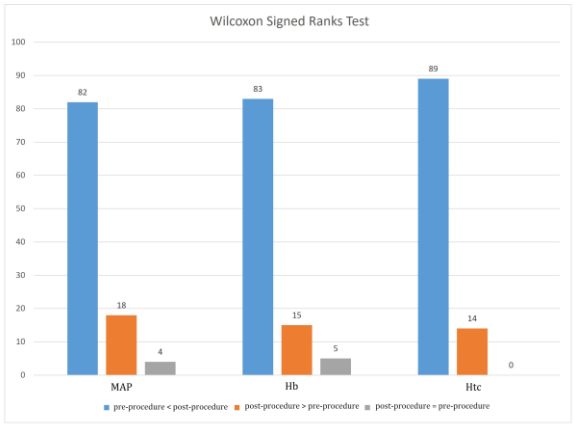
Table 1. Comparison between hypotensive and normotensive groups concerning possible risk factors.

	Hypotensive group (N= 21)	**Normotensive group (N= 83)**	**p**
DM (%)	47,6	38,6	0,449
CAH (%)	23,8	42,2	0,122
AF (%)	4,8	6	0,651
HT (%)	76,2	66,3	0,383
HL (%)	85,7	77,1	0,388
Smoking (%)	9,5	10,8	0,611
Arc type (%)			0,995
- Type I	76,2	77,1	
- Type II	19	18,1	
- Type III	4,8	4,8	
Procedure time (min)	60,71 ± 21,64	58,61 ± 17,26	0,882
PSSS (%)	91,33 ± 8,38	84,82 ± 11,56	**0,013**
PCS (%)	69,23 ± 22,07	65,63 ± 24,96	0,680
Balloon angioplasty (n)			0,083
-predilatation	6	15	
-postdilatation	3	20	
-pre/postdilation	5	5	
Stent diameter (mm)	8,10 ± 1,04	8,10 ± 1,04	0,416
Stent boyu (mm)	37,62 ± 10,91	37,63 ± 8,30	0,648
Stent length (%)			0,952
-Right	52,4	55,4	
-Left	42,9	41	
Femoral Sheath (%)			**0,013**
-6F-7F	38,1	67,5	
-8F-9F	61,9	32,5	
PPAHU (%)	76,2	41	**0,004**
PPGFR (ml/min)	76,39 ± 31,29	87,91 ± 24,77	**0,037**

DM= diabetes mellitus, CAD= coronary artery disease, AF= atrial fibrillation, HT= hypertension, HL= hyperlipidemia, PSSS= percentage of stented side stenosis, PCS= percentage of contralateral stenosis, PPAHU= pre-procedure anti-hypertensive use, PPGFR= pre-procedure glomerular filtration rate.

The mean values of arterial pressure (MAP), hemoglobin (Hb), and hematocrit (Htc) obtained after the intervention were significantly lower than those obtained before the intervention in all patients (Wilcoxon signed ranks test; p<0.05) (Graph 2). There was no significant difference between the two groups in the mean values of MAP, Hb, and Htc before the intervention (Mann-Whitney U test; p>0.05). After the intervention, the mean MAP, Hb, and Htc values of the hypotensive group were significantly lower than those of the normotensive group (Mann-Whitney U test; p<0.05). Mean GFR before the intervention (76,39±31,29 ml/min/1.73 m^2) was significantly lower in the hypotensive group than the normotensive group (87,91±24,77 ml/min/1.73 m^2) (Mann-Whitney U test; p=0.037). The comparison of mean MAP, Hb, and Htc of the hypotensive and normotensive groups before and after the intervention is shown in Table 2.

Of the 21 patients with hypotension, only



Graph 2. Difference in pre and post mean arterial pressure (MAP), hemoglobin (Hb), and hematocrit (Htc) values of hypotensive and normotensive groups.

Table 2. Comparison of mean values MAP, Hb, and Htc of hypotensive and normotensive groups before and after the procedure.

	Hypotensive group	Normotensive group	p
Pre-procedure			
MAP (mm/Hg)	98,33 ± 16,30	93,23 ± 11,06	0,166
Hb (g/dl)	13,49 ± 1,57	13,56 ± 1,92	0,884
Htc (%)	39,79 ± 4,58	40,80 ± 5,23	0,367
Post-procedure			
MAP (mm/Hg)	64,57 ± 13,09	87,32 ± 9,19	**0,000**
Hb (g/dl)	11,56 ± 1,71	12,50 ± 1,89	**0,035**
Htc (%)	34,47 ± 4,97	37,32 ± 5,25	**0,020**

MAP= mean arterial pressure, Hb= hemoglobin level, Htc= hematocrit percentage.

seven patients were identified whose blood pressure was monitored, 13 who received saline infusion, and one who received saline and inotropic infusion. Patients with hypotension stayed in the hospital for a mean of 5.64 ± 4.15 days, while those with normal blood pressure stayed in the hospital for a mean of 4.38 ± 1.69 days (Mann-Whitney U test; p= 0.310). Thirteen patients who experienced complications within the first 24 hours after the procedure were identified. Eight of these patients suffered an ischemic stroke (five minor strokes, three moderate strokes), hemorrhagic stroke, and four transient ischemic attacks. There was no significant difference between the hypotensive and non-hypotensive groups in the development of complications (X2; p= 0.209).

Correlation analysis showed an inverse relationship between age and Hb, Htc, and GFR values before the intervention, an inverse relationship between the intervention time and the length of hospital stay, and an inverse relationship between the percentage of stenosis on the stented side and Hb and Htc values after the intervention. A significant but weak relationship was found in the same direction between mean arterial pressure (MAP) and postoperative Hb and Htc values (p<0.05). According to binary logistic regression analysis, women were 5 times more likely (OR= 5.041; 95% confidence interval= 1.386-18.339; p= 0.014) to be in the hypotensive group than in the normotensive group and 4.8 times (OR= 4.873; 95% confidence interval=1.324-17.932; p= 0.017) more likely. The results of the logistic regression analysis are summarized in Table 3.

Table 3. Binary logistic regression analysis.

			95% CI	
	P	OR	low	hight
Gender (K)	**0,014**	**5,041**	**1,386**	**18,339**
DM	0,602	1,415	0,384	5,216
HT	0,767	0,802	0,187	3,441
HL	0,400	2,126	0,367	12,307
CAD	0,029	0,185	0,041	0,840
AF	0,891	1,195	0,094	15,217
Smoking	0,607	1,730	0,215	13,921
PPAHU	**0,017**	**4,873**	**1,324**	**17,932**

CI= Confidence interval, F= female gender, DM= diabetes mellitus, HT= hypertension, HL= hyperlipidemia, CAD= coronary artery disease, AF= atrial fibrillation, PPAHU= pre-procedure anti-hypertensive use.

DISCUSSION AND CONCLUSION

In this study, 21 patients who developed hypotension after CAS were identified. In the literature, the rate of hypotension after CAS ranges from 10% to 42% (12-19). It has been suggested that hypotension after the procedure is primarily due to the stretching of the baroreceptors during CAS (12). However, the fact that hypotension after CAS does not occur in all patients highlights the need to investigate possible risk factors for this condition.

In the studies performed to date, there is no standard definition of hypotension after CAS. Nonaka et al. used a systolic blood pressure (SBP) of ≤90 mmHg or a decrease in SBP of > 30 mmHg from baseline as criteria for postprocedural hypotension. In the study by Ishii et al., postprocedural hypotension was defined as a systolic blood pressure of <100 mmHg (9). In contrast, Kojuri et al. used an SBP ≤90 mmHg or a decrease in SBP of ≥50 mmHg from baseline as criteria for hypotension (20). In other studies, a general SBP of <90 mmHg or a decrease of ≥40 mmHg in SBP compared to baseline was accepted

as a criterion for hypotension (6,21). In our study, an SBP <of 90 mmHg or a decrease in SBP of more than 40 mmHg compared with baseline was defined as a criterion for hypotension.

According to CAS, the association between sex and hypotension is unclear. Taha et al. suggested that the male sex may predict the development of hypotension after CAS (22). In contrast, in another study, the female sex was associated with an increased risk of severe hypotension (19). In our study, hypotension after CAS was five times more common in female patients.

Cardiovagal baroreflex sensitivity decreases with age. Accordingly, the ability to respond to acute changes in blood pressure, especially hypotension, decreases with age (23). Many studies have shown that hemodynamic instability (hypotension, bradycardia) after CAS increases with age (4,16,19,24). On the other hand, no significant association was found between the development of hypotension after stenting and age in the study performed by Nonaka et al. (25). In our study, no significant association was found between age and the development of hypotension after CAS.

Previous studies have reported that atherosclerosis causes baroreceptors in the carotid sinus to operate at a higher threshold pressure and decreases baroreflex sensitivity (26-29). It has also been suggested that stenosis of the carotid artery caused by atherosclerosis contributes to increased hemodynamic instability by desensitizing baroreceptors (30). In the study by Nonaka et al., the mean degree of stenosis of the carotid artery on the side of the stent was 78.8%. However, no significant association was found between the degree of carotid stenosis and the development of hypotension (25). In our study, a significant association was found between the percentage of stenosis on the stented side and the development of hypotension after CAS. The higher mean percentage of stenosis can explain this difference on the stented side in our study. In some studies, occlusion of the contralateral carotid artery is associated with the development of hypotension after stenting (15,22). In our study, no significant association was found between contralateral carotid stenosis and the development of hypotension.

It is accepted that performing PTA (pre-post dilation) during muscularization increases the risk of hypotension (30). In this study, hypotension was observed in 14 patients with PTA (n=14/54) and seven patients without PTA (n=7/50), but there was no significant difference between these two groups. This statistical insignificance could be due to the small number of hypotonic patients. Gökçal et al. found no association between the stent diameter and the development of hypotension after CAS (31). Our study also found no association between stent diameter, length, side of stent placement, and hypotension.

Oshin et al. found a significant association between type 3 aortic arch structure and the development of persistent hypotension after CAS (6). In contrast, no significant association was found between aortic arch types and hypotension after CAS in our study. However, this may be due to the small number of type 3 aortic arch types in our study.

Chronic smoking causes an increase in blood pressure and heart rate through the release of epinephrine and norepinephrine (30,32). Diabetes mellitus, on the other hand, increases blood pressure by weakening the cardio-vagal response and overactivity of the sympathetic nervous system (33,34). Therefore, patients with diabetes mellitus or smoking history are thought to be protected from hypotension after CAS (30). In a study of 155 patients, a significant association was found between the development of hypotension after CAS and smoking (35). In our study, no significant association was found between smoking and diabetes mellitus and the development of hypotension after CAS. This may be due to insufficient data on smoking in our study.

Two studies found a significant association between coronary artery disease and hypotension after CAS (6,16). In contrast to these studies, coronary heart disease was more common in the normotensive group in our study, but this was not significant.

Oshin et al. included 21 patients with a history of chronic kidney disease in their study. Persistent hypotension was observed after CAS in only one of these patients. No significant association was found between persistent hypotension after CAS and chronic kidney disease (6). In this study, the preoperative GFR values of patients were investigated. In our study, it was found that patients with low preoperative GFR were more likely to develop hypotension after

CAS. In a retrospective cohort study, periprocedural bleeding, mortality, length of hospital stay, and costs were assessed in patients with large femoral sheaths (≥10F) for endovascular procedures. A statistically significant difference in these parameters was found in patients who had used large catheters(36). In our study, it was found that femoral cannulas with larger diameters (8F-9F) were more likely to be used in the hypotonic group and femoral cannulas with smaller diameters (6F-7F) were more likely to be used in the normotonic group. This study found that the mean values of MAP, Hb, and Htc before the procedure decreased significantly in most patients after the procedure. It was found that this decrease was more pronounced in the hypotonic group than the normotonic group. The greater decrease in mean Hb and Htc levels in both groups after the procedure could be due to blood loss and routine fluid intake in all patients after the procedure. The greater hypotension observed in patients who used a large-diameter femoral sheath could be related to the higher blood loss. In patients undergoing CAS with the MoMa method, a 9F femoral sheath is used, and in this group, 50-60 cc more blood is aspirated in each patient than in the other group. Unfortunately, this study could not examine which patient lost how much blood.

One study found that patients taking two or more antihypertensive medications before surgery had a higher risk of developing hypotension, which required vasopressor treatment after CAS (37). Similarly, in our study, the risk of developing hypotension after CAS was found to be 4.8 times higher in patients who were taking antihypertensive medication before the procedure than the patients who did not receive treatment.

In studies, severe hypotension after CAS requiring vasopressors has been observed in 2% to 21% of patients (8,38). In our study, the need for vasopressors was noted in 4.16% of hypotensive patients. In a study by Im et al., temporary pacemaker therapy was recommended as prophylaxis before CAS (39). In another study, the pacing was recommended only for patients with persistent bradycardia and hypotension after CAS (40). In our study, no patient required a pacemaker after CAS.

There are conflicting reports on whether more complications (TIA or stroke) occurred in the group that developed hypotension after CAS. One study found that the risk of stroke and severe cardiac disease was increased in patients who developed hypotension and that these patients remained in the hospital longer(41). On the other hand, in another study, no significant difference was found between hypotensive and normotensive groups of patients in terms of the development of neurological complications(24). In our study, although the length of hospital stay was longer in the hypotensive group, this difference was not significant. Similarly, no significant difference was found between the groups regarding the development of complications in the first 24 hours.

In the study by Oshin et al., the degree of calcification of the lesion site was assessed in patients undergoing CAS. Later, the lesions here were classified into mild, moderate, and severe calcified lesions according to their grade. In addition, the amount of contrast agent administered during CAS was also investigated in this study. As a result, a significant relationship was found between the degree of calcification in the lesion area and the contrast agent dose and prolonged hypotension after CAS (6). Another study found a significant association between calcified vasculature and hemodynamic instability after CAS (40). In our study, these parameters were not assessed because of lack of data.

The limitations of this study are that it was a retrospective study, the sample size was small and limited to a single center, and carotid artery calcification, which has been considered an essential factor in the development of hypotension in other studies, was not investigated.

In conclusion, female patients, patients with high stent-side stenosis, patients taking antihypertensive medications before the procedure, patients with low GFR before the procedure, and patients who used a large-diameter femoral sheath should be monitored more carefully for the development of hypotension after CAS.

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Ethics

Ethics Committee Approval: The study was approved by Kahramanmaraş Sütçü İmam University Non-interventional Clinical Research Ethics Comittee (Date: 05.04.2021, Number: 18).

Informed Consent: The authors declared that informed consent was not obtained from the patients because of the retrospective study design.

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