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Original Article

The Relationship of CHADS2 Score with In-stent Restenosis in Patients Undergoing Iliac Artery Stenting

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Abstract

Objectives: Percutaneous intervention to aortoiliac occlusive disease (AIOD) is an approved choice of treatment instead of open surgery. However, despite improvement stent technology, in-stent restenosis (ISR) still remains a potential problem, especially in long-term follow-up of these patients. CHADS2 score is mainly a risk stratification tool for atrial fibrillation; however, it is found to be associated with the severity of atherosclerosis and worse outcome of percutaneous interventions. Thus, we aimed to interrogate the relationship between CHADS2 score and ISR in patients with stent implantation for AIOD.

Methods: This was a retrospective, observational study that included 419 consecutive patients who had successful common iliac artery (CIA) and external iliac artery stent implantation. Post-procedural ISR is evaluated by either ultrasonography or angiography for each patient in the follow-up period. Patients were then divided into two groups ISR (+) and ISR (–). CHADS2 score was calculated for every patient.

Results: ISR was detected in 47 out of 419 patients. Patients who had ISR had smaller stent diameter (8.4±0.9 vs. 7.2±2.8, p=0.005) and longer stent length (80 [59–120] mm vs. 59 [39–100] mm, p<0.001) than those without ISR. CHADS2 score was significantly found increased in patients with ISR than those without ISR (2.04 ± 0.98 vs. 1.45±0.93, p<0.001). Chronic obstructive pulmonary disease (COPD) (hazard ratios [HR]: 2.85, 95% confidence interval [CI]: 1.535–5.293, p=0.001), CHADS2 score (HR: 1.571, 95% CI: 1.186–2.081, p=0.002), and decreased stent diameter (HR: 0.582, 95% CI: 0.366–0.926, p=0.022) were found to be independently associated with ISR.

Conclusion: Our study demonstrated that COPD, CHADS2 score, and stent diameter were associated with ISR for patients who had successful iliac artery stent implantation. According to our study, this simple and applicable scoring system can be used to predict patients at high risk for ISR.

Keywords: Atherosclerosis; CHADS2; peripheral arterial disease.

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İliyak Artere Stent Takılan Hastalarda CHADS2 Skorunun Stent İçi Restenoz ile İlişkisi

Özet

Amaç: Aorto-iliyak tıkayıcı hastalığa (AIOD) perkütan müdahale, açık cerrahi yerine onaylanmış bir tedavi seçeneğidir. Ancak stent teknolojisindeki gelişmelere rağmen stent içi restenoz (ISR), özellikle bu hastaların uzun dönem takiplerinde hala potansiyel bir sorun olmaya devam etmektedir. CHADS2 skoru temel olarak atriyal fibrilasyon için bir risk sınıflandırma aracıdır; ancak aterosklerozun şiddeti ve perkütan girişimlerin daha kötü sonuçlarıyla ilişkili olduğu bulunmuştur. Böylece AIOD nedeniyle stent takılan hastalarda CHADS2 skoru ile ISR arasındaki ilişkiyi sorgulamayı amaçladık.

Gereç ve Yöntem: Bu çalışma, başarılı ana iliak arter (CIA) ve eksternal iliyak arter (EIA) stent implantasyonu yapılan 419 ardışık hastayı içeren retrospektif, gözlemsel bir çalışmaydı. İşlem sonrası ISR, takip

döneminde her hasta için ultrasonografi veya anjiyografi ile değerlendirildi. Daha sonra hastalar ISR (+) ve ISR (–) olmak üzere iki gruba ayrıldı. Her hasta için CHADS2 skoru hesaplandı.

Bulgular: 419 hastanın 47'sinde ISR tespit edildi. ISR'si olan hastaların stent çapı daha küçük (8,4±0,9 vs. 7,2±2,8, p=0,005) ve stent uzunluğu daha fazlaydı (80 (59–120) mm vs. 59 (39–100) mm, p<0,001). CHADS2 skoru ISR'si olan hastalarda ISR'si olmayanlara göre anlamlı düzeyde yüksek bulundu (2,04±0,98 vs. 1,45±0,93, p<0,001). KOAH (HR: 2,85, %95 GA: 1,535–5,293, p=0,001), CHADS2 skoru (HR: 1,571, %95 GA: 1,186–2,081, p=0,002) ve stent çapında azalma (HR: 0,582, %95 GA) : 0,366–0,926, p=0,022) bağımsız olarak ISR ile ilişkili olduğu bulundu.

Sonuç: Çalışmamız başarılı iliak arter stent implantasyonu yapılan hastalarda KOAH, CHADS2 skoru ve stent çapının ISR ile ilişkili olduğunu gösterdi. Çalışmamıza göre bu basit ve uygulanabilir skorlama sisteminin ISR açısından yüksek riskli hastaları tahmin etmede kullanılabilabilir.

Anahtar sözcükler: Ateroskleroz; CHADS2; periferik arter hastalığı.

Introduction

Peripheral artery disease (PAD) is a disease that mainly affects the extremity arteries and usually originates from atherosclerotic and thrombotic occlusion of lower extremity arteries.[1] Atherosclerotic involvement of infrarenal aorta and iliac arteries that cause aortoiliac occlusive disease (AIOD) constitutes approximately one third of all PAD patients.[2] In recent years, endovascular techniques include balloon angioplasty and stenting has been improved; therefore, less invasive percutaneous interventions have been preferred instead of open surgical procedures for AIOD. However, despite improvement of stent technology, in-stent restenosis (ISR) still remains a potential problem, especially in long-term follow-up of these patients.[3]

CHADS2 score is a proved and simple risk stratification tool to evaluate stroke risk in patients with atrial fibrillation (AF).[4] Regardless of AF, the applicability of CHADS2 score to predict stroke risk and results were proven and this scoring system can estimate unfavorable clinical results in patients with stabile coronary artery disease and acute coronary syndrome.[5] In addition, according to latest clinical studies, CHADS2 score is successful to estimate ankle-brachial index for patients with PAD. It is related to unfavorable clinical endpoints, such as amputation and death.[6,7] On the other hand, there is a lack of information to show relationship between CHADS2 score and ISR in patients who underwent stent implantation to iliac artery. Thus, we aimed to interrogate relationship between CHADS2 score and ISR in patients who underwent stent implantation for AIOD.

Materials and Methods

Study Population

This was a retrospective, observational research that included 419 consecutive patients who had successful common iliac artery (CIA) and external iliac artery (EIA) stent implantation in our institution from January 2015 to January 2018. The indications of the procedure were life-limiting claudication despite guideline-mediated medical and exercise therapy due to AIOD. In the present study, subjects who had emergency intervention due to acute embolism, history of aortic/iliac aneurysm or dissection, permanent or paroxysmal AF, overt and/or active systemic organ disease, active or chronic infection, malignancy, end-stage liver or kidney diseases, incomplete data, and subjects who did not take antiplatelet agents after procedures were excluded. The study protocol was approved by local ethics committee and it complied with the principles outlined in the Helsinki Declaration.

Data Collection

Demographic and clinical characteristics of subjects, co-morbidities, laboratory findings, echocardiographic data of ejection fraction, and interventional procedural information were retrieved from patients' medical files and hospital's recordings. Target lesion characteristics, catheters, balloons, stents, and other factors related to endovascular intervention were also evaluated. In our center, the severity of claudication is routinely assessed according to the Fontaine, Rutherford classification and baseline characteristics of the Trans-Atlantic Inter-Society Consensus II (TASC II) classification before the procedures. The blood samples were assessed for complete blood count and lipid profile. CHADS2 score that assigned one point for congestive heart failure, hypertension, age (≥75), diabetes mellitus (DM), and two points for stroke or transient ischemic attack calculated for all subjects.

Endovascular Therapy

Pre-procedural antiplatelet regimen is routinely applied to all the patients in our center. All of the patients were treated with dual antiplatelet therapy (81–100 mg/day of aspirin and 75 mg/day of clopidogrel). Aspirin was continued as a lifelong treatment and clopidogrel was recommended for at least 6 months depending on the patients' clinical characteristics by their clinician. All medications that included beta blockers, ACE inhibitors, nitrates, and statins were prescribed according to guidelines. Angiographic data were evaluated using CA-ASV software (version 5.7, Pie Medical Imaging, Maastricht, Holland) at a core laboratory. All endovascular procedures were carried out under systemic heparin therapy to achieve 300 s or over of active clotting time. All lesions were evaluated according to TASC II classification and recommended peripheral arterial calcium scoring system.[8,9] Procedural time was defined as the period of time starting from skin puncture to final dressing application to the access site. Interventional strategies included both ipsilateral and contralateral access to the lesions. The common femoral artery was usually used as a main access site, and brachial artery was rarely cannulated in some subjects if needed. Selection of types of catheters, balloons, stents, and transition approaches during procedure was

noted. Procedure success was defined as less than 30% residual stenosis without any flow-limiting dissection. Access sites were closed by ProGlide (Abbott, USA) vascular closure device or compressed manually after the procedures. All patients were regularly followed up at 1, 6, and 12 months after successful revascularization procedure, and then, duplex ultrasonography was performed every 6–12 months regardless of symptoms. Patients with recurrent claudication were evaluated by duplex ultrasonography and peripheral digital subtraction angiography (DSA) was performed in case of need. ISR was defined as >2.5 peak systolic velocity index by duplex scanning at target lesion and/or >50% stenosis of iliac stent by DSA.[10] Patients were then divided into two groups as ISR (+) and ISR (–).

Statistical Analysis

Data were analyzed using the Statistical Package for the Social Sciences version 26.0 (SPSS Inc., Chicago, Illinois, USA). Visual (histograms, probability curves) and analytical methods (Kolmogorov–Smirnov or Shapiro–Wilk) were performed to evaluate whether the variables show normal distribution. Numerical variables showing normal distribution were expressed as mean ± standard deviation, whereas numerical variables not showing normal distribution were expressed as median (interquartile range) and categorical variables as a percentage (%). Numerical variables were evaluated using Student's t-test and Mann–Whitney U-test between the two groups. Chi-square or Fisher's exact test was used to compare categorical variables. The correlation between the CHADS2 and other numerical variables was evaluated by Pearson and Spearman analysis. Event-free survival curves were constructed using the Kaplan–Meier method and compared using the log-rank test. A univariable and multivariable Cox proportional hazards model was used to calculate hazard ratios (HRs) and 95% confidence intervals (95% CI) for clinical endpoints. Throughout this study, a $p<0.05$ was considered statistically significant.

Results

This study included 419 patients who had successful CIA and EIA stent implantation in our institution. The baseline clinical characteristics of the patients were introduced in Table 1. The mean age of the subjects was 60±8.1 years and most of the patients were male (375 patients-89.7%). The study population was divided into two groups as patients with ISR and those without ISR during follow-up. ISR was detected in 47 out of 419 patients. The presence of hypertension, chronic obstructive pulmonary disease (COPD), AF, and prior cerebrovascular events at baseline were significantly found higher in patients with ISR than those without ISR ($p<0.05$). Patients who had ISR had larger stent diameter (8.4±0.9 vs. 7.2±2.8, $p=0.005$) and longer stent length (80 [59–120] mm vs. 59 [39–100] mm, $p<0.001$) than those without ISR. In spite of longer procedure time in ISR group (41 [28.8–60.5] min vs. 30 [17–48.8] min, $p=0.004$), there was no significant difference in terms of the amount of contrast agent between the two groups (200.8±83.5 mL vs. 173.7±91 mL, $p=0.301$). CHADS score was significantly found to be higher in patients with ISR than those without ISR (2.04±0.98 vs. 1.45±0.93, $p<0.001$). In addition, patients without ISR have longer follow-up period than the patients with ISR because patients with ISR underwent additional procedure due to significant ISR and were therefore excluded from the follow-up after any additional intervention. Table 2 provides laboratory findings of the patients. All laboratory findings were comparable for both groups ($p>0.05$).

In univariable Cox regression analysis, COPD, longer procedure time, presence of AF, higher CHADS2 score, stent diameter and length, and TASC II-B lesion type were found to be related to ISR. After the inclusion of these variables into the multivariable Cox regression analysis, COPD (HR: 2.85, 95% CI: 1.535–5.293, $p=0.001$), CHADS2 score (HR: 1.571, 95% CI: 1.186–2.081, $p=0.002$), and stent diameter (HR: 0.582, 95% CI: 0.366–0.926, $p=0.022$) were found to be independently associated with ISR (Table 3). In Kaplan–Meier curves, patients with CHADS score ≥2 had a significant elevated risk for ISR (log-rank $p=0.003$) (Fig. 1).

Discussion

ISR, after intervention to AIOD, is a major clinical concern in these patients. Clinicians still have limited knowledge about in prediction of the possibility of ISR after the intervention. Our study showed that risk factors such as hypertension, COPD, AF, and cerebrovascular disease are associated with ISR. In addition, procedural information including stent diameter, stent length, and procedural time are associated with ISR, as well. The main result of the current study is that pre-procedural CHADS2 score was associated with the occurrence of ISR. Second, the independent risk factors of ISR are as follows: The presence of COPD, longer stent diameter, and higher CHADS2 score. To the best of our knowledge, this is the first study that interrogates this relationship in this unique patient group.

Regardless of the type of therapeutic modalities, the most common complication of peripheric vascular interventions is restenosis. ISR can be defined as the gradual re-narrowing of a stented segment. Despite technical and technological development in the industry, ISR still remains one of the main concerns for percutaneous procedures. The main mechanism of ISR is endothelial dysfunction, neointimal proliferation, and atherosclerosis.[11] In our study, it is represented that the presence of hypertension, COPD, AF, stroke, and increased CHADS2 score was associated with ISR. Hypertension and DM, which are components of CHADS2 scoring system, can contribute to the progression and worsening of endothelial dysfunction[12,13] However, the presence of DM was not associated with ISR in our study. Similar to our results, in a recent study by Voll et al.,[14] among 256 patients, the presence of DM has a neutral effect on femoropopliteal ISR. Furthermore, relationship between COPD and ISR was questioned previously. Mousa et al.[15] displayed that ISR after subclavian artery stenting in 138 patients was more likely to develop in patients with COPD. With regard to its association with ISR, we have limited knowledge and there is no data in literature that shows

Table 1. Clinical characteristics of all patients at baseline

	Overall (n=419)		ISR (–) (n=372)		ISR (+) (n=47)		p
	n	%	n	%	n	%	
Age, years	60±8.1		60.1±8.1		59.3±8.1		0.539
Male	375	89.7	332	89.5	43	91.5	0.670
BMI, kg/m^2	24.5±2.8		24.5±2.6		24.6±2.7		0.72
Hypertension	266	63.5	229	61.6	37	78.7	**0.021**
Diabetes mellitus	195	46.5	168	45.2	27	57.4	0.112
Dyslipidemia	176	42.3	158	42.8	18	38.3	0.555
Smoking	293	70.4	260	70.5	33	70.2	0.972
CAD	241	57.7	209	56.2	32	69.6	0.083
COPD	84	20.1	66	17.8	18	38.3	**0.001**
Congestive HF	105	25.1	88	23.7	17	36.2	0.062
EF, %	60 (50–65)		60 (55–65)		60 (45–60)		0.152
Atrial Fibrillation	23	5.5	17	4.6	6	12.8	**0.021**
CKD	182	43.4	166	44.6	16	34	0.168
Cerebrovascular disease	30	7.2	23	6.2	7	14.9	**0.031**
Fontaine classification							0.687
Stage IIa	113	27	103	27.7	10	21.3	
Stage IIb	230	54.9	204	54.8	26	55.3	
Stage III	50	11.9	43	11.6	7	14.9	
Stage IV	26	6.2	22	5.9	4	8.5	
Rutherford							0.744
Stage 1	0	0	0	0	0	0	
Stage 2	102	24.3	93	25	9	19.1	
Stage 3	237	56.6	210	56.5	27	57.4	
Stage 4	49	11.7	41	11	8	17	
Stage 5	21	5	19	5.1	2	4.3	
Stage 6	10	2.4	9	2.4	1	2.1	
TASC II classification							**0.012**
Type A	127	30.3	120	32.3	7	14.9	
Type B	164	39.1	141	37.9	23	48.9	
Type C	94	22.4	85	22.8	9	19.1	
Type D	34	8.1	26	7	8	17	
Stent diameter, mm	7.4±2.6		8.4±0.9		7.2±2.8		**0.005**
Stent length, mm	60 (39–100)		59 (39–100)		80 (59–120)		**<0.001**
Procedural time, minutes	32 (18–51)		30 (17–48.8)		41 (28.8–60.5)		**0.004**
The amount of dye injected, mL	175.7±90.1		173.7±91		200.8±83.5		0.301
CHADS2 score	1.52±0.95		1.45±0.93		2.04±0.98		**<0.001**
Follow-up time, month	29.3 ±15.4		30.6±15.5		19±8.9		**<0.001**

Data are presented as percentage, mean±standard deviation or median (interquartile range). ISR: In-stent restenosis; BMI: Body mass index; CAD: Coronary artery disease; COPD: Chronic obstructive pulmonary disease; HF: Heart failure; EF: Ejection fraction; CKD: Chronic kidney disease; TASC: Transatlantic Inter-Society Consensus.

the relationship between the presence of stroke and ISR after AIOD. However, it is well known that patients with a history of stroke have increased atherosclerotic burden.[16] Moreover, as we already know, atherosclerotic process can be related to age that is one of the components of this scoring system.[17] Excluding the presence of COPD, these co-morbidities are components of CHADS2 score and these components are part of calculating the scoring. Therefore, as we have found in our study, CHADS2 was found associated with ISR in patients who had intervention to AIOD.

In a retrospective study, CHADS2 score had a certain value to predict the severity of coronary lesions and the presence of left main coronary artery in ST-elevation myocardial infarction.[5] Not only in patients with coronary artery disease but also CHADS2 score was found closely related with the outcome of PAD. Chi et al.[6] showed that CHADS2 score is a significant predictor to identify high-risk patients for cardiovascular and all-cause mortality in patients with abnormal low and high ankle-brachial index. In another study, Hu et al.[7] determined that CHADS2 score was correlated with the development of lower extremity amputation and mortality in patients with PAD. As a result of fact, these studies represented the close relationship between CHADS2 score and atherosclerotic burden and the outcome of atherosclerosis in patients with high risk in variable manners.

According to our knowledge, there is no study to research relationship between CHADS2 score and ISR in patients with iliac stent implantation. In literature, there are studies that

Table 2. Laboratory parameters of all the patients at baseline

	Overall (n=419)	ISR (–) (n=372)	ISR (+) (n=47)	p
Hemoglobin, mg/dL	13.2±1.6	13.3±1.7	12.9±1.6	0.320
Leukocyte, 10^9/L	2.51±1.12	2.52±1.13	2.46±1.11	0.732
Platelet, 10^9/L	276.3±95.1	275.7±98.1	280.6±70.7	0.744
MPV, fL	10±1.4	10±1.4	10 ±1.4	0.948
eGFR, mL/min/1.73 m^2	83.4±23.9	82.9±24.3	87.3±20.9	0.299
HbA1c, (%)	7.40±1.94	7.4±1.9	7.4±2.4	0.923
CRP	7.6 (3.1–22.3)	6.8 (3.1–22.3)	12.1 (4–24.2)	0.237
Total cholesterol, mg/dL	184.6±52	185.7±50.6	176.7 ±61.1	0.352
LDL cholesterol, mg/dL	109.1±45.4	109.4±44.3	107.5±52.4	0.824
HDL cholesterol, mg/dL	37 (30–45)	36.5 (30–45)	38 (33–46)	0.417
Triglycerides, mg/dL	167 (114.8–250)	170 (115–256)	147 (96.5–200)	0.127

Data are presented as percentage, mean±standard deviation, or median (interquartile range). MPV: Mean platelet volume; GFR: Glomerular filtration rate; HbA1c: Glycated hemoglobin; CRP: C reactive protein; LDL: Low-density lipoprotein; HDL: High-density lipoprotein.

Table 3. Univariable and multivariable Cox regression analyses to determine predictors of in-stent restenosis

	Univariable analysis		p	Multivariable analysis		p
	Hazard ratio	95% CI (lower–upper)		Hazard ratio	95% CI (lower–upper)	
Age	0.994	0.959–1.031	0.755			
Diabetes mellitus	1.207	0.681–2.138	0.520			
Hypertension	1.960	0.997–3.851	0.051			
Hyperlipidemia	0.815	0.453–1.468	0.470			
CKD	0.608	0.329–1.122	0.111			
COPD	3.057	1.697–5.507	**<0.001**	2.850	1.535–5.293	**0.001**
CAD	1.710	0.912–3.206	0.094			
Procedural time	1.010	1.003–1.018	**0.005**	1.004	0.995–1.013	0.385
LVEF	0.979	0.955–1.004	0.094			
Current smoking	0.973	0.521–1.819	0.933			
Atrial fibrillation	2.921	1.237–6.893	**0.014**	1.633	0.623–4.278	0.319
CHADS score	1.655	1.265–2.164	**<0.001**	1.571	1.186–2.081	**0.002**
Stent diameter, mm	0.585	0.386–0.886	**0.011**	0.582	0.366–0.926	**0.022**
Stent length, mm	1.007	1.002–1.012	**0.004**	1.001	0.995–1.008	0.674
HbA1c	1.014	0.784–1.312	0.917			
TASC II lesion classification			**0.031**			0.093
TASC II Type B*	0.243	0.088–0.671	**0.006**	0.877	0.334–2.301	0.790
TASC II Type C*	0.653	0.292–1.461	0.300			
TASC II Type D*	0.417	0.161–1.082	0.072			

HR: Hazard ratio, CI: Confidence interval, CKD: Chronic kidney disease, COPD: Chronic obstructive pulmonary disease, CAD: Coronary artery disease, LVEF: Left ventricular ejection fraction, TASC: Transatlantic Inter-Society Consensus. *Compared to TASC II Type A lesion

show the relationship between CHADS2-VASc score and ISR after coronary artery stent implantation. Yilmaz et al.[18] showed that DM, hyperlipidemia, smoking, stent length, and CHADS2-VASc score were independent predictors of ISR in patients who had bare metal stent implantation. However, Yilmaz et al.'s study was conducted in bare metal stents. Conversely, Zhao et al.[19] found that CHA2DS2-VASs score did not predict ISR in patients who had drug-eluting stent implantation. However, they demonstrated that ISR was associated with the presence of DM and small and longer stent diameter. Therefore, even on the topic of coronary artery stent implantation, we do not have sufficient data to predict ISR and in patients with AIOD who had stent implantation, knowledge about predicting ISR is scarce. Our study demonstrated similar findings to Yilmaz et al's and Zhao et al.'s that DM and stent diameter were associated with ISR and in addition, CHADS2 score was associated with ISR.

The knowledge about association between ISR and stent diameter in AIOD is limited. However, Miki et al.[20] interrogated the association between ISR and stent diameter after stent implantation to superficial femoral artery and downward stent diameter is demonstrated to be related to ISR. This finding has been illustrated in this current study, as well.

There is a clear relationship between ISR and higher CHADS2 score, as represented in our current study. Patients with peripheral artery disease and high CHADS2 score have increased

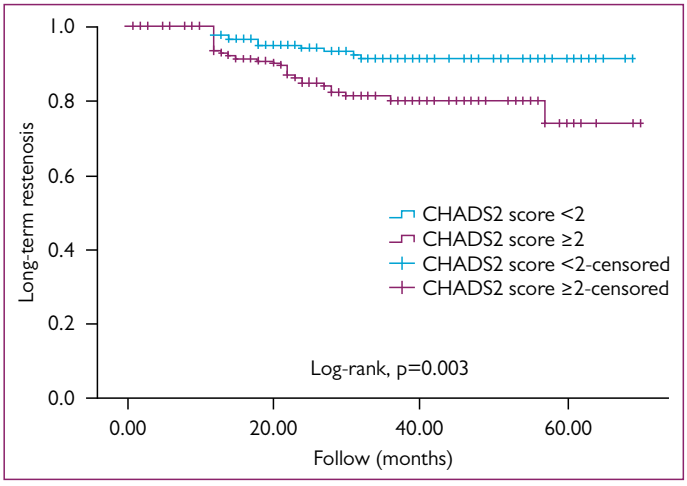

Figure 1. The Kaplan–Meier curves of CHADS2 score for long-term restenosis.

risk of recurrent ischemic events, namely ISR. As a matter of fact, more strict risk factor controlling is required in this patient group. Pro-longed dual antiplatelet regiment may be required, as well. Further trials are needed.

Our study had the following limitations: First of all, it was a retrospective and observational study. Second, our study had a limited number of PAD cases. Third, despite lifestyle modification being recommended for all patients, we did not have a detailed evaluation with respect to adherence to lifestyle modification during follow-up period. Finally, further prospective, randomized, multicenter studies are needed to illustrate the exact power of this scoring system.

Ankle-brachial index has not been used in this patient group. While it is a retrospective study, not all patients have ankle-brachial index values in patients' hospital records. Therefore, researchers could not use it as a pre-procedural and post-procedural assessment method.

Conclusion

Our study demonstrated that COPD, CHADS2 score, and stent diameter were independently related to ISR in long-term follow-up in patients who underwent successful iliac artery stent implantation. Patients with ≥2 points of CHADS2 had statistically significant higher ISR during long-term follow-up. As a result of detailed analysis of our study's findings, this simple and applicable scoring system can be used to estimate high-risk patients for ISR. These patients' medication can be intensified to modify risk factors and more frequent follow-up visits can be arranged to improve long-term outcomes using CHADS2 score.

Disclosures

Ethics Committee Approval: The study was approved by the İstanbul Mehmet Akif Ersoy Thoracic and Cardiovascular Surgery Training and Research Hospital Clinical Research Ethics Committee (no: 2023.01-02, date: 10/01/2023).

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