

# Sensitivity, Specificity and Predictive Value of the Edinburgh Claudication Questionnaire versus Ankle-Brachial Index for the Diagnosis of Lower Extremity Arterial Disease in Turkish Adults

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## ÖZET

**Periferik arter hastalığı tanı testi olan ayak bileği-kol basıncı indeksi ölçümü kullanılarak edinburgh klodikasyon anketinin duyarlılık ve özgüllüğünün değerlendirilmesi**

Alt ekstremité arteriyel hastalığı toplumlara göre değişen sıklıklarda karşılaşılan bir durumdur. Alt ekstremité arteriyel hastalığının non-invaziv yöntemlerle doğru bir şekilde tanısının konulabilmesi önemli bir klinik sorundur. Ayak bileği kol basıncı indeksi ölçümü bu hastalığın tanısında bilinen en duyarlı tanı aracıdır. Bu çalışmanın amacı ayak bileği kol basıncı indeksi ile alt ekstremité arteriyel hastalığı tanısı konulmuş erişkin bir Türk toplumunda, Edinburgh Klodikasyon Anketi'nin hastalığı saptamadaki duyarlılık ve özgüllüğün belirlenmesidir. Çalışmaya 50 yaş ve üzerindeki 200 olgu dahil edildi. Katılımcılara Edinburgh klodikasyon anketi uygulandıktan sonra aynı vizitte ayak bileği kol basıncı indeksi ölçümü yapıldı. Anket sonucunda 27 (%13,5) katılımcıda klodikasyon saptanırken 19 (%9,5) katılımcıda ayak bileği kol basıncı indeksi düşük saptandı. Ayak bileği kol basıncı indeksi ile tanı konulan periferik arter hastalarını saptamada Edinburgh klodikasyon anketi yetersiz kaldı (Duyarlılık %31,6; Özgüllük%88,4; pozitif ve negatif prediktif değerler %22,2 ve %92,5). Edinburgh klodikasyon anketinin düşük duyarlılığa rağmen, yüksek özgüllük ve yüksek negatif prediktif değere sahip olması, bu anketin sadece asemptomatik olgularda, ayak bileği kol basıncı indeksi ölçümü yapmadan alt ekstremité arteriyel hastalığı olmadığının tespit edilmesinde tarama testi olarak kullanılabileceğini gösterdi.

**Anahtar Kelimeler:** Periferik arter hastalığı; Ayak bileği kol basıncı indeksi; Edinburgh Klodikasyon Anketi; Duyarlılık; Özgüllük.

## SUMMARY

Lower extremity arterial disease is a condition with varying frequency in different populations. Accurate diagnosis of lower extremity arterial disease with non-invasive means is an important clinical issue. Ankle brachial index is regarded as the most sensitive tool in the detection of this disease. This study aimed to examine the sensitivity and specificity of Edinburgh claudication questionnaire in detecting lower extremity arterial disease diagnosed by the ankle brachial index test in a group of Turkish adults. Subjects aged 50 years or older (n=200) were first filled the Edinburgh claudication questionnaire to assess leg symptoms and underwent ankle brachial index measurement at the same visit. Edinburgh claudication questionnaire detected claudication in 27 (13.5%) individuals and a low ankle brachial index was found in 19 (9.5%) subjects. Edinburgh claudication questionnaire did not sufficiently identify those peripheral artery disease cases diagnosed by ankle brachial index (sensitivity: 31.6%, specificity: 88.4%, positive and negative predictive values: 22.2% and 92.5%, respectively). Low sensitivity but high specificity and negative predictive values of Edinburgh claudication questionnaire in this Turkish sample suggested that this test as a screening tool only in asymptomatic subjects to confirm the absence of lower extremity arterial disease without measuring ankle brachial index.

**Key words:** Peripheral arterial disease; ankle-brachial pressure index; Edinburgh claudication questionnaire; sensitivity; specificity

## Introduction

Peripheral arterial disease (PAD) is the occlusive atherosclerotic disease of the aorta and lower extremities. Although the incidence of lower extremity arterial disease (LEAD) increases with age, it is recognized as a cause of higher mortality across all age groups. Intermittent claudication is a classic symptom of occlusive LEAD, defined as pain or tiredness that occurs during walking which is relieved by rest (1). Past studies reported significantly low prevalence of intermittent claudication in subjects with LEAD, and only 10% to 30% of patients with LEAD are estimated to present with the classical leg symptoms (2-5).

Definite diagnosis of LEAD can only be established by conventional angiography or computed tomography angiography. However, for long time, non-invasive, cheaper and simpler screening or diagnostic tools such as the Ankle-Brachial Index (ABI) or Edinburgh Claudication Questionnaire (ECQ) are preferable first line options (4,6,7).

Beyond being a screening option ABI has become a diagnostic tool in the assessment of LEAD (4,6). An ABI value less than 0.9 indicates presence of LEAD, with a sensitivity of 79% to 95% and specificity of 90% to 100% for angiographically proven disease (8). ECQ, an improved version of the World Health Organization/Rose Questionnaire which is based on patients' self reported complaints, is a screening tool with a sensitivity of 91% and a specificity of 99% for the detection of intermittent claudication (6,7). Although both tests have displayed similar success in past screening studies for PAD, these two test are not recommended to be used as alternatives to each others.

Questionnaire based screening tools may be subject to misclassifications due to misinterpretation of the questions or cultural differences regarding symptom reporting or grading. Moreover, incomprehensible queries may be put off by the respondents. Therefore, concerning the possibility of variations we aimed to investigate the sensitivity and specificity of ECQ as a screening tool for the detection of LEAD diagnosed by the ABI in a group of Turkish adults.

## Material and Methods

In this single-center, cross-sectional study subjects aged 50 years or older were enrolled prospectively. Enrollees were selected among the attendees of the outpatient clinic of Department of Internal Medicine, Gülhane School of Medicine, Ankara, Turkey. Subjects with apparent speech or hearing disorders, a short life expectancy due to cancer or other diseases, and upper or lower limb disorders limiting optimum ABI measurement were not included.

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All study procedures, including detailed explanation of the objectives and protocol of the study to the patients, demographic records, history taking, physical examination, administration of the ECQ questionnaire and the measurement of ABI, were performed in a private room at the outpatient clinics of Gülhane School of Medicine. The study protocol was approved by the institutional committee of ethics, and a written informed consent was obtained from each participant before enrollment. Study Protocol

All patients were interviewed about the following patient-specific characteristics and variables: age, sex, educational level, smoking habits, history of dyslipidemia, hypertension, diabetes mellitus, coronary heart disease, stroke, presence and duration of PAD, and current medications taken. Then, ECQ printed on a 21 x 29.7 cm plain paper was administered, leaving enough time for completing the form and assisting the subject in case of difficulty in understanding the questions (7). In the following step, height, weight, waist and hip circumference were measured in this environment as the anthropometric measures. Finally, the ABI was measured as described below.

Laboratory findings of the patients were obtained from the hospital records. These included white blood cell, hemoglobin, mean corpuscular volume (MCV), platelet, sedimentation, glucose, urea, creatinine, sodium, potassium, aspartate aminotransferase (AST), alanine aminotransferase (ALT), alkaline phosphatase, direct and indirect bilirubin, uric acid, lactate dehydrogenase, low-density lipoprotein cholesterol (LDL), high-density lipoprotein cholesterol (HDL), total cholesterol, triglycerides, thyroid stimulating hormone (TSH), free T4, ferritin, folate and vitamin B12 values.

#### Evaluation of the Edinburgh Claudication Questionnaire

The EDQs were scored on the basis of the original system introduced by Leng and Fowkes (7). Presence of claudication was confirmed (=positive questionnaire) if the patient answered "yes" to both of questions 1 and 3, "no" to question 2, and "usually disappears in 10 minutes or less" to question 5. Response to question 4 was used to determine the severity of the claudication; "no" suggested lower severity (Grade 1) and "yes" suggested higher severity (Grade 2) of complaints. Site of pain was marked according to response to question 6. Indication of pain in the calf region was regarded as a definitive component of typical claudication, and pain in the thigh and/or buttock regions only was regarded as a significant sign for atypical claudication. Indication of pain in other regions (soles, ankles, shins, knee and hip joints) was regarded as unassociated with the definition of claudication (7).

Then, the participants were classified into two main groups of "subjects with claudication" (ECQ positive ones) and "subjects without claudication" (ECQ negative ones). Participants with claudication were further stratified into three subgroups of Grade 1 typical claudication, Grade 2 typical claudication and atypical claudication;<sup>7</sup>

I. "Subjects with claudication—Grade 1": "yes" to questions 1,2,3,5 plus "no" to question 4 plus pain indicated in at least one calf region

II. "Subjects with claudication—Grade 2": "yes" to Questions 1,2,3,5 plus "yes" to question 4 plus pain indicated in at least one calf region

III. "Subjects with atypical claudication": "yes" to Ques-

tions 1,2,3,5 plus, irrespective of the answer to question 4, absence of pain in calf regions but pain indicated in thigh and/or buttock regions

Patients not falling into any of the 3 groups above were considered "ECQ negative" in terms of presence of claudication.

#### Measurement of ABI

The measurement was performed with the patient supine. To ensure the comfort of the both arms, 2 metal armrests of 25 cm width and 80 cm length were placed on the head of the stretcher at an angel of 30°. For the measurement, 4 fully calibrated aneroid sphygmomanometers with velcro cuffs were used (ERKA, D-83646, Germany). Cuff width was 12 cm and cuff length was 29 to 42 cm. Four extremities of the participant were wrapped with cuffs at the same time and as this preparation made the participant was allowed to rest at least for 5 minutes. Both of the brachial pulses in the upper extremities and dorsalis pedis and tibialis posterior pulses in the lower extremities were recorded. Measurements were obtained using a handheld 8-MHz Doppler instrument (Hadeco, Japan) using transducer gel. The first blood flow sound heard as the cuff was deflated was recorded. The readings were started from the right arm, followed by the right ankle, left ankle and left arm. The cycle was repeated and 2 values were recorded for each vessel. Mean value of the 2 measurements was considered as the final result for the respective vessel.

ABI was calculated based on the Trans-Atlantic Inter-Society Consensus Document on Management of Peripheral Arterial Disease (TASC) II guidelines (4). First, right and left ABIs were calculated separately by dividing the higher systolic blood pressures in each ankle (a. tibialis posterior or a. dorsalis pedis) to the higher brachial systolic blood pressure measured in the right or left upper limbs. Then, the lower one of the right or left ABI values was considered as the final standard ABI value of the tested individual.

#### Statistical Analyses

Descriptive statistics were expressed as mean and standard deviation for continuous variables, and as frequency and percentage distributions for discrete variables. Normally distributed variables were compared using t-test, and non-normally distributed variables were compared using chi-squared test. Statistical analysis was performed using SPSS version 21.0 (SPSS Inc., Chicago, Illinois, USA).

## Results

#### Demographic, Clinical and Laboratory Findings

A total of 200 individuals with a mean age of 64.68±8.97 (50 to 87) were enrolled. Female to male ratio was 119/81 (59.5%/40.5%). Mean duration of education was 6.82±4.18 years. Mean BMI was 30.77±4.85 kg/m<sup>2</sup>. Detailed demographic and clinical characteristics are shown in Table I. As shown in Table II, basic laboratory findings were consisted with the mean age of the group and the number of comorbidities which were classified as LEAD risk factors.

#### LEAD Risk Factors

Risk factors for LEAD or any cardiovascular disease as well as the list of established cardiovascular disease are also shown in Table I. Compared to general population reports in the same country (9), the study group had higher frequency of

**Table I.** Demographic, clinical characteristics of patients, PAD risk factor profile and medical history of cardiovascular diseases (n=200)

	Mean	SD	Minimum-maximum
Age (years)	64.68	8.97	50-87
Duration of education (years)	6.82	4.18	0-15
Height (cm)	159.96	8.51	144-185
Weight (kg)	78.52	12.34	46-124
Body mass index (kg/m <sup>2</sup> )	30.77	4.85	17.63-46.10
Waist circumference (cm)			
Males	97.67	82.9	69-119
Females	100.09	11.24	74-136
Hip circumference (cm)			
Males	103.65	6.88	85-125
Females	109.41	8.96	90-142
Waist/hip circumference ratio			
Males	0.94	0.06	0.76-1.14
Females	0.91	0.07	0.71-1.22
	<b>n</b>	<b>%</b>	
Gender (Males / females)	81 / 119	40.5 / 59.5	
Age (males ≥50)	81	100	
Age (females ≥55)	92	77.3	
Smoking (active or former smoker)	86	43	
Diagnosed with hypertension	125	62.5	
Diagnosed with diabetes mellitus	78	39	
Diagnosed with dyslipidemia	74	37	
LDL-C >130 mg/dL	86	43	
HDL-C <40 mg/dL for males; <50 mg/dL for females	79	39.5	
LDL-C >130 mg/dL and HDL-C <40/50 mg/dL	26	13	
Body Mass Index >30 kg/m <sup>2</sup>	105	52.5	
Medical history of Cardiovascular Disease			
Cardiovascular Disease	34	17	
Stroke	15	7.5	

SD: Standard Deviation; HDL-C: high-density lipoprotein cholesterol; LDL: low-density lipoprotein cholesterol D sunulmasinaenceiondemiol 2001., BPHypertension, and overweight cardiovascular disease or

atherosclerotic risk factors such as hypertension around 60%, diabetes mellitus around 40% and smoking around 45%. Half of the participants were obese and 1 of every 6 subjects had a history of coronary heart disease, indicating higher rates than are known for the general Turkish population (10).

#### Edinburgh Claudication Questionnaire Analyses

Evaluation of responses to ECQ is shown in Table III. The total of number of patients with a positive ECQ was 27 (13.5%). Out of 27 patients with a positive ECQ, 8 (4%) had Grade 1 typical claudication, 14 (7%) had Grade 2 typical claudication, and 5 (2.5%) had atypical claudication (Table IV). ECQ results

did not change according to gender or years of education ( $p=0.292$  and  $p=0.548$ , respectively).

#### Frequency of a low ABI

ABI measurement could not be performed in 2 subjects due to incompressible pulses. These participants were classified as PAD negative patients. For the remaining 198 patients, mean right and left ABI values were  $1.19 \pm 0.19$  and  $1.17 \pm 0.17$ , respectively. The final mean ABI value was  $1.14 \pm 0.18$  (Table V).

Nineteen (9.5%) patients had an ABI value below 0.9, and were classified as having LEAD. Thirty-seven subjects (18.5%)

<b>Table II. Laboratory findings</b>			
Measurement (unit)	Mean	SD	Minimum-maximum
White blood cell (x10 <sup>3</sup> /microL)	6.39	1.57	3.2-13.4
Hemoglobin (g/dL)	13.33	1.34	8.39-16.70
MCV (fL)	86.12	5.98	58-104
Platelets (x10 <sup>3</sup> /microL)	285.71	91.31	109-1119
Sedimentation (mm/s)	22.23	15.71	1-99
Glucose (mg/dL)	111.44	34.36	48-296
Urea (mg/dL)	35.99	10.29	17-78
Creatinine (mg/dL)	0.97	0.38	0.61-5.45
Sodium (mmol/L)	140.30	2.21	134.20-146.30
Potassium (mmol/L)	4.46	0.45	2.66-5.89
AST (U/L)	24.18	9.29	8-103
ALT(U/L)	22.90	11.71	6.11-88
Alkaline phosphatase (U/L)	116.40	41.80	24-411
Direct bilirubin (mg/dL)	0.13	0.07	0.04-0.41
Total bilirubin (mg/dL)	0.77	0.33	0.22-1.99
Uric acid (mg/dL)	5.26	1.45	0.94-12.15
Lactate dehydrogenase (U/L)	376.35	81.80	4.62-746
LDL cholesterol (mg/dL)	125.53	32.39	50-224
HDL cholesterol (mg/dL)	49.61	11.18	26-102
Total cholesterol (mg/dL)	204.16	37.94	87-322
Triglycerides (mg/dL)	153.94	66.82	45-376
TSH (mU/L)	1.90	1.22	0.10-6.47
Free T4 (ng/dL)	1.09	0.20	0.54-1.84
Ferritin (ng/mL)	57.24	47.50	3.10-258.50
Folate (ng/mL)	14.00	5.50	4.36-28.54
Vitamin B12 (pg/ml)	405.78	224.88	143-2030

AST: aspartate aminotransferase; ALT: alanine aminotransferase; HDL: high density lipoprotein; LDL: low density lipoprotein; MCV: mean corpuscular volume; SD: standard deviation; TSH: thyroid stimulating hormone

<b>Table IV. Stratification of patients according to the Edinburgh Claudication Questionnaire results (n=200)</b>	
	n (%)
Patients with claudication (ECQ positive)	27 (13.5)
Patients with typical claudication-Grade 2	14 (7.0)
Patients with typical claudication-Grade 1	8 (4.0)
Patients with atypical claudication	5 (2.5)
Patients without claudication (ECQ negative)	173 (86.5)

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<b>Table III. Responses to Edinburg Claudication Questionnaire (ECQ) (n=200)</b>		
ECQ Question	Yes n (%)	No n (%)
Q1	99 (49.5)	101 (50.5)*
Q2	47 (47.4)	52 (52.6)
Q3	90 (90.9)	9 (9.1)
Q4	62 (62.6)	37 (37.4)
Q5	63 (63.6)**	36 (36.4)**
Q6 Site of Pain		
Right frontal thigh area	10 (10.1)	89 (89.9)
Left frontal thigh area	9 (9.1)	90 (90.9)
Right frontal leg area	18 (18.2)	81 (81.8)
Left frontal leg area	19 (19.2)	80 (80.8)
Right back thigh area	16 (16.2)	83 (83.8)
Left back thigh area	14 (14.1)	85 (85.9)
Right calf	50 (50.5)	49 (49.5)
Left calf	53 (53.5)	46 (46.5)
Knees	30 (30.3)	69 (69.7)
Buttocks	4 (4.1)	95 (95.9)

\*Questionnaires of those who answered "no" to Q1 were discontinued.  
\*\*Question 5= "Usually disappears in <10 minutes"="Yes"

<b>Table V. Mean Ankle-Brachial Index (ABI) values (n=198)</b>		
Measurement side	Mean	SD
Right API	1.19	0.19
Left API	1.17	0.17
Final API	1.14	0.18
SD: Standard deviation		

<b>Table VI. Stratification of patients according to Ankle-Brachial Index (ABI) measurement (n=200)</b>	
ABPI	n (%)
ABI <0.4 – Severe PAD	0 (0)
ABI 0.41-0.9 – Mild and medium PAD	19 (9.5)
ABI 0.91-1.3 – Normal	144 (72)
ABI >1.3 – High ABI	37(18.5)
PAD: peripheral artery disease	
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**Table VII. Sensitivity, specificity, positive and negative predictive values of Edinburgh Claudication Questionnaire (ECQ) positive patient stratifications**

ECQ positive patients	n	Sens. (%)	Spec. (%)	PPV (%)	NPV (%)
Typical claudication- Grade 2	14	31.6	95.6	42.9	93
Typical claudication - Grade 1	8	0	95.6	0	90.1
Atypical claudication	5	0	97.2	0	90.3
All with claudication	27	31.6	88.4	22.2	92.5

NPV: negative predictive value; PPV: positive predictive value;  
Sens.: sensitivity; Spec.: specificity.

with an ABI value above 1.3 were classified as having high ABI due to medial calcification. Finally, 144 (72%) subjects having an ABI value between 0.9-1.3 were classified as having a normal ABI (Table VI).

Specificity, Sensitivity, Negative and Positive Predictive Values of ECQ

LEAD was detected in 27 (13.5%) and 19 (9.5%) subjects according to ECQ and ABI, respectively. ECQ showed a poor sensitivity (31.6%) but high specificity (88.4%) for the ABI detected LEAD. Accordingly, the positive predictive value (PPV) of ECQ was 22.2% and negative predictive value (NPV) was 92.5. Sensitivity and specificity of each of the questions in the ECQ test were also investigated. While presence of pain when walking uphill or in a hurry had the highest sensitivity, absence of pain during sitting or standing still showed the highest specificity for the presence of intermittent claudication.

In the following step, subjects with a positive ECQ were evaluated separately. ECQ results had the highest concordance with the ABI detected LEAD in subjects with grade 2 claudication (sensitivity: 31.6%, specificity: 95.6%; PPV: 42.9%, NPV: 93%), followed by subjects with Grade 1 claudication (sensitivity: 0%, specificity: 95.6%, PPV: 0%, NPV: 90.1%) and subjects with atypical claudication (sensitivity: 0%, specificity: 97.2%, PPV: 0%, NPV: 90.3%;) (Table VII)

## Discussion

The prevalence of LEAD varies significantly across populations, ranging from 11% in France (13) to 18% in Germany (11) and 29% in the USA (12) in high risk group of patients. In the multi-center, nationwide Turkish study titled "Peripheral artery disease assessed by ankle-brachial index in patients with established cardiovascular disease or at least one risk factor for atherothrombosis (CAREFUL)" the prevalence of PAD was reported as 20% among people aged  $\geq 50$  years with at least one cardiovascular risk factor (14) In a very similarly designed study conducted in our clinics among internal medicine outpatients, the prevalence of PAD was found to be 5% (15). In the current study on a group with a higher mean age, the total prevalence of LEAD as diagnosed by an ABI  $\leq 0.9$  was 9.5%.

In a previous study, while the prevalence of intermittent claudication among people aged  $>70$  years was reported to be 7%, up to one-third of the subjects diagnosed with LEAD was found to have intermittent claudication (4). In our study,

the prevalence of claudication among patients aged  $\geq 50$  years and  $\geq 70$  years was 13.5% and 13.4%, respectively. When the patients with atypical claudication were excluded, this rate decreased to 11% in patients aged  $\geq 50$  years and to 8.95% in patients aged  $\geq 70$  years. Prevalence of LEAD patients diagnosed by a low ABI was 31.5% in our work.

At first glance, differences between the results of these studies would seem to be caused by the varying prevalence rates of LEAD across populations. However, in such case, the prevalence of intermittent claudication should also have been higher in PARTNERS which reported a LEAD prevalence of 29% (12). We suggest that differences in these results might be related to research methods—specifically, use of a questionnaire instead of sole clinical assessment in the current study. Differences in the perceived pain might also be possible across societies and cultures.

In a study of randomly selected patients aged  $\geq 40$  years of whom 7.2% had a history of PAD, 11.7% were found to have an unknown PAD and an ABI of  $\leq 0.9$  or  $>1.4$ , therefore totaling to a 18.9% of high risk group patients (16). In our study, 28% of patients, 9.5% whom had low and 18.5% had high ABI, established a high risk group, with a definite increase in mortality due to cardiovascular disease or all causes as shown in previous surveys. These differences are likely to be caused by demographic and epidemiological factors, higher age and greater number of patients with risk factors such as diabetes, hypertension and obesity in our study, as well as by the lower threshold of  $>1.3$  for high ABI.

Identifying the high risk subjects, determining the presence of intermittent claudication (the primary clinical finding of LEAD) among them and subsequently referring for an ABI measurement are required steps to improve PAD detection rates in general. Leng et al (11) suggested that the ECQ, with its sensitivity of 91% and specificity of 99%, could successfully serve for this purpose. However, ECQ has been reported to have variable sensitivity and specificity levels across different populations. For example, the questionnaire showed a sensitivity of 50% and a specificity of 68% study among a group of black African-Caribbean UK immigrants (17), and a sensitivity of 25% and a specificity of 99.4% in a study on a group of Malaysian patients with diabetes (18). In our study, ECQ showed a sensitivity of 31.6% and specificity of 88.4%. These discrepant results may be caused by two facts. First, ECQ was formed as part of the Edinburgh Artery Study which included

a predominantly white, European population (8,19). Second, in the study by Leng et al (11), LEAD was diagnosed solely by the clinical assessment of physicians, not using the ABI testing. It is likely that the ECQ and clinical assessment results had high agreement in that study (11) because both tools can successfully detect symptomatic disease.

Sensitivity refers to the ability of a test to correctly identify those patients with the disease. In our study, ECQ showed a low sensitivity of 31.6%. Furthermore, the PPV of the test—that is, the probability of actually having the disease given a positive test result—was found to be 22.2%. Therefore, despite the small sample size, which limits the generalization of findings for the Turkish population, it could be concluded that the ECQ may not serve as an appropriate diagnostic test. Even the most sensitive question of the test, question 3, showed a very limited ability (57.9%) to distinguish those with the disease from those without. According to the ECQ results, the test was sensitive only to “patients with claudication—Grade 2”, suggesting an advantage of the test mostly limited to severe symptomatic disease. On the other hand, specificity refers to ability of a test to identify correctly those free of disease. In our study, ECQ showed a quite satisfactory specificity of 88.4%. This might indicate that although ECQ may not serve as a good diagnostic test, it can be used as an effective screening tool. Furthermore, the NPV of the test—that is, the probability of actually not having the disease given a negative test result—was found to be 92.5%.

In our study, we used ABI as the standard diagnostic test, and patients with a high ABI did not undergo an advanced imaging test that could detect false negative results in terms of LEAD. Thus, it is possible that some of the ECQ positive patients with true LEAD were misclassified because of a high ABI, further decreasing the sensitivity of the test. However, as the NPV for detecting LEAD was previously reported as 97.3% when a low ABI was used (20), we suggest that sensitivity was only marginally affected by this issue. Enrollment of subjects from a single outpatient setting of internal medicine but not from other sites such as cardiology or cardiovascular surgery sections might limit generalization of the results across all patients at risk.

## Conclusion

The present study showed that, at least in a small group of Turkish adults with multi-morbidity, ECQ was not a sensitive tool to detect LEAD diagnosed by ABI measurement. Although the small sample size and our sampling method limit the generalizability of findings, it can be concluded that ECQ cannot be used as a diagnostic test for PAD. However, a negative ECQ result can practically be used to exclude LEAD in subjects with low probability of the disease. In other words, a negative ECQ can show who do not need to undergo ABI measurement.

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