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ORIGINAL ARTICLE

Is the Edinburgh Claudication Questionnaire a good screening tool for detection of peripheral arterial disease in diabetic patients?

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Abstract

Aims: To determine whether the Edinburgh Claudication Questionnaire (ECQ) can be used as a screening tool for detecting peripheral arterial disease in patients with diabetes mellitus.

Methods: A cross-sectional study of 200 patients with diabetes over 18 years of age who attended a primary care clinic at a teaching hospital in Kuala Lumpur, Malaysia. Face-to-face interviews were conducted using the ECQ for the presence of intermittent claudication. Blood pressure and peripheral neuropathy were assessed. Ankle brachial pressure index (ABPI) was measured and used as a gold standard for the diagnosis of eripheral arterial disease (PAD), which was defined as an ABPI of < 0.9 on either leg.

Results: The overall prevalence of PAD was found to be 16% among patients with diabetes based on ABPI. Among these 32 patients with PAD, eight (25%) had symptoms of intermittent claudication based on the ECQ. The ECQ was found to have a low sensitivity (25%) but a high specificity (99.4%), with a positive predictive value of 88.9% and a negative predictive value of 88% for diagnosing PAD in patients with diabetes.

Conclusions: The ECQ is not a good screening tool for detection of PAD among patients with diabetes due to its low sensitivity.

Key words: ankle brachial pressure, diabetes mellitus, Edinburgh Claudication Questionnaires, intermittent claudication, peripheral arterial disease.

Introduction

Peripheral arterial disease (PAD) is a vascular disease that is a marker of systemic atherosclerosis.[1] The progressive growth of atherosclerotic plaque in the extremities may lead to stenosis of one or more arterial

segments along the iliofemoral-popliteal axis, which may induce the clinical manifestation of PAD such as intermittent claudication (IC) and rest pain. Leriche and Fontaine have classified PAD into four stages.[2] In stage 1, patients are usually asymptomatic, but at this stage a good objective examination will show normal, diminished or absent pulses or an ankle brachial pressure index (ABPI) of < 0.9. In stage 2 patients may exhibit symptoms of IC. Stage 3 is characterized by rest pain (critical ischaemia), which usually gives rise to trouble at night. In stage 4, ulcerations ranging from trophic lesions to gangrene are apparent.[2]

Intermittent claudication presents with a characteristic history of pain in the muscle, typically in the calf, thigh or buttock, which is elicited by exertion and relieved within a few minutes of rest. The distal lesions in the femoral, popliteal or tibial arteries produce a cramping pain in the calf muscles, while proximal or aorto-iliac lesions usually produce an aching discomfort in the hips, buttocks or thigh.[3] The level, severity and extent of PAD determine the location of the pain, and also the amount of exercise needed to produce it. Consequently active patients experience functional limitation before those who are sedentary.[4] Patients with IC often experience a diminishing quality of life due to reduction in walking distance and speed, which translates into progressively limited mobility and independence. Unfortunately, many patients do not alert their physicians of their disease, since they attribute it to the non-specific musculoskeletal symptoms of aging.[5]

In large studies among the general population, prevalence of IC has ranged from 3% to 10% with a sharp increase in those aged 70 years or above. Two to four percent of these patients require major amputations in their lifetime and their life expectancy is approximately 10 years less than that of an age-matched cohort.[6] The progression of PAD has been associated with age, diabetes mellitus (DM) and classic intermittent claudication.[7]

Peripheral arterial disease is more common in patients with diabetes and it occurs at a younger age and progresses more rapidly. It has been estimated that PAD is present in 15% of patients with diabetes, 10 years after the initial diagnosis and in 45% of patients 20 years after diagnosis.[8] Data from the Framingham study showed that the relative risk of symptomatic PAD or intermittent claudication in individuals with DM was 4–5 times higher than those without. In patients with diabetes the prevalence of PAD increases with age, duration of diabetes and male gender.[9]

Patients with diabetes are at greater risk of developing both macro- and microangiopathy. Macroangiopathy usually involves the larger vessels, which are below the knee, primary tibial and peroneal vessels. Microangiopathy involves the small arterioles and microvessels, especially in the distal part of the lower extremities.[9] It has been reported that in patients with diabetes and PAD, over half are asymptomatic or have atypical symptoms, and a third have claudication. These patients usually have peripheral neuropathy with impaired sensory feedback. Thus a classic history of claudication may be less common. However, patients may elicit more subtle symptoms, such as leg fatigue and slow walking velocity. Patients with diabetes and PAD are more prone to develop sudden ischaemia of arterial thrombosis or may have a pivotal event leading to neuroischaemic ulceration or infection that rapidly results in an acute presentation with critical limb ischaemia and risk of amputation. By identifying these patients with subclinical disease and instituting preventative measures, it may be possible to avoid acute limb-threatening ischaemia.[10]

Patients with diabetes and lower extremities PAD are also at increased risk of developing foot complications such as foot ulcer, ischaemia, gangrene and amputation. These foot problems and amputations have major financial and emotional impact for the individuals as well as impact on the health care system.[11]

The diagnosis of PAD can be made on the basis of symptoms using the WHO Rose or Edinburgh Claudication Questionnaires (ECQ) and by measuring ABPI.[4] Further investigations such as duplex ultrasonography and angiography are usually reserved for a small minority of patients in whom invasive intervention is being considered.[12] Classic cases of IC are stereotypical and reproducible enough to allow near-certain diagnosis of PAD by using claudication questionnaires. Consequently, healthcare providers in the community setting can identify the classic case of IC without the use of sophisticated or expensive tests.[13]

There were few questionnaires used in previous studies for screening IC. TheWHO Rose questionnaires were developed for epidemiological surveys. They was moderately sensitive (60–68%), and highly specific (90–100%). The ECQ is an improved version of the WHO Rose Claudication Questionnaires. It was found to be 91.3% sensitive and 99.3% specific in detecting IC in the general population, compared with the diagnosis of

PAD made by clinical examination.[14] The positive predictive value of ECQ was 100% and the negative predictive value was 81%. All patients diagnosed as having claudication by their physicians were also found to have peripheral vascular disease on non-invasive testing. These questionnaires were validated and repeatability of questionnaires after 6 months was excellent ($p = 0.76$, $p < 0.001$).[14]

Ankle brachial pressure index is an important effective simple clinical tool for non-invasive diagnosis of PAD.[15] The correlation of a decrease in ABPI with angiographically documented disease in the large arteries is well established. The sensitivity of ABPI is 90% and specificity is 98% for an angiographically defined stenosis of 50% or more in a major leg artery.[16] However, an ABPI value of more than 1.3 suggests poorly compressible arteries at the ankle level due to the presence of medial arterial calcification, especially in diabetics.[10] Patients with claudication tend to have ABPI in the range of 0.5–0.9 whereas those with critical ischaemia usually have an index below 0.5.8

As the ECQ is a simple instrument that can be easily used in a primary care setting as compared to the ABPI, which is not readily available, we intend to look at how good the ECQ is as a screening test compared to ABPI as a gold standard for the detection of PAD in patients with diabetes.

Methods

This was a cross sectional study on previously diagnosed patients with diabetes over 18 years of age who attended a Malaysian primary care clinic at a teaching institution in 2004. Two hundred patients were recruited using universal sampling. Ethics approval was obtained from the hospital ethics committee.

All patients with DM that attended the clinic during the study period were approached. Of the 202 patients approached, 200 agreed to participate, giving a response rate of 99%. The ECQ was administered face-to-face to determine the prevalence of IC. It consisted of six questions:

• Question 1 assesses whether patients get any pain or discomfort on walking.
• Question 2 evaluates whether patients get this pain when they are standing still or sitting.
• Question 3 estimates whether patients get pain when they walk uphill or walk in a hurry.
• Question 4 determines whether patients get this pain walking at an ordinary pace on level ground.
• Question 5 assesses whether if patients stand still the pain continues for more than 10 min or disappears within 10 min.
• Question 6 requires patients to mark on a diagram, where they actually get pain or discomfort.

Definition of positive claudication requires all of the following responses:

• Yes to Q1;
• No to Q2;
• Yes to Q3;
• No (grade 1) to 4;
• Yes (grade 2) to 4;
• Yes to 5 if pain usually disappears in 10 min.

If these criteria are fulfillled, based on Question 6, a patient with definite claudicantion is one who indicates pain in the calf, regardless of whether the pain is also marked at other sites. A patient with atypical claudication was one who indicated pain in the thigh or buttock in the absence of any calf pain. Subjects were not considered to have claudication if pain is indicated in the hamstrings, feet, shins, joints or appears to radiate, in the absence of any pain in the calf.[14]

Ankle brachial pressure was measured in a supine position with a 12-cm occluding cuff above the ankle and a portable Doppler device was used as the distal sensor at the dorsalis pedis and posterior tibial arteries and brachial systolic blood pressure (BP) was measured from both arms. ABPI was calculated by dividing the higher of the two readings of ankle pressure at the dorsalis pedis or post-tibial artery on one side, by the brachial systolic pressure of the same side.[16] PAD was defined as a ABPI of < 0.9, while ABPI > 0.9 denoted absence of the disease. ABPI > 1.3 suggests partial incompressibility of arteries, which is likely to be due to medial arterial calcification in diabetics.[17]

The ECQ was translated into Malay language and was back-translated. The study was piloted on 10 patients. The data was analyzed using SPSS Version 11.5 for Windows. Chi-square test was used to look for associations between categorical variables. The level of significance was set at $p < 0.05$.

Results

The mean age was 61.10 ± 9.82 years (median, 61 years). Age distribution is shown in Fig. 1. The subgroup analysis did not show any statistical significance between patients with PAD and age < 60 years and those aged ≥ 60 years.

Female patients totalled 60.5% of the total sampled. The ethnic breakdown was Malay 26.0%, Chinese 31.0% and Indian 43.0%. Almost all patients were type 2 diabetics and the mean duration of DM was 10.72 ± 7.56 years (median = 10 years). The distribution of duration of diabetes is shown in Fig. 2. The subgroup analysis did not show any statistical significance between patients with PAD and duration of diabetes < 10 years, and those with duration of diabetes 10 ≥ years.

Six percent of patients were current smokers and 18.0% were ex-smokers. Seventy-five percent of patients had concurrent hypertension and 56% had dyslipidaemia. Regarding treatment of these patients, seven (3.5%) were on diet control only, one (0.5%) was on oral hypoglycaemic agents and insulin, while 177 (88.5%) were on diet and oral hypoglycemic agents, three (1.5%) were on insulin and diet control, one (0.5%) on insulin only, four (2.0%) on oral hypoglycaemic agents only, seven (3.5%) on insulin, oral hypoglycemic agents and diet control.

Using ABPI < 0.90 as the standard in diagnosing PAD, 32 (16%) patients had PAD. Among the 168 with ABPI ≥ 0.9, 15 (8.9%) had ABPI ≥ 1.30. The total number of patients with a positive ECQ was nine (4.5%): eight (4%) were found in patients with PAD and one (0.5%) in patients without PAD. Out of eight subjects with a positive ECQ and PAD, five (62.5%) had typical claudication and three (37.5%) had atypical claudication. A positive ECQ was significantly associated with PAD ($p < 0.0001$). The sensitivity, specificity, positive predictive and negative predictive value of ECQ used in diagnosing PAD is shown in Table 1.

The overall prevalence of peripheral neuropathy was 82 (41%) among the 200 subjects, and more than half (53.1%) of patients with PAD had concomitant peripheral neuropathy.

Discussion

We found the prevalence of PAD was 16% in patients with diabetes based on ABPI and the prevalence of IC using the ECQ was 4.5%. Twenty-five percent of patients with diabetes and PAD and IC. The ECQ showed a low sensitivity of 25% and a high specificity of 99.4%, in diagnosing PAD and the positive predictive value was 88.9% and the negative predictive value was 88%. This signifies that it is a very good test to diagnose PAD due to its high positive and negative predictive values. However, it is not a good screening tool for PAD in diabetic patients due to its low sensitivity, as many patients would have been missed.

Studies done thus far had been on the general population but not on diabetic populations. In Chao's study, the prevalence of PAD was found to be 15.1% in the general population based on ABPI, while the prevalence of IC was 2.71% based on the ECQ, that is less than one-fifth had symptomatic disease.[18] Similarly, other studies on the general population found the prevalence of PAD varied from 8% to 26.7% based on ABPI while prevalence of IC using the Rose Questionnaires varied from 1.6% to 6.4%.[19–22] It appears that few patients have symptomatic disease. Therefore, if questionnaires were used to detect PAD in diabetic patients, they would have missed a large number with the disease. The reason for the low prevalence of IC may be due to concomitant high prevalence of peripheral neuropathy as these patients were unable to feel the pain. It may also be due to either hip or knee pathology that could limit their walking or well-compensated arteriopathies.

Universal sampling and small samples size were limitations of this study. Nevertheless, it suggests that although the ECQ is a good test to diagnose PAD, it is not a good screening tool for PAD in patients with diabetes in the primary care setting.

Conclusion

Peripheral arterial disease is common among patients with diabetes with a prevalence of 16% based on ABPI but the prevalence of IC in patients with diabetes and PAD using the ECQ was only 4% and hence only a quarter of patients with PAD had symptomatic disease. Although the ECQ has high specificity and positive and negative predictive values, its lower sensitivity limits its use as a screening tool for the detection of PAD in patients with diabetes.

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Table 1 - Predictability of the Edinburgh Claudication Questionnaire (ECQ) for peripheral arterial disease (PAD)

	ECQ+	ECQ–
PAD present	8	24
PAD absent	1	176

Specificity (99.4%), sensitivity (25%), positive predictive value (88.8%), negative predictive value (88%)

Figure 1 - Distribution of study patients by age

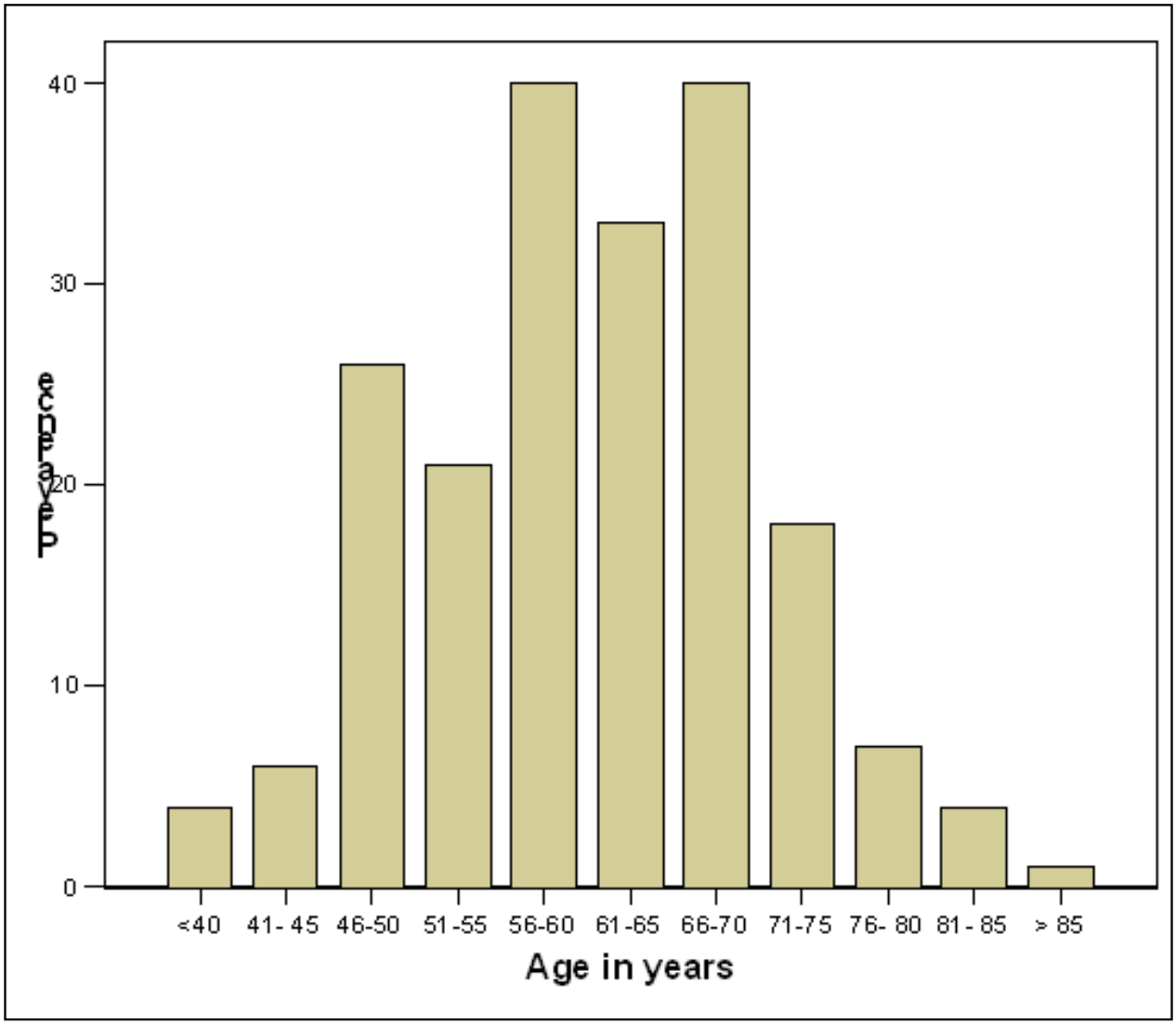
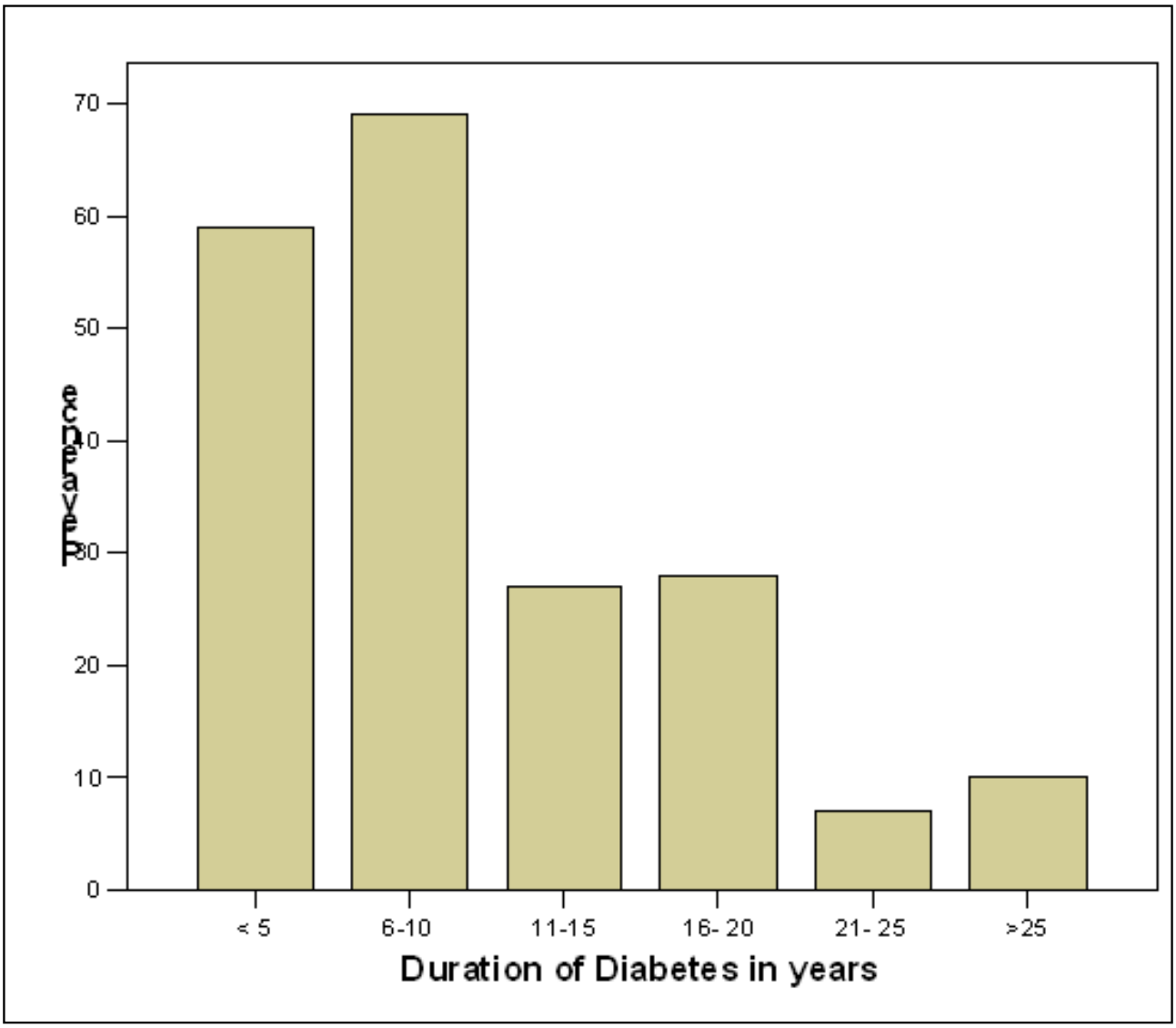


Figure 2 - Duration of diabetes mellitus in study patients



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