Quality in Primary Care 2012;20:409–14

Research paper

Screening for peripheral vascular disease in patients with type 2 diabetes in Malta in a primary care setting

Cynthia Formosa MSc PhD
Head of Podiatry School, Faculty of Health Sciences, University of Malta; Visiting Fellow, Faculty of Health Sciences, Staffordshire University

Alfred Gatt MSc PhD
Lecturer, Faculty of Health Sciences, University of Malta

Nachiappan Chockalingam BEng MSc PhD
Professor of Clinical Biomechanics, Faculty of Health Sciences, Staffordshire University, Stoke on Trent, UK; Affiliate Professor, Faculty of Health Sciences, University of Malta and CSHER

ABSTRACT

Background Peripheral vascular disease (PVD) is strongly associated with type 2 diabetes. PVD assessment and diagnosis are often neglected in primary care office visits, and ankle/brachial pressure index (ABPI) examinations are seldom performed for PVD detection. The purpose of this study was to evaluate the occurrence of PVD in a primary care setting using ABPI in patients with type 2 diabetes in Malta.

Method A retrospective study was conducted on a cohort of 243 patients with type 2 diabetes to address various issues. As part of this large study, data from ABPI measurements collected using a portable hand-held Doppler with ankle pressures of <0.8 suggestive of PVD were extracted.

Results Twenty-six per cent of the sample had to be referred for further vascular assessment following this screening programme due to their critical vascular status. Furthermore, at the time of examination, approximately 7% of the patients had an ABPI of less than 0.8 in both left and right extremities.

Conclusion A significant proportion of Maltese patients with type 2 diabetes who visit primary care present with vascular insufficiency. The use of ABPI should be considered as an added measurement in order to facilitate early detection and treatment and reduce the burden of PVD in this high-risk population.

Keywords: ankle brachial pressure index, critical limb, diabetes foot screening, diabetes mellitus, peripheral vascular disease

How this fits in with quality in primary care

What do we know?
Peripheral vascular disease (PVD) is common in type 2 diabetes, but its assessment and diagnosis are often neglected in primary care. Ankle/brachial pressure index (ABPI) examinations are seldom used for PVD detection.

What does this paper add?
A significant proportion of Maltese patients with type 2 diabetes attending primary care clinics have vascular insufficiency. The use of ABPI measurement should be considered as an adjunct measurement in primary care in order to facilitate early detection and treatment.

Introduction

Peripheral vascular disease (PVD) is strongly associated with type 2 diabetes. PVD assessment and diagnosis are often neglected in primary care office visits,[1] and ankle/brachial pressure index (ABPI) examinations are seldom performed for PVD detection in these clinics. The authors evaluate the occurrence of PVD in a primary care setting using ABPI in patients with type 2 diabetes as recommended by the International Working Group on the Diabetic Foot.[2]

It is estimated that 27 million individuals in Europe and North America have PVD. Risk factors for this condition include smoking, diabetes, dyslipidemia, hypertension and obesity. Age, race and gender are also regarded as non-modifiable risk factors. Only about 25% of patients with PVD are undergoing treatment for this condition.[3] This low percentage is largely attributed to the fact that most people do not know that they have the condition. The majority of people with this condition are said to be asymptomatic, the reason for this being that many patients with diabetes do not report their symptoms such as claudication pain, since their pain perception may be blunted by the presence of peripheral neuropathy. Furthermore, one-third of these asymptomatic patients are said to have complete occlusion of a major leg artery,[3] making it more likely for the patient to present with an ischaemic ulcer which may lead to gangrene and later amputation.

The clinical importance of early identification and treatment of PVD is increasingly acknowledged.[4] Good equipment must be provided to diagnose foot problems in people with diabetes before the condition worsens and becomes more costly to treat.[2] PVD is known to be strongly associated with type 2 diabetes, although its prevalence depends on the diagnostic method employed.[5] Although it has been reported that the prevalence of PVD in primary care practice is high, healthcare professional awareness of the diagnosis is still reported to be low and may be neglected in primary care office visits.[1] Internationally, there is an increasing recognition of the importance of primary care accessibility since stronger primary healthcare systems have been reported to be associated with better health outcomes and lower costs. Improved primary care has also been recognised to have the potential to prevent hospital admissions.[6]

ABPI measurement

An efficient method of objectively recording the presence and severity of lower-extremity vascular insufficiency is the determination of the ankle brachial index (ABI), which consists of a non-invasive, quantitative measurement of the patency of the lower-extremity arterial system. This is known to be a validated and reproducible test which consists of a simple measurement which can be done in any healthcare professional clinic with inexpensive equipment consisting of a blood pressure cuff and a Doppler ultrasonic sensor.[7] This involves measuring the systolic blood pressure in the ankles and arms and then calculating a ratio. The American Diabetes Association Consensus statement[8] reported the ABI as a non-invasive method for evaluating PVD and that, in contrast to the variability of pulse assessment and the non-specific nature of information obtained via history and other components of physical examination, the ABI is reproducible and reasonably accurate.

PVD in primary healthcare

In Malta, data on the prevalence of PVD in the primary care setting among patients with type 2 diabetes are sparse, although it is acknowledged that this information is key for developing strategies to enhance treatment of this condition to prevent lower-extremity amputations.[9] Primary healthcare professionals are said to play a key role in the prevention of limb loss since they are the first point of contact for recognition, diagnosis and referral. However, to date, most primary care clinics in Malta have not yet adopted the use of ABPI measurements as a means of identifying PVD in patients with type 2 diabetes. This method is recommended by both the International Working Group on the Diabetic Foot[2] and other organisations for the measurement of PVD because it is non-invasive and inexpensive, yet a more sensitive (95%) and specific (99%) indicator of arterial obstruction than previously used measures such as intermittent claudication or pulse inspection, which are said to be fraught with limitations because they are both subjective.[5] Furthermore, compared with angiography, this inexpensive measurement has a sensitivity of approximately 90% and almost 100% specificity.[10]

In Malta, 10% of the population have type 2 diabetes, compared with 2–5% of neighbouring countries in Europe.[11] The relationship between PVD and diabetes mellitus is well documented, and it has been reported that a significant number of patients with both these conditions may eventually have limb loss.[12] Furthermore, risk factors such as hypertension, hypercholesterolaemia, obesity and smoking are highly prevalent in this population.[13] Because much of the burden which this condition imposes, especially in high-risk populations, may be preventable by existing interventions such as ABPI measurements, local data could provide policy makers, healthcare professionals and researchers with key data for prevention and treatment efforts in this high-risk population.

Despite the high prevalence of diabetes in Malta and the associated risk factors and complications that this condition imposes, no studies to date have explored the prevalence of PVD in a primary care setting in subjects with type 2 diabetes in Malta.

Method

The data presented are part of a larger retrospective study which was conducted inside a primary care setting in Malta. This study included data from a convenient cohort of the first 243 patients enrolled in a diabetes foot-screening programme inside a primary care setting, in two local catchment areas, namely Floriana and Mosta, with combined populations of 126 000. This study was approved by the University of Malta Ethics Research Committee. All participants provided consent to participate in a local diabetes foot-screening programme. Authorisation was also obtained from the Department of Primary Healthcare to access the database where the data on the diabetes foot-screening program were stored. The reported investigations were carried out in accordance with the principles of the Declaration of Helsinki as revised in 2000.

The testing modalities and examination methods were carried out by two investigators to ensure uniformity. The screening process involved review of the patient's medical history and a lower-extremity physical examination. Each individual's personal lifestyle characteristics and clinical history including duration of diabetes, last HbA1c reading, blood pressure, dyslipidaemia, diabetic retinopathy, nephropathy, weight, height, current medications and smoking habits were recorded. Individual screening assessments took approximately 20 minutes.

PVD

PVD was assessed using documented history of intermittent claudication, rest pain and palpation of peripheral pulses. Palpation of pulses was performed using the fingertips by two experienced clinicians. Dorsalis pedis and posterior tibial pulses were recorded. Cyanosis, cold feet, skin thinning and hair anomalies were also recorded. Claudication was evaluated from information supplied by the patient with regard to exercise-induced calf pain. Measurement of ABI for definitive diagnosis of PVD was performed using a portable hand-held Doppler and blood pressure cuffs using a standard protocol. Measurements in the sitting or semi-sitting position can result in a substantial blood increase in the tibial arteries. Hence, the measurements were carried out after a five-minute rest in a supine position with the upper body as flat as possible. Patients were also asked to undo all tight clothing around the waist and the arm. A blood pressure cuff was applied to the arm (to measure the brachial systolic pressure) and the ankle (to measure the dorsalis pedis and posterior tibial pressures) to determine the ankle pressure. The cuff was inflated to occlude the arterial pressure. The systolic pressure was obtained by listening and noting the pressure on the manometer. The systolic pressure was noted and the higher values of the brachial and the ankle pressures were used to calculate the ABI. Values were interpreted according to the criteria proposed by the American Heart Association and the American Diabetes Association.[14] Lower-extremity vascular disease was defined as an ABI < 0.80 in either foot. An ABI of >1.3 was considered significantly elevated and indicative of vascular calcification.

For the purposes of data analysis, each foot was scored separately. All data were recorded on a spreadsheet designed in Microsoft Excel.

Results

A total of 243 patients (134 (55.1%) males and 109 (44.9%) females) with a mean age of 68.5 years (age range 40–87) and with type 2 diabetes were randomly included in the study. The mean duration of diabetes in the study group was 12.3 years, and blood glucose was controlled mainly by hypoglycaemic drugs. Almost half (46.1%) of the participants did not recall their last HbA1c reading, with the remaining subjects reporting a mean HbA1c level of 7.2%, which is above the 6.5% IDF threshold implying inadequate control. Risk factors such as hypertension (71.2%), dyslipidaemia (65.8%), diabetic retinopathy (19.3%), other visual problems (55%) and nephropathy (4.1%) were also recorded (Figure 1). The prevalence of peripheral sensory neuropathy was 12.8% in the left foot and 13.2% in the right foot of participants. Twenty-one per cent of patients reported having paraesthesia.

The prevalence of PVD at the time of screening was as follows: 24% and 23% of the right and left dorsalis pedis respectively and 28% and 31% of the right and left posterior tibial respectively were not palpable in the study population. On examination, it was found that 20% of the sample reported intermittent claudication, 17% of the sample reported pain during activity, and 11% had foot pain during rest, as demonstrated in Figure 2. Approximately 7% of the patients had an ABPI of less than 0.8 in both left and right extremities. More than one tenth (11.5%) of the patients also complained of rest pain. Patients were categorised into 'low risk 1' (27.16%), 'low risk 2' (28.4%), 'moderate risk 3' (22.6%) and 'high risk 4' (21.4%)

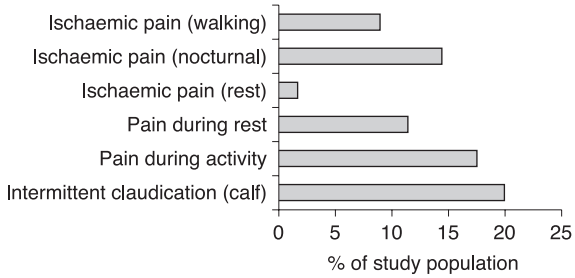

Figure 1 Peripheral arterial disease symptoms in the study group

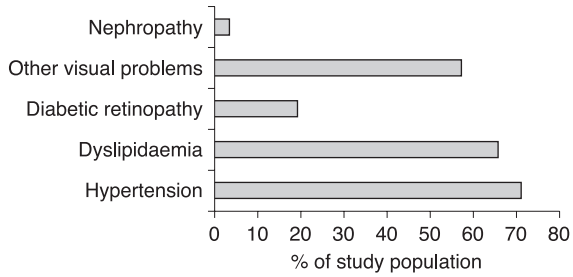

Figure 2 Risk factors in study group

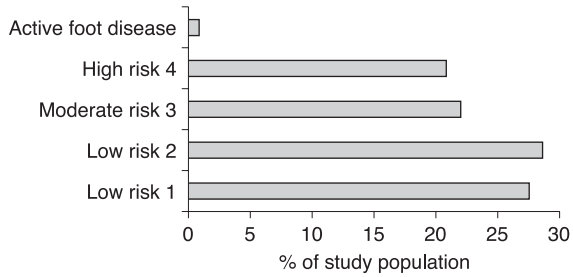

Figure 3 Risk categorisation of sampled population according to NHS Borders Foot Classification System

of developing foot ulcers and active foot disease (0.41%) by two trained healthcare professionals using the NHS Borders Foot Classification System[15] (Figure 3). Low risk 1 patients included those who presented with no neuropathy or ischaemia and no foot problems. Low risk 2 included those patients who presented with no neuropathy and/or ischaemia but had a foot problem. Moderate risk 3 included patients with neuropathy and/or ischaemia but no foot problems, whereas high risk 4 included patients with neuropathy and/or ischaemia, with foot problems. Active foot disease 5 included patients with current ulceration and/or a history of amputation. Following the screening programme 26% of patients were referred for further vascular assessment due to their critical vascular status at the time of the screening.

Discussion

This is the first study to explore the prevalence of PVD using ABI in subjects with type 2 diabetes in a Maltese cohort in a primary care setting. Data on the prevalence of this condition in the primary care setting are sparse, although this information is said to be of critical importance as a scientific basis for developing strategies to improve diagnosis and treatment of this condition.[9] The evidence suggests that PVD is highly prevalent in this specific population. This finding is of both epidemiological and clinical interest.

As ABPI values below 0.9 are clearly indicative of PVD according to the Eurodiale Study both in non-diabetic and diabetic patients,[16] the authors are confident that patients in this study were correctly diagnosed as having PVD. However, we acknowledge that

the use of more sensitive instrumentation, such as toe pressure measurements and duplex scanning, could have yielded more accurate results, but these were not available in the primary care setting. These further investigations were recommended in a recent study conducted by Portier *et al.*[17] In their study the authors concluded that ABPI thresholds of less than 0.9 and more than 1.3 were highly suspicious for PVD in patients with type 2 diabetes. However, when there was concomitant clinical peripheral neuropathy or a high risk of arterial calcification (Monckerberg's sclerosis), a false-positive abnormal ABPI was more likely.[16] In this case, other methods such as those mentioned above should be used.

The frequency of other cardiovascular risk factors such as hypertension and lipid disorders was also substantially high in this specific population. Furthermore, following the screening programme, one-quarter of patients were referred for further vascular assessment due to their critical vascular status (ABI < 0.8) at the time of screening. Other studies[5,16] have investigated different populations and some have applied different ABPI cut-off values (<0.85 or <0.95), but all confirm the high and underestimated prevalence of peripheral arterial disease in primary care practice. These findings are of great concern given the known associations between lower-limb vascular insufficiency and increased risk of ulceration and finally amputation. This implies that the health status of this specific population is under imminent threat due to the concurrence of various risk factors.

The conclusion that having PVD together with other cardiovascular risk factors puts an individual at a much higher risk of morbidity and increased mortality justifies the need for regular screening of asymptomatic patients with type 2 diabetes within a primary care setting. Pulse palpation, assessment of claudication by questionnaire, and physical examination of the feet have been reported to be insensitive since they could be influenced by room temperature, biological variations and physician's skill.[5] Furthermore, the true prevalence of PVD in people with type 2 diabetes is difficult to determine clinically, since most patients are asymptomatic due to peripheral neuropathy. The use of ABPIs in a primary care clinic could help early detection of disease, and initiate early therapy and referral for further investigations, thus reducing the risk of critical limb ischaemia and limb loss.

In Malta, diabetes has long been recognised as a major health problem, and the prevalence of diabetes together with other risk factors is also estimated to increase, with projections indicating a huge burden on the patients, their families and the healthcare system.[18] This study provides Maltese healthcare professionals and policy makers with key data for prevention by introducing ABPI measurements as a routine part of examination for all subjects with type 2 diabetes attending primary care clinics as recommended by the International Consensus on the Management and Prevention of the Diabetic Foot Guidelines (2011). In the case of diagnostic uncertainty, the International Working Group on the Diabetic Foot (2011) also recommends that the measurement of toe–brachial index could have additional diagnostic value.

This study highlights the importance and the role of primary care as the key to an effective and efficient health service for this group of patients.[19] Although there are operational differences in the primary healthcare systems around the world, this sector remains the principal target and the first point of call for investigations and diagnosis. Primary care clinicians are in a pivotal position within the healthcare system to improve the standard of care for patients with type 2 diabetes and asymptomatic PVD. Although specific to Malta, the results of this study show that the clinicians within primary care need to focus on quality improvement to ensure that their interventions achieve full potential. Furthermore, better management at this level can prevent or delay long-term complications, improve outcomes and reduce the financial burden which this condition imposes on both families and the healthcare system. This goal can only be achieved by ensuring that healthcare professionals are well informed about PVD prevention, detection and management, and that they are equipped with the necessary tools to be able to perform ABPI measurements.

Conclusion

This study highlights the high prevalence of PVD in patients with type 2 diabetes attending a primary care clinic. Early identification and management of this condition, especially amongst asymptomatic patients in the primary care setting, is crucial if diabetes foot complications and amputations are to be avoided.

The use of ABPI measurements will aid the early diagnosis of the critical limb and should be adopted amongst all healthcare professionals working in a primary care setting. Given the high costs of ulcers and amputations, the relatively low costs associated with appropriate foot care management at this level should prove to be cost-effective. The study findings can help with the design of rational strategies to further improve service provision at primary care level for early detection of PVD and improved quality of care for patients with PVD.

Although this study was based in Malta, the findings could inform other populations with similar culture within Europe and the rest of the world. The authors hope that this article will highlight the fundamental

importance of improving diabetes primary healthcare services to achieve better health outcomes and reduce healthcare costs.

ACKNOWLEDGEMENTS

The authors would like to thank the two clinicians who assisted in data collection during the diabetes foot screening pilot project held inside the primary care setting.

REFERENCES

1 Akhtar B, Zulfiqar S and Siddique S. The prevalence of peripheral arterial disease in normal population versus high risk individuals. *Biomedica* 2007;23:42–8.
2 International Working Group on the Diabetic Foot. *International Consensus on the Diabetic Foot & Practical and Specific Guidelines on the Management and Prevention of the Diabetic Foot.* Launched at the 6th International Symposium on the Diabetic Foot, May 2011.
3 Harris K. *The worldwide burden of peripheral artery disease.* Inter-Society Consensus for the Management of PAD. (2008, accessed 8 May 2011).
4 Ouriel K. Peripheral arterial disease. *Lancet* 2001;358: 1257–64.
5 Faglia E, Caravaggi C, Marchetti R *et al.* Screening for peripheral arterial disease by means of the ankle-brachial index in newly diagnosed type 2 diabetic patients. *Diab Med* 2005;22:1310–14.
6 Swerissen H. The importance of primary and community care, http://cpd.org.au/2004/06/the-importance-of-primary-and-community-care/, 2004 (accessed 15 October 2011).
7 Greenland P, Abrams I, Aurigemma GP *et al.* Prevention Conference V: Beyond secondary prevention: identifying the high-risk patient for primary prevention: non-invasive tests of atherosclerotic burden: Writing Group III. *Circulation* 2000;101(1):E16–22.
8 American Diabetes Association. Peripheral arterial disease in people with diabetes. *Diabetes Care* 2003;26: 3333–41.
9 Diehm C, Schuster A, Allenberg JR *et al.* High prevalence of peripheral arterial disease and co-morbidity in 6880 primary care patients: cross-sectional study. *Atherosclerosis* 2004;172:95–105.
10 Criqui MH, Denenberg JO, Bird CE *et al.* The correlation between symptoms and non-invasive test results in patients referred for peripheral arterial disease testing. *Vasc Med* 1996;1(1):65–71.
11 Rocchiccioli TJ, O'Donoghue CR, Buttigieg S. Diabetes in Malta: Current findings and future trends. *Malta Medical Journal* 2005;17(1):16–19.
12 Ikem R, Ikem I, Adebayo O *et al.* An assessment of peripheral vascular disease in patients with diabetic foot ulcer. *The Foot* 2010;20:114–17.
13 Formosa C, Lucas K, Mandy A and Keller C. Influence of national culture on diabetes education in Malta: A case example. *Diabetes & Primary Care* 2008;10:109–16.
14 Orchard TJ and Strandness DE. Assessment of peripheral vascular disease in diabetes. Report and Recommendations of the International Workshop sponsored by the American Heart Association and the American Diabetes Association. *Diabetes Care* 1993;16:1199–209.
15 NHS Borders Diabetic Foot Screening Programme. www.bordersdiabetesnetwork.scot.nhsuk/_data/assets/pdf_file/0016/673/3_guidelines_supp_diab_foot_assessmentspdf (accessed 30 May 2010).
16 Prompers L, Apelqvist J, Bakker J *et al.* High prevalence of ischaemia, infection, and serious comorbidity in patients with diabetic foot disease in Europe. Baseline results from the Eurodiale study. *Diabetologia* 2007; 50:18–25.
17 Potier L, Abi Khalil C, Mohammedi K *et al.* Use and utility of ankle brachial index in patients with diabetes. *Eur J Vasc Surg* 2011;41(1):110–16.
18 Cutajar J. An evaluation of type 2 diabetes care in the primary care setting. *Malta Medical Journal* 2008;20(3): 21–31.
19 Starfield B. New paradigms for quality in primary care. *British Journal of General Practice* 2001;51:303–9.

ETHICAL APPROVAL

This study was approved by the University of Malta Ethics Research Committee.

PEER REVIEW

Not commissioned; externally peer reviewed.

CONFLICTS OF INTEREST

None.

ADDRESS FOR CORRESPONDENCE

Nachiappan Chockalingam, CSHER, Faculty of Health, Staffordshire University, Stoke on Trent ST4 2DF, UK. Email: n.chockalingam@ staffs.ac.uk

Received 2 June 2012
Accepted 23 October 2012