Original Article

Comparison of Colour Duplex Ultrasound and Ankle-Brachial Pressure Index Measurements in Peripheral Vascular Disease in Type 2 Diabetic Patients with Foot Infections

G Premalatha, R Ravikumar, R Sanjay, R Deepa, V Mohan

Abstract

- **Background and Objectives : Peripheral vascular disease (PVD) is a common cause of morbidity and mortality and is reported to be more common among diabetic subjects compared to non-diabetic subjects. The aim of the study was to compare the specificity and sensitivity of ankle-brachial index (ABI) measured by peripheral doppler with the colour duplex ultrasound (CDU) for diagnosis of PVD.**
- **Methods : One hundred type 2 diabetic patients admitted to our diabetic centre with foot lesions underwent both colour duplex ultrasound and ankle-brachial index measurements. PVD was diagnosed if the individual had haemodynamically significant obstruction on CDU, or if the ABI was < 0.9. The sensitivity and specificity of ABI was determined using the CDU as 'gold standard'.**
- **Results : The mean age of the study group was 59.5 ± 10.1 years and the mean duration of diabetes was 11.7 ± 8.1 years. Of the total 100 subjects, six subjects had calcification of peripheral vessels and they were not included while calculating for sensitivity and specificity of ABI. Twenty (21.3%) subjects diagnosed as PVD by the CDU were not classified as PVD by the ABI measurements. Conversely, only three subjects (3.2%) classified as PVD by ABI had normal arteries based on CDU scanning. Overall, ABI had low sensitivity (70.6%) but a high specificity (88.5%). The overall agreement between CDU and ABI was poor (k=0.20).**
- **Conclusion : ABI is a good initial screening tool but some patients with significant stenosis in lower extremities would be missed, if ABI measurement alone is used for diagnosis of PVD.**
  (J Assoc Physicians India 2002;50:1240-1244)

Introduction

Peripheral vascular disease (PVD), which is described as atherosclerosis below the bifurcation of abdominal aorta, could lead to progressive narrowing of the lower limb arteries leading to claudication, gangrene and amputation.[1] PVD is a major cause of mortality and morbidity especially among the elderly population.[2] PVD is also several times more common among diabetic subjects compared to non-diabetic subjects.[3,4]

The debilitating nature of PVD calls for accurate diagnosis and treatment. The gold standard for diagnosis of PVD is angiography. However, the use of this technique is limited due to its invasive nature, the use of contrast agents and the cost. The non-invasive techniques used for diagnosis of PVD are colour duplex ultrasound (CDU) and continuous waveform doppler (CWD). Extensive studies have been done on the reliability, reproducibility, sensitivity and specificity of CDU. These studies have identified that CDU is reliable in detecting and locating stenosis and plaques in peripheral arteries and for detection of peripheral embolization.[5,6] Based on the diagnostic accuracy of CDU, reports have been suggested that this technique could be used routinely in the initial evaluation of patients with lower limb arterial disease.[6]

The continuous waveform doppler (CWD) is also a non-invasive method widely used to diagnose PVD.[7,8] This is a simple and painless test where blood pressure in the arms and ankles are checked using a regular blood pressure cuff and a handheld ultrasound Doppler probe. The ankle-brachial pressure index (ABI) has been used to diagnose PVD in several epidemiological studies.[7,8] The international work-

Madras Diabetes Research Foundation and MV Diabetes Specialities Centre (P) Ltd., Gopalapuram, Chennai, India.
Received : 27.6.2001; Revised : 27.1.2002; Accepted : 28.2.2002

shop on assessment of PVD in diabetes held in 1992, recommended ABI measurement for diagnosis of PVD in diabetic subjects.[9] It also emphasized the need for this test at baseline in all diabetic patients.[9]

The prevalence of PVD appears to vary in different ethnic groups.[10-13] Earlier population-based studies conducted by our centre using CWD revealed that the prevalence of PVD among South Indian diabetic subjects was very low (6.3%) compared to Caucasians.[10-13] Since, PVD was diagnosed using CWD in that study, one could argue that if angiography or CDU studies had been done, the prevalence of PVD might have been higher. This emphasizes the need for evaluating ABI measurements against CDU for assessment of PVD. Hence, in this study we tried to compare and correlate ABI measurements with CDU in evaluation of PVD.

Material and Methods

The study group comprised of 100 type 2 diabetic patients from the in-patient division of MV Diabetes Specialities Centre (MVDSC) a tertiary care specialized diabetes centre in Chennai in South India. All patients had severe foot infections, which necessitated admission to hospital. All patients underwent a thorough clinical examination including height and weight measurements. Body mass index (BMI) was calculated using the formula weight in kg divided by the height in metres squared. All palpable lower limb arteries were examined during the routine clinical examination.

CWD studies were done in all these patients using the Kody Vaslab Machine (Kody Lab, Chennai). Blood pressure and velocity graph recordings were done on the brachial pulses in the upper limb. In the lower limb, similar recordings were done on the dorsalis pedis and posterior tibial pulses and the mean of these two readings was taken as the ankle pressure. The ankle/brachial pressure index (ABI) ratio was calculated in every patient and an ABI less than 0.9 in either foot was defined as PVD. ABI was graded as grade 1: if ABI was ≥ 0.9, grade 2: ABI ≥ 0.7-0.9, grade 3: ABI ≥ 0.5-0.7, grade 4: ≥ 0.5.

Colour duplex ultrasound CDU was done in all patients. Imaging of the peripheral arteries of the lower limbs was done using high resolution colour duplex ultrasound (LOGIC 400 MD). The femoral vessels were studied with the extremities slightly externally rotated and using higher frequency transducers (7.5 MHz) to obtain better image resolution. The examination included the common iliac, external iliac and common femoral arteries. The superficial femoral artery was traced up to the popliteal fossa and the profunda was evaluated in its proximal segment. The infrapopliteal vessels, anterior tibial, peroneal, posterior tibial and dorsalis pedis were also evaluated. PVD was diagnosed if the stenosis in the artery was greater than 50% or had an occlusion. Stenosis was graded as grade 1: 1-19%, grade 2: 20-49%; grade 3: 50-99% and grade 4: total occlusion.[14] These gradations were provided based on the peak systolic velocity determined by CDU.

Statistical Analysis

All data were computed on a Foxpro database and statistical analyses were performed using SPSS PC version 4.0.1. The sensitivity, specificity, positive predictive value and negative predictive value of ABI against CDU were calculated. In brief, sensitivity was calculated as number of true positive subjects, (in whom PVD was correctly diagnosed by both the methods) divided by total number of subjects diagnosed as PVD by CDU. Specificity was calculated as the number of true negative subjects (who had no PVD based on both the methods), divided by the total number of subjects negative for PVD as diagnosed by CDU. Positive predictive value was calculated as the number of true positive subjects divided by total subjects diagnosed as PVD by peripheral doppler. Negative predictive value was calculated as the number of true negative subjects divided by the total subjects diagnosed negative for PVD by peripheral Doppler. To examine the agreement between CDU and ABI, Kappa statistics was used. Various cut-offs of ABI was compared with stenosis of the peripheral arteries (> 50% stenosis was considered abnormal). A value of one indicates perfect agreement, a value ≥ 0.75 was taken to represent excellent agreement, values between 0.41 and 0.75 as fair to good agreement, ≤ 0.40 poor agreement while zero indicates that agreement is no better than a chance.

Results

Table 1 presents the clinical and biochemical features of

Table 1 : Clinical and biochemical characteristics of a study subjects

Variables	Values
N	100
Age (yrs)	59.5 ± 10.1
Body mass index (kg/m^2)	24.2 ± 3.5
Systolic blood pressure (mm Hg)	136 ± 19
Diastolic blood pressure (mm Hg)	86 ± 11
Duration (years)	11.7 ± 8.1
Fasting plasma glucose (mg/dl)	186 ± 76
Glycosylated haemoglobin (%)	9.5 ± 2.0
Smoking n (%)	24 (24%)
Treatment	
OHA alone	19 (19%)
Insulin alone	16 (16%)
OHA and insulin	60 (60%)
Diet	5 (5%)

Table 2 : Overall sensitivity and specificity of ABI vs colour duplex ultrasound

Colour duplex ultrasound (CDU)	ABI Normal	ABI Abnormal	Total
Normal	23	3	26
Abnormal	20	48	68
Total	43	51	94

Sensitivity of ABI - 70.6%; Specificity of ABI - 88.5%; Positive predictive value of ABI - 94.1%; Negative predictive value of ABI - 53.4%; ABI < 0.9 was the cut off used for diagnosis of PVD

Table 3 : Agreement between ABI and colour duplex ultrasound (CDU)

ABI ranges	Stenosis 1-19%	20-49%	50-99%	Occlusion
≥ 0.9	18	5	20	—
≥ 0.7 - < 0.9	1	1	25	—
≥ 0.5 - < 0.7	1	—	20	1
< 0.5	—	—	1	1

the study subject. The mean age was 59.5 ± 10.1 years, body mass index was 24.2 ± 3.5, and duration of diabetes 11.7 ± 8.1 years. Twenty four percent were smokers, 19% were on OHA treatment alone. 16% were on insulin, 60% were on both OHA and insulin and five were on diet alone at the time of admission to the centre.

Of the total 100 subjects, six subjects had calcification of peripheral vessels and they were not included while calculating for sensitivity and specificity of ABI. Table 2 presents the overall sensitivity and specificity of ABI. ABI < 0.9 was the cut off used for diagnosis of PVD. Of the 68 individuals diagnosed to have PVD based on CDU, only 48 (48/68 - 70.5%) individuals were categorized as PVD by the ABI. Thus 20 (20/94 - 21.3%) individuals would remain undiagnosed if ABI alone were used for diagnosis. Conversely 3 (3/51-5.9%) of the 51 subjects diagnosed as having PVD according to ABI were classified as normal by the CDU. Though ABI had a very high specificity (88.5%), the sensitivity was quite low (70.6%).

Table 3 presents the agreement between ABI and CDU. The ABI value of < 0.5 showed a 100% agreement with CDU, 0.5-0.7 showed 95.5% and 0.7-0.9 - 92.5%. While ABI of > = 0.9 (negative for PVD) showed only 53.5% agreement with CDU (negative for PVD). The overall agreement of ABI with colour duplex ultrasound (CDU) was poor (42.6% - kappa = 0.2).

Discussion

The recent projection from WHO has identified that by 2025, more than 20% of the diabetic population in the world will be contributed by India i.e. over 57 million diabetic patients.[15] This is likely to cause a tremendous health burden on our country. Accurate estimates of the morbidity due to diabetes are therefore of great importance. In the Chennai Urban Population Study (CUPS), we have reported on the prevalence of macrovascular disease in an urban south Indian population. We found that, while CAD rates were high[16] and carotid atherosclerosis was also quite common,[17] the prevalence of PVD was low.[13] We had used ABI in CUPS to assess PVD, as it is difficult to perform CDU in a population-based study. The aim of this study was to try to compare the sensitivity and specificity of ABI compared to CDU. In order to get a good pick up rate of PVD, we intentionally chose to study a group of type 2 diabetic patients admitted to our centre with severe foot infections.

Earlier studies have suggested ABI as a reliable method for diagnosis of PVD and ABI value of < 0.9 has 95% sensitivity compared to angiography.[8] ABI has also been considered as a marker for increased risk of systemic vascular disease and has been shown to be a good predictor for coronary artery disease. Unlike Caucasian populations, however the ABI was a very weak predictor of coronary artery disease (CAD) in our population.[13]

Recent improvements in the field of imaging have introduced CDU scanning for diagnosis of PVD.[5,6] The Doppler technology has clinical application like blood flow sensing, wave form analysis, localizing blood flow and two dimensional mapping of blood flow.[5] It has been very helpful in detection and grading of atherosclerotic plaques in the arteries.[6]

Comparison of CDU with ABI in the Rancho Bernardo study revealed that ABI ≤ 0.8 had optimum sensitivity and specificity. It also suggested that a single measurement with peripheral Doppler is ideal for identifying majority of the subjects with PVD.[18]

In our study, ABI measurement had 88.5% specificity but the sensitivity was only 70.6%. The low sensitivity indicates that ABI measurement would miss some of the patients with PVD. Our results also showed that ABI < 0.5 had a good agreement with CDU. As the ABI increased, the agreement with CDU decreased. The overall agreement between these two methods was poor (kappa = 0.2). Furthermore about 46.5% of subjects diagnosed to be normal by ABI had greater than 50% stenosis when examined by CDU. The reason for higher ABI values inspite of stenosis could probably be due to collateral circulation that maintains blood flow to the lower limb beyond the ob-

struction. Moreover, higher ABI values also suggest calcification of the vessels.

Support for our study comes from a report from the United Kingdom,[19] which assessed the strength of agreement between CDU and ABI in non-diabetics and showed that ABI technique identifies only those with more serious disease. With higher ABI values, the level of agreement was poor. The addition of post-exercise ABI measurements in determining significant arterial disease increased the strength of relationship between the two techniques by only 2%.[20]

In summary, we conclude that ABI has a very high specificity but the sensitivity is low compared to CDU. If ABI alone is used, many patients with plaques/stenosis in the peripheral artery will be labeled as normal. In view of the ease of performing the CWD and its low cost, ABI would still be a good initial screening test. If abnormal, the diagnosis of PVD is almost certain. If normal and the patient is asymptomatic probably no further testing is needed even if PVD is present as it is unlikely to be clinically significant. If however, there are clinical symptoms of PVD and the ABI is normal, a CDU should be then performed before PVD is definitely excluded. An additional problem with ABI is that if there is medical calcification, falsely high pressures would be obtained and if fully calcified, pressure recording is not possible. This is reported to occur in high frequencies in diabetic individuals[19] and in such patients, only CDU can be used to diagnose PVD accurately. CDU however needs more expensive equipment, is technically more difficult, needs a highly skilled radiologist or technician to perform, is not available widely and cannot be carried out at smaller centres.

References

1. **Hughson WG, Mann JI, Garrod A.** Intermittent claudication: prevalence and risk factors. *Br Med J* 1978;1:1379-81.
2. **Coni N, Tennison B, Troup M.** Prevalence of lower extremity arterial disease among elderly people in the community. *Br J Gen Pract* 1992;42:149-52.
3. **Beach KW, Brunzell JD, Strandness DE Jr.** Prevalence of severe arteriosclerosis obliterans in patients with diabetes mellitus. Relation to smoking and form of therapy. *Arteriosclerosis* 1982;2:275-80.
4. **Beks PJ, MAckaay AJC, de Neeling JN, de Vroes J, Bouter LM, Heine RJ.** Peripheral arterial disease in relation to glycemic level in an elderly Caucasian population: the Hoorn study. *Diabetologia* 1995;38:86-96.
5. **Signel B.** A brief history of Doppler ultrasound in the diagnosis of peripheral vascular disease. *Ultrasound Med Biol* 1998;24:169-76.
6. **Nicholls SC, Smith W.** Peripheral arterial embolization. Doppler ultrasound scan diagnosis. *J Vasc Surg* 2000;31:811-4.
7. **McDermott MM, Feinglass J, Slavensky R, Pearce WH.** The ankle-brachial index as a predictor of survival in patients with peripheral vascular disease. *J Gen Intern Med* 1994;9:445-9.
8. **Strandezz DE, Bell JW.** Peripheral vascular disease: diagnosis and objective evaluation using a mercury strain gauge. *Am Surg* 1965;161(Suppl 1):1-35.
9. **Orchard TJ, Strandness DE Jr.** Assessment of peripheral vascular disease in diabetes. Report and recommendations of an international workshop sponsored by the American Diabetes Association and the American Heart Association. Septempber 18-20, 1992. New Orleans, Louisiana. *Circulation* 1993;88:819-28.
10. **Beach KW, Bedford GR, Bergelin RO, *et al.*** Progression of lower-extremity arterial occlusive disease in type 2 diabetes mellitus. *Diabetes Care* 1998;11:464-72.
11. **Fowkes FGR, Housley E, Cawood EH, Macintyre CC, Ruckley CV, Prescott RJ.** Edinburgh Artery Study: prevalence of asymptomatic and symptomatic peripheral arterial disease in the general population. *Int J Epidemiol* 1991;20:384-92.
12. **Mohan V, Premalatha G, Sastry NG.** Peripheral vascular disease in non-insulin-dependent diabetes mellitus in South India. *Diabetes Res Clin Pract* 1995;27:235-40.
13. **Premalatha G, Shanthirani S, Deepa R, Markovitz J, Mohan V.** Prevalence and risk factors of peripheral vascular disease in a selected South Indian population - the Chennai Urban Population Study (CUPS). *Diabetes Care* 200;23:1295-1300.
14. **Kohler TR, Nance DR, Cramer MM, Vandenburghe N, Shandress DE Jr.** Duplex scanning for diagnosis of aortoiliac and femoropopliteal disease: a prospective study. *Circulation* 1987;76:1074-80.
15. **King H, Aubert RE, Herman WH.** Global burden of diabetes, 1995-2025: prevalence, numerical estimates and projections. *Diabetes Care* 1998;21:1414-31.
16. **Mohan V, Deepa R, Rani SS, Premalatha G.** Prevalence of coronary artery disease and its relationship to lipids in a selected population in South India: The Chennai Urban Population Study (CUPS No. 5). *J Am Coll Cardiol* 2001;38:682-7.
17. **Mohan V, Ravikumar R, Shanthi Rani S, Deepa R.** Intimal medial thickness of the carotid artery in South Indian diabetic and non-diabetic subjects: the Chennai Urban Population Study (CUPS). *Diabetologia* 2000;43:494-9.
18. **Feigelson HS, Criqui MH, Fronek A, Langer RD, Malgaard CA.** Screening for peripheral arterial disease: the sensitivity and specificity, and predictive value of noninvasive tests in a defined population. *Am J Epidemiol* 1994;140:526-34.
19. **Allen J, Oates CP, Henderson J, *et al.*** Comparison of lower limb arterial assessments using colour-duplex ultrasound and ankle/brachial pressure index measurements. *Angiology* 1996;47:225-32.
20. **Everhart JE, Pettitt DJ, Knowler WC, Rose FA, Bennett PH.** Medical arterial calcification and its association with mortality and complications of diabetes. *Diabetologia* 1988;31:16-23.