



RESEARCH ARTICLE

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Ankle Brachial Index (ABI) Versus Point-of-Care Arterial Duplex Ultrasound (DUS) in Early Detection and Diagnosis of Diabetic Foot Ischemia in Hemodialysis Unit

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ABSTRACT

Background: Diabetes is a widespread noncommunicable disease affecting an estimated 463 million adults worldwide in 2019 and will affect 700 million by 2045. Diabetic foot lesions remain a major cause of morbidity in patients with renal failure, especially those on dialysis. Ankle Brachial Index (ABI) may inaccurately assess lower extremity perfusion in patients with highly calcified, non-compressible tibial arteries. Focused Arterial duplex ultrasound (DUS) of the distal anterior and posterior tibial arteries at the ankle can be readily learnt by novices (nurse/physician) and performed rapidly and accurately for early diagnosis and referral.

Objectives: The primary aim of this study is to determine the diagnostic accuracy of the DUS and ABI tests in detecting peripheral arterial disease (PAD) in diabetic patients on hemodialysis (HD) to improve early detection and diagnosis.

Methods: We conducted a cross-sectional study at a single center involving 115 diabetic patients from 212 total patients on regular HD in the 2nd biggest dialysis center in Oman for six months (from 1st of February 2023 to end of July 2023) and we will use Ankle brachial index (ABI) and Arterial duplex ultrasound (DUS) in early detection and early diagnosis of diabetic foot ischemia. We collected the data in three sheets: 1- Demographic data: age, gender, comorbidity, duration of DM, smoking and vascular access of hemodialysis. 2- Laboratory data: random blood sugar, HGB, PTH, phosphorus, lipid profile and serum albumin. 3- Physical foot examinations & image

Results: The study was investigated about 115 diabetic patients undergoing regular hemodialysis from 212 total numbers of our hemodialysis unit. Only 52 patients had weak pulse will focus in our study, two of them expired before complete examination so excluded from the study. Mean age of patients was 59.6 ± 11.9 years, extremes (35-83 y), 50% equal male to female. All the target patients in the study (50 Patients) are type 2 DM with duration >10 years. 8% had foot ulcer and 16% had partial or complete foot amputation. Referral to vascular consultation (due to DUS -PSV<40) as suspected Ischemia 27/50=54% while ABI detect only 20% as suspected ischemia. Suspected cases of vascular insufficiency to total diabetic patients in the unit 27/115=23.4 %.

Conclusion: Physical examination and Ankle Brachial Index (ABI) are disturbed by the presence of calcified and incompressible blood vessels. Point-of-care arterial duplex ultrasound (DUS) may provide an alternative solution to diagnosis of Diabetic foot ischemia in HD patients. The results of this study will improve the diagnosis of PAD in diabetes and inform early referral pathways between HD units and vascular and intervention radiology in tertiary hospital.

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Introduction

Diabetes increases the risk of microvascular and macrovascular diseases. Microvascular complications involve damage to the small blood vessels throughout the body, leading to diabetic retinopathy, diabetic nephropathy, and diabetic neuropathy.

Diabetic retinopathy is the leading cause of blindness in working-age adults, while diabetic nephropathy can lead to end-stage renal disease. Diabetic neuropathy, on the other hand, can result in severe pain, numbness, and tingling sensations in the extremities [1]. Macrovascular diseases include cardiovascular diseases (CVD), cerebrovascular disease or "stroke" and peripheral vascular disease (PVD). On the other hand, peripheral vascular disease can cause pain, numbness, and ulcers in the legs and feet

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and may result in the need for amputation [2].

These complications are associated with considerable morbidity, reduced quality of life, disability, premature mortality and high economic costs. Diabetic foot disease (DFD) is defined as a syndrome in which peripheral neuropathy and peripheral vascular disease may result in foot ulceration, infection, deformity, and/or lower limb amputation in patients with diabetes [3]. It is one of the most debilitating and costly complications of diabetes, with a lifetime prevalence of up to 25% [3-4]. Moreover, around 40–60% of all non-traumatic lower limb amputations are attributed to DFD [4]. In Oman, amputation data from the MOH indicate that diabetes is responsible for about 47% of all lower limb amputations [5]. The low research output in the fields of diabetic foot care and DFD in Oman undoubtedly leaves unanswered questions concerning the epidemiology, prevention, and management of DFD. This paucity of diabetic foot research must be addressed urgently. Studies are needed to improve our understanding of the extent of DFD, and the impact of current diabetes programs on the quality of diabetic foot care in Oman [5]. The diabetic foot syndrome which characterizes the course of survival of patients treated by regular hemodialysis lies upon complex mechanisms, among which "accelerated atherosclerosis", metabolic disorders including phosphorus and calcium balance, malnutrition, and inflammation. Anemia plays a significant role when it is present, and hypertension (High Blood Pressure) greatly aggravates the prognosis of vascular disease [6].

Foot ulceration is a common complication that affects up to 25% of diabetic patients during their lifetime. Moreover, the very high prevalence of foot ulceration in diabetic patients on dialysis is probably a consequence of end-stage renal disease [7].

Remind that patients with a history of foot ulcer have a 34-fold increased risk of ulcer recurrence and that the readmission in-hospital and 30-day mortality after amputation in people with diabetes is higher than in people with coronary artery bypass graft surgery, breast cancer, or stroke [8-10]. Direct costs of diabetic foot ulceration care for health system due to are high; these costs are doubled when foot ulceration leads to amputation [11]. ABI, the most common physiologic parameter used to assess PAD severity, lacks anatomic precision and may inaccurately assess lower extremity perfusion in patients with highly calcified, no compressible tibial arteries. Arterial duplex ultrasound (DUS) is unique as it provides an inexpensive, noninvasive, anatomically precise roadmap and a quantitative and physiologic assessment of arterial flow in the entire lower extremity. Several studies have demonstrated DUS to be an effective and highly accurate diagnostic and surveillance imaging modality [12-13].

We conducted cross section study-single center experience-on 115 diabetic patients from 212 total patients on regular HD in the 2nd biggest dialysis center in Oman for six months (from 1st of February 2023 to end of July 2023) and we will use Ankle brachial index (ABI) and Arterial duplex ultrasound (DUS) in early detection and early diagnosis of diabetic foot ischemia and may be combination of both give more accurate results.

Methods & Materials

Our study is based on a descriptive cross-sectional - single center experience -conducted from 02/1/2023 to 07/31/2023 and concerning 115 diabetic patients (54.2%) among a total of

212 patients undergoing regular hemodialysis in the 2nd biggest hemodialysis center (AL SEEB RENAL DIALYSIS CENTER) in OMAN.

Ministry of Health in Oman has an excellent medical record and information technology system where everything is computerized and had received a well-recognized international certificate of excellence for its achievement in its IT system called AI SHIFAA. All clinical and various laboratory data are collected progressively. All these data were statistically analyzed by STATA edition 13 software.

Foot Examination as: Ankle-brachial index (ABI) was performed using a sphygmomanometer with a cuff width of at least the third of limb circumference. ABPI is an invaluable tool for assessing the severity of PAD. The Society for Vascular Technology and the American Heart Association have produced guidelines for the measurement of ABPI [14,15]. Patient is laying supine, ankles supported and knees straight, with their head supported. Before beginning the measurements, patients should be in rest for approximately 15 min, because physical exercise can distort the value of ABPI. The Pulse wave Doppler is then used to measure the peak systolic velocity (PSV) in both anterior and posterior tibial artery. Only the right brachial artery pressure was measured as most of hemodialysis patients had AVF in left arm or forearm.

ABPI Range: [> 1.4 : Consider presence of calcification; 1.0-1.4: Likely normal; 0.9-1.0 borderline

ABI Value	Interpretation	Recommendation
Greater than 1.4	Calcification/Vessel Hardening	Refer to vascular specialist
1.0-1.4	Normal	None
0.9-1.0	Acceptable	None
0.8-0.9	Some Arterial Disease	Treat risk factors
0.5-0.8	Moderate Arterial Disease	Refer to vascular specialist
Less than 0.5	Severe Arterial Disease	Refer to vascular specialist

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PAD; < 0.9 : Claudication/ischemia].

peak systolic velocity (PSV) measured from the distal segment of the Posterior Tibial artery (PT) & Anterior Tibial artery (AT) at the foot. A PSV of ≥ 40 cm/s is unequivocally normal, whilst a PSV of < 40 cm/s following adequate stimulation indicates definite arterial insufficiency (Ischemia).

We collected the data in three sheets as follow:

1. Demographic data: age, gender, comorbidity, duration of DM, smoking and vascular access of hemodialysis. Figure 1
2. Laboratory data: random blood sugar, HGB, PTH, phosphorus, lipid profile and serum albumin. Figure 2
3. Physical foot examinations & image: Vascular examination, neurological examination, dermatology examination, musculoskeletal examination, Ankle-brachial pressure index (ABPI) and DUS. Table 1

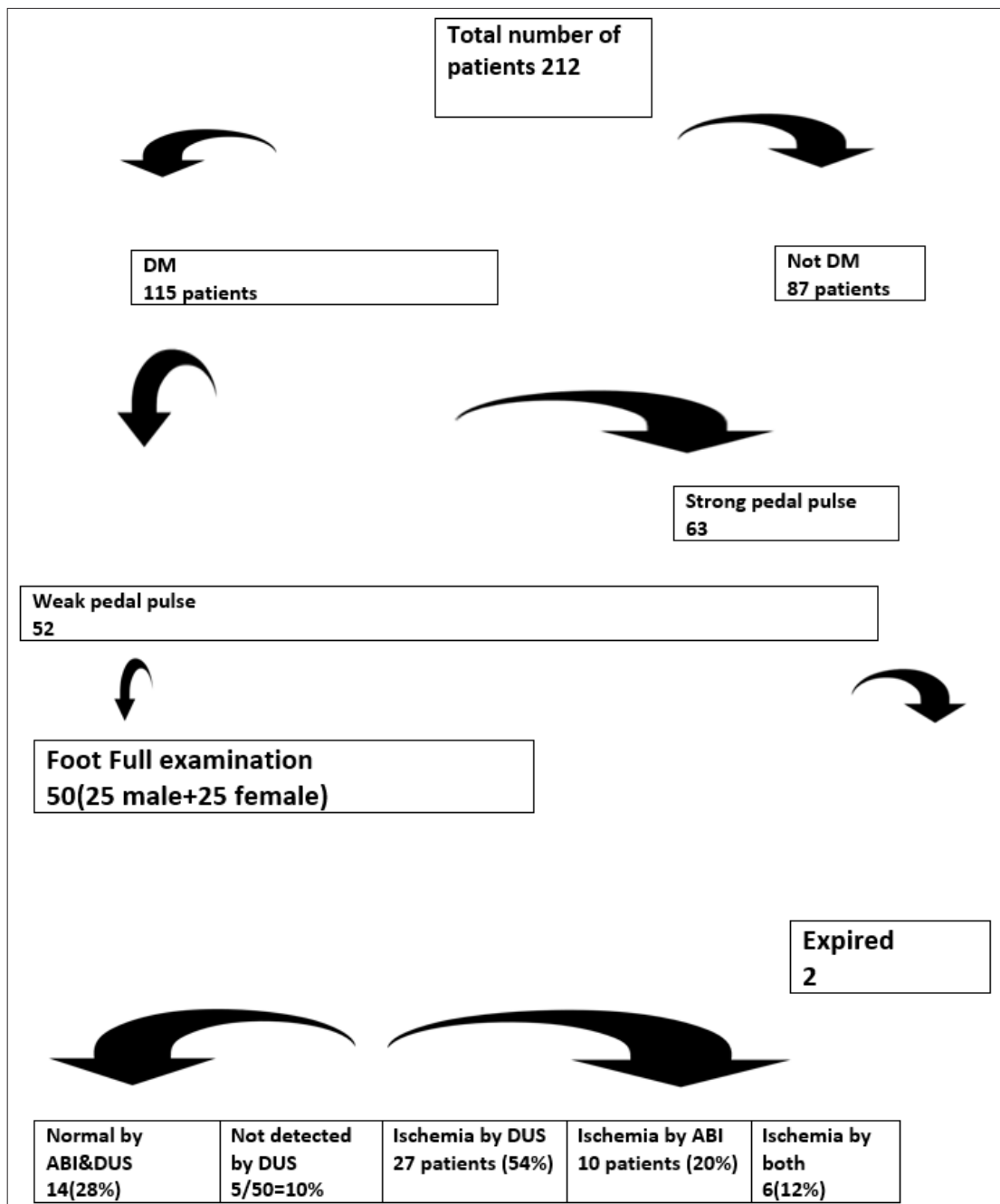
were collected by four investigators one of them had good experience& ISN certificate in DUS.

Results

The study was investigated about 115 diabetic patients undergoing regular hemodialysis from 212 total numbers of our hemodialysis unit. Only 52 patients had weak pulse will focus in our study, two of them expired before complete examination so excluded from the study. Figure 1

Mean age of patients was 59.6 ± 11.9 years, extremes (35-83 y), 50% equal male to female.

All the target patients in the study (50 Patients) are type 2 DM with duration >10 years.



Referral to vascular consultation (due to DUS -PSV<40) as suspected Ischemia 27/50=54%

Suspected cases of vascular insufficient to total diabetic patients in the unit 27/115=23.4 %

Table 1: Physical examinations& history showed

Dermatological	1-Discolouration 19/50=38%	2-Fungal infection 3/50=6%	3-fissures 9/50=18%	4-interdigital maceration 7/50=14%
Neurological	1-Response to touch 15/50=30%	2-Not response 35/50=70%		
MUSCUSKELETAL	1-limited Joint full motion 8/50=16%	2-Deformity 23/50=46%	3-signs of inflammation 7/50=14%	
Vascular	1-Loss of hair 21/50=42%	2-Weak pulse 50/50=100%	3-Temperature difference 6/50=12%	
	4-Ulcer 4/50=8%	5-Amputation 8/50=16%		
Blood sugar control	1-controlled 39/50=78%	2- uncontrolled 11/50=22%		
Comorbidities+ DM	1-HTN 48/50=96%	2-IHD 16/50=32%	3-HF 9/50=18%	
Smoking	5/50=10%			
Gender	Male 25/50=50%	Female 25/50=50%		
Vascular Access:	1-AVF 42/50=84%	2-PER.Catheter 8/50=16%		

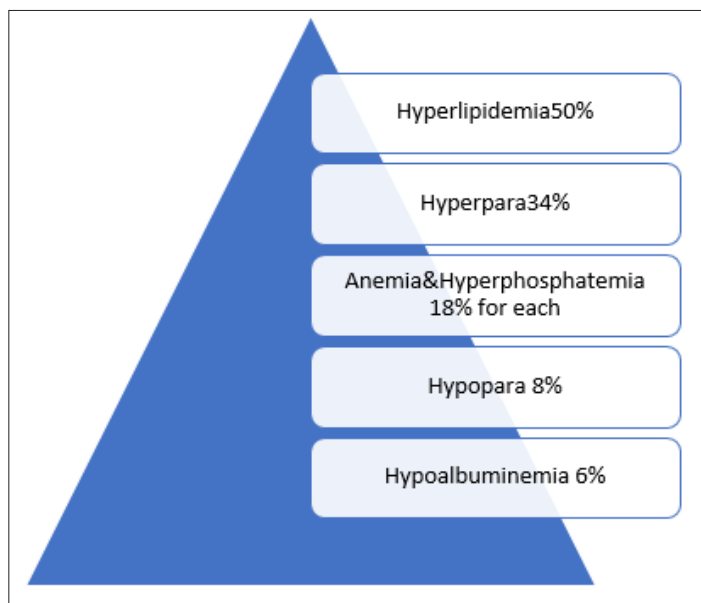


Figure 2: Percentages of Important Laboratory Results

Discussion

Diabetic patients with ESRD is associated with a significant increase in the frequency of diabetic foot lesions.

The vascular disease in diabetic patients is mostly localized in arteries of the lower limb, with dismal prognosis [16,17]. A major risk factor for the development of peripheral vascular disease is atherosclerosis [18,19].

This holds true for all foot complications, namely ulceration, infection, gangrene and amputation, which are encountered at a more than twofold frequency in diabetic patients with ESRD as compared with their non-nephropathic counterparts [20,21]. Tragically enough, the rate of amputations is 6.5–10 times higher among diabetic patients with ESRD in comparison to the general diabetic population [22,23].

In current study about 18% of diabetic foot patient had amputation,14% had signs of inflammation and 8% had ulcer. Diabetic foot ulcers are a serious complication that can arise due to the combination of high blood sugar levels(in current study 22%), nerve damage (neuropathy in current study 70%), and poor blood circulation (peripheral arterial disease in current study 50%) commonly seen in diabetes [24]. To prevent diabetic foot ulcers and their complications, individuals with diabetes

should pay close attention to foot care. This includes daily foot inspections, wearing well-fitting shoes, maintaining good blood sugar control, practicing proper foot hygiene, avoiding prolonged periods of sitting or standing, and seeking medical attention promptly for any signs of foot injury, infection, or non-healing wounds. Regular foot exams by a healthcare professional are also crucial for the early detection of any problems and appropriate management [25,26].

Risk factors for skin complications in diabetes include poor glycemic control, duration of diabetes, neuropathy, peripheral vascular disease, obesity, and smoking. Additionally, certain medications, such as corticosteroids, can increase the risk of skin complications in diabetes. Understanding the epidemiology, pathophysiology, and risk factors for skin complications in diabetes is crucial for developing effective prevention and management strategies [27-29]. In current study skin discoloration(38%),Fungal infection (6%),fissures(18%),interdigital maceration(14%). All the target patients in the study (50 Patients) are type 2 DM with duration >10 years while 10% only are smokers.

Limited joint mobility syndrome (LJMS) is characterized by limited motion of the small hand and finger joints [30]. Stiff hands in patients with longstanding diabetes were first described [31]. The prevalence of LJMS is 25% to 76% in those with type 2 diabetes

mellitus (T2DM); the rate in general populations is 1% to 20% DN principally affects the foot and ankle joints; the symptoms include painless joint swelling, warmth when touched, instability, and deformity [32,33]. In current study limited Joint full motion (16%), deformity 46%), signs of inflammation (14%) Both ESC and ACC guidelines recommend smoking cessation, glycemic control, blood pressure (BP) therapy and treatment with statins [34,35]. The European guidelines further recommend therapeutic goals: low-density lipoprotein (LDL) levels less than 70 mg/dl or >50% reduction from baseline, BP <140/90 mmHg. Both guidelines also suggest the use of renin-angiotensin system inhibitors to reduce ischemic events [36,37]. In current study most of target patients were hypertensive (96%) on medications and 50% were had dyslipidemia.

The aggravating role of smoking, which is a classic feature in the setting up and progression of atherosclerosis, is of great importance for lower extremity arterial disease [35]. In current study 10% of target patients were smoking.

The normal value of HbA1c in patients under regular hemodialysis is [(6.5% to 8.5%); (48 mmol/mol to 69 mmol/mol)], in current study 22% were uncontrolled blood sugar (HbA1c>8.5%).

18% of our studied patients had anemia, the average Hb value in our patients was 10 g/dl, which is below the values found who are around 11.5 g/dl [34,38,39]. This fact would probably be due to parathyroid disorders in our patients which was represented about 34% hyperpara (PTH>580 pg/ml). found a PTHi of 300.17 pg/ml, while found a value of 423.4 pg/ml for patients with no foot ulcers, and 526 pg/ml for those with foot ulcers [39,40]. The high phosphorus level in our study is >1.7 mmol/l corresponding to hyperphosphoremia, which was represented about 18% of our patients which is consistent with and which found respectively a phosphorus level of 1.63 mmol/l and 1.62 mmol/l corresponding also to a hyperphosphoremia [39,40].

Regarding the prevalence of undernutrition (s. albumin <35g/l), our results are less than those who found a prevalence of undernutrition of 30% according to protein intake, while only 6% of our patients have an insufficient protein intake [41].

The ankle-brachial index (ABI) is a non-invasive tool for the assessment of vascular status of diabetic foot. It consists of the ratio between the systolic blood pressure of the lower extremity, specifically the ankle, and the upper extremity. This ratio compares the resistance of the blood vessels, with one of the primary factors being the diameter of the vessels. This diameter is narrowed either from internal factors (plaque, intimal tear) or external factors such as compression by soft tissues. Minimal variations in ABI value occur with race, sex, age, and height, but the overall predictability of PAD similar amongst groups. In one screening study involving asymptomatic 50 years old patients, 20% were identified to have PAD [42]. One study suggested that providers in the general medical community use the information to initiate cardiovascular risk reduction interventions [43]. Both low and high ABI values have an independent association with cardiovascular events. Also, abnormal ABI correlates with the risk of chronic kidney disease. Guidelines exist for monitoring wound care application [44-46].

- Avoid compression dressing with ABI 0.5 and refer to the specialist/supervising provider

- Values 0.5 to 0.8 apply low compression only
- Greater than 0.8 may apply high compression

Although ABI measurement is a reliable, non-invasive objective test for early diagnosis of peripheral vascular disease, its usefulness for diabetic patients is very limited. Diabetes-associated atherosclerosis and vessel wall calcification result in false ABI results. Diabetic patients with significant levels of peripheral arterial stenosis may reveal normal or even high values in ABI measurements [47].

Recently, several authorities raised significant reservations in using ABIs only for the diagnosis of PAD. In a comprehensive study on diabetics with PAD, found low evidence to indicate that ABIs in the normal range excluded PAD. Similarly, concluded that ABIs have a poor relationship to PAD and felt it was a worthless indicator of PAD of lower extremities. Similar conclusions were made [48-53] who also found that, in diabetics with calcified ankle arteries, ABIs can give artificially higher values (>1.4) and was considered to be nondiagnostic.

In current study ABI diagnosed only 20% of cases as ischemic diabetic foot, 2% as calcified vessel and 78% as normal Table 2

ABI Value	Interpretation	Numbers of patients/50	%
> 1.4	Calcification/ Vessel Hardening	1	2%
1.0-1.4	Normal	30	60%
0.9-1.0	Acceptable	9	18%
0.8-<0.9	Some Arterial Disease	1	2%
0.5-<0.8	Moderate Arterial Disease	9	18%
Less than 0.5	Severe Arterial Disease	0	0

Point-of-care arterial duplex ultrasound (DUS) may provide an alternative solution to diagnosis. A full lower limb arterial DUS scan has an accuracy comparable to the gold standard of angiography but is too time consuming to perform and technically challenging to learn due to the difficulty of scanning proximal tibial vessels thus limiting its utility as a bedside test by front line staff [54,55]. Focused scanning of the anterior and posterior tibial arteries at the ankle can provide information regarding the upstream state of the vasculature. Figure 3

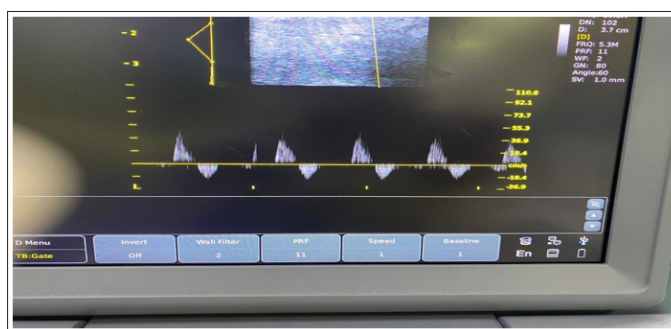


Figure 3: Triphasic Wave-Peak Systolic Velocity (psv) Measured from the Distal Segment of the Posterior Tibial Artery (pt) & Anterior Tibial Artery (at) at the Foot. a psv of ≥40 cm/s is

Unequivocally Normal, whilst a psv of <40 cm/s following Adequate Stimulation Indicates Definite Arterial Insufficiency (Ischemia).

DUS (Ultrasound B-mode and pulse wave Doppler) imaging of foot arteries were conducted in 50 diabetic patients with ESRD on regular HD in current study to determine their morphological (total vascular diameter and flow lumen diameter) and functional parameters (spectral analysis/peak systolic velocity). DUS is highly sensitive in diagnosis of ischemia in diabetic patients in current study (54%) compared to ABI which only diagnosed (20%) of the same patients with weak pulse in ankle-Table 3/Figure 4

Table 3

DUS for ankle	Result/50	%
Not detected	5	10%
Normal (PSV>40)	18	36%
Ischemia (PSV<40)	27	54%

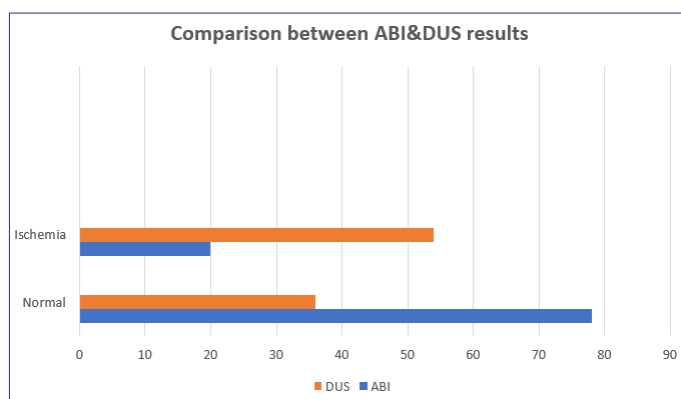


Figure 4: Comparison between ABI&DUS Results

Diabetes is the foremost cause of lower-limb loss worldwide. Every year, more than one million patients with DM suffer a lower limb amputation, and nearly every 20 seconds, an amputation is performed due to diabetic complications so in current study early diagnosis by DUS and referral to vascular consultation (due to DUS -PSV<40) as suspected Ischemia 54% to prevent amputation [56].

Significant geographic variations in PAD prevalence in diabetic patients on HD have been reported in previous international observational studies. For example, the Dialysis Outcomes and Practice Patterns Study found PAD in 17.5%–37.8% of patients in Europe, but only in 11.5% of patients in Japan in current study suspected cases of vascular insufficient (PAD) to total diabetic patients in our HD unit is 23.4 % [57]. The size of the sample analyzed and the lack of more convincing tools of exploration represent a significant bias in our work. A larger study, recruiting a substantial number of patients and more detailed analyzes of the different clinical and bedside ABI/DUS would be more adequate. The main strength of this study is that it is the first to assess PAD in diabetic patients on HD by nephrologists (physician/nurse) who were trained on ABI&DUS.

Conclusion

The results of this study will improve the diagnosis of PAD in diabetes and inform early referral pathways between HD units and vascular and intervention radiology in tertiary hospital. Early

detection, referral and management of PAD in the ulcerated foot will result in faster healing rates, reduction in hospital admissions, reduction in lower limb amputations and cost savings for ministry of health in Oman. In the non-ulcerated foot, detection of PAD may alter foot care behaviors to reduce the risk of ulceration and amputation and allow for optimization of best medical therapy to reduce overall cardiovascular risk.

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