

Study on Pattern of Vascular Insufficiency and Its Clinical Outcome in Diabetic Foot Patients – Original Article

Abstract:

Background: Diabetes mellitus has a marked impact on the quality of life due to the acute and long-term complications secondary to the involvement of micro & macro vasculature with the progression of the natural history of the disease. **AIMS AND OBJECTIVES:** 1. To study the pattern of vascular insufficiency in patients with Diabetic foot using Ultrasound Color Doppler (UCD) 2. To determine its association with clinical outcome which was studied in terms of admissions, minor and major amputations, follow up and mortality.

Materials and Methods: Prospective study in the Department of General Surgery Government Medical College, Nellore. Patients age between 30 years to 70 years. 50 cases of diabetic patients with diabetic foot. The present study done from September 2019 to August 2022. **Results:** The majority of the participants were having ABI levels between 0.4-0.9 (96%). Out of 50 study participants, 58% of them have co-morbidities. The majority of the study participants are having HbA1c levels between 6.5 to 7.5 (50%), followed by 16% having between 9.6 and 10.5. The majority of the study participants are having an ulcer 90%, 42% have gangrene, 22% having osteomyelitis. Greater the HbA1c levels higher are the chances of surgery which was found to be statistically significant. ($p=0.001$). **Conclusion:** Colour Doppler imaging is a safe, cost-effective, non-invasive procedure and the best tool for evaluating patterns of vascular insufficiency in the diabetic foot.

Key Word : Diabetic foot, colour doppler, gangrene, amputation.

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I. Introduction

Diabetes mellitus is a common pathological condition at present times with a higher prevalence rate in developing countries. Diabetes mellitus has a marked impact on the quality of life due to the acute and long-term complications secondary to the involvement of micro & macro vasculature with the progression of the natural history of the disease. The seriousness of the problem is further abetted by concurring peripheral neuropathy, infection and vasculopathy resulting in chronic diabetic foot ulcers, loss of limb. Diabetic foot is a long-standing diabetes complication in which infection, ulceration, and necrosis of tissues of the lower limb occurs owing to the presence of vasculopathy and neuropathy as basic etiological factors^{1,2,3}. The foot ulcer incidence rate ranges between 2% and 10% among patients with diabetes mellitus. Doppler Ultrasound provides the basis for non-invasive and objective measurements of the spectrum and velocity of flow in arteries that can be monitored. This technique is particularly helpful in assessing the pattern of vascular insufficiency in patients with diabetic foot thus allows the evaluation and follow up of the disease by carrying out a precise vascular mapping. Hence Colour Doppler imaging is a safe, popular, cost-effective, repeatable, non-invasive procedure for evaluating patterns of vascular insufficiency in the diabetic foot.

II. Material And Methods

AIMS AND OBJECTIVES: 1. To study the pattern of vascular insufficiency in patients with Diabetic foot using Ultrasound Color Doppler (UCD) 2. To determine its association with clinical outcome which was studied in terms of admissions, minor and major amputations, follow up and mortality. **Study design:** Prospective study done in Department of General Surgery Government Medical College, Nellore. **Study population:** Age between 30 years to 70 years. **Study sample:** 50 cases of diabetic patients with diabetic foot are meeting the criteria of the present study. **Study period:** September 2019 to August 2022.

Patients of either sex suffering from diabetic foot who presented themselves in the surgical OPD. The study consisted of 50 subjects which were matched by age, sex, and data were collected in the prescribed proforma consisting of details of the patient & history, clinical findings, laboratory and radiological investigation, arterial color Doppler study, HbA1c levels. All the patients underwent a detailed history and clinical examination including the evaluation of palpable pulses and the Ankle Brachial Index (ABI).

Patterns of vascular insufficiency on USG Color Doppler studied on diabetic foot patients are -1. **Caliber:** The mean caliber of common femoral artery (CFA), superficial femoral artery (SFA), popliteal artery (PA), anterior tibial artery (ATA), posterior tibial artery (PTA), dorsalis pedis artery (DPA) are studied. 2.

Color pattern, flow pattern whether triphasic, biphasic, monophasic 3. Peak Systolic Velocity (PSV): The mean Peak Systolic Velocity (PSV) of common femoral artery, superficial femoral artery, popliteal artery, anterior tibial artery, posterior tibial artery, dorsalis pedis artery on ultrasound arterial Doppler are studied 4. Plaque characteristics: There were broadly four characteristics of plaque - Intimal thickening, Atheroma, Calcification or thrombus are considered. The patients were followed up every month for three consecutive months and assessment was done for clinical outcome in terms of admissions, minor or major amputation and mortality.

INCLUSION CRITERIA: Age between 30yrs to 70 yrs. All Patients with diabetes presenting with gangrene/ulcer necrosis/Osteomyelitis. Patients who are willing to participate in the study.

EXCLUSION CRITERIA: Patients previously undergone revascularization surgery or Buerger's disease, other peripheral vascular diseases, vasculitis, primary atherosclerotic disease were excluded. Gestational diabetics, Patients who are not willing to participate in the study, All acute inflammatory conditions of leg were also excluded.

ETHICAL CONSIDERATION: The study will take place after obtaining approval from the institutional ethics Committee. Patients will be included in the study after written informed consent and will have the right to opt-out of the study at any time without giving any reason. **STATISTICAL ANALYSIS:** All the data collected will be organized using Microsoft excel software and statistically analyzed using SPSS.

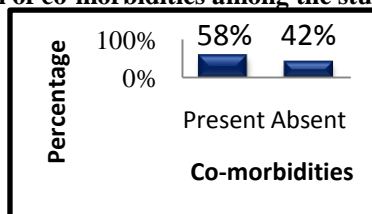
III. Results

Table 1 : Distribution of study participants according to their ABI (N=50)

S/no	ABI	Frequency	Percentage
1	<0.4	1	2.0
2	0.4-0.9	48	96.0
3	0.9-1.0	1	2.0
	Total	50	100

The majority of the participants were having ABI levels between 0.4-0.9 (96%).

Graph1: Distribution of co-morbidities among the study participants (N=50)



Out of 50 study participants, 58% of them have co-morbidities.

Table 2: Distribution of study participants according to HBA1C levels (N=50)

S/no	HBA1C	Frequency	Percentage
1	6.5-7.5	25	50.0
2	7.6-8.5	6	12.0
3	8.6-9.5	4	8.0
4	9.6-10.5	8	16.0
5	10.6-12.0	7	14.0
	Total	50	100.0

Mean=8.38±1.46

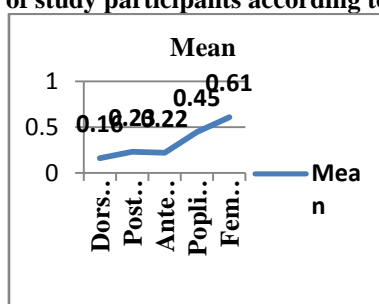
The majority of the study participants are having HBA1C levels between 6.5 to 7.5 (50%), followed by 16% having between 9.6 and 10.5. Around 14% are having in the range of 10.6 to 12.0. Remaining 12% and 8% of the participants are having in the range of 7.6-8.5 and 8.6-9.5 levels.

Table 3: Distribution of study participants according to symptoms (N=50)

Slno	Symptoms	Frequency*	Percentage
1	Gangrene	21	42
2	Osteomyelitis	11	22
3	Neurosis	36	72
4	Ulcer	45	90

The majority of the study participants are having an ulcer (90%), followed by 72% having neurosis. Around 42% have gangrene, and 22% having osteomyelitis.

Graph 2: Distribution of study participants according to the calibration (N=50)



From the 2 graph it shows the mean calibration of DPA is 0.16 cm, PTA 0.23cm, ATA 0.22 cm, PA 0.45 cm and FA 0.61 cms.

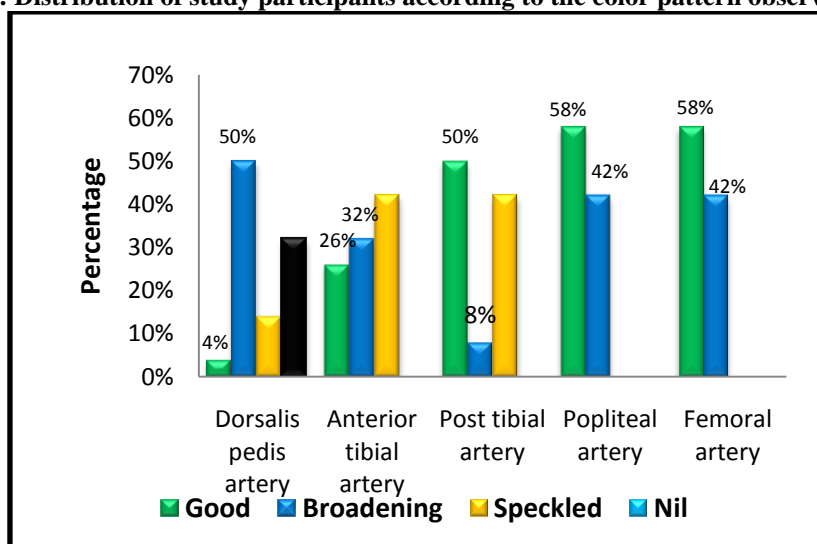
From the 2 graph it shows the mean calibration of DPA is 0.16 cm, PTA 0.23cm, ATA 0.22 cm, PA 0.45 cm and FA 0.61 cms.

Table 4 : Distribution of study participants according to the flow pattern (N=50)

Slno	Flow Pattern	Triphasic	Biphasic	Monophasic	Nil
1	Dorsalis pedis artery	4(8)	24(48)	4(8)	18(36)
2	Anterior tibial artery	13(26)	16(32)	21(42)	-
3	Post tibial artery	22(44)	11(22)	17(34)	-
4	Popliteal artery	32(64)	18(36)	-	-
5	Femoral artery	33(66)	16(32)	1(2)	-

Majority of the study participants were having a combination of triphasic flow in DPA (8%), ATA (26%), PTA (44%), PA (64%), and FA (66%). Among those having biphasic flow are about 48% in DPA, 32% ATA, 22% PTA, 36% PA, and 32% FA. Monophasic flow is seen among 8% DPA, 42% ATA, 34% PTA and 2% FA. No flow was seen in 36% participants with DPA.

Graph 3: Distribution of study participants according to the color pattern observed (N=50)



The majority of the study participants had a good color pattern, which was observed among 4% DPA, 26% ATA, 50% PTA, 58% PA, and 58% FA. Among those having broadening color patterns are about 50% in DPA, 32% ATA, 8% PTA, 42% PA, and 42% FA. The speckled color pattern is seen among 14% DPA, 42% ATA, and 42% PTA. No color was observed in 32% participants with DPA.

Table 5: Distribution of study participants according to Peak systolic velocity{PSV} (N=50)

S/no	PSV	Dampened	Decreased	Increased	Normal
1	Dorsalis pedis artery	21(42)	-	25(50)	4(8)
2	Anterior tibial artery	9(18)	12(24)	16(32)	13(26)
3	Post tibial artery	-	5(10)	27(54)	18(36)
4	Popliteal artery	-	-	24(48)	26(52)
5	Femoral artery	-	1(2)	22(44)	27(54)

The majority of the study participants were having increased PSV, which was observed among with 50% DPA, 32% ATA, 54% PTA, 48% PA, and 44% FA. Among those having normal PSV are about 8% in DPA, 26% ATA, 36% PTA, 52% PA, and 54% FA. Decreased PSV is seen among 24% ATA, 10% PTA, and 2% FA. Dampened PSV was observed in 42% of participants with DPA and 18% with ATA.

Table 6: Distribution of study participants according to the presence of plaque-type (N=50)

S/no	Plaque type	Intimal thickening	Atheroma	Calcification	Thrombus
1	Dorsalis pedis rtery	43(86)	26(52)	24(48)	12(24)
2	Anterior tibial rtery	41(82)	9(18)	32(64)	-
3	Post tibial artery	35(70)	16(32)	31(62)	-
4	Popliteal artery	23(46)	35(70)	4(8)	-
5	Femoral artery	21(42)	27(54)	4(8)	1(2)

Majority of the study participants were having intimal thickening which was observed among with 86% DPA, 82% ATA, 70% PTA, 70% PA and 42% FA. Among those having atheroma are about 52% in DPA, 18% ATA, 32% PTA, 70% PA and 54% FA. Calcification was seen among 48% DPA, 62% PTA, 8% PA and 8% FA. Thrombus was observed in 24% participants with DPA and 2% with FA.

Table 7: Association of study participants according to the duration of diabetes mellitus with the outcome (N=50)

Duration of DM	Surgery (n=23)	Conservative management (n=27)	Fischer's exact (df) p-value
1-5 yrs	3(13)	18(66.7)	17.601 (3) 0.001
6-10 yrs	11(47.8)	8(29.6)	
11-15 yrs	5(21.7)	1(3.7)	
16-20 yrs	4(17.4)	0	

There was a statistically significant difference in the outcome with the duration of diabetes mellitus. Higher the duration of diabetes chances of surgery is more, (p<0.001)

Table 8 : Association of co-morbidities with the final outcome (N=50)

Co-morbidities	Surgery (n=23)	Conservative management (n=27)	Fischer's exact (df) p value
Present	23(100)	6(22.2)	30.843 (1)
Absent	0(0)	21(77.8)	<0.001

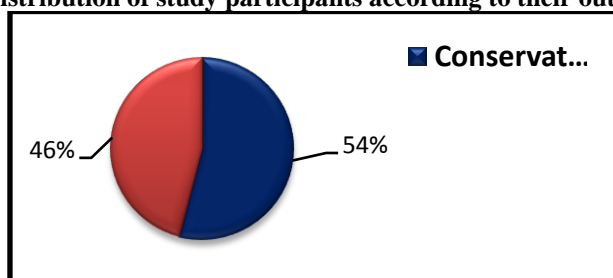
There was statistical significant difference in the outcome with the co-morbidities. The person with co-morbid condition had higher chances of surgery (p<0.001).

Table 9: Association of study participants according to the HBA1C levels with outcome (N=50)

HBA1C	Surgery (n=23)	Conservative management (n=27)	Fischer's exact (df) p-value
6.5-7.5	0(0)	25(92.6)	50.920 (4) 0.001
7.6-8.5	4(17.4)	2(7.4)	
8.6-9.5	4(17.4)	0(0)	
9.6-10.5	8(34.8)	0(0)	
10.6-12.0	7(30.4)	0(0)	

There is a statistically significant difference between HBA1C levels and outcomes. Greater the HBA1C levels higher are the chances of surgery, which was found to be statistically significant. (p=0.001)

Graph 4: Distribution of study participants according to their outcome (N=50)



The majority of the participants underwent conservative management i.e., Limb Salvage (54%), followed by 46% who underwent surgery. i.e., Amputation.

IV. Discussion

The remarkable discovery of Doppler and its application in the medical field had served its purpose in developing a non-invasive method to measure the pressure in arteries⁵. The development of grey scale and subsequent use of ultrasound for locating the artery and Doppler for measuring the PSV (Peak systolic velocity) lead to the concept of duplex sonography⁶. Ultrasound Color Doppler method is a valuable non-invasive tool that may provide useful information about the anatomy and physiology of the vessels^{7,8}. In this study the mean duration of Diabetes Mellitus was 7.5yrs with mean HBA1C levels were 8.38. In an Indian study done by Seth A 26 the mean duration of Diabetes Mellitus was 12 years, with mean HBA1c of 7.23 was been reported. In this study the majority of the study participants were having an ulcer (90%) followed by 72% having necrosis. Around 42% have gangrene and 22% having osteomyelitis. Intermittent claudication, rest pain, and ulcer are very important signs of lower limb ischemia⁹. Tetsuo Ostida et al 27 in his study found 70% of patients having intermittent claudication. B Ranjan et al 28 reported around one hundred and five patients having rest pain and sixty two having gangrene or ulceration out of one hundred and eighty cases. Always clinical evaluation of peripheral pulses is a very important adjunct to color Doppler study^{10,11}. It helps to suspect the possible site of a block and can find a good correlation between the clinical level of block and color Doppler findings in the majority of studies. The majority of the study participants in this study were having a combination of triphasic and biphasic flow and monophasic was observed in all the peripheral arteries studied. Monophasic flow and biphasic flow was seen more among anterior tibial (42% & 32%), posterior tibial (34% & 22%) and dorsalis pedis arteries(48%) (infra-popliteal arteries). And triphasic flow more in femoral (66%) and popliteal arteries(64%). In an Indian study by Abhinav et al 26 reported similar findings, the normal triphasic pattern of the spectral wave form was observed more in proximal vessels. The biphasic and monophasic flow became prominent in infra popliteal vessels with biphasic flow becoming the predominant pattern in the posterior tibial artery and dorsalis tibial artery. In a study done by Shaheen et al, they reported triphasic flow in 38% of vessels and monophasic flow 21% of vessels in patients with diabetes. The majority of the study participants in this study have a good color pattern in popliteal (58%) and femoral (58%) arteries. Among those having broadening color patterns are predominant in the dorsalis pedis artery (50%). The speckled color pattern is predominantly observed in infrapopliteal arteries (42%). Abhinav et al 26 study reported all the arteries in their study predominantly showed good color, but the percentage of speckled and spectral broadening color pattern increased in the infra popliteal vessels. Peak systolic velocity is usually increased in proximal vessels and decreased in distal vessels as we go down. The majority of the participants in this study have increased PSV which was observed more among 50% DPA, 32% ATA, 54% PTA (distal smaller vessels or infrapopliteal vessels) indicates stenosis at this level. Few of them showing high-grade stenosis showing a liasing monophasic flow spectral broadening and post stenotic turbulence. Decreased PSV is seen in the anterior tibial artery(24%) posterior tibial artery(10%), indicating proximal occlusion with increased resistance and distal parvus tardus with decreased resistance. Few cases were showing collaterals that bypass the occluded segment showing decreased PSV and decreased resistance. Few patients with diabetic foot in this study showing increased PSV and end-diastolic velocities with decreased resistance. These changes are compatible with hyperemia with distal infection^{12,13}. In an Indian study done by Seth A et al. where they reported all proximal bigger arteries had higher mean peak systolic velocity than distal smaller vessels. Plaque type: There were broadly 4 characteristics of plaque- Intimal thickening, Atheroma, Calcification, or thrombus. The majority of the study participants have intimal thickening, which was observed more among dorsalis pedis artery(86%). Atheroma is seen more among the popliteal artery(70%). Calcification was seen more among the posterior tibial artery(62%). Thrombus was observed more in the Dorsalis pedis artery. Plaque involvement was more common in below-knee vessels. Abhinav et al reported calcification was seen more common in anterior and posterior tibial arteries, whereas thrombus was most common in the common femoral artery. Das et al in his study reported that the femoral artery was the most common site of plaque deposition. Turini et al did a study comparing Digital Subtraction Angiography (DSA) and duplex sonography using a shortened Color Doppler Study (CDS) protocol and he reported around thirteen patients out of sixty-seven patients had plaques in the proximal superficial femoral artery on digital subtraction angiography and eight patients had plaques as seen on color Doppler study.

V. Conclusion

Colour Doppler imaging is a safe, cost-effective, non-invasive procedure and the best tool for evaluating patterns of vascular insufficiency in the diabetic foot. Clinical and radiological evaluation helps in early diagnosis and early intervention, thus reducing the risk of diabetic patients to go for amputation and helpful in proceeding for limb salvaging procedures by detecting the areas which are prone to further deterioration.

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