MAK HILL Publications Research Journal of Medical Sciences

Research Article
doi: 10.36478/makrjms.2024.12.523.527

OPEN ACCESS

Key Words
Diabetes mellitus, vasculopathy, amputation

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Received: 20 August 2024
Accepted: 03 December 2024
Published: 06 December 2024

Citation: Kunal Majoka, Shivaji H. Vidyarthi, Shweta khandelwal and Lalu Prasad Yadav, 2024. Study of Vasculopathies in Diabetic Foot. Res. J. Med. Sci., 18: 523-527, doi: 10.36478/makrjms.2024.12.523.527

Study of Vasculopathies in Diabetic Foot

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ABSTRACT
Diabetes mellitus is often referred to as "a disease of complications" due to its diverse clinical presentations and involvement of multiple organ systems. This study aims to explore vasculopathies in diabetic foot patients by examining their A prospective randomized single-blinded trial involving 100 patients was conducted in the Department of General Surgery at J.L.N. Medical College and Hospital, Ajmer. In our study, the prevalence of diabetic foot complications was highest in patients aged 54-65 years (30%). The amputation rate was notably high at 34%, with below-knee amputations being most common and 76% of vasculopathy patients showed significant improvement with cilostazol treatment. Our study emphasizes the critical role of early detection and management of vasculopathy and diabetes to prevent diabetic foot complications and reduce amputation rates.

INTRODUCTION

Diabetes mellitus is often referred to as "a disease of complications" due to its diverse clinical presentations and involvement of multiple organ systems. Historically, syphilis was considered the "king of all diseases" because of its varied manifestations. Today, diabetes[1] has taken that title, affecting the eyes, kidneys, blood vessels and peripheral nerves. Alarmingly, around 20% of hospitalized diabetics are admitted for foot-related issues, which result in significant suffering, disability and economic burden. As Bloom noted, elderly diabetics often struggle with awareness of their foot health due to poor eyesight and sensory loss. A pivotal moment in diabetes management was the discovery of insulin in 1922 by Nobel Laureates Frederick Grant Banting and Charles Herbert Best, which dramatically reduced surgical complication mortality rates from 60% to just 1%. Peripheral Arterial Disease (PAD) is a significant risk factor[2] for lower-extremity amputation, particularly among diabetic patients. Peripheral Arterial Disease (PAD) is a critical indicator of systemic vascular disease, increasing the risk of serious events like myocardial infarction and stroke, particularly in diabetics. Factors such as diabetes, smoking, advanced age, hypertension and hyperlipidemia CVD[3] contribute to PAD, but its prevalence is often underestimated due to many asymptomatic cases and under reporting. Accurate diagnosis is essential, as diabetic patients may show subtle signs rather than classic symptoms, necessitating effective screening to identify those at high risk. Those with both diabetes and PAD face worse lower extremity function and a higher risk of acute ischemia, leading to critical limb ischemia (CLI) and potential amputation. The progression of PAD can severely impact quality of life, resulting in long-term disability, slower walking speeds and a cycle of reconditioning. Economically, PAD incurs significant healthcare costs and productivity losses. Approximately 27% of PAD patients experience symptom progression over five years, with a notable cardiovascular event rate and high mortality associated with CLI. The urgency of prevention is underscored by alarming amputation rates and the associated mortality, which reaches 70% within five years post-amputation. Thus, the primary goal in managing diabetic foot problems is to prevent limb loss and reduce major amputation rates. Foot complications[4] in diabetes arise from a combination of ischemia, ulceration, infection and diabetic Charcot's joint, but can be mitigated through effective prevention and management[5] These guidelines aim to help identify at-risk patients and tailor treatment based on individual clinical, socioeconomic and domestic factors. Peripheral Arterial Occlusive Disease[6], indicated by low TcPO2 levels, poses a greater risk for foot ulceration and amputation than neuropathy[7], emphasizing the need for accurate vascular assessment using methods like Doppler scanning.

Aims and Objectives: Our aim is to explore vasculopathies in diabetic foot patients by examining their prevalence, amputation rates and the role of hemorheological agents in management.

MATERIALS AND METHODS

A prospective randomized single-blinded trial involving 100 patients was conducted in the Department of General Surgery at J.L.N. Medical College and Hospital, Ajmer. Each patient underwent a detailed history, physical examination and various investigations. Those meeting the selection criteria were informed about the study, and written informed consent along with ethical clearance was obtained. Inclusion criteria consisted of diabetic patients with lower limb ulcers or infections aged over 20 years, while exclusion criteria included non-diabetic patients and those with ulcers or infections outside the lower limbs. Investigations performed included haemoglobin (Hb), erythrocyte sedimentation rate (ESR), total leukocyte count (TLC), peripheral blood film (PBF), differential leukocyte count (DLC), urine sugar and ketones, blood sugar (fasting and postprandial), blood urea nitrogen (BUN), serum creatinine, serum electrolytes, pus culture, X-ray of the foot, bilateral lower limb Doppler ultrasound and biopsies for microscopic studies.

King's Classification:

- **Stage 1:** Normal.
- **Stage 2:** High Risk.
- **Stage 3:** Ulcerated.
- **Stage 4:** Cellulitis.
- **Stage 5:** Necrotic.
- **Stage 6:** Major Amputation.

RESULTS AND DISCUSSIONS

In present study, the youngest patient was 26 years male and the oldest was 80 years male. Maximum number of patients belongs to 55-64 years age group. In our study, discoloration and intermittent claudication were more common presentations noted in vasculopathy patients. In this study total 34 patients required amputation out of which 21 had vasculopathies and 13 did not have vasculopathy. The amputation pattern indicates that among 34 patients, 3 underwent above-knee amputation, 10 below-knee and 21 in other categories, with vasculopathy identified in varying proportions. Specifically, 14.3% of above-knee, 38.1% of below-knee and 47.6% of others had vascular issues on arterial Doppler studies. Among patients receiving hemorheological agents, 76.5% reported improved wound healing and relief from ischemic pain or claudication, while 100% of those not treated with these agents showed no improvement.

Table No.1 :Age Distribution Among the Cases

Age Group (years)	No. of patients	Percentage(%)
25-34	2	2
35-34	13	13
45-54	23	23
55-64	30	30
65-74	21	21
75-84	11	11
Total	100	100

Table No. 2: Association Between Symptoms and Vasculopathies

Symptoms		Vasculopathies		Total	Chi-square test	
		Yes	No		Value	p-value
Pain	No.	16	43	59	3.130	0.077
	%	45.7%	66.2%	59.0%	Not significant	
Swelling	No.	24	34	58	1.848	0.174
	%	68.6%	52.3%	58.0%	Not significant	
Wound	No.	35	58	93	2.567	0.109
	%	100%	89.2%	86.0%	Not significant	
Discharge	No.	22	30	52	1.918	0.166
	%	62.9%	46.2%	52.0%	Not significant	
Discolouration	No.	30	9	39	46.418	9.5E-12
	%	85.7%	13.8%	404.0%	Significant	
Intermittent claudication	No.	11	1	12	16.521	4.8E-05
	%	31.4%	1.5%	12.0%	Significant	

Table No.3: Association Between Vasculopathy and Amputation

		Vasculopathies		
Required surgical amputation		Yes	No	Total
Yes	No.	21	13	34
	%	60.0%	20.0%	34.0%
No	No.	14	52	66
	%	40.0%	80.0%	66.0%
Total	No.	35	65	100
	%	100.0%	100.0%	100.0%
Pearson Chi-Square	16.221	1	5.46E-05	Significant
Continuity Correction	14.487	1	0.00014	Significant

Table No. 4: Association Among the Cases Between Pattern of Amputation Required and Vasculopathies

		Vasculopathies on arterial doppler study		
		Yes	No	Total
Above knee	No.	3	0	3
	%	14.3%	0%	8.8%
Below knee	No.	8	2	10
	%	38.1%	15.4%	29.4%
Others	No.	10	11	21
	%	47.6%	84.6%	61.8%
Total	No.	21	13	34
	%	100%	100%	100%

Table No. 5: Association Between Hemorheological Agent Used and Improved Wound and/or Relief of Ischemic Pain/Claudication

Hemorheological agents used		Improved wound and/or relief of ischemic pain/claudication		
		Yes	No	Total
Yes	No.	13	4	17
	%	76.5%	23.5%	100.0%
NO	No.	0	18	18
	%	0.00%	100.0%	100.0%
Total	No.	13	22	35
	%	37.1%	62.9%	100.0%

Overall, only 37.1% of the total cohort experienced benefits from the treatment, with 62.9% showing no positive effects. In our study the prevalence of diabetic foot in diabetes is greater in persons over the age of 50 years. In our study of 100 patients ranging from 26 years to 80 years, it was found that age group 54-65 years had the highest number of 30(30%) patients.The common age group in different studies, In A. K. Ramani[8] study it was 51-60 years, in Badderty and Fulford"4 study it was 61-70 years and in Oakley[9] it was 71-80 years. If the patient is the earning member of the family, the points to reduce the hospital stay must be considered to improve his life. Mean duration of hospital stay in Bouter[10] 126 was 40 days (1988), 38.3 days (1989) and in our study, it is 50.23 days. In our study, it was wound 93(93%), discharge 52(52%), pain 59(59%), swelling 58(58%), discoloration 39(39%) and numbness and/or intermittent Claudication 12(12%). It is shown that commonest presentation during admission was wound. In some patients, there were more than one symptoms. Amputation rate in our study is 34% where as in other studies it is low e.g.

in Ahuja[11] it is 18.3%, in Bhaskar Reddy[12] 27.3%, Knighton[13] -7.0%, Kao Hsiung[14] -16%, Apelquist[15]-22.04%. In this study, out of 34, 29.40% were below knee, 8.8% were above knee amputations and 61.08% other minor type of amputation. Out of those 34 patients 21(60%) had Vasculopathy and 13(40%) did not have vasculopathy. The amputation pattern was more in distal parts both in vasculopathy as well as in non vasculopathy patients, but proximal amputation pattern was prominently required in vasculopathy patients. In our study, compared to other studies, rate of amputation is more, may be due to ignorance, late presentation and large number of patients belong to Wagner's Grade 3,4,5. For this study, amputations were considered on the clinical basis like absent distal pulsations, life threatening sepsis, gangrene and osteomyelitis, where conservative management had failed. But, in other studies to decide the level of amputation, they have conducted useful investigations like measurement of segmental lower extremity systolic pressure and pulse volume. Measurement of skin blood flow adjacent to the amputation level was measured by Xenon.Below knee amputation found in different studies is as follows Bhaskar Reddy[12] 10.8%, H.T. Williams[16] 3%, 16. In present study, below knee amputation was considered in suspected gas gangrene with spreading cellulites and septicaemia in 6 (6%) cases. In case of failure of below knee amputation, above knee amputation was considered. Out of 8 (8%) above knee amputations, 4 patients died. High mortality is because this procedure was done in patients with severe infection and gangrene and where the patient's general condition was very poor at the time of surgery.Wound healing in above knee amputation is better but prosthetic fitting is difficult. Amputation level was decided keeping in mind certain goals-To remove all nonviable or diseased tissue, To preserve optimal residual function, To minimize surgical morbidity, Preserve maximal limb length, Co-morbidities and Survival. Out of 35 patients of vasculopathies 17 patients were given Hemorheological agent. 13 patients (76%) showed improvement in symptoms which was statistically significant. In the control group of 18 patients who were not given the drug showed delayed improvement. The patients described here were either not ideal candidates for invasive therapy or refused for invasive therapy. Thus, the addition of a relatively new pharmacologic agent was a feasible option when the course of traditional supportive measures failed. Despite underlying chronic critical limb ischemia, between 7 and 24 weeks after starting cilostazol[17], the ischemic ulcerations completely healed in many patients. Other patients experienced resolution of ischemic rest pain. All 17 patients have continued taking cilostazol and 14 of them remained free of recurrent ulcerations during a follow-up period ranging from 2-12 months. 3 patients developed recurrent ulcer due to trauma but those too healed between 2-3 months later on.

CONCLUSION

This study highlights vasculopathy as a significant risk factor for diabetic foot lesions, noting that typical signs of lower limb ischemia may be absent or misleading in diabetic patients. Early detection and treatment of macrovascular disease, alongside laboratory vascular assessments, are crucial for preventing severe complications, including amputation. The research also underscores the effectiveness of cilostazol in treating diabetic foot related to vascular issues. It concludes that diabetic foot lesions often arise from both vasculopathy and neuropathy, with late presentations linked to factors like illiteracy and poor awareness, leading to higher mortality rates. Key strategies for reducing amputations include good diabetes management, nutritional improvement, careful wound care and infection control. The study advocates for early detection of Peripheral Vascular Disease using accessible tools, emphasizing its importance in mitigating diabetic foot complications.

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