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A STUDY FROM MAHARASHTRA STATE: FOOT EXAMINATION IN PREVALENT DIABETIC HEMODIALYSIS PATIENTS

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ABSTRACT

Aim: to analyze the occurrence of foot complications after the introduction of a standardized foot examination within an extensive cohort of prevalent diabetic Hemodialysis patients across three Hemodialysis centers in the Marathwada region of Maharashtra state.

Methods: A standardized foot examination was performed in 200 prevalent diabetic Hemodialysis patients in Aurangabad (n=94), Jalna (n =56), and Beed (n=50) in the Marathwada region of Maharashtra state for two years (October 2021 – September 2023). Foot complications were categorized using the Wagner classification system, which spans grades 0 to 5. Peripheral artery disease (PAD) was assessed based on clinical pulse measurements, with classifications assigned as normal (grade 0), weak (grade 1), or absent (grade 2).

Results: Based on the Gavin weighted score, in individuals with diabetic nephropathy undergoing haemodialysis, the diabetic foot risk factors were distributed as follows: 20.63% in the low-risk group, 69.84% in the medium-risk group, and 9.52% in the high-risk group. Within the diabetic nephropathy with haemodialysis cohort, cases classified as Grade 0 according to the Wagner classification amounted to 57, constituting 90.47%. The remaining cases comprised 6 cases of diabetic foot (9.52%), along with 4 cases classified as Grade 1 (6.35%), 1 case as Grade 2 (1.59%), and 1 case as Grade 4 (1.59%), respectively.

Conclusion: The implementation of a standardized foot examination protocol among diabetic patients undergoing hemodialysis revealed a noteworthy prevalence of clinically significant complications that demand careful consideration.

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Keywords: haemodialysis, diabetic patients, Wagner classification

1. INTRODUCTION

Diabetes mellitus poses a significant worldwide health concern. The majority of lower extremity amputations (LEA) primarily result from diabetic foot complications, including both diabetic foot ulcers (DFU) and diabetic foot infections (DFI). Over a quarter of individuals diagnosed with diabetes experience foot amputations throughout their lives, with over 85% of lower extremity amputations attributed to complications arising from foot infections or ulcerations. Moreover, diabetes is currently acknowledged as the leading preventable cause of Charcot neuroarthropathy. Diabetic foot problems are considered a complex group of pathologies and also known as diabetic foot syndrome (DFS), including both neuropathy and vasculopathy or vascular insufficiency [1-6].

Diabetes mellitus is a strong risk factor for chronic kidney disease (CKD). The chronic impairment of the kidneys that arises as a consequence of long-term diabetes mellitus is now termed as diabetic kidney disease (DKD). Primarily triggered by elevated blood pressure (HTN), DKD initially manifests as microalbuminuria or gross proteinuria, progressing to nephropathy, and in cases of uncontrolled diabetes, may culminate in end-stage renal disease (ESRD). Additionally, hypertension (HTN) or elevated systolic and diastolic pressures represent significant contributors to the risk of proteinuria, nephropathy, and ESRD.

Hypertension and atherosclerotic cardiovascular disease (ASCVD) stand out as prominent contributors to morbidity and mortality in individuals with diabetes concurrent with DKD [7-12].

Patients with diabetic nephropathy undergoing maintenance haemodialysis exhibit a heightened prevalence of foot ulcers and amputations. This study aims to evaluate the podiatric status of individuals on maintenance haemodialysis, screen high-risk patients, and enhance tailored foot care interventions. Individuals with diabetes encounter an increased vulnerability to foot complications arising from diabetic neuropathy, peripheral artery disease (PAD), and microvascular issues. This risk is further accentuated in patients undergoing haemodialysis, where additional factors such as uremic neuropathy and secondary hyperparathyroidism come into play. Furthermore, patients with diabetes undergoing haemodialysis face an increased risk of developing diabetic foot ulcers (FU), infections, and limb amputations. The presence of neuropathy often leads to reduced sensation, contributing to delayed diagnoses of pain and other symptoms.

The objective of this study was to analyze the occurrence of foot complications after the introduction of a standardized foot examination within an extensive cohort of prevalent diabetic Hemodialysis patients across three Hemodialysis centers in the Marathwada region of Maharashtra state.

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2. MATERIAL & METHODS

A standardized foot examination was performed in 200 prevalent diabetic Hemodialysis patients in Aurangabad (n=94), Jalna (n =56), and Beed (n=50) in the Marathwada region of Maharashtra state for two years (October 2021 – September 2023).

Inclusion criteria: Patients who are voluntarily willing to participate in the study.

Exclusion criteria: a) Psychiatric illness b) Any lower limb surgery within the last three months c) Vision loss/ Blindness

Protocol of the study:

A) History of the patient - history of toe amputation/ foot amputation
B) Inspection of feet - skin, nails
C) Examination of the pedal pulses - dorsalis pedis and tibialis posterior
D) Examination of foot sensory level using monofilament and tuning fork

Foot complications were categorized using the Wagner classification system, which spans grades 0 to 5. Peripheral artery disease (PAD) was assessed based on clinical pulse measurements, with classifications assigned as normal (grade 0), weak (grade 1), or absent (grade 2).

Statistical Analysis:

Continuous variables are presented as the Mean ± Standard Deviation (SD), while non-parametric variables are presented as the median and interquartile ranges.

Categorical variables are presented as percentages and frequency. Where appropriate, a non-parametric test was used to compare continuous variables between groups.

Depending on applicability, differences between categorical variables were analyzed using a chi-square test or double-tailed Fisher's exact test. All values are two-tailed, and $P < 0.05$ was considered statistically significant. Data were analyzed using IBM SPSS.

3. RESULTS

The mean age in all groups was 70.40 (±14 SD) years, with no statistical difference between districts and no statistical differences in gender, duration of diabetes, history of foot ulcer, and history of previous amputations.

Table 1: Demographics and clinical characteristics:

	Beed	Jalna	Aurangabad	P
Age (in years)	-	-	70.40 ± 14	-
Male: Female Ratio	-	-	126: 74	-
Duration of hemodialysis (in years)	-	-	4 (2-5)	-
Duration of diabetes (in years)	11 (6-14)	12 (7-14)	12 (7-15)	0.658
H/o foot ulcer	3%	2%	5%	0.54
H/o previous amputations	1.7	3.7	2.7	0.32

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Table 2: Foot assessment:

Variables	Beed	Jalna	Aurangabad	P
Abnormal toenail (N/%)	4/5.71%	15/11.28%	11/17.46%	0.032
Temperature sensation abnormal (N/%)	15/21.43%	45/33.83%	30/47.62%	0.001
Tuning fork abnormal (N/%)	6/8.57%	9/6.77%	3/4.76%	0.382
Decreased or absent posterior tibial artery pulse (N/%)	14/20.00%	37/27.82%	23/36.50%	0.034
Decreased or absent dorsalis pedis artery pulse (N/%)	13/18.57%	30/22.56%	17/26.98%	0.246

Based on the Gavin weighted score, in individuals with diabetic nephropathy undergoing haemodialysis, the diabetic foot risk factors were distributed as follows: 20.63% in the low-risk group, 69.84% in the medium-risk group, and 9.52% in the high-risk group.
Within the diabetic nephropathy with haemodialysis cohort, cases classified as Grade 0 according to the Wagner classification amounted to 57, constituting 90.47%. The remaining cases comprised 6 cases of diabetic foot (9.52%), along with 4 cases classified as Grade 1 (6.35%), 1 case as Grade 2 (1.59%), and 1 case as Grade 4 (1.59%), respectively.

4. DISCUSSION

The mismanagement of foot lesions remains a prominent concern for individuals contending with diabetes mellitus and concurrent renal disease. The cumulative lifetime prevalence of amputations in both type 1 and type 2 diabetic patients is approximately 15%, a statistic consistently observed in both European and United States populations [13-14]. Amputations represent a deeply feared tragedy in the journey of a diabetic patient, further exacerbated by the unfortunate reality that a significant proportion of these amputations are either unwarranted or excessively aggressive. The perioperative mortality for above-ankle amputations stands at 20%, with over one-third of patients left unable to attend to their care.
The correlation between diabetic foot lesions and advanced diabetic nephropathy can be elucidated by: (a) the prolonged duration of diabetes, creating a susceptibility to both nephropathy and foot lesions; (b) the notably heightened risk among nephropathic patients for the development of macroangiopathic or neuropathic complications; or (c) a combination of both factors. In patients experiencing both diabetic peripheral neuropathy and renal failure, the presence of superimposed uremic peripheral neuropathy exacerbates the condition, explaining the notably frequent and severe lesions observed in individuals who are both uremic and diabetic.

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Peripheral arterial disease is a more prevalent occurrence in diabetic patients when compared to matched non-diabetic individuals [15]. Utilizing ultrasound Doppler assessment to examine pulses reveals the presence of peripheral arterial disease in 30% of all diabetic patients [16]. The prevalence of this condition ranges from 15 to 20% in individuals aged 70 and increases to more than 50% in those aged 80 and above.

In diabetic patients, lower limb atherosclerosis is characterized by a distinctive pattern, predominantly affecting the lower leg, with 70% of diabetic patients affected, as opposed to only 20% of non-diabetic patients experiencing peripheral arterial disease. The involvement of the deep femoral artery is also a typical manifestation in diabetic patients, often accompanied by the stenosis of multiple arterial segments. Notably, a significant proportion of patients do not exhibit symptoms of claudication.

Risk factors associated with macroangiopathy and ischemic foot lesions in diabetic patients mirror those in non-diabetic patients, with a particular emphasis on smoking. The prevalence of peripheral arterial disease in diabetic patients is 2.5 to 6 times higher than in non-diabetic counterparts and tends to manifest a decade earlier. Several epidemiologic studies suggest an essential role of uncontrolled hyperglycaemia, contributing in part to the heightened risk observed in diabetic patients.

It is essential to explore a history of trauma when assessing foot conditions. Attention should be directed towards potential tissue trauma resulting from the pressure exerted by tightly fitted shoes, necessitating a thorough examination of both shoes and socks. A comprehensive assessment should encompass the inspection of nails, evaluation for interdigital mycosis, examination of hyperkeratotic plaques and minor lesions, and the identification of any deformities in the foot. Particularly, one should observe for flat-footedness coupled with downward movement of the metatarsal heads, loss of pedal arch, and the formation of hammer toes.

To identify tissue ischemia, doppler measurements can be employed to measure ankle perfusion pressure and, if feasible, toe perfusion pressure. Caution should be exercised, as arterial media calcifications and reduced arterial compressibility may yield falsely elevated arterial pressure values. However, arterial stenoses should be suspected if pressures are consistently lower by 10 mmHg or more compared to brachial pressure. Critical ischemia is indicated by ankle pressure values of 50 mmHg and toe pressure values of 30 mmHg, and this can be corroborated through transcutaneous oxygen partial pressure measurements, where values below 10 mmHg signify critical ischemia.

In managing diabetic foot lesions, it is crucial to ascertain whether the patient experiences pain. The absence of pain suggests a neuropathic component, though regrettably, it does not preclude the simultaneous presence of ischemia. A thorough neurological examination involves eliciting reflexes, assessing thermal sensation, gauging vibration perception using a quantitative tuning fork, and evaluating touch and pain perception. The measurement of dynamic foot pressure distribution through petrography proves helpful in identifying faulty loading patterns and guiding the selection of appropriate footwear.

Wound care protocols should be tailored to the specific stage of evolution. Local application of powders or ointments is contraindicated in this context. If correctable ischemia is

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identified, prioritizing this intervention is imperative. In the absence of correctable ischemia, surgical debridement, elimination of necrotic tissue, and implementation of antiseptic measures are typically warranted. Active intervention is frequently essential for neuropathic ulcers, involving the removal of callus and excessive growth and alleviating pressure from extensive tissue infiltration through broad incisions [Fig. 1]. In cases where tendons and bones are affected, minimal surgery should be considered, such as resecting metatarsal heads and toes [17,18]. Caution should be exercised to avoid overly aggressive surgical approaches.

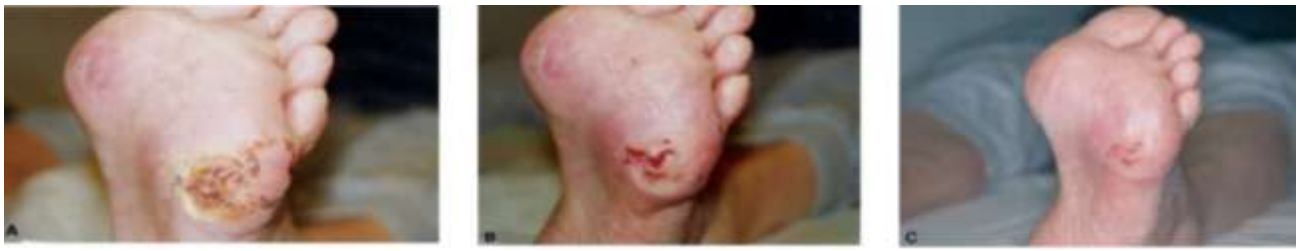

Fig. 1: Neuropathic ulcer. (A) Deep callous ulcer of the lateral part of forefoot (B) After surgical removal (C) Complete healing after two weeks

In severe infection in foot lesions, an open wound care strategy is generally preferred, with attempts to circumvent unnecessary amputation. If amputation becomes unavoidable, covering the defect with an interpolated flap is recommended. Later, moist wound dressings should be applied to enhance fibroblast proliferation, followed by tulle gras wound contact dressings to promote epithelialization. Ischemic gangrenous toes require dry management, and the surrounding skin should be cleansed. Whenever feasible, patience for spontaneous demarcation is advised.

Bacterial inflammation of ulcers and fissures often stems from mixed infections [19,20], including anaerobes. Obtaining bacterial cultures is crucial, as specific antibiotics may be needed for microbes like pseudomonas or methicillin-resistant Staphylococcus aureus. Systemic treatments currently involve a combination of major antibiotics, including metronidazole, quinolones, β-lactam antibiotics with or without clavulanic acid, cephalosporins, and clindamycin. Patients with fever and gangrene, who often face a higher risk of failure, may necessitate amputation. For patients undergoing below-ankle micro-amputation, continued follow-up care is essential to ensure proper redistribution of pressure loads, preventing the recurrence of ulcers at new sites or in the opposite foot.

Haemodialysis can prolong the survival time of patients with end-stage renal disease. However, as the survival time of haemodialysis patients is gradually prolonged, the long-term complications of end-stage renal disease, chronic kidney disease - Mineral and Bone Disorder (CKD-MBD) might lead to calcification, stiffness, and even necrosis of the foot blood vessels, which seriously affect the survival rate and quality life of haemodialysis patients [21]. According to research, diabetes is one of the leading causes of end-stage renal disease and is also the main risk factor for vascular calcification [22].

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Diabetic Foot Risk Factor Scale [23]:

Gavin weighted score of diabetic Classification foot risk factors (Table 1) was used to screen the high-risk group of diabetic nephropathy patients. Meanwhile, the Wagner classification for diabetic foot (Table 2) was used to grade diabetic foot.

Table 1: Gavin weighted score of diabetic foot risk factors.

Diabetic foot risk factors	**Gavin weighted score**
Vascular lesions	1
Foot deformity	2
Protective anesthesia	3
History of heart disease and/or smoking	1
History of diabetes > 10 years	2
Diabetic nephropathy or retinopathy	1
Previous foot ulcers or amputations	3

According to the cumulative score, 1 - 3 was classified as low-risk group, 4 - 8 as medium-risk group, and 9 - 13 as high-risk group.

Table 2: Wagner classification for diabetic foot [24]:

Grade	**Clinical manifestations**
0	Risk factors for foot ulcers, no ulcers at present
1	Surface ulcer, no clinical infection
2	Deeper ulcers, often with soft tissue inflammation, without abscess or bone infection
3	Deep infection with bone lesions or abscesses
4	Localized gangrene (toe, heel, or forefoot)
5	The whole foot gangrene

This study presents both merits and constraints. Initially, we thoroughly examined the patients' feet and performed a risk assessment in diabetic nephropathy patients undergoing hemodialysis, proposing practical recommendations for diabetic foot management. Notably, our utilization of a non-invasive foot evaluation demonstrated a substantial predictive value for diabetic foot complications, rendering it suitable for clinical implementation.

However, certain limitations warrant consideration: the relatively modest sample size, and the inclusion of only three centers necessitating future multicenter data and follow-up investigations. Furthermore, as an observational study, the establishment of causation is beyond our scope, necessitating further foundational research.

As dialysis technology advances and the age of dialysis patients progressively rises, heightened vigilance is warranted regarding foot lesions arising from vascular calcification and diabetes. Therefore, there is a crucial imperative to reinforce personalized health education and implement systematic diabetic foot management. The prevalence of medium-

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risk groups for diabetic foot complications is notably elevated among individuals with diabetic nephropathy undergoing hemodialysis. Hence, it is imperative to intensify health education efforts and promote self-care practices to effectively prevent and manage diabetic foot issues in this patient cohort.

5. CONCLUSIONS

The implementation of a standardized foot examination protocol among diabetic patients undergoing hemodialysis revealed a noteworthy prevalence of clinically significant complications that demand careful consideration. This uncomplicated clinical tool effectively identifies individuals at high risk, thus laying the foundation for a program to enhance overall health outcomes.

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