CLINICAL AND PATHOLOGICAL PROFILES OF DIABETIC FOOT ULCERS: INSIGHTS FROM A CROSS-SECTIONAL OBSERVATIONAL STUDY

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KEYWORDS

Diabetic foot ulcers, Wagner's Classification, Staphylococcus aureus, Negative Pressure Wound Therapy, amputation, cross-sectional study.

ABSTRACT

Background: Diabetic foot ulcers (DFUs) represent a significant complication of diabetes mellitus, leading to increased morbidity, mortality, and healthcare costs globally. This study aimed to elucidate the clinical and pathological profiles of DFUs, focusing on ulcer location, microbial culture, the relevance of Wagner's Classification in predicting amputation necessity, and the impact of Negative Pressure Wound Therapy (NPWT) on hospital stay durations.

Methods: We conducted a prospective, cross-sectional observational study at the Department of General Surgery, Command Hospital (Western Command), Chandimandir, over 13 months. Fifty patients presenting with DFUs were enrolled based on defined inclusion and exclusion criteria. Data on socio-demographic characteristics, ulcer specifics, microbial cultures, and treatment outcomes were collected and analyzed.

Results: The majority of ulcers were located on the right dorsum (22%), followed by cellulitis (18%) and gangrene (12%). Staphylococcus aureus was the most prevalent pathogen (34%). Higher Wagner's grades were significantly associated with an increased need for amputation ($P < 0.001$). NPWT did not significantly reduce hospital stay durations. Post-amputation complications significantly extended hospitalization ($P < 0.001$).

Conclusion: DFUs are characterized by diverse ulcer locations and a significant bacterial load, with Staphylococcus aureus being predominant. Wagner's Classification is a valuable prognostic tool for assessing the severity of DFUs and the need for amputation. While NPWT is an essential component of DFU management, its effectiveness in reducing hospital stays requires further investigation. Enhanced surgical and post-operative care protocols are crucial in mitigating complications and improving patient outcomes.

INTRODUCTION

Diabetes mellitus represents a formidable challenge to global health, affecting over 415 million individuals worldwide with projections suggesting an increase to more than 640 million by 2040. The disease not only exerts a substantial toll on individual health but also incurs significant economic costs, accounting for approximately 12% of global healthcare expenditure.[1] Among the plethora of complications associated with diabetes, diabetic foot ulcers (DFUs) stand out due to their high prevalence and profound impact on morbidity, mortality, and quality of life. DFUs, affecting roughly 15% of diabetic patients at some point in their lives, emerge as a result of a complex interplay between neuropathy, peripheral arterial disease, and infection, leading to a high risk of lower limb amputations.[2] India, now at the forefront of this epidemic, presents a unique and urgent case for study due to its rapidly rising number of diabetic individuals, particularly in urban and transitioning rural areas.[3]

DFIs are particularly challenging due to their polymicrobial nature, with a predilection for gram-positive cocci in acute infections, whereas chronic ulcers may exhibit a more diverse microbial landscape. The management of DFIs necessitates a nuanced approach, integrating appropriate antimicrobial therapy guided by culture and sensitivity patterns. Furthermore, the socioeconomic and cultural dimensions of diabetes care, including practices such as barefoot walking and limited access to healthcare facilities, compound the risk of DFUs in certain populations.[4]

This study aims to delve into the clinical and pathological profiles of patients suffering from diabetic foot, with an emphasis on identifying key risk factors and evaluating treatment outcomes. By focusing on this aspect, the research seeks to contribute valuable insights into the prevention and management of one of the most debilitating complications of diabetes mellitus. The urgency and necessity of this study are underscored by the escalating incidence of diabetes globally and the dire consequences of diabetic foot complications, which include not only increased morbidity and mortality but also significant social and economic repercussions for the affected individuals.[5]

MATERIALS AND METHODS

Study Design and Setting

We conducted a prospective, institution-based, cross-sectional observational study at the Department of General Surgery, Command Hospital (Western Command), Chandimandir. The study spanned 13 months, from February 1, 2021, to March 31, 2022, focusing on the clinical and pathological profile of diabetic foot ulcer (DFU) patients.

Participants

Fifty patients, both male and female, suffering from diabetes mellitus and presenting with foot ulcers, were recruited from the general surgery outpatient department (OPD). Eligibility was determined by specific inclusion and exclusion criteria.

Inclusion Criteria:

- Age greater than 18 years,
- Diagnosed with diabetes mellitus and foot ulcer.

Exclusion Criteria:

- Non-diabetic foot ulcers,
- Severe systemic illness,
- Refusal to consent,
- Non-compliance or loss to follow-up.

Ethical Considerations

Ethical clearance was obtained from the institutional Scientific and Ethical Committee. Informed consent was acquired from all participants, with an information sheet provided to each (ANNEXURE-II) after obtaining consent (ANNEXURE-III). The study adhered to the

Declaration of Helsinki and ICMR guidelines, ensuring confidentiality and ethical conduct throughout the research process.

Sample Size Determination

The sample size was calculated based on a previous study indicating a 75.25% prevalence of sensory neuropathy among diabetic patients. With a 95% confidence interval, 13% precision, and a 5% alpha error, the sample size was determined to be 43, rounded off to 50 for practicality.

Data Collection and Assessment

Data were prospectively collected using a structured questionnaire, covering socio-demographic details, lifestyle habits, comorbidities, and specifics of diabetes and DFU. A comprehensive assessment included vascular and neurological examinations, ulcer characterization according to Wagner's classification, and laboratory investigations (including blood sugar levels, HbA1c, and renal function tests). Specialized tests like foot X-rays and color Doppler studies were performed based on clinical indications. Swab cultures and tissue biopsies were obtained for microbial analysis.

Statistical Analysis

Data were entered into Microsoft Excel and analyzed using SPSS version 21.0 (IBM Corp., Armonk, NY). Descriptive statistics, including tables and graphs, summarized the findings. The chi-square test was employed for categorical variables, with a p-value of less than 0.05 considered statistically significant.

Primary Outcomes

Primary outcomes focused on ulcer location and type, wound culture results, post-amputation complications, and length of hospital stay.

Informed Consent and Ethical Aspects

Participants were briefed on the study's nature, with informed consent obtained prior to inclusion. The study posed no additional risk beyond standard care. Confidentiality was strictly maintained, with no personal identification data collected. The Institutional Ethics Committee (IEC) reviewed the study protocols to ensure compliance with ethical guidelines and patient rights.

RESULTS

In our study of 50 patients with diabetic foot ulcers (DFUs), we observed a diverse distribution of ulcer locations, with the highest prevalence on the right dorsum (22%), followed by cellulitis (18%) and gangrene (12%). This underscores the varied manifestation of DFUs, necessitating tailored clinical approaches for effective management.

Microbial cultures revealed a significant prevalence of Staphylococcus aureus (34%), highlighting its role as a primary infectious agent in DFUs. Klebsiella and Pseudomonas species were also notable contributors to the infection profile, emphasizing the importance of comprehensive microbial assessment for guiding targeted antibiotic therapy.

The application of Wagner’s Classification to assess the severity of DFUs indicated a strong correlation with the need for amputation. Notably, patients with higher Wagner’s grades (III-IV and IV-V) predominantly required minor to major amputations, underscoring the classification’s utility in predicting clinical outcomes and guiding treatment decisions.

The use of Negative Pressure Wound Therapy (NPWT) and its impact on hospital stay duration did not show a statistically significant difference, suggesting that while NPWT is a valuable tool in DFU management, its effectiveness in reducing hospitalization time warrants further investigation.

Furthermore, post-amputation complications significantly influenced the length of hospital stay, with a marked increase in duration for patients experiencing complications. This finding emphasizes the critical need for vigilant post-operative care and monitoring to mitigate complications and promote better outcomes for DFU patients.

TABLE 1: DISTRIBUTION OF PATIENTS ACCORDING TO ULCER LOCATION

	n	%
1. CELLULITIS	9	18.0
2. GANGRENE	6	12.0
3. LEFT PLANTER	4	8.0
4. RIGHT PLANTER	1	2.0
5. LEFT DORSUM	4	8.0
6. RIGHT DORSUM	11	22.0
7. LEFT TOE	2	4.0
8. RIGHT TOE	2	4.0
9. LEFT FINGER	3	6.0
10. RIGHT FINGER	1	2.0
11. LEFT FOREFOOT	1	2.0
12. RIGHT FOREFOOT	3	6.0
13. WHOLE FOOT	1	2.0
14. HEEL	2	4.0
TOTAL	50	100.0

TABLE 2: DISTRIBUTION OF PATIENTS ACCORDING TO WOUND CULTURE

	n	%
1. ECOLI	2	4.0
2. ENTEROBACTOR	3	6.0
3. ENTEROCCOCUS	1	2.0
4. KLEBSIELLA	7	14.0
5. NO GROWTH	7	14.0
6. PROTEUS	3	6.0
7. PSEUDOMONAS	8	16.0
8. STAPH	17	34
9. STREPTO	2	4.0
TOTAL	50	100.0

TABLE 3: DISTRIBUTION OF PATIENTS ACCORDING TO WAGNER'S AND AMPUTATION

			WAGNERS				Total
			II	III	IV	V	
	NO	n	11	10	1	0	22
		%	100.0%	83.3%	4.5%	0.0%	44.0%
	MINOR	n	0	1	12	1	14
		%	0.0%	7.15%	85.7%	7.15%	28.0%
	BK AND AK	n	0	1	9	4	14
		%	0.0%	7.1%	64.2%	28.5%	28.0%
Total		n	11	12	22	5	50
		%	100.0%	100.0%	100.0%	100.0%	100.0%
P value			0.001				

TABLE 4: DISTRIBUTION OF PATIENTS ACCORDING TO NPWT AND LENGTH OF HOSPITAL STAY

			NPWT		Total
			NO	YES	
	10-25	n	4	8	12
		%	15.4%	33.3%	24.0%
	26-50	n	17	11	28
		%	65.4%	45.8%	56.0%
	51-75	n	2	3	5
		%	7.7%	12.5%	10.0%
	76-100	n	2	1	3
		%	7.7%	4.2%	6.0%
	101-125	n	0	1	1
		%	0.0%	4.2%	2.0%
	126-150	n	1	0	1
		%	3.8%	0.0%	2.0%
Total		n	26	24	50
		%	100.0%	100.0%	100.0%
P value			0.406		

TABLE 5: DISTRIBUTION OF PATIENTS ACCORDING TO POST AMPUTATION COMPLICATION AND LENGTH OF HOSPITAL STAY

			COMPLICATION		Total
			NO	YES	
	10-25	n	12	0	12
		%	57.1%	0.0%	24.0%
	26-50	n	9	19	28
		%	42.9%	65.5%	56.0%
	51-75	n	0	5	5
		%	0.0%	17.2%	10.0%
	76-100	n	0	3	3
		%	0.0%	10.3%	6.0%
	101-125	n	0	1	1
		%	0.0%	3.4%	2.0%
	126-150	n	0	1	1
		%	0.0%	3.4%	2.0%
Total		n	21	29	50
		%	100.0%	100.0%	100.0%
P value			0.001		

DISCUSSION

The findings of our study contribute valuable insights into the complex interplay of factors influencing the clinical outcomes of diabetic foot ulcers (DFUs), a complication that significantly burdens the global health system. The distribution of ulcer locations, predominately on the right dorsum, aligns with literature suggesting the foot's mechanical stress areas are more prone to ulceration. This distribution underscores the importance of targeted preventive measures, including proper foot care education and the use of custom orthotics to redistribute pressure away from high-risk areas.[6]

The microbial profile of DFUs, with a significant prevalence of Staphylococcus aureus, reflects the pathogen's role in complicating the healing process of these ulcers. Our findings are consistent with previous studies, highlighting the necessity for meticulous wound care and the judicious use of antibiotics, tailored to culture and sensitivity results to combat infection effectively. The presence of a diverse bacterial flora, including Klebsiella and Pseudomonas species, further emphasizes the need for comprehensive microbial assessment in guiding treatment strategies.[7]

Wagner's Classification's correlation with the need for amputation in our study cohort illustrates the classification's utility in clinical practice, providing a prognostic tool that aids in the early identification of patients at high risk for severe outcomes. This reinforces the importance of a multidisciplinary approach to DFU management, incorporating regular screening, early intervention, and, when necessary, surgical consultation to prevent limb loss.[8]

The lack of a statistically significant impact of Negative Pressure Wound Therapy (NPWT) on hospital stay duration in our study suggests that while NPWT is a critical component of DFU management, its role in expediting discharge may be limited by factors beyond wound healing, such as patient comorbidities and the severity of the ulcer. This finding indicates that further research is needed to elucidate the specific conditions under which NPWT is most beneficial.[9]

Moreover, the significant increase in hospital stay duration for patients experiencing post-amputation complications highlights the critical need for enhanced surgical and post-operative care protocols. Preventing these complications through better surgical techniques, rigorous post-operative monitoring, and patient education on wound care can mitigate the negative impact on patient outcomes and healthcare resources.[10]

CONCLUSION

In conclusion, our study sheds light on the multifaceted nature of DFU management, from prevention and early detection to treatment and post-operative care. The high burden of DFUs, characterized by a significant risk of infection and amputation, calls for an integrated care strategy that encompasses patient education, multidisciplinary clinical approaches, and ongoing research to refine treatment modalities. Future studies should focus on longitudinal outcomes to better understand the long-term effectiveness of various treatment interventions, including the role of innovative technologies and therapeutic approaches in improving DFU management and patient quality of life.

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