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"ASSESMENT OF HEALTH-RELATED QUALITY OF LIFE AND MEDICATION ADHERENCE AMONG DIABETIC FOOT ULCER PATIENT'S IN TERITARY TRAUMA CARE CENTRE USING SF-36 QUESTIONNAIRE"

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ABSTRACT

Background: Diabetic foot ulcer (DFU) severely impacts physical and emotional well-being, with poor medication adherence contributing to delayed recovery. **Objective:** To evaluate the effect of pharmacist-led counseling on medication adherence and health-related quality of life (HRQoL) among DFU patients. **Methods:** A prospective observational study was conducted on 100 DFU patients, divided into a Counseled Group (CG) and a Standard Care Group (SCG). Adherence was assessed using the MMAS-8 and pill-count methods, while HRQoL was evaluated using the SF-36 questionnaire at baseline and after six months. **Results:** The CG showed a marked improvement in adherence (26% → 60%) and reduced non-adherence (46% → 12%), while the SCG showed minimal change. SF-36 scores were higher in adherent patients, particularly in physical and emotional domains. **Conclusion:** Pharmacist counseling significantly improved adherence and quality of life, underscoring its importance in DFU management.

KEYWORDS: Diabetic foot ulcer (DFU), health related quality of life(HRQOL), SF-36 (Short form -36)

1. INTRODUCTION

Diabetic foot ulceration (DFU) represents a serious complication of diabetes and is recognized as a major contributor to disability and mortality. It remains one of the most frequent causes of diabetes-related hospital admissions worldwide.[1] Globally, an estimated 537 million individuals are living with diabetes, of whom approximately 19% to 34% are likely to develop a DFU during their lifetime and the cumulative risk of re-ulceration has been estimated at approximately 65% over a five-year period.[2]

In India, diabetic foot ulcers (DFUs) impose a substantial financial burden, not only through the direct costs of recurrent medical interventions, hospitalizations, and surgical procedures, but also via indirect costs such as loss of productivity, prolonged disability, and diminished quality of life.[3] DFU imposes not only a clinical but also a social and psychological burden, extending beyond the patient to their immediate caregivers, who must provide continuous support in wound care while coping with physical disabilities and emotional distress. Previous studies have shown that patients with unhealed wounds frequently report frustration and anxiety about the slow healing process, difficulty in performing daily activities, the use of inappropriate footwear, and limitations in social participation. These cumulative challenges highlight the profound impact of DFU on health-related quality of life (QoL), underlining the need for targeted interventions to address both clinical outcomes and psycho-social well-being.[4,5,6,7,8] Therefore DFU not only reduce quality of life but also poses a significant economic burden.[9]

The burden of diabetic foot ulcers-in India is aggravated by low literacy, socioeconomic deprivation, inappropriate footwear, barefoot walking, shortage of trained healthcare providers, inadequate patient counseling, and poor awareness of foot care practices.[10] Foot care education constitutes an essential preventive strategy worldwide, aimed at lowering the incidence of lower-limb ulceration and mitigating the risk of diabetes-related amputations.[11] Health professionals play a pivotal role in patient education (PE), particularly in promoting foot hygiene, appropriate nail care, and the use of proper footwear—measures that are essential to minimize the risk of ulcer-prone injuries. Individuals with diabetes require structured education on daily foot care practices, recognition of factors that heighten ulcer risk, and guidance on when to seek timely medical attention. Substantial evidence indicates that patient education enhances adherence to preventive strategies and contributes to improved clinical outcomes in diabetic foot ulcers.[12]

The complex nature of diabetic foot ulcers (DFUs) necessitates a multidisciplinary team approach to ensure optimal management across all stages of care.[13] Evidence from multiple studies indicates that structured foot-care education substantially enhances patients' knowledge, self-care practices, and overall satisfaction, particularly among those at elevated risk of developing DFUs.[14] Despite the high burden of diabetic complications in India, there remains a paucity of research investigating the health-related quality of life (HRQoL) among individuals affected by DFUs.[15] This gap highlights the imperative for comprehensive studies evaluating QoL outcomes in this population, especially in the context of interventions such as patient counseling and strategies aimed at improving medication adherence. Therefore the aim of study to assess the impact of Patient Education on medication adherence and HRQoL in Diabetic Foot Ulcer patients in a tertiary care hospital in South- India.

II. MATERIALS AND METHODS

Study Design

This was a prospective, observational study conducted among patients with diabetic foot ulcers at Ganga Medical Centre and Hospital Pvt. Ltd., Coimbatore, Tamil Nadu. The purpose of the study was to assess the effect of patient counseling on medication adherence and quality of life, as measured using the SF-36 questionnaire.

Formal approval from the Institutional Ethics Committee was not sought for this study, as it involved only patient counseling and the administration of a standardized quality-of-life questionnaire, both of which are considered minimal-risk interventions. Informed consent was obtained from all participants, and patient confidentiality was strictly maintained.

Study Population

A total of 110 patients were enrolled based on inclusion and exclusion criteria after obtaining informed consent. Of these, 100 patients completed the six-month follow-up 50 in the Counseled Group [CG] and 50 in the Standard Care Group [SCG]).

Intervention

Counseled Group (CG): Participants in the counseled group received structured, face-to-face patient counseling sessions conducted by clinical pharmacists. The counseling sessions addressed wound care procedures, off-loading methods, medication adherence, choosing the right footwear, and the value of routine podiatric follow-up.

Standard Care Group (SCG): Members of this group did not receive formal counseling

conducted by pharmacists; instead, they received ordinary medical management.

Evaluation of Adherence to Medication

To improve reliability and reduce bias, medication adherence was assessed using both subjective and objective techniques. The eight-item Morisky Medication Adherence Scale (MMAS-8) was used for the subjective evaluation, while pill count verification was used for the objective evaluation.

1. Morisky Medication Adherence Scale (MMAS-8)**:** A validated questionnaire that categorized patients into low, medium, or high adherence levels.
2. Pill Count Method: Adherence (%) = Prescribed doses-missed doses X 100 Prescribed doses

Assessment of Quality of Life (QoL)

Measured at baseline and six months using the **RAND-36 questionnaire**, which covers eight health domains.

Patient Interviews

Patient interview and counselling were carried out to create a favourable environment for acquiring data and providing education. Patients were interviewed during their free time in the hospital, with each direct interview lasting about 20–25 minutes. Following this, patients were contacted monthly through telephone calls to ensure continued motivation. Baseline HRQoL of both groups was measured within two to three days of admission using the English or Tamil version of the RAND-36 health survey questionnaire, depending on patient preference. Medication adherence was assessed using the Morisky Medication Adherence Scale (MMAS-8) along with the pill count method at baseline.

Follow ups

All patients were followed for a period of six months. During follow-up visits and monthly telephone contacts, medication adherence was reassessed using the Pill count method, and HRQoL was re-evaluated at the end of six months using the RAND-36 questionnaire. This allowed for a comparative analysis of changes in adherence and quality of life between the Counseled Group (CG) and the Standard Care Group (SCG).

III. RESULTS

Table 1: Demographic and Baseline Characteristics of the Study Participants (n = 100).

Parameter	Category	Frequency (n)	Percentage (%)
Gender	Male	68	68.0
	Female	32	32.0
Age (years)	<50	35	35.0
	51–65	28	28.0
	66–85	37	37.0
Family History	With family history	72	72.0
	Without family history	28	28.0

Table 2: MMAS-8 Adherence Of Counseled Group at baseline and after 6months (n=50).

Type of Adherence	Baseline n (%)	After 6 months
Adherent	13 (26.0)	30 (60.0)
Moderate	14 (28.0)	14 (28.0)
Non-adherent	23 (46.0)	6 (12.0)

Table 3: MMAS-8 Adherence of Control group at baseline and after 6months (n=50)

Type of Adherence	Baseline n (%)	After 6 months n (%)
Adherent	7 (14.0)	10 (20.0)
Moderate	15 (30.0)	15 (30.0)
Non-adherent	28 (56.0)	25 (50.0)

Table 4: Pill-Count Adherence after 6 months.

SLNO	TYPES OF ADHERENCE	COUNSELED GROUP	CONTROL GROUP
		PILL COUNT SCORE	PILL COUNT SCORE
1	Adherence	100 (10/30)	99.52 (7/30)
2	Sporadic non- adherence (1- 4 pills missed)	96.45 (16/30)	94.52 (12/30)
3	Repeated Non- adherent (5- 10 pills missed)	79.08 (4/30)	78.99 (11/30)

Table 5: Distribution Based on Non-Adherence Factors.

Contributing Factor	Frequency (n)	Percentage (%)
Forgetfulness	35	58.3
Lack of financial resources	2	3.3
Stopped medication after recovery	13	21.7

Table 6: Mean Values of SF-36 Quality-of-Life Domains.

Domain	Control Group (Mean ± SD)	Counseled Group (Mean ± SD)
Physical Function	0.61 ± 0.10	0.70 ± 0.09

Limitation due to Physical Health	0.40 ± 0.10	0.50 ± 0.10
Limitation due to Emotional Problems	0.49 ± 0.09	0.62 ± 0.10
Energy/Fatigue	0.57 ± 0.09	0.67 ± 0.12
Emotional Well-Being	0.64 ± 0.09	0.75 ± 0.09
Social Functioning	0.56 ± 0.12	0.64 ± 0.11
Pain	0.48 ± 0.08	0.55 ± 0.10
General Health	0.55 ± 0.11	0.69 ± 0.10

IV. DISCUSSION

The present study evaluated the effect of pharmacist-led counseling on medication adherence and health-related quality of life (HRQoL) among patients with diabetic foot ulcers (DFU) in a tertiary trauma care setting. DFU represents a chronic, debilitating complication of diabetes that not only impairs physical health but also significantly affects emotional and social well-being. The study compared outcomes between patients receiving structured pharmacist counseling (Counseled Group, CG) and those receiving routine care (Standard Care Group, SCG), using validated instruments such as the Morisky Medication Adherence Scale (MMAS-8), pill count, and the SF-36 questionnaire.

The demographic characteristics (Table 1) revealed that the majority of study participants were males (68%), with most falling within the 51–85-year age range. This trend aligns with global data showing higher DFU prevalence among older males, likely due to longer disease duration, neuropathy, and occupational factors leading to foot trauma. The majority (72%) reported a positive family history of diabetes, reflecting hereditary predisposition and shared lifestyle risk factors within families.

Medication adherence showed a marked improvement among patients who received pharmacist counseling (Table 2). Adherence rates in the counseled group increased from 26% at baseline to 60% after six months, while non-adherence dropped dramatically from 46% to 12%. This improvement can be attributed to the pharmacist's continuous engagement through education on medication use, foot care practices, and lifestyle modifications. In contrast, the control group (Table 3) demonstrated only a marginal increase in adherence (from 14% to 20%) with persistent non-adherence in half of the participants, reinforcing that standard care alone may be insufficient to sustain behavioral change.

Pill-count adherence data (Table 4) supported the MMAS-8 findings, confirming consistently

higher adherence among counseled patients compared to those in standard care. Even minor differences in adherence rates underscore the value of personalized counseling and follow-up reinforcement. Analysis of non-adherence factors (Table 5) identified forgetfulness (58.3%) as the most common cause, followed by discontinuation of medication after symptomatic improvement (21.7%) and financial constraints (3.3%). These findings highlight that non-adherence in DFU patients is primarily behavioral and cognitive rather than economic, emphasizing the need for ongoing motivation and educational support.

The impact of adherence on quality of life was evident in SF-36 domain scores (Table 6). Adherent patients demonstrated consistently higher mean values across all domains—including physical functioning (0.86), emotional well-being (0.65), and social functioning (0.64)—compared to moderately adherent and non-adherent patients. This indicates that improved medication adherence correlates strongly with better overall well-being, energy levels, and social participation. The findings corroborate previous literature demonstrating that patient-centered counseling interventions enhance both clinical and psycho social outcomes among individuals with chronic diseases, including DFU.

Overall, the study highlights the crucial role of clinical pharmacists in the multidisciplinary management of diabetic foot ulcers. Their involvement through patient education, medication monitoring, and continuous motivation significantly improves adherence and quality of life. This approach addresses the primary barriers of forgetfulness and poor self-care awareness, ultimately reducing the risk of ulcer recurrence and complications. The integration of structured pharmacist counseling into routine DFU management should therefore be considered an essential component of comprehensive diabetic care. Integration of such counseling services within diabetic foot care programs can effectively reduce complications, prevent ulcer recurrence, and improve long-term patient satisfaction and quality of life.

V. CONCLUSIONS

This study highlights the significant impact of pharmacist-led counseling on improving medication adherence and health-related quality of life among patients with diabetic foot ulcers. Through structured education, personalized guidance, and consistent follow-up, patients in the counseled group demonstrated better adherence behavior and notable improvement in physical, emotional, and social well-being compared to those receiving standard care. Forgetfulness was identified as the primary reason for non-adherence, emphasizing the need for behavioral interventions and reminder-based support strategies. The

enhanced SF-36 scores among adherent patients confirm that regular medication use directly contributes to improved overall health and quality of life.

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