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Impact of Clinical Pharmacists Mediated Counselling on the Glycemic levels of Diabetic Foot Patients: A Prospective Observational Study

Dr. Ritika Bhagat[a], Dr. Tapan Yadav[a], Dr. Jay Patel[a], Dr. Abhay Dharamsi[b], Dr. Priyanshi Shah[a], Dr. Madhavan Iyengar[c]

[a] Department of Pharmacy Practice, Parul Institute of Pharmacy, Parul University, Vadodara, Gujarat, India

[b] Parul University of Pharmacy, Parul University, Vadodara, Gujarat, India

[c] Department Of General Surgery. PIMSR, Parul Institute of Pharmacy, Vadodara, Gujarat, India

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KEYWORDS

Diabetic foot.

Clinical pharmacist.

HbA1c level.

KAP.

HADS.

QOL.

ABSTRACT:

Introduction: Diabetic foot is one of the most devasting and lethal complications of diabetes mellitus wherein clinical pharmacists play a huge impact in improving the glycemic level and thus improving the quality of life of these patients.

Objectives: To assess the Impact of Clinical Pharmacist-mediated counseling on HbA1C, Knowledge, Attitude, Practice (KAP), Quality of Life (QOL) and Hospital Anxiety Depression Scale (HADS).

Methods: A baseline comparison study was conducted on 360 diabetic foot subjects in a tertiary care teaching hospital to evaluate the effect of above-mentioned intervention by clinical pharmacist over a period of 1 year. Subjects were counseled and the data were obtained at baseline (visit 0) and follow-up after 3 months (visit 1). KAP, QOL and HADS were assessed by KAP questionnaire, The Diabetic Foot Ulcer Scale- short form and Hospital Anxiety Depression Scale respectively. Along with that HbA1C was also assessed pre and post-impact.

Results: A total of 348 subjects completed the study follow-up. Pre & post KAP, QOL, HADS scores were improved significantly from baseline to follow-up. Thus, HbA1C was also improved.

Conclusions: This study presents that clinical pharmacist plays a pivotal role in improving the patient's condition with diabetic foot in terms of KAP, QOL, HADS as well as HbA1C levels.

1. Introduction

Diabetic Foot (DF) is one of the most devasting and lethal complications of diabetes mellitus wherein a foot is affected by ulceration that results from peripheral artery disease (PAD) and/or neuropathy affecting the lower extremities.1 The risk of developing diabetic foot ulcer (DFU) in diabetic patients ranges from 15-25% in which males are more likely to develop DFU as compared to females. Studies reported that every 30 seconds a person loses a limb due to diabetic-related complications 2,3 and it has multifactorial causes including PAD, lower limb neuropathy, poor glycemic control, foot deformities, calluses, edema, ischemia, infections, excessively dry skin with inappropriate foot care and footwear. In countries like India, barefoot walking is a significant concern, further exacerbating the risk of developing diabetic foot infections.4 Left untreated, diabetic foot ulcers can lead to severe complications including gangrene, sepsis, and the eventual amputation of toes or the entire foot.5 These physical consequences are not the only challenges patients face; the deteriorating health associated with DFU can also have a profound impact on their psychological well-being. The progression of diabetic foot disease can significantly impair the quality of life (QoL) for affected individuals. Prolonged impairment in QoL can lead to heightened levels of anxiety and depression, which are major psychological concerns

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associated with this condition. One of the primary contributing factors to the psychological distress experienced by these patients is the lack of knowledge about proper foot care practices and other essential lifestyle modifications. This knowledge gap places an enormous burden on the healthcare system, as patients struggle with the consequences of their condition, both physically and mentally.

In this challenging landscape, clinical pharmacists emerge as essential healthcare providers who can make a significant difference in the lives of diabetic foot patients. Their role extends far beyond traditional medication management. Clinical pharmacists play a pivotal role in educating patients about diabetic foot care practices, prevention strategies, and lifestyle modifications. By effectively imparting knowledge and guidance, clinical pharmacists empower patients to take control of their condition and minimize its impact on their lives.

The impact of pharmacist-led education extends beyond knowledge enhancement. It has a direct and positive influence on the QoL of diabetic foot patients. Equipped with the right information, patients can better manage their condition, reduce the risk of complications, and regain a sense of control over their lives. This, in turn, helps alleviate the anxiety and depression that often accompany diabetic foot disease.

Furthermore, as patients become more capable of managing their condition through improved knowledge and self-care practices, there is a notable improvement in glycaemic control. This positive impact on glycaemic control is reflected in reduced HbA1C levels, which are a crucial marker of diabetes management. Lower HbA1C levels signify better diabetes control and a decreased risk of diabetes-related complications, including diabetic foot.

In conclusion, diabetic foot is a devastating complication of diabetes mellitus, with profound physical and psychological consequences. However, with the intervention of clinical pharmacists who provide education and support, the knowledge gap can be bridged, leading to enhanced QoL, reduced anxiety and depression, and improved glycemic control. This holistic approach not only benefits individual patients but also contributes to the overall well-being of the diabetic population. It emphasizes the critical role of clinical pharmacists in combating diabetic foot disease and its associated challenges.

2. Objectives

To assess the Impact of Clinical Pharmacist-mediated counselling on HbA1C, Knowledge, Attitude, Practice (KAP), Quality of Life (QOL) and Hospital Anxiety Depression Scale (HADS).

3. Material and Methods

Study Design and Duration: A Prospective Comparative Study was conducted in the eastern part of Gujarat over a period of 1 year.

Inclusion and Exclusion Criteria:

All participants diagnosed with DF due to type I and II diabetes mellitus, whose age is above 18 years (irrespective of gender) and with/without comorbidities were eligible. While pregnant and lactating women, history of mental illness, with other life-threatening conditions (comatose, poisoning, malignancy), traumatic ulcer due to other causes non-diabetic, post-traumatic, arterial and venous disorder, non-diabetic peripheral neuropathy secondary to implant infection were excluded from the study.

Ethical Consideration:

The ethics clearance was obtained from the Parul University Institutional Ethics Committee (PUIECHR/PIMSR/00/081734/5202) and the recruitment was started after approval.

Preparation of Data Collection Tool:

We carried out a pilot study to assess the possibility of smoothly conduction of the study as per the objectives. A validated questionnaire and data collection form was used in the study which was approved by the ethics consisting of Knowledge, Attitude, Practice (KAP), Quality of Life (QOL) and Hospital Anxiety Depression Scale (HADS). The questionnaire was meticulously designed to assess the pre-existing knowledge, attitude and practice toward diabetic foot care, anxiety and depression associated with the condition and impact of the knowledge, practice and lifestyle on the quality of life of patients, this data collection was designed to assess the glycaemic levels i.e., mainly HbA1C. The patients were assessed based on the above-mentioned questionnaire pre and post-counselling sessions.

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Statistical analysis:

The data were recorded initially in Microsoft Office Excel from data collection form and later the statistical analysis was done using GraphPad Prism version 8.0.1., paired t-tests was used for analysis and the level of significance was kept at $p<0.05$.

4. Results

A total of 360 diabetic foot patients were recruited fulfilling the inclusion criteria and patients completed the study follow-up.

The demographic details of the 180 DF patients are presented in Table 1.

Among 360 patients, 62.2% were males and 68.8% were in the age group of Adults and the least 4.4% were Young adults. Almost three-quarters of DF patients (73.3%) were having diabetes mellitus since last 1-10 years and two-thirds (66.6%) have no addiction to any substance. 73.3% of patients have completed their schooling while only 11.1% completed graduation.

Table 1 Demographics of DF patients.

Baseline Characteristics	No. Of subjects	Percentage
GENDER		
Male	224	62.22
Female	136	37.77
AGE		
18 - 40 (Young adult)	16	4.44
41 -65 (Adult)	248	68.88
>65 (Elderly)	96	26.67
WAGNER		
0	88	24.44
1	80	22.22
2	72	20
3	40	11.11
4	48	13.33
5	32	8.88
DURATION(DM)		
1 - 5	128	35.56
6 -10	136	37.78
11 -15	64	17.78
16-20	32	8.88
SOCIAL HISTORY		
Addicted	120	33.33
Non – addicted	240	66.67
EDUCATION		
Schooling	264	73.34
Graduation	40	11.11
Illiterate	56	15.55

Firstly, Wagner classification was used to group patients according to their clinical severity, and p-value was used to determine whether counseling had an effect. Every grade of KAP, with the exception of the fifth-grade attitude, shows statistical differences ($p < 0.05$).

When pre & post counselling KAP was compared based on education, the highest impact was observed in patients who completed their schooling ($p <0.0001$) followed by illiterate and graduation.

Table 2 Pre- post counselling KAP based on Wagner classification

Wagner	**0**	**1**	**2**	**3**	**4**	**5**	**Mean**	**SD**
N	**88**	**80**	**72**	**40**	**48**	**32**	**N=360**	
Pre Couns. Kno	3 ± 1.183	3.300±	4.667 ±	4.600 ±	5.333 ±	3.750 ±	3.95	2.12

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wledge		2.406	2.000	2.608	2.503	1.708		
Post Couns. Knowledge	10.36 ±2.014	9.900 ±2.558	11.78 ±2.386	12.60 ±2.608	11.17 ± 2.563	13.25 ± 0.957	11.15	2.4
p-value	<0.0001	<0.0001	0.0002	0.0088	0.0002	0.0016	<0.0001	
Pre Couns. Attitude	2.455± 0.8202	2.500 ± 1.080	2.778 ± 0.8333	2.000 ± 1.000	2.000 ± 1.265	3.250 ± 0.9574	2.49	0.99
Post Couns. Attitude	3.818± 0.6030	3.600± 0.6992	3.778 ± 0.66667	3.600 ± 0.54777	3.500 ± 0.54777	3.250 ± 0.9574	3.64	0.65
p-value	0.002	0.032	0.0085	0.0161	0.0446	Ns	<0.0001	
Pre Couns. Practice	8.364± 3.075	7.400± 3.134	9.889 ± 3.180	7.800 ± 2.168	7.833 ± 2.563	7.750 ± 3.862	8.27	
Post Couns. Practice	16.55± 2.583	14.60± 2.914	16.00 ± 16.00	18.20 ± 3.114	16.33 ± 4.502	16.75 ± 3.862	16.18	3.26
p-value	<0.0001	<0.0001	0.0041	0.0018	0.0021	0.0149	<0.0001	

Simultaneously, anxiety and depression were assessed by Hospital Anxiety and Depression Scale and found that 57.77% of diabetic foot patients suffer from anxiety and depression (11-21 score), 24.44% have borderline depression (8-10 score) and 17.77% have no anxiety and depression.

Based on age distribution, the highest A & D was found in Adults (41-65 years) {11.68± 3.74, 11.65 ± 3.31} followed by Young adults (18-40 years) {11±1.41, 10.5 ±2.12} and the least in Elders (>65 years){ 8.5±4.46, 8.91±4.68}. Additionally, it was found that Wagner grades are directly proportional to A & D i.e., as Wagner grade increases the A & D also increases. Subsequently, A & D were compared against the Addiction/ Non-addiction (alcohol, tobacco or any other substances) and revealed no statistical correlation was obtained.

Table 3 Pre-post counselling effects on Anxiety and Depression based on Wagner classification

Wagner	N	Pre Couns. QOL	Post Couns. QOL	p-value
0	88	52.73 ±11.88	46.73 ±8.878	0.0823
1	80	79.30 ±28.16	68.20±68.20*	0.0002
2	72	86.78 ±26.07	72.44 ±22.19*	0.0004
3	40	90.40 ±23.37	84.40 ±25.43	0.2615
4	48	105.5 ±14.24	90.83 ±8.377*	0.0213
5	32	115.8 ±5.620	105.3 ±8.382	0.1150

This table presents the pre & post counselling effects on QOL. In Wagner grades 1,2 and 4 statistically significant differences were obtained.

Table 4 Pre-post counselling effects on Quality of Life based on Wagner classification

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Wagner	N	Pre Couns.HbA1c	Post Couns. HbA1c	p-value
0	88	10.58 ± 1.747	9.245 ±1.064*	0.0418
1	80	7.08 ± 1.395	6.43 ± 1.113*	0.2646
2	72	8.822 ± 3.564	7.188±1.328*	0.0497
3	40	8.44 ±1.368	6.804±0.760*	0.477
4	48	9.3±2.585	8.633 ±2.281	0.6460
5	32	7.55 ±0.946	6.1±0.216*	0.0245

QOL Score: Signifies Impairment In QOL; 0-29(Not at all),30- 58(Slightly), 59 – 87(Moderately), 88-116(Quite a bit), 117-145(Extremely).

Pre & post counselling QOL were compared based on education and revealed impact was obtained only in patients who completed their schooling (p <0.0001), not statically significant in Graduation and illiterate patients.

This table presents the pre & post counselling HbA1C. Among all Wagner grades, except Grade 4 statistically significant differences were obtained (p< 0.05).

Table 5 Pre-post counselling HbA1C based on Wagner classification

Wagner	N	Pre Couns.HbA1c	Post Couns. HbA1c	p-value
0	88	10.58 ± 1.747	9.245 ±1.064*	0.0418
1	80	7.08 ± 1.395	6.43 ± 1.113*	0.2646
2	72	8.822 ± 3.564	7.188±1.328*	0.0497
3	40	8.44 ±1.368	6.804±0.760*	0.477
4	48	9.3±2.585	8.633 ±2.281	0.6460
5	32	7.55 ±0.946	6.1±0.216*	0.0245

5. Discussion

In this study, males were 62.2% while females were 37.7% and most of them were above 41years (95.5%) similar to gender and age distribution by Açelya TÜRKMEN et al. which reports males (67.1%) and females (32.9%) and majority of them (95.9%) were 45 years and older.[6] The result obtained from these studies shows that males and the age group >41 years are majorly affected by DF. This study demonstrates that majority of the patients were not addicted (66.67%) to any prohibited substances i.e., no correlation between addiction and the occurrence diabetic foot. 88.89% of patients have not completed their graduation, similarly, findings were supported by Açelya TÜRKMEN et al. that 93.2% of patients had not completed their graduation.[7] This study shows that most of the subjects (88.9%) have not completed their graduation, therefore, lack of knowledge is one of the factors of improper diabetic foot care and development of diabetic foot. Another possible reason is rural areas where awareness about personal hygiene is very low.

The mean and SD of pre and post counselling KAP were found to be p value<0.0001, which signifies difference is statistically significant. Similarly, a study conducted by Thomas et al. shows that post counselling scores improved and p value 0.041 which signifies statistically significant differences were found.[8] In all Wagner Grades, post counselling knowledge and practice significantly improved, except in Grade 5 of post counselling attitude. This study indicates that more than half (57.7%) of DF patients suffer from anxiety and depression which is higher than Ali Ahmad et al 39.6% have depression and 37.7% have anxiety. [9] Additionally, a study conducted by Monami et al found higher depression score is directly related to delayed healing of diabetic foot ulcers. [10] This study shows that Adults (41-65 years) were at higher risk of anxiety and depression than young adults and elderly similar to [11,12] which indicates > 50 years of patients are more prone to depression. The present data doesn't show any relationship between addiction and anxiety &/or depression contrast to several studies [13,14] which indicate a positive correlation between smoking and depression. The study result shows that Grade 0, post counselling anxiety and depression means were increased as these were the patients who were not aware of their diseases previously. In contrast, in Grades 1,2

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and 5 significant improvement (p value< 0.05) in anxiety and depression were observed. In Grades 1,2 and 4 post counselling QOL was improved while in Grade 0, no significant improvement as these patient quality of life was not much affected. More than a half percentage of the patients HbA1C improved as the combined effect of KAP, QOL and HADS which also significantly improved post counselling.

6. Conclusion

Health education plays a key role in preventing and controlling diabetic foot progression. Since there is a huge gap between knowledge, attitude and practices towards diabetic foot care among these patients, clinical pharmacist plays a crucial role in counselling the patients regarding lifestyle changes including proper foot care, diet to control glycemic levels, medication adherence and proper dressing of wound to prevent infection. As the KAP improved, the Quality of life also improved and thus anxiety and depression due to diabetic foot also got reduced. In conclusion, HbA1C also improved as the above-mentioned parameters improved.

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