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Assessment of compliance with the therapeutic regimen and risk for diabetic foot ulcers among patients with diabetes mellitus during COVID-19 pandemic

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Original Article

Assessment of compliance with the therapeutic regimen and risk for diabetic foot ulcers among patients with diabetes mellitus during COVID-19 pandemic

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Abstract

Background: According to the data from the World Health Organization (2011), over three million people die worldwide from diabetes and its related complications every year because of non-compliance. **Aim:** The present study aimed to assess the compliance with the therapeutic regimen and risk for diabetic foot ulcers during the COVID-19 pandemic among patients with diabetes mellitus. **Method:** The research approach was quantitative and descriptive research design was used. The study was conducted among 100 patients with diabetes mellitus in selected hospitals, Chennai. The samples were selected by the non-probability purposive sampling technique. A structured 3-point rating scale was used to assess the compliance with the therapeutic regimen and a checklist was used to assess the risk for diabetic foot ulcers. **Results:** The study findings revealed that 60% of the patients were in poor compliance and 39% of them were in fair compliance with the therapeutic regimen during the COVID-19 pandemic. The majority of the patients were at low risk for diabetic foot ulcers in both right foot (93%) and left foot (92%). There was a low negative correlation found between compliance with the therapeutic regimen and risk for diabetic foot ulcers during the COVID-19 pandemic at a 5% level of significance. **Conclusion:** Most of the patients were in poor compliance with the therapeutic regimen during the COVID-19 pandemic and the risk for diabetic foot ulcers was low in both feet among the patients. Compliance with the therapeutic regimen during the COVID-19 pandemic can be challenging to patients due to restrictive measures that compromise the health care delivery system. Nurses play a pivotal role in creating awareness among patients with diabetes about the importance of compliance with the therapeutic regimen in maintaining glycaemic control and in preventing complications.

Keywords: compliance, COVID-19 pandemic, diabetes mellitus, foot ulcer risk, therapeutic regimen

Introduction

According to the International Diabetes Federation (IDF), 463 million people have diabetes in the world and 88 million people in the Southeast Asia region (IDF, 2020).

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Over 346 million people worldwide have diabetes mellitus (DM), and India ranks second in the world with 65.1 million diabetic patients. The Indian Council of Medical Research (ICMR)-India Diabetes Study (2016), reported that the overall weighted prevalence of diabetes was 10.4% (95% CI: 9.0-11.0%) in Tamil Nadu, and the overall weighted prevalence of pre-diabetes in Tamil Nadu, was 8.3% (ICMR, 2016).

During the COVID-19 pandemic, people were forced to stay in their homes, which have resulted in a change in physical activity, dietary pattern, and psychological status of the individuals. All of these can especially affect glucose control in patients with diabetes. Routine care of diabetes is significantly disrupted during the current pandemic. Stress levels and disruptions to diet

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and physical activity may also contribute to worsening outcomes during and following the pandemic. This has greatly affected their ability to access and receive health care, obtain diabetes medications and supplies, and maintain a healthy lifestyle and social connections (Hartmann-Boyce et al., 2020). During the COVID-19 pandemic, it was observed that patients with DM had difficulty accessing health care facilities. Hence, the present study aimed to assess the compliance with therapeutic regimen and risk for diabetic foot ulcers during COVID-19.

Objectives

The objectives of the study were to:

- Assess the compliance with the therapeutic regimen and risk for diabetic foot ulcers during the COVID-19 pandemic among patients with DM.
- Correlate the compliance with the therapeutic regimen with risk for diabetic foot ulcers during the COVID-19 pandemic among patients with DM.
- Associate the compliance with the therapeutics regimen during the COVID-19 pandemic with selected demographic variables of patients with DM.

Materials and Methods

The research approach was quantitative and descriptive research design was used to assess compliance with the therapeutic regimen and risk for diabetic foot ulcers during the COVID-19 pandemic among patients with DM. The study was conducted in the diabetic outpatient department (OPD) of VHS Multispecialty hospital, Taramani, Chennai. The samples were selected by the non-probability purposive sampling technique. The sample size was determined based on the literature review. A total of 100 patients diagnosed with DM were selected as samples. The inclusion criteria were both male and female patients with DM for more than five years of duration attending the diabetic OPD and those who can understand Tamil, English, Hindi, and Telugu. Patients who had diabetic foot ulcers, with impaired vision and self-care capacity, those who were critically ill, and COVID-19 positive patients were excluded.

The tool used in the study was a questionnaire to collect demographic and clinical data. A 3-point rating scale was used to assess compliance with the therapeutic regimen. It consisted of four components such as intake of medications, diet and exercise, blood sugar testing, follow-up and stress management, foot care, and each component consisted of five questions both positive and negative. The total compliance score was 40. The scale legends were Never, Sometimes, Always and scored as follows; for positive questions Never (0), Sometimes (1), and Always (2), for negative questions Never (2), Sometimes (1), and Always (0). Then the percentage was calculated, and the scores were interpreted as good (>75%), fair (50% to 75%), and poor (<50%) compliance. A checklist was used to assess the risk for diabetic foot ulcers. It consisted of ten questions to assess the risk of foot ulcers in both feet. The total risk score was ten for the right and left foot separately. The scores were interpreted as <50%-minimal risk, 50%-75%-moderate risk, and >75%-high risk. The tool was validated. Content validity was obtained from the two diabetologists and medical surgical nursing experts. The reliability coefficient for the rating scale was r=0.78, and the checklist was r=0.83. This showed that the tool was reliable and feasible for conducting the main study. Institutional ethical committee approval was obtained after obtaining informed consent from the patients; data were collected by the researcher. Anonymity was maintained.

Results

Table 1 shows that the majority (56%) of the patients were in the age group of 56-60 years and 54% of the patients were male. About 82% of the patients belonged to the Hindu religion and 75% of the patients were married. The majority (68%) of the patients were in the nuclear family and 62% of the patients were residing in the urban area. About 44% of the patients had completed primary education and 39% of them were employed in which 61.5% of the patients were working in the private sector. The majority (65%) of the patients were sedentary workers. About 32% of the patients' family monthly income was above Rs 15, 000/- and the majority (69%) of the patients were non-vegetarian.

Table 1
Frequency and Percentage Distribution of the Samples Based on Their Demographic Variables

N = 100

Demographic variables	Frequency	Percentage *(%)*
Age in years		
40 - 45	13	13
46 - 50	10	10
51 - 55	21	21
56 - 60	56	56
Gender		
Male	54	54
Female	46	46
Religion		
Hindu	82	82
Christian	10	10
Muslim	8	8
Marital status		
Single	9	9
Married	75	75
Widow/widower	16	16
Type of family		
Nuclear family	68	68
Joint family	32	32
Area of residence		
Urban	62	62
Semi-urban	30	30
Rural	8	8
Educational status		
No formal education	19	19
Primary education	44	44
Secondary education	10	10
Higher education	3	3
Graduate	14	14
Postgraduate	10	10
Occupation		
Employed	39	39
Unemployed	61	61
If employed (n = 39)		
Government	4	10.3
Private	24	61.5
usinessman	3	7.7
Daily wages	3	7.7
Retired	5	12.8
Nature of occupation		
Heavy worker	6	6
Moderate worker	29	29
Sedentary worker	65	65
Family monthly income		
<Rs 5,000/-	21	21
Rs 5,001-10,000/-	27	27
Rs 10,001-15, 000/-	20	20
>Rs 15,000/-	32	32
Dietary pattern		
Vegetarian	31	31
Non-vegetarian	69	69

Table 2
Frequency and Percentage distribution of the Samples based on their Clinical variables

N = 100

Demographic variables	Frequency	Percentage *(%)*
Type of diabetes mellitus		
Type one	10	10
Type two	90	90
Family history of diabetes mellitus		
Yes	55	55
No	45	45
If 'Yes', mention the relationship		
Father	23	41.8
Mother	14	25.8
Sibling	15	27.3
Grandparents	2	3.6
Others, specify	1	1.8
History of co-morbidities		
Yes	51	51
No	49	49
If 'Yes', specify		
Chronic kidney disease	6	11.8
Cardiac disease	4	7.8
Hypertension	25	49.0
Respiratory diseases	8	15.7
Endocrine diseases	8	15.7
Treatment taken for diabetes mellitus		
Oral hypoglycaemic	64	64
agent	20	20
Insulin	16	16
Combined		
Awareness of diabetic foot care		
Yes	86	86
No	14	14
If 'Yes', source of information		
Mass media	8	9.3
Health care members	50	58.2
Friends	23	26.7
Others	5	5.8
Use of diabetic footwear (MCR) inside the house		
Yes	16	16
No	84	84
Awareness of teleconsultation		
Yes	1	1
No	99	99

Table 2 shows that the majority (90%) of the patients had type II DM and 55% of them had a family history of DM. Fifty-one per cent of the patients had a history of co-morbid illness of which 49% of them were having hypertension. Almost 64% of the patients were taking only oral hypoglycaemic agents whereas 16% of them were taking both oral hypoglycaemic agents and insulin. The majority (86%) of them were aware of diabetic foot care in which 58.2% of the patients have received information through health care members. About 84% of the patients were not using diabetic footwear at the house and the majority (99%) of the patients were not aware of e-consultation.

Assessment of compliance with the therapeutic regimen and risk for diabetic foot ulcers during the COVID-19 pandemic

Table 3

Frequency and Percentage Distribution of Areawise Level of Compliance with the Therapeutic Regimen during the COVID-19 Pandemic

N = 100

Level of compliance	Good		Fair		Poor	
	f	*(%)*	*f*	*(%)*	*f*	*(%)*
Medications	56	56	27	27	17	17
Diet and exercise	34	34	17	17	49	49
Blood sugar testing, follow up and stress management	4	4	28	28	68	68
Foot care	1	1	0	0	99	99

Note. f = Frequency; *(%)* = Percentage.

Table 3 shows the majority (99%) of the patients had poor compliance with foot care and 68% of the patients had poor compliance towards blood sugar testing, follow-up, and stress management. Forty-nine percent of the patients were in poor compliance with diet and exercise whereas 56% of the patients were in good compliance with medications.

Table 4 shows that the majority (60%) of the patients were in poor compliance and 39% of them were in fair compliance with the therapeutic regimen during the COVID-19 pandemic with a mean score value of 18.28 and a standard deviation of 5.857.

Table 4

Frequency and Percentage Distribution of Overall Level of Compliance to the Therapeutic Regimen during COVID-19 Pandemic

N = 100

Level of compliance	Frequency	Percentage	Mean	Standard deviation
Good (>75%)	1	1		
Fair (50%-75%)	39	39	18.28	5.857
Poor (<50%)	60	60		

Table 5

Frequency and Percentage Distribution of Risk for Diabetic Foot Ulcer during COVID-19 Pandemic

N = 100

Level of risk for diabetic foot ulcer	Right foot		Left foot	
	Frequency	Percentage *(%)*	Frequency	Percentage *(%)*
Low risk (<50%)	93	93	92	92
Moderate risk (50%-75%)	7	7	8	8
High risk (>75%)	-	-	-	-

Table 5 shows that the majority (93%) of the patients were at low risk for diabetic foot ulcers in the right foot and the left foot (92%).

Table 6

Mean and Standard Deviation of Level of Risk for Diabetic Foot Ulcer during COVID-19 Pandemic

N = 100

Risk of diabetic foot ulcer	Right foot		Left foot	
	Mean	Standard deviation	Mean	Standard deviation
	2.42	2.031	2.41	2.085

Table 6 shows that the mean score for risk of diabetic foot ulcer at the right foot was 2.42 with a standard deviation of 2.031 and the mean score for risk of diabetic foot ulcer at the left foot was 2.41 with a standard deviation of 2.085.

Table 7
Correlation of Compliance with the Therapeutic Regimen with Risk for Diabetic Foot Ulcer during COVID-19 Pandemic

Variables	*'r'* value	*'p'* value
Compliance and risk for left foot ulcer	-0.137	.174
Compliance and risk for right foot ulcer	-0.134	.184

There was a low negative correlation (r = - 0.137, p < .05) found between compliance with the therapeutic regimen and risk for diabetic foot ulcer in the left foot and the right foot (r = - 0.134, p < .05) during the COVID-19 pandemic at .05 level of significance.

Table 8
Association of Compliance with the Therapeutics Regimen during COVID-19 Pandemic with Selected Demographic Variables

N = 100

Demographic variables	Level of compliance			Chi Square	*p* value
	Good	Fair	Poor		
Nature of occupation					
Heavy worker	5	1	0	10.137	.038
Moderate worker	22	6	1		
Sedentary worker	33	32	0		
Dietary pattern					
Vegetarian	12	19	0	9.567	.008
Non-vegetarian	48	20	1		
Type of diabetes mellitus					
Type I diabetes mellitus	3	6	1	11.923	.003
Type II diabetes mellitus	57	33	0		

Table 8 shows that there was a significant association of level of compliance with nature of occupation (χ^2 =10.137, p = .038) at 0.05 level of significance and with the dietary pattern (χ^2 =9.567, p = .008) at 0.01 level of significance. There was a significant association of level of compliance with the type of DM (χ^2 =11.923, p = .003) at .01 level of significance.

Discussion

The results of the study showed that the majority (99%) of the patients had poor compliance with foot care and 68% of the patients had poor compliance towards blood sugar testing follow-up and stress management. Forty-nine per cent of the patients were in poor compliance with diet and exercise during the COVID-19 pandemic. The findings of the study were supported by the study conducted by Alshareef et al. (2020) to explore the impact of the coronavirus disease lockdown on 394 diabetes patients in terms of their compliance with medication intake and lifestyle habits, and quality of life. The study findings revealed that the patients' levels of compliance with medications and healthy lifestyle habits were significantly reduced during the lockdown. The results were also consistent with the findings of Jaly et al. (2020), who performed a comprehensive review of the literature to evaluate the impact of COVID-19 pandemic on diabetic foot care services. The study identified that for the patients, the task of maintaining a healthy lifestyle during this pandemic has been easier said than done. 'Lockdown' measures have meant that these patients have lost their normal routine. Many patients who used to maintain a very active lifestyle as a method of helping control their DM can no longer access gyms, swimming pools, and related facilities. In addition, large periods spent indoors can cause patients to fall into unhealthy eating habits.

The present study findings showed that majority of the patients were aware of diabetic foot care. The findings were contrary to the comprehensive review of literature done by Jaly et al. (2020) reported that poor patient awareness and lack of knowledge regarding diabetes complications and diabetic foot disease is well recognized.

The results of the present study showed that the majority (84%) of the patients were not using diabetic footwear at the house. The findings were supportive of the comprehensive review of literature done by Jaly et al. (2020) which reported the factors challenging as -education level and literacy, cultural influences (e.g., no footwear indoors) etc. These issues have been compounded by the COVID-19 pandemic worldwide,

highlighting key areas of concern and putting many patients with diabetic foot ulcers at potential risk.

Conclusion

The majority of the patients were in poor compliance with the therapeutic regimen and the risk for diabetic foot ulcers was low among patients with DM during the COVID-19 pandemic. There was no correlation between compliance to therapeutic regimen and risk for diabetic foot ulcer during the COVID-19 pandemic. The study also helped to rule out that majority of the patients were not aware of teleconsultation services. It also helped to understand the nurse's responsibility towards imparting knowledge among patients with DM about teleconsultation, importance of mobile app-based self-management and compliance to the therapeutic regimen.

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