Journal of Taibah University Medical Sciences (2017) 12(2), 164–168

Taibah University

Journal of Taibah University Medical Sciences

www.sciencedirect.com

Original Article

Assessment of patient medication adherence among the type 2 diabetes mellitus population with peripheral diabetic neuropathy in South India

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Received 16 October 2016; revised 13 December 2016; accepted 18 December 2016; Available online 16 February 2017

الملخص

أهداف البحث: حاولت هذه الدراسة استقصاء العلاقة بين عدم الالتزام بأخذ الدواء واعتلال الأعصاب الطرفي السكري بين مرضى السكري من النوع ٢ بمستشفى خاص في جنوب الهند.

طرق البحث: أجريت دراسة مستقبلية خلال الفترة من يناير ٢٠١٥م وحتى ديسمبر ٢٠١٥م. شملت الدراسة ٨٦ مريضا بالسكري من النوع ٢ مع وجود اعتلال الأعصاب الطرفي السكري. تمت متابعة المرضى شهريا، ولمدة ثلاثة أشهر. أخذت عينات الدم لفحص مستوى السكر بالدم عند الصوم، وبعد الأكل بالإضافة إلى قياس مستوى الهيموغلوبين السكري. واستخدمت استبانة مقياس موريسكي لتقييم التزام المرضى لأخذ الدواء، ومقياس إدراك الاهتزاز لفحص درجة اعتلال الأعصاب الطرفي السكري. وجرى تقديم المشورة للمرضى أثناء كل متابعة بشأن مرضهم، والحاجة إلى مراقبة نسبة السكر بالدم، وأهمية الالتزام بأخذ الدواء.

النتائج: من بين ١٢٠ مريضا تم فحصهم، شملت هذه الدراسة ٨٦ مريضا. كانت الغالبية (٧٦.٧٪) تعاني من زيادة الوزن، و٥١٪ منهم لديهم داء السكري منذ ١١-١٥ عاما. استخدمت طريقة أنوفا ذات الاتجاه الواحد لمقارنة وضع نسبة السكر في الدم، وفحص اعتلال الأعصاب الطرفي السكري والالتزام بأخذ الدواء في جميع الزيارات الثلاث. لوحظ تحسن كبير في الالتزام بأخذ الدواء والحد من شدة اعتلال الأعصاب الطرفي السكري من الزيارة الأولى للثالثة.

الاستنتاجات: تعليم المرضى مهم لتحقيق الالتزام بأخذ الدواء ويمكن أن يُعزز مراقبة نسبة السكرالأمثل بالدم، ويقلل من انتشار اعتلال الأعصاب الطرفي السكري. يلعب ممارسي الرعاية الصحية دورا محوريا في تثقيف مرضى السكري بما يخص الالتزام بأخذ الدواء.

الكلمات المفتاحية: داء السكري؛ الالتزام بأخذ الدواء؛ الاعتلال العصبي الطرفي؛ مراقبة نسبة السكر بالدم؛ تعليم المرضى

Abstract

Objectives: The present study attempted to explore the relationship between non-adherence with medication and diabetic peripheral neuropathy in patients with type 2 diabetes mellitus (DM) in a private hospital located in South India.

Methods: A prospective study was carried out from January 2015 to December 2015. This study included 86 type 2 DM patients with diabetic peripheral neuropathy. The patients were followed-up for three months, once a month. Blood samples were taken to test for fasting blood sugar (FBS), postprandial blood sugar (PPBS) and HbA1c. A Morisky scale questionnaire was used to assess patients' medication adherence and a biothesiometer was used to screen the degree to which patients were affected by diabetic peripheral neuropathy. Patient counselling, which focused on the need for maintaining glycaemic control and the importance of medication adherence, was carried out during each follow-up.

Results: Of the 120 screened subjects, 86 patients were included in the present study. A majority (76.7%) were overweight, and 51% had DM for the past 11–15 years. ANOVA was used to compare patients' glycaemic status, peripheral diabetic neuropathy screening and medication

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Peer review under responsibility of Taibah University.

Production and hosting by Elsevier

 http://dx.doi.org/10.1016/j.jtumed.2016.12.006

adherence in all three follow-up visits, and $p < 0.0001$ was considered as significant. Significant improvement in medication adherence and reduction of the peripheral diabetic neuropathy severity ($p < 0.0001$) were observed from patients' first to third visits.

Conclusions: Patient education is prudent for improving medication adherence, a result that can potentially promote optimal glycaemic control and can reduce the prevalence of diabetic peripheral neuropathy in patients with DM. Health-care practitioners play a pivotal role in educating the diabetic population about medication adherence.

Keywords: Diabetes mellitus; Glycaemic control; Medication adherence; Patient education; Peripheral neuropathy

Introduction

India has more people with diabetes than does any other country in the world, according to the International Diabetes Foundation, although more recent data suggest that China now has more people with diabetes than does India. The disease affects more than 62 million Indians, which is more than 7.1% of India's adult population. An estimate shows that nearly 1 million Indians die every year due to diabetes.[1] The average age of onset is 42.5 years.[2] The high incidence is attributed to the combination of genetic susceptibility and the adoption of a high-calorie, low-activity lifestyle by India's growing middle class.[3,4] Additionally, a study by the American Diabetes Association reports that India will see the greatest increase in people diagnosed with diabetes by 2030.[4]

Diabetes has both macro-vascular complications (ischaemic heart disease, stroke, and peripheral vascular disease) and micro-vascular complications (diabetic neuropathy, diabetic retinopathy, and diabetic nephropathy). Diabetic peripheral neuropathy (DPN) is a frequent complication of diabetes and a leading cause of morbidity and increased mortality; it is associated with the duration that a person is affected by diabetes, hyperlipidaemia, and poor glycaemic control. DPN is typically characterized by significant deficits in tactile sensitivity, vibration sense, lower limb proprioception, and kinaesthesia.[5] Diabetic neuropathy affects all peripheral nerves, including pain fibres, motor neurons and the autonomic nervous system.[6]

Diabetic neuropathy affects up to 50% of patients with diabetes, and new cases occur at an annual incidence of approximately 2%. In absolute numbers, in contrast to the estimated global prevalence of 220 million cases of diabetes by 2010, DPN is likely to affect as many as 110 million people worldwide.[7] In India, studies revealed that diabetic neuropathy occurs in 19%–27.5% of patients with type 2 diabetes.[8] Glycaemic control is crucial for individuals with diabetes to prevent the progression of neuropathy, and intensive glucose lowering therapy reduces the risk of developing diabetic neuropathy.[9] Glucose management focuses on keeping blood sugar levels as close to normal as possible.[10] Hence, patients' medication adherence is important to the treatment of diabetes.[11]

Medication adherence usually refers to whether patients take their medications as prescribed (e.g., twice daily), as well as whether patients take a prescribed medication. Medication nonadherence is a growing concern to clinicians, healthcare systems, and other stakeholders (e.g., payers) because of the mounting evidence that nonadherence is prevalent and is associated with adverse outcomes and higher costs of care. To date, in routine clinical practice, the measurement of patients' medication adherence and the use of interventions by clinicians to improve adherence are rare.[12]

Worldwide, the medication adherence rate for patients with diabetes varies between 36% and 93%.[13] Adherence to prescribed medication is crucial for attaining metabolic control, and nonadherence with blood glucose lowering and lipid lowering drugs is associated with higher HbA1c and cholesterol levels, respectively.[13]

Nonadherence with medication in patients with diabetes resulted in poor glycaemic control and, hence, an increased risk of developing chronic complications, such as diabetic neuropathy. So medication adherence is necessary for the effective management of diabetes and its complications.[14] The present study is one of a number of worldwide studies that show the significant relationship between medication adherence and diabetic peripheral neuropathy. To our knowledge, no previous study of patients in India has been conducted to understand the relationship between medication adherence and diabetic peripheral neuropathy. Hence, the present study attempted to investigate this relationship in patients with diabetes in a private hospital in Kollam, Kerala.

Materials and Methods

A prospective study was carried out from January 2015 to December 2015 in a private hospital in the city of Kottarakara, Kollam, Kerala, India. Ethical approval was granted by the Institutional Ethics Committee of Swamy Vivekanandha College of Pharmacy, Namakkal, Tamilnadu, India. Type 2 DM patients with diabetic peripheral neuropathy but no other complications from type 2 DM were included in the study; patients were of both genders and were between 45 and 70 years old. Patients who were severely ill or who were not following their prescribed diets or exercise were excluded from the study. The patients in the study population were well informed and were provided with patient information forms in English and the local language (Malayalam) that contained the details of the study, i.e., information about the parameters that would be investigated (FBS, PPBS, and HbA_1C level) and about the foot screening process utilizing a biothesiometer.

The study and its importance were explained to the potential participants. After interviewing 120 patients, 86 patients, who responded positively and passed inclusion criteria, were selected for this study. Blood samples were taken on the same day to determine patients' initial FBS, PPBS and HbA1c levels. Glucose levels were determined using the hexokinase method in an Olympus 2700 analyser

with commercially available Olympus kits (Olympus Optical Co. Ltd, Shizuoka ken, Japan) and FBS <110 and PPBS <140 levels were considered normal.[15] HbA1c levels were estimated using a glycol haemoglobin reagent set from HbA1c Siemens Healthcare Diagnostics Newark, DE 19714, USA, and a HbA1c of <7 was considered optimal.[16] The study was conducted in the hospital's Diabetic clinic department. Data were also gathered through patient interviews using a Morisky questionnaire, an 8-item scaled questionnaire that assesses medication adherence.[17] A biothesiometer was used to screen patients' diabetic peripheral neuropathy; VPT was measured on the big toe of each foot and was assessed as normal (≤15 V), grade I (16–25 V) and grade II (>25 V).[18,19] The patient details were collected during each of their three follow-up visits to the clinic.

Patient counselling occurred for each of the 86 patients during each of their follow-up visits. Patient counselling included information about their disease, prescribed medications, and the complications of uncontrolled blood sugar levels as well as the need for maintaining glycaemic control, regular dietary patterns, and motivation to improve their lifestyles. The patients were asked to come back for follow-up once a month, for three months. All of the patients (n = 86) returned for the regular check-ups and participated in the study. The counselling aimed to achieve patients' normal metabolic control and to prevent or delay DPN in the patients.

The data collected from all patients by means of the questionnaire during the interviews were thoroughly analysed in regard to medication adherence and the quality of life of the patients. Graphpad InStat Prism 4.0 software 4.0 was used to analyse the statistical data.

Table 1: Demographics of the study population (n = 86).

Demographics	Percentage of patients (number of patients)
Age	
45–50 years	26.7% (n = 23)
51–65 years	65.1% (n = 56)
65 years	8.2% (n = 7)
Gender	
Male	44% (n = 38)
Female	56% (n = 48)
Body Mass Index	
Overweight	81.3% (n = 70)
Normal	18.6% (n = 16)
Education status	
Primary Education (I to V standard)	23.3% (n = 20)
Secondary Education (VI to XII standard)	38.3% (n = 33)
Higher Education (>XII or graduates)	38.3% (n = 33)
Past medical history	
5–10 years	25.5% (n = 22)
11–15 years	51.2% (n = 44)
16–20 years	23.3% (n = 20)

Results

A total of 86 patients, from an initial screening of 120, were included in the present study and the demographics of the patients correspond with those given in Table 1.

ANOVA was used to compare patients' glycaemic status, peripheral diabetic neuropathy screening and medication adherence in all three follow-up visits, and $p < 0.0001$ was considered as significant. Fasting blood sugar and postprandial blood sugar were found to be significantly reduced ($p < 0.0001$) from the first to third visit. Diabetic neuropathy screening on right foot indicated that the study population was found to have grade I peripheral diabetic neuropathy (20 ± 5.233) during the first visit, grade I (15.69 ± 3.89) during the second visit, and normal (13.08 ± 2.29) during the third visit. The peripheral diabetic neuropathy severity was significantly reduced from the first to third visits ($p < 0.0001$). According to results of screening the left foot, the study population was found to have a grade I (18.87 ± 5.01) during the first visit, and normal in the second (14.67 ± 3.78) and third (12.77 ± 1.83) visits. The peripheral diabetic neuropathy risk was significantly reduced from the first to third visits. Low medication adherence (4.26 ± 2.31) was observed during the first visit, and adherence improved to medium adherence (1.83 ± 1.96) and to high adherence (0.39 ± 0.84) during second and third visits, respectively. Significant improvement in medication adherence ($p < 0.0001$) was observed from the first to third visits (Table 2).

Regression analysis was used to analyse the relationship between medication nonadherence and glycaemic status, and $p < 0.0001$ (95% confidence interval) was considered as significant. Significant positive correlation was observed between medication nonadherence and glycaemic status (FBS, PPBS, HbA1c) during all the visits (Table 3).

Initially, 20% and 13% of patients had grade II diabetic neuropathy on the right foot and left foot, respectively; however, none reported grade II diabetic neuropathy during the second and third visits. Seventy-seven percent (right foot) and 81% (left foot) of the study population were found to be normal according to diabetic neuropathy screening during the third visit. On the contrary, only 8% (right foot) and 3.4% (left foot) were normal during the first visit. The majority of the study population belongs to grade I (right foot:

Table 2: Glycaemic status, peripheral diabetic neuropathy screening and medication adherence among the study population (n = 86).

Parameters	First visit	Second visit	Third visit	*p* value	F value
FBS	284.32 ± 80.19	173.53 ± 79.35	108.32 ± 61.16	<0.0001	534.27
PPBS	322.01 ± 83.5	211.39 ± 72.19	142.83 ± 61.54	<0.0001	527.62
Right foot Value	20.02 ± 5.233	15.69 ± 3.89	13.08 ± 2.29	<0.0001	251.21
Left foot Value	18.87 ± 5.01	14.67 ± 3.78	12.77 ± 1.83	<0.0001	199.56
Medication Adherence score	4.26 ± 2.31	1.83 ± 1.96	0.39 ± 0.84	<0.0001	285.72

Table 3: Relationship between medication nonadherence and glycaemic status (n = 86).

Parameter	95% confidence interval	r value	*p* value
FBS			
First visit	26.273 to 33.749	0.8676	<0.0001
Second visit	30.038 to 39.128	0.8557	<0.0001
Third visit	54.872 to 70.625	0.866	<0.0001
PPBS			
First visit	26.749 to 34.863	0.8553	<0.0001
Second visit	26.856 to 35.371	0.8462	<0.0001
Third visit	52.860 to 69.949	0.8422	<0.0001
HbA1c level			
First visit (At the first month)	0.5492 to 0.7011	0.8729	<0.0001
Second visit (At the third month)	0.5908 to 0.7459	0.8822	<0.0001

first visit 34%, second visit 40%, third visit 19%; left foot: first visit 50%, second visit 28%, third visit 15%) or to grade II (right foot: first visit 38%, second visit 20%, third visit 5%; left foot: first visit 29%, second visit 15%, third visit 3.4%) for risk of peripheral diabetic neuropathy (Table 4).

Regression analysis was used to analyse the relationship between medication nonadherence and diabetic peripheral neuropathy, and $p < 0.0001$ (95% confidence interval) was considered as significant. Significant positive correlation was observed between medication nonadherence (0–8) and diabetic peripheral neuropathy (15–32) in both right and left feet during all three visits (Table 5).

Discussion

High medication adherence was observed among those in the study population who were between 45 and 65 years old, whereas poor adherence was reported in those older than 65. Thus, age may interfere with achieving glycaemic control and also to worsening diabetic peripheral neuropathy. These results correspond to similar results observed in multicentre hospital clinics in the UK.[20]

Female patients were found to have higher medication adherence when compared with male patients. The results of the present study show that high medication adherence correlates with high income (>10,000) and these results coincide with previous studies.[21–25] High medication adherence was noted in those in the study population who had completed their secondary or higher educations, results that are consistent with previous studies.[26,27]

Educating patients about medication adherence resulted in improvements in medication adherence, glycaemic control, and improvement of diabetic peripheral diabetic neuropathy

Table 5: Relationship between medication nonadherence and peripheral diabetic neuropathy (n = 86).

Parameter	95% confidence interval	r value	*p* value
Right foot			
First visit	1.838 to 2.253	0.9061	<0.0001
Second visit	1.698 to 2.005	0.9346	<0.0001
Third visit	2.396 to 2.764	0.9502	<0.0001
Left foot			
First visit	1.357 to 1.961	0.7666	<0.0001
Second visit	1.221 to 1.754	0.7719	<0.0001
Third visit	1.526 to 2.057	0.8263	<0.0001

(Table 2). Patient education, understanding, and participation are vital since the complications of diabetes are far less common and less severe in people who have well-managed blood sugar levels.[28,29] Previous studies concluded that optimal glycaemic control can be achieved with effective patient counselling.[26,27] The present study investigated the medication adherence, glycaemic status, and diabetic peripheral neuropathy in a frequent interval to know the effectiveness of patient counselling. There was continuous improvement on these parameters on subsequent visits (Table 2).

Our findings are consistent with Nathan et al., 2005, who emphasized patient education, understanding and participation are vital because the complications of diabetes are far less common and less severe in people who have well-managed blood sugar levels.[10,30,31]

The present study aimed to understand the relationship of medication adherence with glycaemic status and diabetic peripheral neuropathy. This study showed a significant association of medication adherence in both glycaemic control and peripheral neuropathy (Table 2). The study population was found to have better glycaemic control with high medication adherence, which substantiates previous studies conducted with Ethiopian,[20] Malaysian,[14] and Indian[11] populations.

The results from regression analysis (Table 5) indicate significant positive correlations between medication nonadherence and diabetic peripheral neuropathy, which shows that medication nonadherence induces peripheral diabetic neuropathy over time. Similarly, Kuo et al., 2003 and Sokol et al., 2005 reported that nonadherence with medication among diabetic patients resulted in poor glycaemic control and, hence, increased the risk of developing chronic complications as well as increased hospitalization and mortality.[32,33]

In conclusion, patient education is prudent for improving medication adherence, a result that can potentially promote optimal glycaemic control and reduce the prevalence of diabetic peripheral neuropathy in patients with DM. Healthcare practitioners play a pivotal role in educating the diabetic population about medication adherence.

Table 4: Peripheral diabetic neuropathy screening among the study population (n = 86).

Parameters	Right foot screening			Left foot screening		
	First visit	Second visit	Third visit	First visit	Second visit	Third visit
Normal	7 (8%)	35 (41%)	66 (77%)	3 (3.4%)	49 (57%)	70 (81%)
Mild	29 (34%)	34 (40%)	16 (19%)	43 (50%)	24 (28%)	13 (15%)
Moderate	33 (38%)	17 (20%)	4 (5%)	25 (29%)	13 (15%)	3 (3.4%)
Severe	17 (20%)	0 (0%)	0 (0%)	11 (13%)	0 (0%)	0 (0%)

Authors' contributions

Ms. AMS conceived and designed the study, conducted research, provided research materials, and collected and organized data. PSA analysed and interpreted data. OSM wrote the initial and final drafts of the article and provided logistic support. All authors have critically reviewed and approved the final draft and are responsible for the content and similarity index of the manuscript.

Conflict of interest

The authors have no conflict of interest to declare.

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How to cite this article: Samu AM, Amirthalingam PS, Mohammed OS. Assessment of patient medication adherence among the type 2 diabetes mellitus population with peripheral diabetic neuropathy in South India. J Taibah Univ Med Sc 2017;12(2):164–168.