ความสัมพันธ์ระหว่างความผิดปกติของระบบประสาทส่วนปลายบริเวณเท้าในผู้ป่วยโรคเบาหวานชนิดที่ 2 กับการทรงตัวและความเสี่ยงในการหกล้ม

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บทคัดย่อ

ที่มาและความสำคัญ: ความผิดปกติของระบบประสาทส่วนปลายบริเวณเท้า (DN) เป็นภาวะแทรกซ้อนจากโรคเบาหวานชนิดที่ 2(T2DM) มีผลกระทบต่อผู้ป่วย อาจทำให้หกล้ม การศึกษานี้มีวัตถุประสงค์เพื่อศึกษาความสัมพันธ์ระหว่าง DN และปัจจัยเสี่ยงอื่นใน T2DM กับการทรงตัวและความเสี่ยงในการหกล้ม

วิธีการศึกษา: การวิจัยเชิงปริมาณภาคตัดขวาง ในผู้ป่วย T2DM อายุ 18 ปีขึ้นไป จำนวน 120 คน ที่มารับบริการที่คลินิกผู้ป่วยนอก ช่วง 1 กุมภาพันธ์ – 31 พฤษภาคม 2562 ใช้แบบสัมภาษณ์ แบบประเมิน The Michigan Neuropathy screening Instrument ทดสอบ Timed Up and Go Test (TUG) และ Single leg stance test (SLS) หาความสัมพันธ์ระหว่าง DN ในผู้ป่วย T2DM และปัจจัยเสี่ยงอื่น วิเคราะห์โดยสถิติ multivariate analysis (p-value < 0.05)

ผลการศึกษา: พบว่า DN ในผู้ป่วย T2DM สัมพันธ์กับการทรงตัวและความเสี่ยงในการหกล้ม SLS (adjusted OR: 23.1; 95% CI 2.09 – 255.22; p=0.01) และ TUG (adjusted OR: 41.3; 95% CI 9.83 – 173.61; p < 0.001) และพบว่า เพศหญิง, ไขมันในเลือดสูง, ความดันโลหิตสูง, เข่าเสื่อม, ต้อกระจก, ปัญหาสายตา, กลัวการหกล้ม, ใช้ยานอนหลับ, อายุ, ระยะเวลาของT2DM เป็นปัจจัยเสี่ยงต่อการหกล้ม

สรุปผล: DN ในผู้ป่วย T2DM มีความสัมพันธ์กับการทรงตัวและความเสี่ยงในการหกล้ม ผู้ป่วย T2DM และ DN ควรได้รับการประเมินการทรงตัวและความเสี่ยงในการหกล้ม

คำสำคัญ: ความผิดปกติของระบบประสาทส่วนปลายบริเวณเท้า; ผู้ป่วยโรคเบาหวานชนิดที่ 2; การทรงตัวและความเสี่ยงในการหกล้ม

Association Between Diabetic Neuropathy and Balance and Risk of Falling in Type 2 Diabetic Patient: A Cross-Sectional Study

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Abstract

Background: Diabetic neuropathy (DN) is a complication of type 2 diabetes mellitus (T2DM). It has major impacts on the health of the affected patient and is a leading cause of falls. This study aimed to explore the relationship between DN and risk of falls, and other risk factors among patients with T2DM.

Methods: In this cross-sectional study we enrolled, according to consecutive cases, 120 patients with T2DM aged 18 years or older who visited the outpatient clinic, Pramongkutklao Hospital from February -May 2019. Data were recorded on a form. The presence of DN was evaluated using the Michigan Neuropathy Screening Instrument. The balance impairment and the risk of falls were evaluated using two tools: Timed Up and Go Test (TUG) and Single Leg Stand Test (SLS). The relationship between DN among patients with T2DM and other factors on balance and risk of falls was analyzed using multivariate analysis (p-value < 0.05).

Results: The presence of DN was significantly associated with balance and risk of falls SLS (adjusted OR: 23.1; 95% CI 2.09 – 255.22; p = 0.01) and TUG (adjusted OR: 41.304; 95% CI 9.83 – 173.62; p < 0.001). The patients' sex, vision problems, fear of falling, using hypnotic drugs, age, and duration of T2DM were significant predictors for the risk of falls among patients with T2DM.

Conclusion: The presence of DN among patients with T2DM is associated with impaired balance and risk of falls. Patients with T2DM and DN should be evaluated for balance and risk of falls.

Keywords: Diabetic Neuropathy; Type 2 Diabetics Mellitus; Balance; Risk of falls

Background

The prevalence of diabetes mellitus (DM) is higher among Asians, while type 2 diabetes accounts for 90% to 95% of all diabetes cases [1]; 425 million people have diabetes globally. Over 4,208,600 cases of diabetes were reported in Thailand in 2017[2]. Complications of DM account for increased morbidity, disability, and mortality. Atherosclerosis is a macrovascular complication of DM. Diabetic nephropathy, neuropathy (DN), and retinopathy are the main microvascular complications [3]. Diabetic polyneuropathy, presenting a prevalence of approximately 50%, is the most common diabetic complication [4]. DN is a complication of patients with DM is 2.4% in public hospitals in Bangkok [5]. DN is a leading cause of disability due to foot ulceration and amputation, gait disturbance, and falling [4]. A person with DM who is older than 65 is 17 times more likely to fall than a younger man or woman who does not have the disease. Chronically elevated glucose has a large impact on the longest nerves in bodies. The resulting loss of sensation and muscle tone is often worse in the feet and ankles, which can make it harder to stand up and walk [6]. As there are few of these kinds of studies in Thailand, we undertook this study to show the importance between DN and balance and the risk of falls.

This study aimed to evaluate the association between DN on balance impairment and the risk of falls among patients with T2DM. The secondary objective was to assess other risk factors of falls among patients with T2DM.

The author hypothesized that the presence of DN may impair the balance of patients with T2DM. The risk of falls continues to increase among T2DM patients with DN.

Materials and Methods

Study Design and Subjects

Approval was obtained from the Ethics Committee Board of the Institutional Review Board of the Royal Thai Army Medical Department (IRBTA). In this cross-sectional study we enrolled, according to a consecutive-case, 120 patients with T2DM aged 18 years or older who visited in the outpatient clinic, Pramongkutklao Hospital from February to May 2019. All patients provided written informed consent. The patients were followed up regarding the study at their next visit. The following were considered inclusion criteria: participants with T2DM aged 18 years or older. Exclusion criteria included the inability to provide informed consent, balance assessment, or accurate medical history data, prior history of DN, and major cardiovascular events three months before screening.

Clinical, Anthropometric and Laboratory Data

The patient's data: age, body mass index, diabetes duration, HBA1C, history of diabetes treatment, history of diabetic retinopathy, diabetic nephropathy, DN, osteoarthritis, cataract, smoking, alcohol consumption history and underlying diseases including dyslipidemia, cardiovascular disease, chronic kidney disease were collected from the patients' medical records. The use of hypnotic drugs, and vision and balance problems were collected from the patients' questionnaires. The Fall Efficacy Scale in Thai version [8] was used to evaluate the fear of falling. Orthostatic hypotension measurements were taken using the standard method; a systolic blood pressure decrease of at least 20 mmHg or a diastolic blood pressure decrease of at least 10 mm Hg within three minutes of standing was noted [12].

Diabetic Neuropathy Assessment

The Michigan Neuropathy Screening Instrument (MNSI), a validated score instrument for DN, was used to diagnose DN. The Thai version of MNSI consists of two parts: a 15-item self-administered questionnaire scored by summing abnormal answers provided by the patient and a lower extremity examination performed by the author including inspecting and evaluating ankle reflexes and vibration perception at the great toe. The MNSI has both high sensitivity and specificity; a self-administered questionnaire scoring 7 or above, or a clinical examination score of 2.5 or above provided a positive diagnosis of DN [7].

Balance Assessment

Balance impairment was evaluated using two components: The Single Leg Stand Test (SLS) and Timed Up and Go Test (TUG) and using the Thai version of the Fall Efficacy Scale [8].

The TUG comprises a reliable and valid test. The TUG test is quick, does not require any special equipment, and can easily be included as part of a routine medical examination [9]. The patient was asked to sit in a chair, stand up, walk ten feet, turn around, walk back to the chair, and sit down. A time of 12 seconds or greater indicates an increased risk of falls [10].

SLS tests static balance and records the time a participant can stand on one leg unassisted. The subjects were free to choose which leg they preferred to lift. The initial position was standing relaxed with eyes open and weight evenly distributed between both feet. Then the subjects were instructed to stand on one leg for as long as possible and interrupted the test after 30 seconds by auditory clue, or if the subject touched the floor with the lifted leg. The subject was instructed to keep his or her arms along the side of the body. To prevent falls or injuries, the author stood close to the subject throughout the session. Three trials were performed. Standing for less than five seconds indicates an impairment of static balance and an increased risk of falls [11].

Data Analysis

Data were collected and analyzed using SPSS, Version 23, statistical software package and are presented as average ± standard deviation (SD), compared between two groups using the independent sample t-test. Categorical variables were compared between two groups using the Chi-Square test. Multivariate analysis (p-value < 0.05) was conducted to identify the risk of falls among patients with T2DM and was adjusted for sex, vision problems, fear of falling, DN, using hypnotic drugs, age, and duration of T2DM. The prevalence of DN was analyzed by percentage, and $P < 0.05$ was considered statistically significant.

Results

Patient demographics and clinical data are shown in Table 1. No significant differences between the DN and non-DN groups in respect of gender, HbA1c, HTN, DLP, CVS, CKD, stroke, OA, cataract, osteoporosis, hypoglycemia, DR, Diabetic nephropathy, history of DN, smoking, alcohol, and BMI. Age, status, and duration of diabetes were significantly different between the two groups ($p < 0.05$).

Neuropathy and Neuropathy-Related Associations

In this study, the prevalence of DN, as diagnosed according to the MNSI criteria was 35% (42 cases). The presence of overt neuropathy was associated with increased age (65.3 vs. 58.7 years; $p < 0.001$) and diabetes duration (9.1 vs. 6.1 years;

p = 0.028). The differences in the other studied parameters had no significant differences between the groups: HbA1c, hypertension, dyslipidemia, cardiovascular disease, chronic kidney disease, stroke, osteoarthritis, hypoglycemia, diabetic retinopathy, diabetic nephropathy, the prevalence of smoking, alcohol consumption and BMI (Table 1).

Neuropathy Impact on Balance Parameters

In this study, the presence of overt neuropathy, diagnosed as presented in the Method section based on the MNSI score, was associated with SLS (adjusted OR: 23.01; 95% CI 2.09 – 255.22; p = 0.01) and TUG (adjusted OR: 41.3; 95% CI 9.83-173.62; p< 0.001). These results are significant indicating the negative impact of DN on the patient's balance parameters (Table 2), leading indirectly, to an increased risk of falls.

Using multivariate analysis, we observed that patient's sex, vision problems, fear of falling, use of hypnotic drugs, age, and duration of T2DM were significant predictors for risk of falls in patients with T2DM

Discussion

The results revealed that the presence of DN was significantly associated with impairment of balance and risk of falls and observed that patient's sex, vision problems, fear of falling, use of hypnotic drugs, age and duration of T2DM were significant predictors for the risk of falls among patients with T2DM.

Falls are one of the greatest health challenges, particularly among diabetic adults. The consequences of falls, such as fractures, poorer rehabilitation, an increased number of falls were said to be more severe among the elderly with diabetes [13]. However, one related study demonstrated that balance impairment and the risk of falls, many times were underestimated and under-screened, as a frequent condition among patients having DN. Therefore, patients with T2DM and DN should be evaluated regarding balance and risk of falls [14].

Patients with T2DM and DN need to have their balance parameters evaluated. When impairments are found, these patients should be included in a rehabilitation program. Rehabilitation can decrease the risk of falls with an aim to improve their balance and walking stability.

This study found an elevated risk of falling among older women with diabetes. Related studies of falls and diabetes have produced mixed results. In the Third National Health and Nutrition Examination Survey, diabetes was one risk factor for falls among older women. However, the Rotterdam Study found no association among women aged 55 years. An increased risk of serious injury due to a fall was reported among diabetic adults. The prospective cohort study suggested that poor balance is a factor in the pathway between diabetes and increased risk of falling. Notably, a poor balance has been previously identified as a risk factor for falls among older women [15].

In this study, visual problems were a risk factor for falls among patients with T2DM. Confirming earlier studies, visual impairment is a risk factor for falls, on average, approximately doubling falls risk in a wide variety of studies. Falls risk increases as visual impairment worsens [16].

This study found fear of falling is a risk factor for falls among patients with T2DM. Confirming earlier studies, T2DM is associated with increased fear of falling and fear-associated activity restriction, and the risk of falls even in the face of increased fall risk factors including worsened mobility. Related prospective cohort studies revealed that using nonbenzodiazepine sedative-hypnotics is associated

with an increased risk of falls. Nonpharmacologic approaches to sleep disturbances may represent the safest approach to sleep difficulties among older adults.[18] In this study, patients with T2DM who reported using hypnotic drugs had a risk of falls, so the type of hypnotic drug should be clarified in a future study.

Another risk factor for falls among patients with T2DM is age. We found patients with increased age had increased risk of falls. Falls are a major concern for elderly adults with DM.[19] The high prevalence of falls among elderly individuals with DM has been well established with reported annual incidence rates of 39% among those over 65 years [20] and 35% among those over 55 years.[21] In addition to the reported high incidence of falls in this population, it has been established that individuals with DM are at a higher risk for falls.[22]

This study's subjects had long term duration of T2DM, which was significantly longer in the group of patients with T2DM who presented balance impairment in the TUGT (median duration 9.08) and SLS (median duration 2.79). The median T2DM duration of one related study was 11 years [23] confirming the long-term duration of diabetes and DPN was significantly longer in the fall group.

Conclusion

The presence of DN among patients with T2DM was associated with impaired balance and increase the risk of falls. In addition to our findings, patients with T2DM are associated with an excessive risk of falls. Patients with T2DM and DN should have their balance parameters evaluated. When impairments are found, these patients should be included in a rehabilitation program, to improve their balance and walking stability.

Strengths

The strengths of this study are emphasized by the patient's consecutive enrollment principle which comprises a heterogeneous study having the baseline characteristics matching the characteristics of the T2DM general population, containing both patients with overt DM and patients without any signs of DN.

This study demonstrated the need for using tests to evaluate the risk of falls among patients with DPN and suggested that DPN is a specific entity for planning prevention programs. DN is a common complication of T2DM, so detecting DN using appropriate tools is important. Using simple screening tools including MNSI, TUGT, and SLS to identify DN and evaluate balance impairment can be applied in primary care.

Tools to identify patients at risk of having DN, i.e., the MNSI, are inexpensive and easy to use in outpatient and community settings.[24] The sample size was another strong point of this study, providing enough statistical power to make solid conclusions.

Study limitations

One limitation of this study was the small number of patients. Some questions (use of hypnotic drugs and vision and balance problems) were used in self-report questionnaires. The data might have been under- or overestimated especially the effect of diabetes concerning the risk of falls.

This study employed a cross-sectional design, indicating its relation to the association between DN and inadequate glycemic control. The development of DN is a well-known long-term process and cross-sectional evaluation of glycemic control. In this study, the value of HbA1c an indicator, which may have reflected glycemic control for no

longer than three months, may not always be associated with the development of T2DM complications. However, this weak point of the study did not interfere with the study's aim. Further studies incorporating a larger sample size, longitudinal follow-up, and multicenter study should be conducted.

Acknowledgements

The authors would like to express our gratitude to the participants and the PMK team in the outpatient clinic, Pramongkutklao Hospital.

Table 1 Patient Demographics Data

Characteristics	Non-DN (n = 78) mean ± SD	DN (N = 42) mean ± SD	Total 120	p-value
Age (years)	58.7 ± 9.2	65.3 ± 9.2	61 ± 9.7	< 0.001*b
Male, n (%)	36 (72)	14 (28)	50 (41.7)	0.174a
Single, n (%)	10 (83.3)	2 (16.7)	12 (10)	0.013*a
Married, n (%)	56 (70.9)	23 (29.1)	79 (65.8)	
Separated, n (%)	6 (50)	6 (50)	12 (10)	
Widowed, n (%)	6 (35.3)	11 (64.7)	17 (14.2)	
T2DM duration (years)	6.1 ± 5.3	9.1 ± 7.8	7.2 ± 6.4	0.028*b
HbA1c (%)	7 ± 1.2	7.1 ± 1.1	7.1 ± 1.2	0.782b
Hypertension, n (%)	52 (59.8)	35 (40.2)	87 (72.5)	0.051a
Dyslipidemia, n (%)	67 (63.2)	39 (36.8)	106 (88.3)	0.257a
CVD, n (%)	2 (66.7)	1 (33.3)	3 (2.5)	0.951a
CKD, n (%)	6 (50)	6 (50)	12 (10)	0.251a
Stroke, n (%)	1 (25)	3 (75)	4 (3.3)	0.088a
Osteoarthritis, n (%)	9 (64.3)	5 (35.7)	14 (11.7)	0.952a
Cataract, n (%)	14 (53.8)	12 (46.2)	26 (21.7)	0.178a
Osteoporosis, n (%)	2 (100)	0 (0)	2 (1.7)	0.295a
Hypoglycemia, n (%)	2 (50)	2 (50)	4 (3.3)	0.522a
DR, n (%)	2 (50)	2 (50)	4 (3.3)	0.522a
DN, n (%)	78 (65)	42 (35)	120 (100)	NA
Smoke, n (%)				
No	48 (64)	27 (36)	75 (62.5)	0.205a
Quit	21 (60)	14 (40)	35 (29.2)	
Yes	9 (90)	1 (10)	10 (8.3)	
Alcohol, n (%)				
No	33 (60)	22 (40)	55 (45.8)	0.274a
Quit	29 (64.4)	16 (35.6)	45 (37.5)	
Yes	16 (80)	4 (20)	20 (16.7)	
BMI (kg/m2)	26.13 ± 3.98	27.56 ± 4.28	26.63 ± 4.13	0.070a

Notes: a. Chi-square test, b. Independent sample t-test. Abbreviations: HbA1c, Hemoglobin A1c; CVD, Cardiovascular disease; CKD, chronic kidney disease; DR, Diabetic retinopathy; DN, Diabetic neuropathy BMI, Body mass index

Table 2. Comparison of the Multivariate Risk Factors Between Positive and Negative Groups

	TUG					SLS				
	Positive n (%)	Negative n (%)	Adjusted			Positive n (%)	Negative n (%)	Adjusted		
			Odds ratio	95% CI	p-value			Odds ratio	95% CI	p-value
Gender										
Male	34 (68)	16 (32)				46 (92)	4 (8)			
Female	26 (37.1)	44 (62.9)	5.2	1.66-16.3	0.008*	60 (85.7)	10 (14.3)	1.9	0.56-6.50	0.29
Dyslipidemia										
No	33 (56.9)	25 (43.1)				13 (92.9)	1 (7.1)			
Yes	27 (43.5)	35 (56.5)	1.7	0.83-3.52	0.14	93 (87.7)	13 (12.3)	1.8	0.22-15.07	0.58
CKD										
No	56 (51.9)	52 (48.1)				97 (89.8)	11 (10.2)			
Yes	4 (33.3)	8 (66.7)	2.2	0.61-7.58	0.23	9 (75)	3 (25)	2.9	0.69-12.50	0.14
Osteoarthritis										
No	56 (52.8)	50 (47.2)				48 (51.1)	46 (48.9)			
Yes	4 (28.6)	10 (71.4)	2.8	0.83-9.49	0.09	9 (34.6)	17 (65.4)	1.9	0.79-4.86	0.141
Cataract										
No	48 (51.1)	46 (48.9)				82 (87.2)	12 (12.8)			
Yes	9 (34.6)	17 (65.4)	1.9	0.79-4.86	0.14	24 (92.3)	2 (7.7)	0.6	0.12-2.72	0.48
Smoke										
No	32 (42.7)	43 (57.3)				50 (90.9)	5 (9.1)			
Quit	21 (60)	14 (40)	0.5	0.22-1.12	0.09	37 (82.2)	8 (17.8)			
Yes	7 (70)	3 (30)	0.3	0.07-1.33	0.12	19 (95)	1 (5)	0.5	0.05-4.80	0.57
Alcohol										
No	23 (41.8)	32 (58.2)				50 (90.9)	5 (9.1)			
Quit	25 (55.6)	20 (44.4)	0.6	0.26-1.27	0.17	37 (82.2)	8 (17.8)	2.2	0.65-7.14	0.20
Yes	12 (60)	8 (40)	0.5	1.16-1.35	0.16	19 (95)	1 (5)	0.53	0.05-4.80	0.569

	TUG					SLS				
	Positive n (%)	Negative n (%)	Adjusted			Positive n (%)	Negative n (%)	Adjusted		
			Odds ratio	95% CI	p-value			Odds ratio	95% CI	p-value
OH										
No	49 (48.5)	52 (51.5)				48 (47.5)	53 (52.5)			
Yes	11 (57.9)	8 (42.1)	0.7	0.25-1.84	0.455	9 (47.4)	10 (52.6)	1.0	0.37-2.68	0.99
Hypnotic drug										
No	53 (55.8)	42 (44.2)				89(93.7)	6 (6.3)			
Yes	7 (28)	18 (72)	3.2	1.24-8.49	0.01	17 (68)	8 (32)	22.4	2.52-198.93	0.005*
Vision problem										
No	54 (58.7)	38 (41.3)				88 (95.7)	4 (4.3)			
Yes	6 (21.4)	22 (78.6)	4.0	1.07-15.04	0.038*	18 (64.3)	10 (35.7)	23.0	2.49-213.13	0.006*
Fear of falling										
No	58 (54.7)	48 (45.3)				98 (92.5)	8 (7.5)			
Yes	2 (14.3)	12 (85.7)	8.1	1.13-57.07	0.037*	8 (57.1)	6 (42.9)	9.2	2.55-33.06	0.010*
Age (years)	57.8 ± 10.2	64.3 ± 8.1	1.1	1.03-1.13	0.001	60 ± 9.8	68 ± 5.0	1.1	1.00-1.28	0.049*
T2DM duration (years)	5.3 ± 4.4	9.1 ± 7.5	1.1	1.04-1.19	0.002	6.4 ± 5.9	12.8 ± 7.6	1.1	1.02-1.27	0.016*
HbA1c (%)	7 ± 1.2	7.1 ± 1.1	1.1	0.79-1.48	0.59	7 ± 1.1	7.2 ± 1.4	1.2	0.72-1.83	0.54
BMI (kg/m^2)	25.9 ± 3.9	27.3 ± 4.2	1.1	0.99-1.19	0.06	26.6 ± 4.2	26.7 ± 3.9	1.0	0.87-1.14	0.96
Medication	4.1 ± 1.9	4.7 ± 1.7	1.2	0.97-1.46	0.08	4.3 ± 1.8	5.3 ± 1.8	1.3	0.99-1.80	0.05
DN*										
No	57 (73.1)	21 (26.9)				76 (97.4)	2 (2.6)			
Yes	3 (7.1)	39 (92.9)	41.3	9.83-173.62	< 0.001*	30 (71.4)	12 (28.6)	23.1	2.09-255.22	0.01*

Notes: CKD – Chronic kidney disease, OH – Orthostatic hypotension, BMI – Body mass index, DN – Diabetic neuropathy

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