

RESEARCH ARTICLE

Evaluation of controlled type II diabetics ascending and descending a ramp surface at an imposed speed: A case-control study [version 1; referees: awaiting peer review]

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First published: 28 Mar 2018, 7:408 (doi: 10.12688/f1000research.14401.1)

Latest published: 28 Mar 2018, 7:408 (doi: 10.12688/f1000research.14401.1)

Abstract

Background: Patients with diabetes have been shown to suffer from increased fall risk. Research shows that this risk is higher on irregular surfaces. Existing studies evaluate gait on irregular surfaces, such as stairs, asphalt, grass and stones. This study evaluates gait parameters in individuals with diabetes mellitus type II (DMII) with no history of peripheral neuropathy, while ascending and descending a ramp at an imposed speed, and compares them with healthy controls.

Methods: Fifteen healthy volunteer participants and fifteen participants with DMII and no peripheral neuropathy (females and males) between the ages of 40-65 were recruited for this study. Participants walked three times at 100 bpm while ascending and descending a wooden ramp. Temporospatial and kinematic parameters were analyzed.

Results: We observed minimal changes in temporospatial and kinetic parameters in people with controlled DMII with no evidence of peripheral neuropathy.

Conclusion: Focusing on individuals with controlled DMII allowed us to determine if only the diagnosis of diabetes without peripheral neuropathy influenced gait parameters. Clinicians and researchers should focus their assessments on neuromuscular activation during this stage of the condition, thus preventing complications, such as abnormal gait, that increases the risk for falls.

Kevwords

controlled diabetes, ramp surface, kinematics and temporospatial parameters

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Referee Status: AWAITING PEER

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Competing interests: No competing interests were disclosed.

Grant information: This article was published with support from Texas Woman's University Libraries' Open Access Fund. The funders had no role in study design, data collection and analysis, decision to publish, or preparation of the manuscript.

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How to cite this article: Rosario MG, Orozco E, Babilonia N *et al.* Evaluation of controlled type II diabetics ascending and descending a ramp surface at an imposed speed: A case-control study [version 1; referees: awaiting peer review] *F1000Research* 2018, **7**:408 (doi: 10.12688/f1000research.14401.1)

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Introduction

Significant gait and balance deficits have been found in persons with type two diabetes mellitus (DMII) compared to individuals without DMII (Brach et al., 2008). In fact, individuals with DMII are two to three times more likely to report difficulty walking a quarter of a mile, climbing stairs, or doing housework, and require the use of an assistive device for ambulation (Cavanagh et al., 1992; Crowther et al., 2007; Wallace et al., 2002). Current evidence suggests that multiple factors contribute to these gait and balance deficits, such as impaired lower extremity strength and sensation, low physical activity levels, increased age, BMI, and time since diagnosis (Brach et al., 2008; da Cruz Anjos et al., 2017).

As a result of having gait and balance deficits, Dingwell *et al.* found that people with diabetes demonstrated a 15% greater fall risk than healthy individuals (Dingwell *et al.*, 2000). The risk of falling increases by 17-fold for individuals older than 65 with diabetes (Vinik *et al.*, 2017). Persons with DMII and peripheral neuropathy (PN) will present with characteristics of postural instability (increased postural sway and poor static balance) and demonstrate a more conservative gait pattern, with temporospatial deficits such as decreased speed, step length, stride length, and single limb support time when compared to controls without DMII (Mustapa *et al.*, 2016). These deficits can occur because of impaired proprioceptive feedback, lower extremity muscle weakness, and potential visual deficits due to elevated glucose levels that damage the retina (Mustapa *et al.*, 2016).

However, recent evidence suggests that similar gait and balance deficits can be found in individuals with DMII without PN (Hewston & Deshpande, 2016). In a study by Vaz and colleagues (2013) postural control and functional strength were assessed in individuals with DMII (with or without PN) compared to controls (Vaz et al., 2013). Postural control was evaluated by observing participant's static balance in four different conditions as well as the Berg Balance Scale. Functional strength and mobility were assessed using the Five-Times-Sit-to-Stand and Timed Up & Go, respectively. Vaz and colleagues found that both DMII groups (with and without PN) demonstrated decreased postural control and functional strength compared to healthy individuals of the same age (Vaz et al., 2013). For individuals with DMII and no symptoms of PN, these impairments are most noticeable when they are exposed to challenging everyday activities like reaching, ascending stairs, or walking over unstable surfaces, which require greater postural stability. Centomo and colleagues (2007) found that participants with DMII and no PN demonstrated greater postural instability and difficulty recovering their balance after performing a forward reach test compared to age-matched healthy controls (Centomo et al., 2007).

In addition, patients with DMII also use different compensatory strategies during walking or standing (Manor *et al.*, 2008). In a study conducted by Mueller and colleagues (1994), participants between the ages of 35–75 were instructed to walk on an elevated 6.8m walkway, using shoes that were 2.54cm tall. According to the authors, patients with diabetes used more hip strategy than the ankle strategy during ambulation. This strategy resulted in a

decrease in stride length and velocity, as compared to the control group (Mueller *et al.*, 1994). Allet *et al.* concluded that walking in real-life conditions revealed gait impairments in patients with DMII (Allet *et al.*, 2009). Onodera and colleagues (2011) found that individuals with DMII between the ages 55–62 presented with a reduction in plantarflexion during the early phase of weight acceptance while ambulating stairs. This alteration impairs the mechanism of impact on absorption and load distribution when the forefoot contacts the ground. These changes can increase the risk for ulcer formation in real-life activities. Patients with DMII and PN use an adapted motor strategy to use stairs, which promotes a biomechanical deficit giving place to a decrease in range of motion (Onodera *et al.*, 2011).

Various studies have evaluated the gait on irregular surfaces of individuals with DMII; however, to the best of our knowledge, there is not any research that focuses on gait when ascending and descending ramps in this population. Therefore, our study is aimed at answering the following: What are the temporospatial and kinematic deficits demonstrated in individuals with DMII while ascending and descending a ramp during an imposed speed?

Therefore, we hypothesized that, compared with healthy individuals, (i) individuals with controlled DMII and no evidence of PN would show an alteration in temporospatial parameters (stride length, step length, cadence, single limb support and double limb support) while ascending and descending a ramp at an imposed speed; and (ii) individuals with controlled DMII and no evidence of PN would demonstrate altered kinematic parameters of the lower limb (active range of motion of hip, knee, and ankle) ascending and descending a ramp at an imposed speed. Even with controlled diabetes and the absence of PN (non-PN cDMII), we believe that imposing a velocity of 100 beats per minute will make temporospatial and kinematic alterations more evident in this population. The imposed speed (faster than normal walking speed) adds a further challenge to the ramp surface walking. Therefore, by identifying the biomechanical properties in patients with DMII while ascending and descending this sloped surface, will enable better comprehension of the underlying mechanisms involved in this task; therefore allowing us to develop interventions that strive to prevent falls in this population.

Methods

Ethical statement

The study protocol was approved by the Institutional Review Board of the University of Puerto Rico Medical Sciences Campus (Protocol A2540413). Each participant read and signed an informed consent document after being informed of all the risks, their rights, and potential discomforts they could encounter while participating in this gait study. The study was conducted at a Physical Therapy Laboratory that is affiliated with the School of Health Professions at the University of Puerto Rico Medical Sciences Campus.

Participants

Fifteen non-PN cDMII adults (eight men and seven women; age=57.7± 5.12 years, height 167.1±4.3 cm, mass 80.1±34.3kg) formed the diabetic group (8.0±5.8 years with the diagnosis of

DMII), and fifteen healthy adults (seven men and eight women, age=54.4± 6.28 years, height 164.8±3.9cm, mass 73.6± 28.9 kg) made the control group (CG) (for participant enrollment see Figure 1). Patients with type two diabetes and healthy volunteers were recruited homogeneously as per sex, age, body mass

index, and level of physical activity (Table 1). Diabetics were classified as controlled diabetes which according to the American Diabetes Association is defined as individuals with a glycosylated hemoglobin level of 7.5% or less. This sample size takes into consideration the primary variables (step/stride

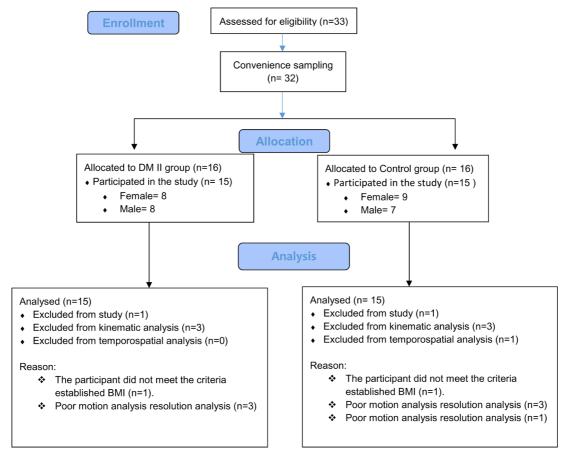


Figure 1. Participant flow diagram.

Table 1. Demographic and clinical variables (mean \pm standard deviation) of the non-peripheral neuropathy controlled type II diabetes group (non PN cDMII) and healthy non-diabetic control group (CG). Results of Student's *t*-test performed between the two sample groups. Significance threshold = $P \le 0.05$; significant P = threshold value; non-significant P = threshold value; non-significant P = threshold

	Non PN cDMII (N=15)	CG (N=15)	P-value
Age (years)	57.7±5.1	56.0 ±4.7	0.39
Height (cm)	167.1±4.3	164.8±3.9	0.59
Weight (kg)	80.1±34.3	73.6±28.9	0.27
BMI	28.6±3.3	26.6±3.1	0.13
HbA1c	6.7±0.5	NA	NA
Years following diagnosis of diabetes	8.0±5.8	NA	NA

length, cadence, the velocity of ambulation and AROM), the highly-instrumented nature and the novelty of this study. The sample size for this study is comparable to other studies that involve similar variables and population characteristics (Dingwell *et al.*, 2000; Mueller *et al.*, 1994; Petrofsky *et al.*, 2005).

Individuals with non-PN controlled DMII (cDMII) and healthy participants were recruited through flyers that were placed around the University of Puerto Rico, Medical Sciences Campus. The inclusion criteria for individuals without diabetes (control group; CG): female or male, 40 to 65 years old, and can ambulate without an assistive device. The exclusion criteria were: BMI>30, severe balance problems, current ulcer(s) or history of ulcers, the absence of sensation in the lower extremities, amputations, cardiopulmonary disease, back or lower extremity pain, disease or surgery in low back in the last year, pregnant women, or lower extremity surgery.

The inclusion criteria for the non-PN cDMII group: type II diabetes diagnosed by a physician, female or male, age between 40–65 years old. The exclusion criteria for the diabetic group: BMI>30, severe balance problem, current ulcer(s) or history of ulcers, absence of sensation in lower extremities, amputations, lower extremity surgery, cardiopulmonary disease, pregnant women, back or lower extremity pain, disease or surgery in low back within the last year, or glycosylated hemoglobin higher than 7%.

In addition to the inclusion and exclusion criteria above, all non-PN cDMII and CG participants were further screened using the AHA/ACSM Health/Fitness Participation pre-screening questionnaire. This tool assessed medical history pertinent to our study and to determine the overall health status and exercise capabilities of each participant before testing (Balady *et al.*, 1998). To ensure a more homogeneous non-PN cDMII and CG samples, two additional steps were taken:

Body mass index (BMI): BMI is the ratio of body mass (kg) divided by the square of body height (meters). Participants with BMI of 18.5 or below (underweight) and 30.0 and above (obese) were excluded from the study.

Standard anthropometric measurements: The height (cm) and mass (kg) of each participant were measured with a stadiometer and scale, respectively. These measurements are essential for accurate motion tracking by the three-dimensional motion analysis system defined below.

Clinical evaluation

To ensure that participants could safely partake in this study and meet the criteria, participants were further screened according to the following five clinical criteria.

Sensibility assessment: Any participant who was unable to detect the 10 g applied force of a 5.07 Semmes-Weinstein monofilament in more than two areas on the plantar aspect of the foot was considered to have PN (i.e., loss of protective sensation and deep pressure sensation) (Bell-Krotoski *et al.*, 1993; Thomson *et al.*, 2008) and excluded from the study.

Oxygen saturation: This noninvasive method of measuring oxygen saturation with a meter (ChoiceMMed OxyWatch C20 Fingertip Pulse Oximeter #TM66018) attached to the index finger of the left hand and the second toe of the left foot was used to define the basic respiratory function. Participants with less than 90% oxygen saturation at rest were excluded from the study.

Sit-to-Stand Test: This test was used to determine if the participant had sufficient lower extremity strength to complete the tasks with minimal fall risk. Each participant was required to successfully sit and stand five times in 15 seconds or less (Whitney et al., 2005). Participants who were unable to meet this standard were excluded from the study.

Step (Tecumseh) Test: To test for cardiorespiratory fitness, the participants were required to ascend and descend a stair step (height: 20.32 cm) for two minutes at a rate of 96 steps/minute. Heart rate, blood pressure, and oxygen saturation were measured before and after the test. Those participants who were unable to complete the task were excluded from the study.

Screening Questions (Supplementary File 1)(non-PN cDMII patients): This tool is a brief questionnaire that is used to obtain the medical history of each participant. Questions for the non-PN cDMII included the extent of their diabetes, their HbA1c values within the last three months, and the medications they have been prescribed.

Instrumentation

For testing, the participants were instructed to wear shorts and T-shirt and no shoes or socks. Fifteen retro-reflective markers were placed on each participant based on the plug-ingait model at anatomical landmarks on the participant's lower limbs and pelvis (Figure 2) to define the body segments of interest to the study. The instrument used in this investigation during walking for kinematic analysis were captured with a six-camera, three-dimensional, motion analysis system (Vicon Motion System, Denver, CO, USA) recording at 120 Hz. The Vicon System measures spatiotemporal parameters and hip, knee and ankle active range of motion (AROM) during gait. Prior to each data collection session, the equipment was calibrated according to manufacturer instructions. After space calibration, a static trial with the participant standing in a T-position was performed to align joint centers coordinates to the laboratory space. Data was recorded at 120 Hz with six infrared cameras. A member of the research team demonstrated the task to the participant. Each participant had the opportunity to practice the task three times with rest intervals of at least one minute.

Ramp protocol

Participants stood in front of a taped line on the floor. Each participant was instructed to walk 2.44 meters (8 feet) to the wooden ramp, ascend it, walk to the end of the leveled platform, make a U-turn, descend the ramp, and walk back to the starting point. The timer began immediately after the participant was instructed to "go" and stopped as soon as the participant crossed the line on the floor with both feet. The participant walked on this surface three times at 100 beats per minute (bpm). A

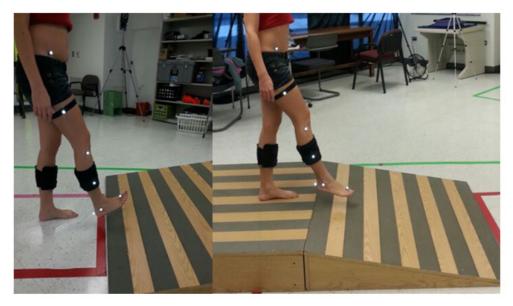


Figure 2. Demonstration of where the markers were placed on the pelvis and limb. The retroflective markers were placed on different anatomical locations based off the plug-in-gait model.

metronome was set to 100bpm and participants were asked to walk in sync with the sound of the beat, thus ensuring that participants ascended and descended the ramp at a velocity of 100 bpm.

Statistical analysis

Statistical analysis was performed using SPSS version 20 software package for Windows. Significant difference for each temporospatial and kinematic variables was evaluated using MANOVA. A p-value ≤0.05 was considered statistically significant. Results are expressed as the mean ± standard deviation (SD). As the participant ascended and descended the ramp at 100bpm, AROM measurements (hip, knee, and ankle) were taken at the exact moment when the foot made the change from a smooth surface to a ramp surface, at the precise moment of heel strike, which we define as maximum dorsiflexion. Also, toe off was described as maximum plantar flexion while ascending and (after the turn around) descending just before heel strike at the smooth surface. Therefore, all kinematic data (hip, knee, and ankle) was collected when the participant was at maximum dorsiflexion and plantar flexion in a sagittal plane (flex/ext). Temporospatial data was collected and analyzed the entire length of the walkway. A t-test was performed to determine the differences for each variable between the control group and non-PN DMII group (Table 1).

Results

Kinematic parameters

Table 1 shows demographic and clinical variables (mean \pm standard deviation), along with years of diabetes diagnosis and percent of glycosylated hemoglobin in diabetic participants. No significant difference was found in the kinematic parameters

(AROM) for hip, knee, and ankle (Table 2). During the ascending of a ramp at a speed of 100 bpm, the non-PN DMII group showed a slight increase in AROM of the joints of the hip, knee, and ankle. While descending the ramp at a speed of 100 bpm, non-PN DMII participants showed a minimal decrease in the AROM of the hip, and minimal increase in AROM with knee flexion and plantar flexion, which was not significantly different from the CG.

Temporospatial parameters

The temporospatial variables considered in this study were cadence, gait speed, single/double limb support, step length and stride length. The temporal parameters are cadence, gait speed, single limb support and double limb support, and the spatial parameters are step length and stride length.

Table 3 shows the temporospatial parameters results with their standard deviations values. The CG and DMII participants were comparable in all variables.

Dataset 1. Ramp ascending and descending data for the non-peripheral neuropathy controlled type 2 diabetes and control groups

http://dx.doi.org/10.5256/f1000research.14401.d199072

Discussion

The purpose of this study was to analyze kinematics (hip, knee, and ankle) and temporospatial gait parameters while ascending and descending a ramp at a velocity of 100 bpm in people with non-PN DMII group compared to healthy controls.

Table 2. Kinematic data (degrees) in the sagittal plane of the hip and knee joints at the instant of maximal ankle joint dorsiflexion during Ramp ascent and maximal ankle joint plantar flexion during ramp descent. Results of analysis (MANOVA) performed between the two sample groups: controlled diabetic group without peripheral neuropathy (non-PN cDMII) and healthy non-diabetic control group (CG). Significance threshold = P < 0.05; significant P= threshold value; non-significant P=calculated value.

								P-value		
Ramp	Group	Hip (H)	SD	Knee (K)	SD	Ankle (A)	S.D.	Н	K	Α
Ascending	CG	41.0	±9.9	23.52	±25.5	4.49	±4.7	0.74	0.34	0.30
100 bpm	non-PN cDMII	42.4	±10.6	29.02	±24.0	6.75	±6.3			
Descending	CG	32.4	±8.5	17.88	±13.5	-3.10	±9.8	0.48	0.54	0.51
100 bpm	non-PN cDMII	29.1	±13.9	22.08	±21.6	-0.53	±8.9			

Table 3. Temporal spatial variables during ramp ascent and descent (mean ±SD). Results of analysis (MANOVA) was performed between the two sample groups: controlled diabetic group without peripheral neuropathy (non-PN cDMII) and healthy non-diabetic control group (CG). Significance threshold = P < 0.05; significant P= threshold value; non-significant P=calculated value.

Parameter	CG	non-PN cDMII	P-value
Cadence (step/minutes)	98.3±7.8	95.8±3.7	0.27
Walking speed (meters/seconds)	0.94±0.1	0.88±0.1	0.28
Step length (meters)	0.54±0.1	0.51±0.1	0.40
Stride length (meters)	1.13±0.1	1.11±0.2	0.40
Single leg Support (seconds)	0.37±0.1	0.42±0.14	0.33
Double leg Support (seconds)	0.24±0.22	0.12±0.16	0.08

We hypothesized that people with controlled diabetes and no history of PN would show significant differences in temporospatial parameters and kinematics while ascending and descending the ramp. However, our study rejects this hypothesis. Results demonstrated that the non-PN DMII group did not show significant differences in AROM of hip, knee, and ankle and any of the temporospatial parameters compared with the CG.

In our study, we did not find any differences between groups. This could be because our participants had no history of neuropathy and the testing surface was not challenging enough to detect significant deviations in kinematic or temporospatial parameters. Similar to our study, Mueller *et al.* (1994) found that while walking on an elevated walkway, the PN-DMII group demonstrated a decrease in dorsiflexion and plantar flexion AROM, but the reduction was not significant. However, Onodera *et al.* (2011) found a significant decrease in dorsiflexion and plantar flexion in their participants with diabetes and PN when they ascend stairs and a significant decrease of plantar flexion while descending stairs.

In our study, no significant difference was found in the speed of ambulation between the two groups while the ascending and descending the ramp. This outcome was expected due to the protocol that called for an imposed speed of 100bpm and the controlled glucose levels in our participants. Meanwhile, Dingwell et al. (2000) and Chiles et al. (2014) found that individuals with DMII and PN have a significant decrease in their speed of ambulation on level surfaces. In addition, Petrofsky et al. (2005) found the same in persons with DMII with no evidence of PN. Both agreed that individuals with DMII with and without neuropathy demonstrated a reduction in speed as an adaptive mechanism to feel safer while walking on smooth surfaces. Also, Allet and colleagues (2009) found that participants with DMII and DMII/PN demonstrated a significant decrease in their speed of ambulation when changing from asphalt to stones and from grass to stones, to feel safer during the ambulation.

As noted, in the early stage of controlled DMII, speed of ambulation is not significantly affected, as the reduction in speed occurs in the later stages. In our study, the most affected variable was step length, where there was a decrease in the non-PN DMII group; however, this was not significant. The stride length was shorter in the non-PN DMII group compared with the CG. In the studies of Dingwell *et al.* (2000), Mueller *et al.* (1994), and Camargo *et al.* (2015) found that individuals with DMII/PN showed a significant decrease in the stride length compared to the control group.

Finally, we found that the non-PN DMII group showed a minimal decrease in cadence during ramp ascent and descent. In comparison, Mueller et al. (1994) and Courtemanche et al. (1996), found that individuals with DMII/PN showed a decrease in cadence (not significant) during ambulation on an elevated walkway compared to the control group. In the study of Allet and colleagues (2009) both the control group and the groups with DMII (with and without PN) showed a significant decrease in cadence when changing from one surface to another.

Conclusion

The variable that was most affected while ascending and descending the ramp in participants with controlled DMII (≤ 7% glycosylated hemoglobin) was step length. We observed minimal changes in temporospatial and kinetic parameters in people with controlled DMII with no evidence of peripheral neuropathy. Focusing on individuals with controlled DMII allowed us to

determine if controlled diabetes with no history of PN influenced gait parameters, most specifically while ascending and descending a ramp. Clinicians should emphasize their assessments in these areas to prevent complications, such as gait abnormalities, that can increase the risk for falls.

For future studies, we suggest measurement of lower extremity muscular activation and different degrees of slopes, making the ramp surface more challenging.

Data availability

Dataset 1: Ramp ascending and descending data for the non-peripheral neuropathy controlled type 2 diabetes and control groups. DOI, 10.5256/f1000research.14401.d199072 (Rosario et al., 2018).

Competing interests

No competing interests were disclosed.

Grant information

This article was published with support from Texas Woman's University Libraries' Open Access Fund.

The funders had no role in study design, data collection and analysis, decision to publish, or preparation of the manuscript.

Supplementary material

Supplementary File 1: Diabetes assessment screening questions.

Click here to access the data.

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