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The steel ball-bearing test: a new test for evaluating protective sensation in the diabetic foot

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Abstract *Aims/hypothesis:* The aim of the study was to assess a new steel ball-bearing test as a means of evaluating protective sensation in the diabetic foot. *Methods:* Subjects were enrolled for this study as follows: (1) 39 patients (mean age 61.3 ± 9.7 years) with neuropathy and prior neuropathic ulcer (Group A); (2) 36 patients (mean age 63.7 ± 10.1 years) with neuropathy without neuropathic ulcer (Group B); (3) 34 patients (mean age 52.1 ± 10.4 years) without neuropathy (Group C); and (4) 21 healthy volunteers (mean age 46.7 ± 8.7 years) (Group D). Neuropathy was diagnosed by means of neuropathy disability score (NDS). The plantar area over the second metatarsal head of each foot was examined with steel ball-bearings of varying diameters. The smallest diameter that the patient could feel was used to define the ball-bearing score (range 1–6). *Results:* A high ball-bearing score was significantly more frequent in patients with neuropathic ulceration than in neuropathic patients without ulceration and in diabetic patients without neuropathy ($p < 0.001$). A high score was also more frequent in neuropathic patients without ulceration, than in patients without neuropathy ($p < 0.001$). The ball-bearing score was significantly ($p = 0.01$) correlated with the NDS, the monofilament test, the vibration perception threshold and the thermal perception threshold. The ball-bearing test had a sensitivity of 84% and a specificity of 100% for impaired protective sensation due to neuropathy, and a

sensitivity of 84.6% and a specificity of 86.1% for detection of patients with prior neuropathic ulceration. *Conclusions/interpretation:* The steel ball-bearing test has a high sensitivity and specificity both for the evaluation of protective sensation and for detection of patients with prior neuropathic ulceration.

Keywords Diabetes mellitus · Diabetic foot · Neuropathic ulcer · Neuropathy

Abbreviations ABI: ankle-brachial index · NDS: neuropathy disability score · ROC: receiver operator curve · TCD: tactile circumferential discriminator · TPT: thermal perception threshold · VPT: vibration perception threshold

Introduction

Sensory loss due to neuropathy plays a pivotal role in the pathogenesis of ulceration in the diabetic foot [1]. This prompted us to design a new diagnostic test, the steel ball-bearing test, to examine sensation of stepping on a foreign object. The aim of the present study was to evaluate this new test in the assessment of protective sensation and in the detection of patients with prior neuropathic ulceration.

Subjects and methods

Study population

This study included 109 subjects with diabetes (64 men). Twenty-two patients had type 1 and 87 patients had type 2 diabetes mellitus. Patients were divided into Group A (39 patients with neuropathy and previous neuropathic ulceration), Group B (36 patients who had neuropathy without history of ulcer) and Group C (34 patients without neuropathy). Twenty-one healthy volunteers (Group D) were also included (Table 1). Patients were recruited from the Diabetes Centre and the Outpatient Department of St

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Bonifatius Hospital at Lingen, University of Hanover, Germany. The study was performed in accordance with the Helsinki Declaration of Human Rights. It was approved by the institutional ethics committee and all subjects gave written informed consent.

Exclusion criteria

Exclusion criteria were as follows: age <17 years or >75 years, peripheral arterial occlusive disease, medial arterial calcification, other potential causes of neuropathy (end-stage renal failure, alcohol abuse, vitamin B₁₂ depletion, malignancy) and peripheral nerve lesions (traumatic lesions, plexus paresis, spinal root compression, herpes zoster, polyradiculopathy).

Diagnosis of neuropathy and neuropathic ulcer

Diabetic neuropathy was diagnosed by the neuropathy disability score (NDS) [2]: a standardised examination of ankle reflexes, as well as 128 Hz tuning fork, pin-prick and temperature (cold tuning fork) sensations at the hallux, as described earlier [2]. Diagnosis of neuropathy was defined as an NDS ≥ 6 [2, 3]. Ankle reflexes, a component of NDS,

were also recorded separately as follows: for each foot, ankle reflex was graded as 0 if absent, 1 if present with reinforcement and 2 if absent. These grades were added to form the ankle reflex score (range 0–4) [4].

In addition, patients were examined with the 10 g Semmes–Weinstein monofilament, the vibration perception threshold (VPT) and the thermal perception threshold (TPT) (Table 1). A 10 g Semmes–Weinstein monofilament was applied on three sites on the plantar aspect of the foot (first and fifth metatarsal head, heel), along the perimeter and not on an ulcer site, callus or necrotic tissue. The monofilament was applied perpendicular to the skin surface, with enough force to cause it to buckle. The test was regarded as abnormal if the monofilament was not felt at any one site on either foot [4]. The VPT was assessed with a neurothesiometer (Horwell Scientific Laboratory Supplies, London, UK) whose tractor was applied vertically on the pulp of the hallux [5]. The test was repeated three times and the mean voltage was recorded [5]. The TPT was measured with a thermal tester (Somedic, Stockholm, Sweden) on the dorsum of the foot. The baseline temperature of the thermode was 32°C for all measurements. TPT was assessed separately in six consecutive measurements for cold and six consecutive measurements for hot. TPT was calculated as a mean value of the third to the sixth measurements: the first two measurements were discarded [6]. Each of the quantitative tests outlined above was

Table 1 Characteristics of the four groups included in the study

Characteristic	Group A	Group B	Group C	Group D	<i>p</i> values
Subjects (<i>n</i>)	39	36	34	21	
Male (<i>n</i>) ^a	29	18	17	9	A vs B: 0.052; A vs C: 0.056; A vs D: 0.033; B vs C: 1; B vs D: 0.8; C vs D: 0.812
Female (<i>n</i>) ^a	10	18	17	12	
Age (years, mean $\pm$ SD) ^b	61.3 $\pm$ 9.7	63.7 $\pm$ 10.1	52.1 $\pm$ 10.4	46.7 $\pm$ 8.7	A vs B: 0.8; A vs C: 0.03; A vs D: 0.01; B vs C: 0.04; B vs D: 0.01; C vs D: 0.049
Diabetes duration (years, mean $\pm$ SD) ^b	17.9 $\pm$ 3.1	17.6 $\pm$ 2.9	9 $\pm$ 1.1	–	A vs B: 0.99; A vs C: 0.01; B vs C: 0.02
HbA _{1c} (%; mean $\pm$ SD) ^b	7.81 $\pm$ 1.1 %	8.34 $\pm$ 1.4 %	8.44 $\pm$ 1.3 %	–	A vs B: 0.8; A vs C: 0.75; B vs C: 0.9
BMI (kg/m ² , mean $\pm$ SD) ^b	28.91 $\pm$ 1.4	29.32 $\pm$ 1.6	27.97 $\pm$ 1.1	28.94 $\pm$ 1.2	A vs B: 0.9; A vs C: 0.82; A vs D: 0.99; B vs C: 0.81; B vs D: 0.84; C vs D: 0.79
NDS (mean $\pm$ SD) ^b	7.89 $\pm$ 1.33	5.14 $\pm$ 1.91	2.44 $\pm$ 1.16	0.19 $\pm$ 0.40	A vs B: 0.001; A vs C: 0.001; A vs D: 0.001; B vs C: 0.001; B vs D: 0.001; C vs D: 0.003
Normal monofilament perception (<i>n</i> , %) ^a	9 (23%)	16 (44.4%)	27 (79.4%)	19 (90.5%)	A vs B: 0.05; A vs C: 0.001; A vs D: 0.001; B vs C: 0.001; B vs D: 0.01; C vs D: 0.543
VPT (volts; median, range) ^c	40 (27–50)	31 (23–38)	14 (8–19)	12 (6–17)	A vs B: 0.01; A vs C: 0.001; A vs D: 0.001; B vs C: 0.001; B vs D: 0.001; C vs D: 0.7
Cold TPT (°C; mean $\pm$ SD) ^b	9.76 $\pm$ 1.64	8.22 $\pm$ 3.16	4.56 $\pm$ 2.51	3.64 $\pm$ 2.52	A vs B: 0.4; A vs C: 0.001; A vs D: 0.001; B vs C: 0.001; B vs D: 0.001; C vs D: 0.54
Hot TPT (°C; mean $\pm$ SD) ^b	8.8 $\pm$ 1.4	8.93 $\pm$ 2.4	4.98 $\pm$ 2.05	3.17 $\pm$ 1.86	A vs B: 0.03; A vs C: 0.001; A vs D: 0.001; B vs C: 0.001; B vs D: 0.001; C vs D: 0.6
Ankle reflex score (mean $\pm$ SD) ^b	2.8 $\pm$ 0.5	2.1 $\pm$ 0.8	1.1 $\pm$ 0.9	0.5 $\pm$ 0.7	A vs B: 0.05; A vs C: 0.001; A vs D: 0.001; B vs C: 0.01; B vs D: 0.001; C vs D: 0.05

^a χ^2 test

^bUnpaired *t* test

^cMann–Whitney *U* test

performed on both feet and the greater of the results for right and left was used. Each test (NDS with ankle reflex score, monofilament, VPT, TPT) was conducted by an operator blinded to the results of the other tests.

History of neuropathic ulcer was recorded. A neuropathic ulcer was defined as a break in the skin, greater than 3 mm in diameter extending to all its layers and attributable to neuropathy.

Diagnosis of peripheral arterial occlusive disease

Peripheral arterial occlusive disease was evaluated by means of ankle-brachial index (ABI) measurement with a Doppler apparatus. Peripheral arterial disease was diagnosed in patients with ABI <0.9 [7]. Medial arterial calcification was diagnosed in patients with ABI >1.3 or radiologically visible extensive linear calcification [7].

Examination with the steel ball-bearing

Patients were examined with specially designed ball-bearings made of steel. Each steel ball-bearing had been stuck to a commercially available plaster (5×4 cm; HAN-Samed, Mississauga, ON, Canada) using common glue (UHU Kraft, Bolton Group, Amsterdam, the Netherlands). The plaster was applied in the plantar area over the second metatarsal head of each foot, while an empty control plaster was applied on the contralateral foot. Callus was appropriately removed prior to examination. Each foot was examined separately, beginning on the right. Five ball-bearings were used: ball-bearing 1 (1.5 mm diameter), ball-bearing 2 (2.0 mm diameter), ball-bearing 3 (2.5 mm diameter), ball-bearing 4 (3.0 mm diameter) and ball-bearing 5 (3.5 mm diameter). The examination began with ball-bearing 1 and the diameter was increased until the patient could feel the ball-bearing when walking barefoot on flat ground (five steps). The ball-bearing score (range 1–6) was defined as the smallest ball-bearing that the patient could feel, patients not being able to feel any of the ball-bearings being scored as 6. Both feet were examined and the greater of the results for right and left was used as the ball-bearing score. A new ball-bearing was used for every patient. Examination with the steel ball-bearing was carried out by a physician who was blinded to the results of neurological examination and was unaware which group the subject belonged to.

Reproducibility of the new test

In order to assess reproducibility of the steel ball-bearing test, 20 patients selected at random from the four groups were examined by a second physician, who was kept blinded to the results of the examination by the first physician (inter-observer reproducibility). Moreover, these patients were re-examined by the first physician on the same day (intra-observer reproducibility).

Statistical analysis

Statistical analysis was performed in the Institute for Biometrics at Hanover University using the SPSS (version 11.0; SPSS, Chicago, IL, USA). Significance of qualitative variables was assessed by χ^2 test (with Yates' correction for 2×2 contingency tables). Normally distributed quantitative variables were analysed by unpaired *t* test. Quantitative variables without normal distribution were studied by Mann–Whitney *U* test. Correlations between the ball-bearing score and the other diagnostic methods (abnormal or normal monofilament perception, NDS, VPT [volts], TPT [°C], ankle reflex score) were assessed by Pearson's coefficient and Spearman's rank coefficient. Sensitivity and specificity of each test were calculated using receiver operator curve (ROC) analysis. Reproducibility was assessed by κ statistics. Significance was defined at the 5% level ($p<0.05$).

Results

Ball-bearing score

A highly significant (χ^2 , overall significance $p<0.001$) difference in the ball-bearing score was found between the four groups (Table 2). By contrast, no association was found between age and ball-bearing score (Pearson's coefficient $r=0.12$, $p=0.56$).

Correlation between the steel ball-bearing test and the standardised tests

Table 3 shows significant correlations between the ball-bearing score and the other diagnostic tests. Furthermore, a significant correlation ($p=0.01$, Pearson's coefficient $r=0.89$) in the ball-bearing score was found between the two feet.

Reproducibility of the new test

Analysis showed very good inter-observer reproducibility, with a κ value of 0.811 (95% CI 0.710–0.912). Moreover,

Table 2 Ball-bearing score in the four groups of subjects

Group	Ball-bearing score (range 1–6) ^{a,b}					
	1	2	3	4	5	6
Group A ($n=39$)	1	3	4	6	11	14
Group B ($n=36$)	2	9	12	8	1	4
Group C ($n=34$)	13	20	1	0	0	0
Group D ($n=21$)	9	12	0	0	0	0

^aValues in the body of the table represent patients (n)

^bOverall significance between the groups (χ^2 test): $p<0.001$; A vs B: $p<0.001$; A vs C: $p<0.001$; A vs D: $p<0.001$; B vs C: $p<0.001$; B vs D: $p<0.001$; C vs D: $p=0.707$

Table 3 Correlations between the ball-bearing score and the other diagnostic tests used in the study

Diagnostic test	<i>p</i> value	Pearson's coefficient <i>r</i>
Right foot		
NDS	0.01	0.698
Monofilament test	0.01	-0.423
Ankle reflex score	0.01	0.58
VPT	0.01	0.470 ^a
TPT: cold	0.01	0.596
TPT: hot	0.01	0.699
Left foot		
NDS	0.01	0.701
Monofilament test	0.01	-0.582
Ankle reflex score	0.01	0.583
VPT	0.01	0.484 ^a
TPT: cold	0.01	0.594
TPT: hot	0.01	0.691

^aSpearman's rank coefficient (*r_s*)

intra-observer reproducibility was good, with a κ value of 0.749 (95% CI 0.639–0.858).

Sensitivity and specificity of the steel ball-bearing test and other tests

A ball-bearing score of 2 had a sensitivity of 84% and a specificity of 100% for the diagnosis of neuropathy. Positive and negative predictive values were 86.5% and 100% respectively. A ball-bearing score of 4 had a sensitivity of 84.6% and a specificity of 86.1% for detection of patients with prior neuropathic ulceration.

Table 4 Sensitivity and specificity of the steel ball-bearing and the other diagnostic tests for the diagnosis of neuropathy, as well as for detection of patients with a history of neuropathic ulcer

Method	Cut-off value	Sensitivity (%)	Specificity (%)
Diagnosis of neuropathy			
Ball-bearing score	2	84	100
Monofilament test	One out of three sites tested	67.9	90.5
TPT: cold (°C)	4.0	89.3	71.4
TPT: hot (°C)	4.0	88	70.5
VPT: (volts)	25	69.3	85.7
Ankle reflex score	2	92	91
Detection of patients with history of neuropathic ulcer			
Ball-bearing score	4	84.6	86.1
NDS	8	84.7	41.7
Monofilament test	One out of three sites tested	77.9	43.1
TPT: cold (°C)	8.5	87.2	36.1
TPT: hot (°C)	8.5	79.5	41.1
VPT (volts)	35	79.5	91
Ankle reflex score	4	82	74

Positive and negative predictive values were 86.8% and 83.8% respectively. Sensitivity and specificity of the other tests are summarised in Table 4.

Discussion

The ball-bearing score differed significantly ($p<0.001$) between the four groups. A high score was significantly more frequent in patients with neuropathic ulceration than in neuropathic patients without ulceration and in diabetic patients without neuropathy. A high score was also significantly more frequent in neuropathic patients without ulceration than in patients without neuropathy. Moreover, a significant correlation in ball-bearing score was demonstrated between the two feet, in line with the symmetrical involvement of diabetic neuropathy [1, 2]. No significant impact of age on ball-bearing score was found. Thus, no substantial influence on results obtained with the ball-bearing test could be attributed to the significant difference in age that was observed between the four groups. Consequently, the ball-bearing test contributed to the diagnosis of impaired protective sensation due to neuropathy, as well as to detection of patients with prior neuropathic ulcer.

The ball-bearing score showed a significant ($p=0.01$) correlation with NDS, as well as with the VPT, the TPT, the monofilament test and the ankle reflex score. This agreement is of particular importance, since a markedly increased risk of developing foot ulceration has been shown in association with high NDS [4, 8], VPT [8, 9], reduced monofilament perception [4, 8, 10] and diminished ankle reflexes [4, 10].

Previous investigators have shown a high sensitivity and moderately high specificity for NDS, monofilament and VPT in the diagnosis of neuropathy [3, 5, 11, 12] and in the detection of patients with previous foot ulcer [13–15], a finding that was confirmed in the present study. More importantly, sensitivity and specificity of the steel ball-bearing test were high, both for the diagnosis of impaired protective sensation due to neuropathy and for detection of patients with prior neuropathic ulceration. Indeed, the ball-bearing test belonged to the most sensitive and specific among all diagnostic tests used, and was not inferior to the other tests. In addition, sensitivity of the ball-bearing test was comparable with that reported for the tactile circumferential discriminator (TCD), an alternative test of protective sensation (92.3% sensitivity for neuropathy and 100% sensitivity for neuropathic ulceration) [15]. Nonetheless, specificity of TCD is rather lower (64.2% for neuropathy and 58.3% for neuropathic ulceration) [15]. Certainly, the TCD is easier to use than the steel ball-bearing test, but it does not directly demonstrate to the patient the potential danger of unperceived trauma.

Interestingly, patients who could not feel the ball-bearing were very impressed and wanted to know more about diabetic neuropathy. Some of them realised that their shoes did not fit appropriately and were given instructions on suitable footwear. Since most neuropathic patients fail to

appreciate that their feet are at risk [1], the ability of the ball-bearing test to show the danger of unperceived trauma to the patient was found to represent an additional advantage of this new test. Hence, the ball-bearing test appears to contribute to patient education, which has been recognised as an important aspect in the overall foot care [1].

These results indicate that the steel ball-bearing test might prove useful in clinical practice as a screening test of protective sensation. The strengths of the new test lie in the high sensitivity and specificity, as well as in the contribution to patient education. The significant association between a high ball-bearing score (at least 4) and the history of previous neuropathic ulcer should be particularly noted. Whether patients with a ball-bearing score of at least 4 have an increased risk of ulceration needs to be evaluated by prospective studies. The weakness of the ball-bearing test is that it is not widely available and is relatively time-consuming (15 to 20 min). By contrast, the monofilament test has the advantage of being simpler, widely applicable, standardised and validated [1, 4, 8, 10].

In conclusion, the steel ball-bearing test appears to have a high sensitivity and a very high specificity both for the evaluation of protective sensation and for detection of patients with prior neuropathic ulceration. It may, therefore, prove to be of value in detection of patients who have an increased risk for foot ulceration. However, prospective studies are required to confirm these encouraging results and to thoroughly examine the utility of the steel ball-bearing test in everyday clinical practice.

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