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Mobile phone generated vibrations used to detect diabetic peripheral neuropathy

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ABSTRACT

Background: In the current United Kingdom population the incidence of diabetic peripheral neuropathy is increasing. The presence of diabetic neuropathy affects decision making and treatment options. This study seeks to evaluate if the vibrations generated from a mobile phone can be used to screen patients for diabetic peripheral neuropathy.
Methods: This study comprised of 61 patients; a control group of 21 patients; a lower limb injury group of 19 patients; a diabetic peripheral neuropathy group of 21 patients. The control and injury group were recruited randomly from fracture clinics. The diabetic peripheral neuropathy group were randomly recruited from the diabetic foot clinic. The 61 patients were examined using a 10 g Semmes-Weinstein monofilament, a 128 Hz tuning fork and a vibrating mobile phone. The points tested were, index finger, patella, lateral malleoli, medial malleoli, heel, first and fifth metatarsal heads.
Results: The most accurate location of all the clinical tests was the head of the 1st metatarsal at 0.86. The overall accuracy of the tuning fork was 0.77, the ten gram monofilament 0.79 and the mobile phone accuracy was 0.88. The control group felt 420 of 441 tests (95%). The injury group felt 349 of 399 tests (87%). The neuropathic group felt 216 of 441 tests (48%). There is a significant difference in the number of tests felt between the control and both the injury and neuropathic groups. $p < 0.0001$ using N-1 Two Proportion Test.
Conclusion: A mobile phone is an accurate screening tool for diabetic peripheral neuropathy. The most accurate location to test for diabetic peripheral neuropathy is the head of the 1st metatarsal. Screening for diabetic peripheral neuropathy in the index finger and patella were inaccurate. An injury to the lower limb affects the patient's vibration sensation, we would therefore recommend screening the contralateral limb to the injury.
Level of evidence: This study represents level II evidence of a new diagnostic investigation.

1. Aim

To create a widely available, cost effective, easily portable, accurate way of screening for diabetic peripheral neuropathy.

2. Introduction

In the current United Kingdom population, the incidence of diabetes is increasing [1]. This has an associated rise in the incidence of diabetic peripheral neuropathy [2,3]. The presence of diabetic neuropathy in a patient presenting to the orthopaedic department affects decision making and treatment options. It has been shown to affect the outcomes of both surgical and non surgical interventions [4]. Therefore the prompt detection of neuropathic limbs in patients with diabetes is important, so that optimal care can be provided [5,6].

There are several methods for the detection of neuropathic limbs at present [7,8]. These include a thorough medical history and clinical examination coupled with specific tests. There are several non-invasive clinical tests that can be used to detect diabetic peripheral neuropathy. These included a ten gram Semmes-Weinstein monofilament, calibrated biothesiometers and a 128 Hz tuning fork [8–10].

The current recommendations as quoted by National Institute for Health and Care Excellence (NICE) guidelines is to test patients

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with diabetes annually using a 10 g Semmes-Weinstein monofilament [11,12]. Using multiple clinical tests has been shown to improve the accuracy of diagnosis in diabetic peripheral neuropathy [7,13]. The validated Ipswitch toe touch test is a good clinical examination and takes the role of light touch testing [14]. This paper reports the accuracy of a novel technique that can take up the role of the tuning fork in terms a vibration sensation testing.

The lead author has anecdotally noted that the junior staff in teaching hospitals are reluctant to carry with them the selection of tools required to test patients. Therefore, the tools have to be available in each clinical area. Those clinical tests that are rarely performed in these areas are inevitably lost or forgotten about. However most modern junior doctors in teaching hospitals carry their personal mobile phone device. These devices are constantly being utilised for medical reasons. Everything from the British National Formulary (BNF) to Scoliometers can be found online and used to improve the quality of care for patients. This technology can be used by patients, their friends and family. This would allow screening to be an ongoing patient centered process, potentially avoiding the need for annual screening by healthcare providers.

The vibration function of a mobile phone generates vibration by a motor. This motor rotates a weight that is off center to the axis of rotation causing displacement of the handset at a set frequency and amplitude. This study seeks evaluate if vibrations generated from a mobile phone can be used to screen patients for loss of vibration sensation associated with diabetic peripheral neuropathy.

We hypothesise vibrations generated from a mobile phone are accurate in the screening of diabetic peripheral neuropathy.

3. Materials and methods

The human subjects of this original scientific article have given their informed consent to be involved in this study. They have also consented for the use of their data collected, to be published and presented in scientific media.

This study has been granted a favorable ethical opinion by the National Ethics Research Service UK (NRES). The study was conducted at a district general hospital from May 2014 to July 2014. The lead author recruited all human subjects to the study. The lead author conducted all medical histories and examinations.

The study comprised of 61 patients; firstly a control group of 21 patients; secondly 19 patients that had a lower limb injury but were otherwise well and thirdly 21 patients that are known to have diabetic peripheral neuropathy.

The control and injury groups were recruited randomly from fracture clinics. Patients were included in these groups if there was no medical history of diabetes, nerve injury or if the patients American Society of Anesthesiologists grade (ASA) was 1 or 2. The diabetic peripheral neuropathy group n_3 were randomly recruited from the diabetic foot clinic. They were included in the trial if they had either type I or II diabetes and were currently being treated for the complications of diabetic peripheral neuropathy, e.g., foot ulcers.

The 61 patients recruited were examined using a 10 g Semmes-Weinstein monofilament, a 128 Hz tuning fork and a mobile phone. Each patient was tested with the three clinical tests, in a random order, in the same sitting. A commonly available mobile phone was used (iPhone, Apple, CA, USA). Mobile phones and specifically the (iPhone 4S) have not been cleared by the FDA to be used as a biothesiometer/medical device, therefore, its use is off label. The mobile phone has an inbuilt linear oscillating motor (LOM). It vibrates at 25 Hz approximately. An App was created (NeurApathy, Goldfish Systems, Sheffield, South Yorkshire) by the 1st author for the (iPhone) to standardise the vibrations that were created. This App activates the motor within the mobile phone in a consistent pattern and frequency eliminating potential variables within the mobile phones software. This application has no financial gain for any people, relatives or associations of this study. A rubber glove was used as a protective barrier between the patient's foot and the mobile phone to ensure infection control standards were maintained.

The points of skin that were tested with each instrument were; the pulp of the index finger; centre of the patella; the lateral malleoli; the medial malleoli; the plantar aspect of the heel; the plantar aspect of the first and fifth metatarsal head. When testing patients with callosities the instrument was placed at the edge of the callosity on the most normal skin, while still being over a boney prominence. The patients were asked they could "feel" the monofilament or "feel the vibrations" from the tuning fork. When testing patients with the mobile phone, the phone was applied to the skin via a rubber glove with enough force to stop any sliding at the interfaces. This is approximately enough force to cause blanching of the skin in the testers thumb. The phone is placed with the vibration function turned off and the screen facing away from the patient. The vibrations were then activated and the patient asked if they could "feel the vibrations" generated.

3.1. Data analysis

A post hoc power analysis was performed on (Statistical Package for the Social Sciences). Confidence intervals of 95% with an alpha value of 0.05. This study has a power of 93.5% to detect a difference between the mobile phone and the ten gram monofilament.

Using the neuropathic group as the disease positive group and the control group as a disease negative group the sensitivity, specificity, positive/negative predictive value and overall accuracy could be calculated. The accuracy was calculated by summing the true positives to the true negatives then dividing this by the sum total of all the results. An accepted standard of 0.8 was used as the level that a test is considered accurate or not.

4. Results

The tests performed on the index fingers and patellae were not accurate at 0.51 and 0.55 respectively and therefore the data from these locations was excluded from subsequent analysis. The most accurate location using a mean average of all the clinical tests was the head of the 1st metatarsal at 0.86. See Table 1 for full results on location accuracy.

The sensitivity; specificity; positive predictive value; negative predictive value and accuracy are displayed in Table 2.

There is a statistically significant difference in the number of tests felt between the control group and both the injury group and neuropathic group. See Table 3. $p < 0.0001$ using N-1 Two Proportion Test.

5. Discussion

In this population group the vibrations generated from a mobile phone can be used to screen for diabetic peripheral neuropathy accurately. This study has demonstrated that the most accurate location to test for diabetic peripheral neuropathy is the head of the 1st metatarsal. Vibration sensation is effected by a lower limb injury. The strengths of this study are the direct and simultaneous testing of patients with three clinical tests. The tuning fork and the monofilament are well documented in the literature as being able to screen for diabetic peripheral neuropathy and the mobile phone is more accurate than both of these clinical tests [8,14–17].

The main weakness of this study comes from vibrating motor within the mobile phone. The mobile phone used in this study has

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