

Evaluation studies of a new screening device – NEURO TOUCHTM for screening Diabetic Peripheral Neuropathy

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PURPOSE

Increased incidence and cost of Diabetic Peripheral Neuropathy (DPN) have necessitated large scale screening for DPN. The present available devices do not support the same. A multi-parameter screening device NEURO TOUCHTM is helping doctors/paramedics in screening patients for symptoms of DPN. This is a comparative study of NEURO TOUCHTM with the predicate devices.

METHODS

In this comparative study:

- A total of 1,344 study participants were recruited from different hospitals in India.
- The paramedic staff were trained to eliminate inter measurer and intra-measurer variability.
- 4 tests were executed with NEURO TOUCH™ and the predicate devices.
- The data was analyzed for various parameters such as reliability, repeatability and correlation co-efficients.

Table 1: Baseline Characteristics

Demographic Measurements N = 1344		
Variable	Mean±SD	
Age (years)	48.9 ± 10.0	
BMI (kg/m2)	26.4 ± 3.7	

Table 2: Instruments used

Sensation	NEURO TOUCH TM	Predicate Device
Tactile Sensation	Protective Sensation (1 – 50 g)	
Vibration Perception Test	VPT (1 – 50 V, 170 Hz)	Vibrotest
Hot and Cold Perception Test	Hot and Cold Thermal (10 °C - Ambient – 49 °C)	Sensitometer HCP
Foot Skin Temperature	IR Thermometer	IR Thermometer



RESULTS

Tactile Sensation – NEURO TOUCH™ gives quantitative results in grams of force applied by the filament tip, thereby determining the tactile perception threshold. A separate study was done to establish normal tactile perception threshold in Indian subjects.

Vibration Perception Test — The vibration perception threshold was fixed at 20 V level for assessment of specificity & sensitivity. Diagnostic accuracy analysis was performed by applying chi-square test.

Hot and Cold Perception Test and Foot Skin Temperature Measurement – Interclass correlation was obtained for thermal perception and skin temperature measurement of NEURO TOUCH™ VS Predicate Device.

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Variable	Specificity	Sensitivity
Vibration Perception Test	95%	80.7%

Table 4: Analysis of Interclass correlation

Table 3: Analysis of diagnostic accuracy

Variable	r value (Average of 6 points)
Hot Perception Test	0.89
Cold Perception Test	0.85
Infrared Thermometer	0.92

CONCLUSION

NEURO TOUCH™ device presents an innovative, compact and multimodality approach for screening peripheral neuropathy in type 2 Diabetes. It showed good sensitivity and specificity especially across all the four parameters when compared with predicate devices. It is a single valuable device for screening neuropathic abnormalities at point of care. Thus overall, the NEURO TOUCH™ provides the clinician with a unique, sensitive tool to screen DPN with a single device in type 2 Diabetic patients.

ACKNOWLEDGEMENT

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