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A comparative study to evaluate effect of planter tactile stimulation versus foot insoles to improve balance, mobility and reduce fall in diabetic peripheral neuropathy

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Abstract
Background: Diabetic peripheral neuropathy ulcers on the plantar surface of the foot are typically found in diabetic patients with peripheral neuropathy. Pressure beneath planter surface of foot is increased in diabetic foot result of a combination of morphological sensory abnormalities. Sensory loss plays a vital role in predisposing to the development of these lesions. A new technique that may improve tactile, and possibly proprioceptive, feedback is the application of noise to the plantar surface of the feet. By adding sub threshold electrical or mechanical noise (vibration with a randomly varying frequency) to a sub Threshold sensory input, the sensory threshold may be crossed.
Objective of the study: To compare the effectiveness of foot insoles and plantar tactile stimulation in improving balance, mobility and reduction of falls in diabetic peripheral neuropathy patients.
Methodology: study conducted on 100 adults with diabetic peripheral neuropathy participants were randomized to reserve planter tactile stimulation group A (n=50) and foot insole group B (n=50) to be ware for 12 weeks. The primary outcome measure functional advance balance scale with lower value indicating poor balance.
Results: it is observed Significant difference in FABS score among subjects of group A and group B subjects were observed at 1, 4, 8, and 12 weeks. ($P< 0.05$) thus in subjects of group A and group B the average difference in FABS score was not matched from 1 week to 12 weeks and more increase in FABS score was observed in group B as compared to group A.
Also significant increase in FABS score was observed in both the groups from the day of arrival till 12 weeks. ($P< 0.05$).
Conclusion: This study suggests that effectiveness of foot insoles and plantar tactile stimulation in improving balance, mobility and reduction of falls in people with Diabetic peripheral neuropathy.

Keywords: Foot insoles, planter tactile stimulation, diabetic peripheral neuropathy, balance, mobility, FABS

Introduction
Diabetes mellitus is a group of metabolic diseases resulting from defects in insulin secretion, insulin action, or both. Type I diabetes is caused by the autoimmune destruction of the insulin producing beta cells of the pancreas. Absolute insulin deficiency and a high propensity for ketoacidosis are the common characteristics. Type II diabetes (NIDDM) is caused by insulin resistance with an insulin secretory defect. Approximately 90-95% of all diabetics are Type II.

Diabetic neuropathy (DN) is a nerve damaging disorder associated with diabetes and one of the most common complications. This condition is thought to be result from micro vascular injury involving small blood vessels that supply to the nerve (vas nervorum) in addition to macro vascular condition that can culminate in diabetic neuropathy. Neuropathy frequently results in significant morbidities such as a pain, loss of sensation, foot ulcers, gangrene and amputations which is much feared sequel that results in hospitalizations.

Diabetic peripheral neuropathy, which involves damage to and dysfunction of peripheral nerves-starting at the extremities of the limbs, then progressing towards the torso. A loss of peripheral sensory function-and thus pain signaling-compounded by autonomic and neuromuscular complications increases the risk of foot ulceration due to trauma or repetitive loading of the plantar surface of the foot.

If left untreated, these ulcers can become infected-and due to reduced healing capacity, infected wounds can become gangrenous and lower-limb amputation may ultimately be required.

Pressures beneath the plantar surface of the foot are increased in the diabetic foot compared to healthy populations [10]. These increases in pressure are the result of a combination of morphological, muscular and sensory abnormalities. For example, clawing' of the toes is common among the diabetic population, as is the deformity known as hallux valgus [12]which arises in one-third of all patients with diabetes due to weakening of intrinsic foot musculature in the hallux region. These foot and toe deformities ultimately lead to localized increases in plantar pressure, particularly at the metatarsal heads. Crucially, there is a high correlation between elevated plantar pressure and foot ulceration.

The international recommendations for preventing diabetic foot ulcers includes the prescription of appropriate footwear (insoles and shoes), foot care, regular foot checks, and education. These preventive steps have been proven to have positive effects on patient

Quality of life and in reducing healthcare expenditure.

Information from the somatosensory, visual, and vestibular systems is used for the detection of postural changes, and attention plays a crucial part as well. The somatosensory system can be subdivided into the tactile and the proprioceptive systems. Feedback from both these systems plays a part in the control of balance. The tactile system provides the central nervous system (CNS) with information concerning the sense of touch. Mechanoreceptors such as Meissner's corpuscles, Pacinian corpuscles, Merkel's disks, and Ruffini endings are responsible for the detection of tactile input. Mechanoreceptors situated on the plantar side of the feet provide the CNS with information concerning the pressure distribution under the feet. During stance, shear stresses and changes in pressure are related to changes in the Centre of mass position, which are mediated by the plantar mechanoreceptors. Feedback concerning these changes is important for the maintenance of balance during standing. In persons with neuropathy, neither tactile nor proprioceptive information is conducted to the CNS with as much intensity as in persons without neuropathy. This reduction in somatosensory perception has detrimental effects on postural stability, resulting in an increased risk for falling. Appliances for the foot (which do or do not encompass the ankle) may compensate for these detrimental effects.

A new technique that may improve tactile, and possibly proprioceptive, feedback is the application of noise to the plantar surface of the feet. By adding subthreshold electrical or input, the sensory threshold may be crossed. In this way, a signal that is not detected during normal circumstances can be detected. The subthreshold noise signal can enhance the tactile sensation of changes in pressure under the foot, resulting in more sensitive detection of these pressure changes. More sensitive detection may result in an earlier reaction to the change in pressure, which may result in better balance performance. The mechanism by which signal detection is improved by noise is called stochastic resonance (SR).

Kastenbauer T (2004) conducted a study to investigate the predictive value of Rydel-Seiffer tuning fork and the results showed the tuning fork had a high sensitivity and positive predictive value for the diagnosis of symptomatic neuropathy. A tuning fork is a useful screening test for diabetic neuropathy.

However, there is a need for long-term studies in which the pressure redistribution capacities of different types of insoles are compared. There is also a need for a global consensus on how to interpret the results from in-shoe pressure measurement devices. Purpose of this study is to develop an effective rehabilitation and to compare effectiveness of plantar tactile stimulation and foot insoles to improve balance, mobility and reduce falls in diabetic peripheral neuropathy.

Insoles are piece of material that are placed inside your shoes or boots for extra comfort, warmth and better fit sometimes referred to as "foot beds" or "inner soles". The primary purpose of insoles is to make shoes more comfortable to wear. Secondary purpose to Increase patient sensation in planter area. Thus to improve balance and mobility.

Incidence of prevelane: Diabetes. India has over 60 million diabetics out of a population of 1.3 billion. In 2015, over 0.9 million deaths in India were attributed to diabetics directly or indirectly. The number of diabetics in the country is expected increase to a staggering 109 million cases by 2035 out of an estimated population of 1.5 billion.

In India, an estimated 7.8% of the population above 18 years of age has raised blood glucose level are on the treatment for diabetes. Risk factors most consistently associated with polyneuropathy in type 2 diabetes mellitus patients at population level were increasing age, duration of diabetes mellitus, height and poor glycemic control. India has one of the highest prevalence of type-2 diabetes mellitus in the world. It is estimated that by the year 2030 there will be nearly so million Indians with type-2 diabetes mellitus in the country. In India, peripheral neuropathy is compounded by poor foot hygiene, improper foot wear, frequent bare foot walking and noncompliance to medications

Need of the study

Purpose of this study is to develop an effective rehabilitation and to compare effectiveness of plantar tactile stimulation and foot insoles to improve balance, mobility and reduce falls in diabetic peripheral neuropathy.

Subject sustaining diabetic peripheral neuropathy and who were diagnosed with balance and mobility affected and on the risk of fall were included for study**.** The study samples were collected from community settings and hospitals from both inpatient and outpatient department as per the inclusion and exclusion criteria during the period 2017-19

Objectives of the study

- To evaluate the effect of plantar tactile stimulation in improving balance, mobility and reduction of falls in diabetic peripheral neuropathy patients.
- To evaluate the effect of foot insoles and plantar tactile stimulation in improving balance, mobility and reduction of falls in diabetic peripheral neuropathy patients.

Methodology

Study conducted on 100 adults with diabetic peripheral neuropathy participants were randomized to reserve planter tactile stimulation 30 repetitions each session and 3 session per day group A (n=50) and foot insole group B (n=50) to be ware 3 hours per day for 12 weeks. The primary outcome measure functional advance balance scale (FABS) with lower value indicating poor balance secondary outcomes measure functional gait assessment

The sample size of study is 100 subjects was obtained from independent Sample 't' test by the use of G power 3.1

software. The sample size were allocated of 50 subjects to group A (planter tactile stimulation group) & 50 subjects to group B (foot insole). The estimated power calculated was 0.80.

The data collected on 100 subjects as per the protocol of the study was analyzed using appropriate statistical techniques by the use of IBM SPSS statistic 24.0, SPSS South Asia of Pvt. Ltd. (www.spss.co.in). The statistical analysis involves Chi Square test of Association for the study of Age and gender distribution by groups. Independent sample t test for comparison of means of different characteristics such as mean age and also mean difference of 0 day-12 weeks for FABS score for both the groups. ANOVA was used to compare the means of more than 2 variables.

Inclusion criteria

- Diabetic patients both male and female with age group of 40-60 years.
- Ability to walk unaided.
- No present foot ulcers.
- Altered foot sensation.

Exclusion criteria

- Tubercular neuropathy
- Drug induced neuropathy
- Neurological abnormalities
- Ulcerations/infections on plantar aspect of feet.
- Toe or foot amputation
- Severe visual impairment.

Materials

- Foot insoles.
- Tuning fork
- Stopwatch
- Pencil
- 2 and 36 inch rulers
- 6 inch high bench (18'X18' stepping surface)
- Masking tape
- 2 Airex® pads
- A Marked 6-m (20ft) walkways that is marked 20.48cm (12in) in width.
- Step or shoe box
- Stairs

In the total sample of 100 subjects, 29% were in age group 40-45 years, 16% in 45-50 years, 28% in 50-55 years and 27% in 55-60 years. The age distribution was compared with the help of Chi Square distribution for study of association.

The distribution of the sample subjects in the two groups were evenly matched as revealed by Chi Square test of independence.

Mean age of the 50 subjects undergone Plantar Tactile Stimulation was found to be 49.02 years with SD to be 6.07 and among 50 subjects undergone foot insole it was found to be 49.88 years with SD 6.05.

Statistically Insignificant difference in age was observed between group with Plantar Tectile Stimulation and foot insole (P>0.05) and thus two groups are matched in terms of age distribution

Patient belonging to foot insoles had more improvement in balance and mobility reduce risk of fall in FABS (Fullerton advance balance scale) score as compared to planter tactile stimulation in FABS (Fullerton advance balance scale) score.

Gait pattern of high FABS score patient shows better improvement in balance and mobility and reduce risk of fall in patient treated with foot insoles than the score of planter tactile stimulation group of patients after 12 weeks of treatment session

Results: it is observed Significant difference in FABS score among subjects of group A and group B subjects were observed at 1, 4, 8, and 12 weeks. (P< 0.05) thus in subjects of group A and group B the average difference in FABS score was not matched from 1 week to 12 weeks and more increase in FABS score was observed in group B as compared to group A.

Also significant increase in FABS score was observed in both the groups from the day of arrival till 12 weeks. (P< 0.05)

Mean age of the 50 subjects undergone Plantar Tactile Stimulation was found to be 49.02 years with SD to be 6.07 and among 50 subjects undergone foot insole it was found to be 49.88 years with SD 6.05.

Statistically Insignificant difference in age was observed between group with Plantar Tactile Stimulation and foot insole Shoe Insert (P>0.05) and thus two groups are matched in terms of age distribution

In Group A, Mean age of the 25 male subjects was found to be 47.96 years with SD to be 6.09 and among 25 female subjects it was found to be 50.08 years with SD 5.97.

Statistically Insignificant difference in age was observed between male and female of group A (P>0.05) and thus male and females of group B are matched in terms of age distribution presented it was observed that there was insignificant difference in FABS score in male and female subjects on the day of arrival. (P>0.05) and also insignificant difference in FABS score between male and female subjects was observed at 1, 4, 8 and 12 weeks. (P>0.05). Thus male and female of Group B are matched according to FABS score.

This showed that in Group A the average difference in FABS score was matched in females and males from 0 day to 12 weeks it was observed that there was insignificant difference in FABS score among subjects of Group A and Group B on the day of arrival. (P > 0.05) which showed that in subjects of Group A and B the average difference in FABS score was matched on 0 day. But significant difference in FABS score among subjects of Group A and Group B subjects was observed at 1, 4, 8 and 12 weeks. (P< 0.05) thusin subjects of Group A and B the average difference in FABS score was not matched from 1 week to 12 weeks and more increase in FABS score was observed in Group B as compared to Group A.

Also significant increase in FABS score was observed in both the groups from the day of arrival till 12 weeks. (P < 0.05)

Our study demonstrated that daily use of foot insoles shoe is practical, feasible and improves motor performance in people with DPN. To our knowledge this is the first trial that examined therapeutic effectiveness of daily home use of foot insoles of shoe No adverse events were reported due to daily use of foot insole no complain was reported from the daily home use of foot insole.

Patient belonging foot insole had more improvement in balance and mobility reduce risk of fall in FABS (Fullerton advance balance scale) score as compared planter tactile stimulation in FABS (Fullerton advance balance scale) score.

Gait pattern of high FABS score patient shows better improvement in balance and mobility and reduce risk of fall in patient treated with foot insoles than the score of planter tactile stimulation group of patients after 12 weeks of treatment session

Discussion

In the findings of present study, there was significant increase in FABS score was observed in both males and females from the day of arrival till 12 weeks and our result findings FABS score more increase in Group B (foot insole) as compared to Group A (Plantar Tactile Stimulation)

Our study demonstrated that daily use of foot insoles is practical, feasible and improves motor performance in people with DPN. To our knowledge this is the first trial that examined therapeutic effectiveness of daily home use of foot insoles of shoe No adverse events were reported due to daily use of foot insole no complain was reported from the daily home use of foot insoles.

While many studies suggested that planter tactile stimulation is effective to enhance balance. Plantar tactile stimulation in enhancement of motor performance, vascular health, and plantar sensation in patients suffering from DPN and poor plantar sensation.

This study confirmed that daily basis use of foot insole shoe could be effective to enhance plantar sensation as quantified by significant increase in FABS score was observed in both males and females of Group B from the day of arrival till 12 weeks.

This is aligned with previous study in which it has been revealed that neurological stimulation could improve the performance of mechanoreceptor cells that provide protective sensation in the feet. Previous clinical studies have also demonstrated significant reduction in vibration perception threshold and an increase in monofilament detection after electrical stimulation treatment in people with DPN. The recovery of plantar sensation could be explained by improvement in plantar skin perfusion in response to daily use of foot insoles. Diminished local blood flow can initiate oxidative stress and the release of factors that impede the normal passage of neurological signals as described by Malik and colleagues. A recent systematic review by assessing 21 randomized clinical trials that used electrical stimulation for wound healing confirmed that electrical stimulation increases cutaneous perfusion possibly through a release of vasoendothelial growth factor

The increase in FABS may counter the pathways to DPN through stimulation of angiogenesis for increase perfusion of endoneurial microvessels. In addition, FABS has been shown to induce Schwann cell proliferation, stimulate axonal outgrowth and promote survival of neurons and Schwann cells in cultured animal cells.

If a person loses vibratory sensation first? It would mean that the muscle spindle-detecting stretch of the tendons would be attenuated, which can have an effect on steadiness of gait and on reaction to unanticipated terrain. Can that affect the firing of the various muscles during the gait cycle? It certainly would tend to slow the velocity of gait, increasing the time and decreasing propulsion.

Since motor nerve fibers are also large myelinated fibers, it would be logical to assume that any neuropathy that affects the vibratory senses could also indicate onset of motor neuropathy. It is well-documented that sensory neuropathy is also accompanied by autonomic neuropathy and motor neuropathy. The body's own natural reducer of pressure is the fat pad under the heel and under the metatarsal heads. One may also include the fat pads under parts of the toes as well. These fat pads are made up of tiny collagen fibers, most of which are vertical, interlaced together like a closed net with fat globules in the spaces.

Because the collagen fibers create closed cells for the fat globules, when pressure is placed on the closed cell, hydraulic pressure is created within the cell in all directions.

Pressure is placed on the cell above it and also on all the cells adjoining the sides. Each of these cells then puts pressure sideways and upwards, and the process proceeds outward. the insole must push back.

The more that the foot insole is compressed, the more it is able to push upward. Therefore, the portions of the insole into which the greatest indentation is made will still be pushing back against the plantar foot harder than the areas that have less indentation. This means that foam materials do indeed spread out the force under the foot, but it is very difficult to do so in an even manner. Therefore, soft and cushiony insoles are only mildly effective in alleviating pressure Points on the bottom of the foot. The most prominent plantar prominences still have more pressure being placed against them than the less prominent prominences.

Poor postural balance is a major concerns in people with DPN and leads to increasing risk of falling, reduced mobility, and increased fall concerns. This study suggests that daily use of foot insoles, could enhance balance and gait, thus may reduce risk of falling and enhance motilities.

Interestingly, the magnitude of improvement in balance after 12 weeks of daily use of foot insoles is comparable with magnitude of improvement in balance post–balance exercise therapy program among people with DPN.

Conclusion

This study suggests opportunities for better patient care, enhancement of plantar sensation, and improvement of motor performance among people suffering from diabetic peripheral neuropathy using foot insoles that has no obvious adverse effects. This study suggest that effectiveness of foot insole and planter tactile stimulation both technique in improving balance, mobility and reduction of falls in diabetic peripheral neuropathy patients Thus, from all the above results it is concluded that the effectiveness of foot insole more effective as compared to planter tactile stimulation in improving balance, postural stability during various walking tasks, mobility and reduction of falls in diabetic peripheral neuropathy patients.

Limitation of the study: This study has few limitations. The sample size is underpowered to detect changes in vascular health, activity parameters, and psychosocial parameters. In addition, we had not observed between groups differences were observed at baseline for the parameters of interest, suggesting successful randomization of participants.

Further scope of the study: Further studies with larger sample size and better randomization protocol are required to confirm these results and address potential long term retention of planar electrical stimulation intervention. According to participants' log report, they had 100% adherence in daily use of the system during treatment phase. The log of the SENSU system also confirmed the system was activated on daily basis.

In addition, other studies examine long term benefit of different type of foot insole shoe in particular among those with peripheral vascular diseases. In addition, other studies are warranted to examine long term benefit of different type of foot insole specially vibrothotic vibrating shoe insert stimulation to reduce consequences of DPN such as prospective falls and prevention of plantar ulcers.

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