Neuromuscular Taping Decompression Technique in Diabetic Painful Distal Symmetrical Polyneuropathy: The Impact On Pain Intensity in a randomised trial

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Research Article

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Abstract

This study aims to assess the effects of neuromuscular taping decompression technique (NMT) to modify pain scale in diabetic patients with painful distal symmetrical polyneuropathy and was conducted at Wahidin Sudirohusodo Hospital, Makassar, Indonesia. The study design used a pure experimental design with the pre-test and post-test control group method, where samples were collected using a consecutive sampling technique. 30 patients with diabetic painful distal symmetrical polyneuropathy were studied consisting of 15 treatment and 15 control subjects. The treatment group received a specific decompression NMT application over the dorsal and plantar aspect of the foot, bilaterally, 2 times a week for 4 weeks together with vitamin B complex oral supplementation. While a control group only received vitamin B complex.

Mann-Whitney test, showed a significant (p <0.05) improved pain scale in the treatment group at day 28, and the average NPRS value of the treatment group was lower than the control.

This study has shown a significant effect of NMT decompression technique in reducing pain in Diabetic Painful Distal Symmetrical Polyneuropathy patients. Pain is the major debilitating aspect that negatively influences DM patient mobility and quality of life. The combination of vitamin B1 (100mg), B6 (100mg) and B12 (5000mcg) supplementation and a specific NMT treatment application repeated 8 times over 28 days (5 treatments over 17 days to achieve minimum effective time) to reduce the mean value of NPRS pain scale to 0 (p<0.05). Trial results indicate a possible treatment cycle of 2 NMT1 treatments a week for 4 weeks to significantly reduce pain to mean value 0 in combination with vit. B supplementation. Treatment time was calculated 5-8 min with a tape cost for 50cm approx USD 0.50 per treatment.

Introduction

Diabetic neuropathy (ND) is a disorder of the peripheral, autonomic and cranial nerves that are associated with DM. This condition is caused by microvascular damage caused by diabetes which includes small blood vessels providing blood supply to peripheral nerves, specifically to interior parts of nerves and their coverings (vasa nervorum). These neuropathic disorders include somatic and/or autonomic manifestations of the peripheral nervous system [1]. ND is the most common microvascular complication of diabetes mellitus (DM), where diabetic neuropathy affects various parts of the nervous system and displays diverse clinical manifestations[2]. In the United States, it is estimated that 50% of patients with DM have ND and 2.7 million suffer from diabetic neuropathic pain (NND) [3]. Painful diabetic neuropathy (P-DPN) is stated to affect up to one-third of the general diabetic population[4]. It is estimated that 15% of people with diabetes have diabetic feet and is a major cause of non-traumatic foot amputation. ND is a complication of DM type I and II that requires constant medical interventions and in America, it is estimated that it costs more than 10.9 million USD [5].

David Blow, Australian acupuncturist and practitioner of traditional Chinese medicine, founder of Taping NeuroMuscular Institute in 2003 developed a taping concept of differentiating decompression and compression techniques known as (NMT) Neuromuscular Taping [6]. This specific methodology creates the formation of folds on the skin (wrinkling) which is increased when the body is moving or during specific exercise. This wrinkling and non-wrinkling action created by the tape is known to facilitate lymphatic drainage and improve blood flow, including at the vascular level through its superficial pumping mechanism. In addition, this type of taping application causes mechanical stimuli (reduction of mechanoreceptor pressure) which will alter the transmission of pain stimuli due to the excitation of Aβ fibers in the inhibitory neurons of the substantia
gelatinosa of Rolando (SGR) in the posterior horn of the spinal cord so that it can prevent the transmission of pain signals. Certain NMT applications acts as a mechanical stimulus in Gate Control Theory while also repairing neurons through enhancing fluid exchange nourishing the vasa nervorum[7].

One of the theories of occurrence of diabetic neuropathic pain is due to the accumulation of sodium channels at the location of damaged nerves, especially along nerve axons, causing ectopic electrical discharges and hyperexcitability. Increased electrical impulses to the dorsal horn and triggering changes in the mechanism Gate Control Theory (GCT) and expression of substance P as a pain mediator. As disclosed in 1960s by Melzack and Wall, neurons in the substantiagelatinosa of Rolando serves as the gate, which can be closed or open, facilitate or inhibit pain impulses. Where neurons in SGR function as pain inhibitors when transmitted by large nerve fibers, namely Aβ fibers. On the other hand, if the Aδ and C nerve fibers transmit pain, the pain inhibitory neurons will be inhibited so they cannot block the transmission of pain signals to the thalamus and cerebral cortex, resulting in pain perception[6]. Even though it has been showed that exercise is an effective therapy for DM it has not been showed to be effective for P-PDN this study aims to verify if a mobility activated taping application may influence neuropathy pain.

To our knowledge there has been no previous study on the action of NMT and P-DPN. NMT has been recently studied in its capacity to improve diabetic ulcer healing capacity using Bates-Jensen Wound Assessment Tool[8] and to reduce pain and impaired physical mobility in cases including foot problems of athletes, multiple sclerosis, cerebral palsy hemiplegia, post-stroke upper limbs, shoulder pain and Joint Hypermobility Syndrome[9]. A case report has indicated that NMT was able to affect the modulation of micro Ribonucleic Acids (miRNAs) in a multiple sclerosis patient during the rehabilitation phase[10].

**Methods**

The research design used in this study was purely experimental with the method pre-test and post-test control group design conducted at the Wahidin Sudirohusodo Hospital, Makassar, Indonesia. The study population was all type II DM patients suffering from diabetic neuropathy. Samples were collected using consecutive sampling technique by medical staff independent to the treatment process with a total sample size of 30 people, where the treatment group consisted of 15 people and the control group consisted of 15 people (figure 1).

Inclusion criteria covers patients diagnosed with type 2DM, Aged between 18-75 years, DNS score min. 1 and expressing no objection to inclusion in the study. Exclusion criteria covers patients with chronic kidney disease, chronic liver disease, HIV/AIDS infection and Morbus Hansen, DM patients with trap neuropathy, cancer malignancy, patient history of exposure to toxins, pesticides, mercury, organophosphates, lead, and alcohol use, open wound/sores at the site of attachment (including diabetic ulcers), skin infection in the treatment site, signs of deep vein thrombosis and/or phlebitis, melanoma and warts in the treatment site, consumption of pain medication within 48 hours prior to screening/treatment. Samples are declared out of the study or drop out (DO), if during the study the patient does not follow the taping treatment according to their schedule, there is allergy or irritation due to the tape application, taking pain relievers during treatment, patient death, discontinue due to other reasons.

At the time of screening, the researcher gave an explanation of the research and treatment procedure. If the patient meets the inclusion criteria, and is willing to participate in the study, the patient is asked to sign a letter of consent to follow the research procedure, witnessed by family members. Patients recruitment between July and November 2019.
Pain scale was assessed using the NPRS (day 0). In the treatment group, NMT was applied using a decompression technique (NMT1 procedure). The NMT1 procedure was performed by a medical practitioner certified and trained in the NMT methodology and changed 2 times a week for 4 weeks. Bilateral application and the patient was advised to keep the tape on the foot between appointments and the tape was removed, the skin cleaned prior to the next application. Vitamin therapy was given to both treatment and control group; B complex, B1 (100mg), B6 (100mg) and B12 (5000mcg) tablets once a day. In the control group, no NMT was applied. Pain scale was assessed using NPRS on days 4,7,10,14,17,21,24,28.

*NMT1 application procedure*

Tape was applied on both the dorsal and plantar aspect of the foot. Dorsal application required tape cut into single strips 6mm in width and 30-35 cm in length. The foot was placed on the edge of the treatment table with the foot in maximum plantar flexion up to the pain threshold. The 6mm wide tape was applied at the base of the large toe nail and applied in the direction of the foot extensors lateral to the tibia. Tape has elastic properties and is detached from the backing paper and applied without any tension (known as zero stretch). Assuring that no tension was applied to the tape, the length of the tape adhered to the skin must be shorter than the length of the backing paper. Tape was applied to each of the toes in a longitudinal direction following the same procedure with increasing foot inversion from the 2nd to the 5th toe. Once completed the foot is placed in a neutral position and the tape/skin wrinkling is evident.

Plantar application required tape cut into single strips 8mm in width and 20-25 cm in length. The foot was placed on the edge of the treatment table with the foot in maximum dorsiflexed position respecting the pain threshold. The 8mm wide tape was applied at the base of the large toe pad and applied in the direction of the heel. Tape has elastic properties and is detached from the backing paper and applied without any tension (known as zero stretch). Assuring that no tension was applied to the tape, the length of the tape adhered to the skin must be shorter than the length of the backing paper. Tape was applied to each of the toes in a longitudinal direction following the same procedure from the 2nd to the 5th toe. Once completed the foot is placed in a plantar flexed position and the tape/skin wrinkling is evident.

**Results**

The number of samples that met the inclusion criteria were 30 people, consisting of 15 treatment samples and 15 control samples, and 2 samples were declared drop out (DO). Age distribution was 43-71 years old, with a mean age of 59.87 years for the treatment group and 57.01 for the control group. The treatment group consisted of 44.4% male and 52.4% female and the control group consisted of 55.6% male and 47.6% female. DM <5 years consisted of 33.3% in the treatment group and 66.7% in the control group. Meanwhile, those suffering from DM ≥ 5 years consisted of 51.9% of the treatment group and 48.1% of the control group. HbA1C levels <7 consisted of 33.3% in the treatment group and 66.7% in the control group. Meanwhile, those with HbA1C levels 7 consisted of 51.9% in the treatment group and 48.1% in the control group.
Table 1. Characteristics of the sample by gender, education, occupation, duration of diabetes mellitus, HbA1c levels.*Chi-Square Test. Source: Primary Data

No significant difference (p <0.05) between the treatment and control groups based on gender (p= 0.690), education (p= 0.813), duration of suffering from diabetes (p = 0.543), and HbA1c levels (p = 0.543). However, occupation appeared to have a significant difference between the groups (p = 0.05). No significant difference due to age between the treatment sample and the control sample(p= 0.310).

Table 2. Characteristicsof sample by age.*Mann-Whitney test. Source: Primary Data

Pain Scale Analysis (NPRS) on day 0 showed both the treatment and control group had a minimum value of 3, a maximum of 7 median 5.0 which were not statistically significantly different, p > 0.05 (table 3).
<table>
<thead>
<tr>
<th>Group</th>
<th>NPRS</th>
<th></th>
<th></th>
<th></th>
<th></th>
<th>p-score</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N</td>
<td>Min</td>
<td>Max</td>
<td>Median</td>
<td>Mean</td>
<td>Standarddeviation</td>
</tr>
<tr>
<td>Visit</td>
<td>Treatment</td>
<td>15</td>
<td>3</td>
<td>7</td>
<td>5.0</td>
<td>5.0</td>
</tr>
<tr>
<td></td>
<td>Control</td>
<td>15</td>
<td>3</td>
<td>7</td>
<td>5.0</td>
<td>4.73</td>
</tr>
</tbody>
</table>

**Table 3.** Analysis pain scale (NPRS) on day 0.* MannWhitney test. Source: Primary Data 2019

NPRS value on the 28 day visit in the treatment group had a minimum value of 0, a maximum of 1 and a median of 0.0. Meanwhile the control group had minimum value of 0, maximum of 3, and median of 2.0, statistical test p <0.05 (table 4).

<table>
<thead>
<tr>
<th>Test Group</th>
<th>NPRS</th>
<th></th>
<th></th>
<th></th>
<th></th>
<th>p-score</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N</td>
<td>Min</td>
<td>Max</td>
<td>Median</td>
<td>Mean</td>
<td>Standarddeviation</td>
</tr>
<tr>
<td>Visit</td>
<td>Treatment</td>
<td>15</td>
<td>0</td>
<td>1</td>
<td>0.0</td>
<td>0.13</td>
</tr>
<tr>
<td>H28</td>
<td>Control</td>
<td>15</td>
<td>0</td>
<td>3</td>
<td>2.0</td>
<td>2.13</td>
</tr>
</tbody>
</table>

**Table 4.** Numerical Pain Rating Scale (NPRS) on the last visit day (H28).* Mann Whitney test. Source: Primary Data 2019

Both the treatment and control group showed a significant reduction NPRS over the 28 days (p<0.05), graph 1. The treatment group showed a significantly increased pain reduction (p<0.001)

Table 5 shows a statistically difference (p<0.001) in the average effect of pain scale reduction (NPRS) between the treatment group and the control group, where the treatment group had a higher average decrease of 4.87±1,246 while the control group was only 2.6±1,454.
<table>
<thead>
<tr>
<th>Group</th>
<th>NPRS</th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th>p-score</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N</td>
<td>Min</td>
<td>Max</td>
<td>Median</td>
<td>Mean</td>
<td>Standarddeviation</td>
<td></td>
</tr>
<tr>
<td>Average</td>
<td>Treatment</td>
<td>15</td>
<td>3</td>
<td>7</td>
<td>5.0</td>
<td>4.87</td>
<td>1.246</td>
</tr>
<tr>
<td>Control</td>
<td>15</td>
<td>1</td>
<td>5</td>
<td>3.0</td>
<td>2.6</td>
<td>1.454</td>
<td></td>
</tr>
</tbody>
</table>

*Table 5. Analysis of the average decrease in pain scale (NPRS Day0-Day28) between treatment and control groups. *T-test. Source: Primary Data*

<table>
<thead>
<tr>
<th>GROUP</th>
<th>Average NPRS Day0-day28</th>
<th>Comparison</th>
</tr>
</thead>
<tbody>
<tr>
<td>Treatment</td>
<td>4.87</td>
<td>1.87</td>
</tr>
<tr>
<td>Control</td>
<td>2.6</td>
<td></td>
</tr>
</tbody>
</table>

*Table 6. Comparative analysis of the average decrease in pain scale (NPRSDay0-Day28) between treatment and control groups.*

From table 6 it can be concluded that the average decrease in pain scale (NPRS H0-H28) of the treatment group was 1.87 ≈ 2 times greater than the control group.

No patient indicated an allergic reaction or skin irritation to the tape application.

**Discussion**

The numbers of samples that met the inclusion criteria were 30 DM patients, consisting of 15 treatment samples and 15 control samples, with a sample age distribution of 43-71 years and mean age of 59.87 years for the treatment group and 57.01 for the control group. The treatment group consisted of 44.4% male and 52.4% female and control group consisted of 55.6% male and 47.6% female. The percentage of samples suffering from DM <5 years consisted of 33.3% of the treatment group and 66.7% of the control group. Meanwhile, those suffering from DM ≥ 5 years consisted of 51.9% of the treatment group and 48.1% of the control group. The percentage of samples that had HbA1c levels <7 consisted of 33.3% of the treatment group and 66.7% of the control group. Meanwhile, those with HbA1c levels ≥ 7 consisted of 51.9% of the treatment group and 48.1% of the control group.

The demographic characteristics of this research sample appear to be homogeneous. This can be seen from the absence of significant differences between the treatment sample and the control sample based on gender (p= 0.690), education (p= 0.813), duration of diabetes mellitus (p= 0.543), HbA1c levels (p= 0.543) and age (p= 0.310). However, based on occupation, the samples between the treatment and control groups appeared to have a significant difference (p< 0.05).
On visit day 0 it was found that the treatment group had an NPRS with a minimum value of 3, a maximum of 7 median 5.0, while the control group had a minimum value of 3, a maximum of 7 and a median of 5.0, which were not statistically significantly different (p > 0.05). NPRS value on day 28, the treatment group obtained a minimum value of 0, a maximum of 1 and a median of 0.0. While the control group had a minimum value of 0, a maximum of 3 and a median of 2.0, indicating a better pain scale improvement than the control group (p < 0.05). In this study, the pain scale (NPRS) over the 28 day trial showed reduced pain in both Diabetic Painful Distal Symmetrical Polyneuropathy patients groups (p<0.05). Hakim, in 2018, examined the administration of vitamin B complex in diabetic neuropathy patients significantly reducing pain scale and DM associated symptoms[11]. The effect vitamin B1, B6, B12 supplementation in diabetic neuropathy in pain reduction and nerve regeneration has been recently documented [12], [13]. This study through the comparison analysis of the mean pain scale indicated that a combination of treatments were able to reduce the mean pain scale (p<0.05) to 0 over the first 17 days treatment (5th application of NMT1) graph 1. In addition, this study showed a difference in the mean reduction in NPRS pain scale (p<0.05) between the diabetic painful DSPN treatment group (4.87±1.246) and the control group (2.6±1.454) concluding that the combination of the NMT decompression technique accompanied by vitamin B complex supplementation achieved a pain scale reduction 2 times greater. This difference proved to be statistically significant (p<0.05), table 5. The results seem to support the hypothesis of NMT decompression technique action, in that mechanical stimulus of skin folds which are formed by the tape application increases interstitial space and decreases skin compression assisting in fluid exchange in the treatment area. Improved fluid exchange in a diabetic foot will result in plasma rich in vitamin B arriving at the target area and metabolic return assisting in repairing neurons through the vasa nervorum. In a recent study NMT applications in decompression improving microvascular circulation has been hypothesised as being the mechanism of action for improved diabetic ulcer healing capacity [8]. Other studies have indicated NMT induced vascular modification in systemic sclerosis patients reducing Raynaud’s phenomenon[14] while in another study reduction of blood pressure in systemic arterial hypertension was studied through the application of decompression taping [15]. Simultaneous, reduced compression over the larger area will interfere with the transmission of pain stimuli due to the excitation of Aβ fibers in the inhibitory neurons of Rolando's substantia gelatinosa in the posterior horn of the spinal cord so that it can prevent the transmission of pain signals[7], [16], [17].

Limitations and Disadvantages of research

NeuroMuscular Taping elastic decompression methodology is a relatively new treatment modality and this study is the first discussing the effect of NMT on diabetic neuropathic pain. Limitations in this study is that the severity of DSPN was not differentiated through Nerve Conduction Study (NCS) while sural nerve conduction velocity (SNCV), sural nerve action potential (SNAP) and vibration perception threshold (VPT) testing would investigate potential nerves benefits. Vascular testing through cardiovasculautonomic reflex, Valsalva test, Capillaroscopy investigating foot capillary architecture and orthostatic hypotension. Furthermore we advise further testing using QoL questionnaires to evaluate pain reduction and quality of life issues. Future studies will assess results over a longer follow-up period from 1 to 6 months further creating result evidence in creating treatment prognosis background.

Conclusion

This study has shown a significant effect of NMT decompression technique in reducing pain in Diabetic Painful Distal Symmetrical Polyneuropathy patients. The combination of vitamin B1 (100mg), B6 (100mg) and B12 (5000mcg) supplementation and a specific NMT treatment application repeated 8 times over 28 days (5 treatments over 17 days to achieve minimum effective time) to reduce the mean value of NPRS pain scale to 0
(p<0.05). Trial results indicate a possible treatment cycle of 2 NMT1 treatments a week for 4 weeks to significantly reduce pain to near 0 in combination with vit. B supplementation. While expected "no pain" results will be achieved after 5 treatments over 17 days. These results further indicate that the combination of NMT1 and vit. B reduced pain 2 times faster than B complex vitamin alone. NeuroMuscular Taping is considered a low cost non pharmacological intervention based upon precise application procedures done by medical staff correctly trained. Treatment time was calculated 5-8 min with a tape cost for 50cm approx USD 0,50. Continuous pain is one of the major debilitating aspects that negatively influences DM patient mobility and quality of life.

Declarations

- Research trial registered Wahidin Sudirohusodo Hospital, Makassar, Indonesia
- Ethics approval and patient consent to participate obtained.
- Full trial protocol, ethics approval, patient consent documentation, patient outcome data are available from the corresponding author.
- Competing interests
  - The authors have not been paid to write this article nor are in any way dependent on any pharmaceutical/medical device company. The authors have received no financial funding for this study.
  - David Blow is author of NeuroMuscular Taping: from theory to practice and NeuroMuscular Taping: treatment of edema, bruising and scarring.

References


Figures
Figure 1

Study participant flow chart. Two participants dropped out (The 1st participant cannot continue the treatment in 2nd weeks because she must to back to her town. The 2nd participant cannot continue the treatment because on the 2nd week, she suffered dislocation of left ankle after fall into the pit.

Supplementary Files

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- Additionalimages.docx