Effects of transcutaneous auricular vagus nerve stimulation (tVNS) on balance in patient with chronic lower back pain

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ABSTRACT

Background: tVNS is a technique of electrical stimulation of vagus nerve afferents that is used as a therapy for chronic pain. This study to analyze the effect of adding tVNS to exercise therapy on dynamic balance in chronic LBP patients measured by Maximized Reach Distance (%MAXD) and composite score of Modified Excursion Balance Test (MSEBT).

Method: an experimental study with a pretest-posttest randomized controlled group study. 22 people with mechanical chronic LBP aged 16-55 years who were randomly allocated into an exercise group (control group) and an exercise plus tVNS group (intervention group). MSEBT dynamic balance was measured before and after intervention.

Results: In the intervention group the average. MSEBT anterior right and left leg before (74.57± 14.72;73.53 ± 15.0) after (86.45± 15.98;86.98 ± 15.9), posteromedial right and left before (88 .23 ± 16.76; 75.15 ± 15.04) after (99.65 ± 14.56, 92.19 ± 11.91), right and left posterolateral before (76.66 ± 13.89, 78, 02 ± 13.44) after (84.00 ± 17.25, 84.30 ± 13.90) there was a significant difference ($p<0.05$). Comparison of anterior ∆MSEBT, right composite score and left posteromedial posterolateral ∆MSEBT between groups, there was a significant difference ($p<0.05$) and not significant in right posteromedial posterolateral ∆MSEBT.

Conclusion: The addition of tVNS to exercise therapy after 2 weeks on dynamic balance with MSEBT assessment showed a significant improvement in the intervention group. The results were better in the intervention group than in the control group. Further research is still needed to investigate the potential of adding tVNS to chronic LBP.

Keywords: Chronic Low Back Pain, Transcutaneous Auricular Vagus Nerve Stimulation, exercise therapy, balance, Modified Star Excursion Balance Test (MSEBT)

Abbreviations: American College of Sports Medicine (ACSM), Corona virus disease (COVID-19), Food and Drug Administration (FDA), Hamilton Depression Rating Scale (HDRS), Low back pain (LBP), Maximized Reach Distance (%MAXD), minimum detectable change (MDC), Modified Excursion Balance Test (MSEBT), Numeric Pain Rating Scale (NPRS), Transcutaneous electrical nerve stimulation (TENS) Transcutaneous Auricular Vagus Nerve Stimulation (tVNS), The Star Excursion Balance Test (SEBT),

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INTRODUCTION

Low back pain is a musculoskeletal problem and the main cause of activity limitations which then results in disability and decreased quality of life. According to data from the Global Burden of Disease Study from 1990 to 2019, disability associated with low back pain increased in all age groups, highest in the 50-54 year age group, where around 70% of years lived with disability (YLDs) were found in the working age group (20-65 years). The number lower back pain case in Indonesia is not known for certain, but it is estimated to be between 7.6% and 37% [1]. The prevalence of LBP in Asia was 58.1%[2]. Healthcare professionals have a higher risk of suffering LBP than other industrial workers and adult women who have a high body mass index are likely to experience LBP[3].

The prevalence of chronic low back pain worldwide is 20.1% and has increased in the last 3 decades. Chronic low back pain is the second leading cause of disability in adults in the United States. Poor cure rates (58% at 1 month) and high recurrence (73% at 12 months) result in high socioeconomic costs. The percentage of adults in America who reported experiencing low back pain at least 1 day within 3 months was 26% [4].

Postural control has an important role in daily functional activities. The mechanisms underlying impaired postural control in low back pain are influenced by several factors. Pain can cause reduced proprioception. Trunk postural control depends on the interaction between sensorimotor information and motor output in the active zone (muscles, and control) and passive zone (bone and spinal ligaments). The central nervous system receives reduced proprioceptive information from spinal tissues due to impaired muscle recruitment. This causes disturbances in the centre of mass (COM) estimates. Mismatches between muscle responses and impaired postural control mechanisms contribute to postural instability. Core muscles such as the multifidus which is a stabilizing muscle will experience problems due to atrophy starting from 24 hours from the onset of low back pain which will develop into impaired proprioception and spinal stability. Postural control plays a role in spinal stability, posture, and movement. Decreased muscle strength and coordination contribute to decreased postural stability and neuromuscular con troll in chronic low back pain. Chronic low back pain is associated with trunk muscle weakness and reduced trunk muscle coordination resulting in decreased postural stability, balance and neuromuscular control. The greater the lumbar pain and disability, the more the individual will have poor static and dynamic balance [5][6].

The Star Excursion Balance Test (SEBT) is a simple tool that has been used to measure functional and dynamic balance. Several studies have used SEBT to detect dynamic balance disorders in LBP patient. The Star Excursion Balance Test (SEBT) is considered a challenging task for LBP patient. Therefore, SEBT can provide valuable information to clinicians regarding impaired postural control and movement strategies in people with LBP. A modified version of SEBT (MSEBT) was used to reduce potential fatigue effects and redundancy among the eight directions in the original SEBT. The MSEBT examination consists of three directions including anterior, posteromedial and posterolateral. The MSEBT examination has been shown to have excellent interrater reliability and strong intra-rater and test-retest reliability in detecting dynamic balance disorders[7].

Study regarding chronic pain and modalities for reducing chronic pain has developed a lot. One of them is the use of electrical stimulation modalities on the vagus nerve, known as trans auricular vagal nerve stimulation (tVNS). The anatomical target of tVNS is the outer ear which is innervated by the auricular branch of the vagal nerve with the most common placement being the anterior wall of the external acoustic meatus (tragus) and cymba conchae. The tVNS modality has inflammatory and pain modulating effects so it can be given as therapy for low back pain[5][6]. Addition of tVNS to exercise therapy has beneficial effects on lower extremity muscle strength and functional mobility in chronic LBP patients during relatively short period in two weeks of intervention[10]. Transcutaneous auricular vagus nerve stimulation reduce pain intensity and improved patient's quality of life in chronic low back pain[8][9]. It was well tolerated and no side effects were reported[10][11].

Studies regarding the effect of tVNS on balance in chronic low back pain is limited. This study aims to analyze the effect of adding tVNS therapy to exercise therapy on the balance of chronic low back pain.

Materials and methods

This research is a randomized controlled trial, open trial single blind, with pre-test and post-test design. The research was carried out at the Medical Rehabilitation Installation at Dr. Soetomo Surabaya on January 2022. This research received a certificate of ethical clearance from the Health Research Ethics Committee of Dr. Soetomo Surabaya Hospital with number 0411 / KEPK/ IV / 2022. The research subjects were chronic low back pain patient who visited medical rehabilitation polyclinic at RSUD Dr. Soetomo. Inclusion criteria in this study include 1) Male or female aged 18-55 years, 2) Diagnosis of non-organic mechanical chronic low back pain ≥ 3 months to ≤ 1 year without signs of red flags, 3) Numeric Pain Rating Scale (NPRS) pain score ≥ 4, and 4) Understanding and comprehending instructions.

Exclusion criteria in this study are: 1) Consuming analgesics other than paracetamol and NSAIDs or consuming new analgesics in the last 2 weeks, 2) Using other modalities in the last 1 week, 3) History of pain, trauma, and skin disorders (burns or open wounds) on the ear, 4) History facial pain, 5) Using metal implants including pacemakers, 6) Pregnancy, 7) History of heart disease (heart rhythm disorders, coronary heart disease), 8) History of neurological disorders (including seizures or epilepsy), 9) History of moderate to severe depression with a Hamilton Depression Rating Scale (HDRS) score ≥ 17, 10) History of vasovagal syncope, 11) History of metal skin allergies, 12) Dependence on alcohol and illegal drugs, 13) Communication disorders, 14) Grade II obesity (BMI ≥30 kg/m2 according to ASIA classification), and 15) Refuse to participate in the study. Criteria for dropping out of the test are 1) The research subject is not willing to continue the research for any reason, 2) The subject does not come for 2 scheduled training sessions, 3) The subject does not come for 3 scheduled stimulation times, and 4) The subject experiences allergies in the stimulation area that persists after stimulation is given.

Subjects were given information about the aims and objectives of the research. Subject are asked to sign a research consent form (informed consent) if they are willing to become research subjects. Data collection on subject characteristics (name and age), subjective examination (anamnesis) and physical examination, as well as other examinations necessary to determine inclusion and exclusion criteria. Subjects were given an explanation of the aims and objectives of the research as well as examination procedures. If the subject is willing, the subject is asked to sign a consent form to become a research subject. Subjects have the right to resign and fill out a resignation form. Data on subject characteristics were collected. Screening was also carried out using the COVID-19 risk Self-Assessment Instrument issued by the

Indonesian Ministry of Health. If the subject has a high risk of exposure to the COVID-19 virus, the subject is referred to health services. To reduce bias, single blinding will be carried out where the control and intervention groups will be allocated to two different places.

The treatment group received Transcutaneous Auricular Vagus Nerve Stimulation (tVNS) 5 times per week for 2 weeks and exercise therapy 2 times per week for 2 weeks, while the control group received exercise therapy 2 times per week for 2 weeks. Transcutaneous Auricular Vagus Nerve Stimulation (tVNS) is given with a stimulation dose frequency of 25 Hz, pulse width 250 μs, intensity according to patient tolerance, and a time of 20 minutes. The addition of Transcutaneous Auricular Vagus Nerve Stimulation with a frequency of 25 Hz to the intervention group was in accordance with recommendations from the Food and Drug Administration (FDA). Prescription of stretching and strengthening exercise therapy is also in accordance with the recommendations of the American College of Sports Medicine (ACSM)[6][12]. Control group only received exercise therapy for lower back pain includes breathing exercises, posture correction, core strengthening exercise with abdominal drawing in and cat and camel, and William flexion exercise with single – double knee to chest and pelvic tilt. The exercise led by a physiotherapist. For safety and correct implementation of stimulation, stimulation will be given by 2 doctors as researchers, and stimulation must comply with the stimulation protocol during the COVID-19 pandemic. During the program subjects are asked to fill out a stimulation monitoring card every time stimulation is administered to assist monitoring.

The Modified Star Excursion Balance Test (MSEBT) assessment was carried out before administering exercise and the first transcutaneous vagus nerve stimulation in the intervention group and before administering exercise in the control group. One day after the patient completes the last intervention, the subject will be reassessed for MSEBT. MSEBT measurements were carried out by one of the research members who did not know whether the subjects were in the control or intervention group.

Results and Discussion

The total research subjects were 22 subjects, who were divided into treatment groups (n=11) and control groups (n=11). In the treatment group, the sample size was 8 men (36.4%) and 3 women (13.6%). In the control group, the sample size was 9 men (40.9%) and 2 women (9.1%). The mean age of patients in the treatment group was 40.72 ± 10.68 years with an age range between 21-55 years, while in the control group it was 44.90 ± 10.07 years with an age range between 31-55 years. The mean body weight of the treatment group was 67.09 ± 11.97 kg with a body weight range of 52-86 kg, while the control group was 67.90 ± 14.80 kg with a body weight range of 50-93 kg. The mean height of the treatment group was 164.63 ± 8.64 cm with a height range of 150-177 cm, while the control group was 166.63 ± 9.26 cm with a height range of 144-178 cm. The mean BMI of the treatment group was 24.92 ± 3.59 kg/m^2 with a BMI range of 18.7-29.5 kg/m^2, while the control group was 24.84 ± 3.63 kg/m^2 with a BMI range of 19.4- 29.68 kg/m^2. The characteristics of the research subjects can be seen in Table 1.

Table 1. Characteristic of Subject

	Treatment Group (n = 11 subjects, 22 feet)	Control Group (n = 11 subjects, 22 feet)	*p-value*
Sex[1]			0.611

Male	8 (36.4%)	9 (40.9%)	
Female	3 (13.6%)	2 (9.1%)	
Age (years) [2]	40.72 ± 10.68	44.90 ± 10.07	0.356
Body Weight (Kilogram)[2]	67.09 ± 11.97	67.90 ± 14.80	0.888
Body Height (Centimeter)[2]	164.63 ± 8.64	166.63 ± 9.26	0.606
Body Mass Index (kg/m^2)[2]	24.92 ± 3.59	24.84 ± 3.63	0.961
Category of Body Mass Index			0.620
Normal	2 (9.1%)	4 (18.2%)	
Overweight	3 (13.6%)	2 (9.1%)	
Obese grade 1	6 (27.3%)	5 (22.7%)	
Right Leg Length (Centimeter)[2]	86.36 ± 4.92	84.36 ± 2.83	0.257
Left Leg Length (Centimeter)[2]	86.36 ± 4.92	84.36 ± 2.83	0.257
NPRS Pre-Intervention[2]	5.45 ± 1.12	5.81 ± 1.07	0.449
HDRS Pre-Intervention [2]	4.18 ± 4.06	3.36 ± 2.90	0.593
MSEBT ANT dextra Pre-Intervention[2]	74.57 ± 14.72	70.14 ± 13.79	0.476
%MSEBT PM Dextra Pre-Intervention[2]	88.23 ± 16.76	84.11 ± 11.93	0.514
%MAXD MSEBT Posterolateral Dextra Pre-Intervention[2]	76.66 ± 13.89	74.76 ± 16.65	0.775
Composite Dextra Pre-Intervention[2]	79.82 ± 13.22	76.34 ± 12.62	0.535
%MAXD MSEBT ANT Sinistra Pre-Intervention[2]	73.53 ± 15.01	70.40 ± 15.59	0.637

%MAXD MSEBT PM Sinistra Pre-Intervention[2] (%)	75.15 ± 15.04	82.56 ± 14.90	0.260
%MAXD MSEBT PL Sinistra Pre-Intervention[2] (%)	81.46 ± 14.90	76.80 ± 12.42	0.576
Composite Sinistra Pre-Intervention[2] (%)	76.72 ± 12.37	76.59 ± 13.22	0.961

Values are expressed as [1]sum (percentage) and [2]mean ± standard deviation. P-value is based on 1Chi-square test and 2Independent t-test. Significant if p-value <0.05

%MAXD MSEBT assessment was carried out at the beginning and end of each research group. In the treatment group, there was a significant improvement in anterior MSEBT of the right leg (p-value = 0.001) and left leg (p-value = 0.001), posteromedial MSEBT of the right leg (p-value = 0.001) and left leg (p-value = 0.001), as well as posterolateral MSEBT of the right leg (p-value = 0.00) and left leg (p-value = 0.001). There was also a significant improvement in the composite site MSEBT of the right leg (p-value = 0.00) and in the composite site MSEBT of the left leg (p-value = 0.001). In the control group, there was a significant improvement in anterior MSEBT in the control group both on the right leg (p-value = 0.001) and left leg (p-value = 0.001), posteromedial MSEBT of the right leg (p-value = 0.01) and left leg (p-value = 0.001). left (p-value = 0.001), as well as posterolateral MSEBT of the right leg (p-value = 0.001) and left leg (p-value = 0.001). There was also a significant improvement in the MSEBT composite on the right leg (p-value = 0.00) and left leg (p-value = 0.001). The MSEBT values for both sides of the leg between the treatment group and in the control group before and after intervention are shown in table 2.

Table 2. %MAXD MSEBT result before and after intervention.

	Treatment Group						Control Group					
	Right Foot (n = 11)			Left Foot (n = 11)			Right Foot (n = 11)			Left Foot (n = 11)		
	Pre	Post	*p-value*	Pre	Post	*p-value*	Pre	Post	*p-value*	Pre	Post	*p-value*
MSEBT ANT (%)	74.57 ± 14.72	86.45 ± 15.98	0.001*	73.53 ± 15.01	86.98 ± 15.98	0.001*	70.15 ± 13.79	76.91 ± 12.60	0.001*	70.40 ± 15.59	78.94 ± 12.90	0.001*
MSEBT PM (%)	88.23 ± 16.76	99.65 ± 14.56	0.001*	75.15 ± 15.04	92.19 ± 11.91	0.001*	84.11 ± 11.93	93.05 ± 13.39	0.001*	82.56 ± 14.90	90.94 ± 14.24	0.001*
MSEBT PL (%)	76.66 ± 13.89	89.26 ± 11.97	0.001*	81.46 ± 14.89	94.66 ± 11.51	0.001*	74.76 ± 16.65	84.00 ± 17.25	0.001*	78.02 ± 13.44	84.30 ± 13.90	0.001*
Composite MSEBT (%)	79.82 ± 13.22	91.79 ± 12.85	0.001*	76.72 ± 12.37	91.28 ± 10.37	0.001*	76.34 ± 12.62	84.66 ± 13.38	0.001*	76.99 ± 13.56	84.72 ± 12.53	0.001*

*Significant if $p < 0.05$. Abbreviations : ANT, anterior; PL, posterolateral; PM, posteromedial

The Modified Star Excursion Balance Test (MSEBT) difference was higher in the treatment group that received additional tVNS. There was a significant difference in the difference between the Modified Star Excursion Balance Test (MSEBT) before and after therapy, between the treatment group and the control group in the anterior and composite directions of the right leg as well as in the anterior, posteromedial, posterolateral and composite directions of the left leg (p-value > 0 .05). The difference values of MSEBT before and after giving exercise therapy to both sides of the legs of each group are shown in table 3.

Table 3. Δ %MAXD MSEBT result before and after intervention

	Treatment Group (n = 11)	Control Group (n = 11)	*p-value*	*Effect Size*
Δ %MAXD MSEBT ANT Dextra	11.88 ± 6.58	6.77 ± 4.52	0.046*	0.91
Δ %MAXD MSEBT PM Dextra	11.42 ± 3.86	8.94 ± 7.89	0.360	0,40
Δ %MAXD MSEBT PL Dextra	12.60 ± 3.60	9.24 ± 6.48	0.148	0,64
Δ Composite MSEBT Dextra	11.96 ± 2.47	8.31 ± 4.30	0.024*	1.04
Δ %MAXD MSEBT ANT Sinistra	13.44 ± 5.09	8.53 ± 4.73	0.030*	1.00
Δ %MAXD MSEBT PM Sinistra	17.03 ± 9.90	8.38 ± 6.90	0.027*	1.01
Δ %MAXD MSEBT PL Sinistra	13.20 ± 7.57	6.28 ± 2.90	0.010*	1.21
Δ Composite MSEBT Sinistra	14.56 ± 6.77	7.73 ± 2.98	0.006*	1.32

*Significant if $p < 0.05$. Abbreviations : ANT, anterior; PL, posterolateral; PM, posteromedial

The effect size of the difference in the Modified Star Excursion Balance Test (MSEBT) before and after administering tVNS therapy was calculated using Cohen's D. On the right leg, delta MSEBT showed an effect size of -0.91 (strong) in the anterior direction, -0.40 (low) in the posteromedial direction, -0.64 (moderate) in the posterolateral direction, and -1.04 (strong) on composite MSEBT. On the left leg, delta MSEBT showed an effect size of -1.00 (strong) in the anterior direction, -1.01 (strong) in the posteromedial direction, -1.21 (strong) in the posterolateral direction, and -1.32 (strong) on composite MSEBT.

Postural control is maintained by sensory information provided by the somatosensory, vestibular, and visual systems. Age is negatively correlated with MSEBT results for the posteromedial direction and composite scores for both legs. Both treatment and control groups are middle-aged group and it is expected to has normal ability to maintain postural stability[16]. There are some differences between the sexes in terms of proprioception, electromyographic activity, postural stability, and strength characteristics. Imbalances in strength, activation timing, and recruitment patterns of lower extremity muscles are more commonly seen in women. There were no differences in static and dynamic postural control between women and men; however, kinesiophobia and pain intensity during activity were more associated with impaired dynamic balance in women with chronic unspecified LBP than in men. Although existing evidence suggests that LBP affects the ability to control posture, there is little evidence of gender differences in posture control in people with chronic, nonspecific LBP[17].

In this study, the majority subject were obese grade I, 45.5% in the control group and 54.5% in the treatment group. People with obesity have a higher risk of balance disorders and falls. This is caused by several pathologies that occur in the body's systems, such as mechanical factors that cause lumbar lordosis and a shift in the center of gravity to the anterior as well as an increase in the inflammatory response that causes neurological disorders, neuropathy and proprioceptive disorders[18]. Body mass influences the MSEBT results. The heavier the body mass, the more it will influence the MSEBT measurement results[19]. Adolescents with obesity have dynamic balance disorders and these disorders can be corrected by providing balance training[18].

All study participants were had no depression (HDRS score 0-7) or mild depression (HDRS score 8-16). Depression and pain are interrelated and higher levels of depression have been associated with increased sensitivity to pain and functional disability. Depression is also associated with deficits in visual and proprioceptive integration that may impact sensorimotor task performance and fall prevention effectiveness and is associated with worsened balance in neurological conditions such as stroke or Parkinson's disease[20].

Patients with chronic LBP experience changes in their dynamic balance. Deficits in the neuromusculoskeletal system, such as reduced somatosensory input, processing, or motor output, have been found to contribute to altered postural control in people with chronic LBP. LBP can influence postural stability through various existing factors such as pain, changes in movement strategies, and fear of pain[7]. Both groups experienced moderate pain (NPRS 4-6). Pain intensity has been shown to be one of the determining factors influencing dynamic balance in chronic LBP. There were differences in balance reactions for those suffering from chronic LBP according to the severity of their pain. Pain will cause changes in back muscle activation patterns and lead to a marked decrease in proprioception through increased presynaptic inhibition of muscle afferents at the spinal level or by down-regulation of cortical proprioceptive processing[21]. Discharge from high-threshold nociceptive afferents interacts with spinal motor pathways and primary somatosensory and motor cortices leading to adaptive changes in postural control[5].

LBP patient had a significant decrease in MSEBT range in the anterior, posteromedial and posterolateral directions[5]. The weakness and atrophy of the paraspinal muscles and other trunk muscles that occur in chronic LBP causes reduced function and stabilization coordination of the lower back muscles which contributes to decreased postural stability and neuromuscular control in subjects with chronic LBP. Balance disorders in chronic LBP caused by changes in information transmitted by mechanoreceptors, paraspinal muscle spindle dysfunction, decreased muscle strength and coordination, delayed muscle recruitment or increased active muscle tension along with lack of postural control and altered proprioception[22].

This study result is different from the Shallan *et al* (2019) found that differences in MSEBT scores in the group of patients experiencing chronic LBP were found in measurements in the posteromedial and posterolateral directions, but no differences were found in the anterior direction. Chronic LBP patient may have limited pelvic anterior tilt movement compared with healthy subjects, leading to decreased posterolateral and posteromedial ranges. Additionally, reaching posteriorly in MSEBT is more challenging than reaching anteriorly because lumbar lordosis is required to complete the task. The required lumbar lordosis will overload the postural control system thereby limiting the reach of subjects with chronic LBP. Chronic LBP patient are more dependent on visual feedback due to altered proprioceptive input. Reaching backwards requires the subject to rely on proprioceptive input and the vestibular system to maintain balance on one leg compared to reaching forward where the subject can use their vision for assistance[7].

There was an improvement in all mean anterior MSEBT, posteromedial MSEBT, posterolateral MSEBT and composite MSEBT of the right and left legs in both groups. Core muscle strengthening exercises with supervision for 8 weeks are effective in improving dynamic balance in patients with chronic LBP. Core muscle strengthening exercises were more effective than trunk flexibility exercises in improving dynamic balance, but not pain intensity or disability levels in adults with chronic LBP[23]. Core muscle strengthening exercises given for 45 minutes every day for 8 weeks can improve dynamic balance and muscle endurance[24]. Supervised spinal stabilization exercises for 8 weeks showed significant improvements in MSEBT measurements after 4 weeks of exercise compared to home exercise[23]. There is a relationship between core muscle strength and dynamic balance reflected in significant positive correlation between core muscle isometric strength and MSEBT measurement results[25].

The core muscles (pelvic floor muscles, transversus abdominis, multifidus, internal and external obliques, rectus abdominis, erector spinae, and diaphragm) contribute to overall spinal stability. The core muscles form a rigid cylinder and provide a strong foundation for lower extremity mobility and movement. The transversus abdominis muscle has also been shown to be significant in stabilizing the lumbar spine. When the transversus abdominis muscle contracts, it will increase intra-abdominal pressure and tighten the thoracolumbar fascia. Core muscle contraction occurs before the initiation of leg movement, providing the leg with a strong foundation for movement and muscle activation. The obliqus abdominis and rectus abdominis muscles are excited in specific movement patterns, providing postural protection before limb movement. Retraining core muscles has been reported to reduce pain and improve static and dynamic balance. Exercises are designed not only to strengthen muscles but also to increase endurance and initiation (start of contraction) of core muscles[25]. Delayed activation of core muscles, especially the transversus abdominis muscle, is associated with chronic low back pain[26].

There are no studies assessing the effect of tVNS in chronic LBP patient that evaluate dynamic balance using MSEBT. It is still unclear the mechanism that caused significant improvement in the treatment group given additional tVNS therapy, but it is estimated that this improvement was obtained from the mechanism of action of tVNS which provides analgesic effects, systemic anti-inflammation, psychological improvements, such as depression and mood[27]–[29]. The effect of giving tVNS on the pain scale of chronic LBP patient still produces varying results. The tVNS research in Indonesia on chronic LBP showed a significant improvement in the pain scale in the treatment group given the addition of tVNS to exercise therapy (breathing exercises, posture correction, stretching, and core muscle strengthening), but there was no significant difference from the control group (p=0.104)[11].

Chronic LBP patient have increased levels of Interleukin 6 (IL-6) as a marker of systemic inflammation. This inflammatory process will disrupt the sleep cycle and contribute to pain sensitivity[30]. One possible cause was the anti-inflammatory effect of tVNS which was characterized by a decrease in IL-6 in all study participants[31]. The presence of muscle guarding and splinting in the lower back muscles has an impact on the flexibility and speed of movement of the lumbar spine [32]. Several studies have linked improvements in low back pain scales with improvements in MSEBT scores. So by reducing pain in the back, there is an increase in the ability of the lower back extensor muscle activity when making anterior movements and the activity of the back lateral flexor and hip flexor muscles to make posterolateral and posteromedial movements[33].

The results of this study showed that there was a significant improvement in MSEBT results in the treatment group compared to the control group in the anterior and composite directions of the right leg as well as in the anterior, posteromedial, posterolateral and composite directions of the left leg. The minimum detectable change (MDC) from the MSEBT examination in the anterior direction is 5.9%. There was an improvement in MSEBT values towards the anterior clinically in both groups, both in the right and left legs, but the improvement was greater found in the treatment group. The minimum detectable change (MDC) from the MSEBT examination in the posteromedial direction is 7.8%. There was an improvement in the MSEBT value towards posteromedial clinically in both groups, both in the right and left legs, but a greater improvement was obtained in treatment group. The minimum detectable change (MDC) from the MSEBT examination in the posterolateral direction is 7.6%. In this study, there was an improvement in MSEBT values towards posterolateral clinically in both groups, on the right leg, while improvement on the left leg was only obtained in the treatment. The minimum detectable change (MDC) from the composite MSEBT examination is 6.7%. In this study, there was clinical improvement in MSEBT composite scores in both groups, both in the right and left legs, but the improvement was greater found in the treatment group[34]. These results are in line with the research of Otadi *et al* (2021) that showed improvements in pain, function and balance in the intervention group who received exercise therapy and TENS compared to the control group who received TENS only. This research shows that the addition of pain modulation to exercise therapy can improve dynamic balance function in patients with low back pain[35].

There has been limited study regarding the administration of tVNS to chronic LBP with MSEBT outcomes. The correlation between dynamic balance and pain scores still provides varying results. Ruhe *et al* (2011) reported that there was a relationship between the speed of body center shift and pain scores[36]. Sipko and Kuczy'nski found a relationship between pain intensity and stability limits in chronic LBP patients[37]. Soliman *et al* 2017, found the effect of pain intensity on dynamic balance in chronic LBP patients as measured by the biodex[38]. The presence of pain in the lower back is believed to alter the timing of paraspinal muscle activity, resulting in delayed muscle response and poor segmental stability. Additionally, muscle inhibition due to pain increases non-primary muscle activation to compensate. Pain will cause muscle spasm, stiffness, muscle coactivation or muscle guarding and splinting of the lower back extensor muscles with the aim of avoiding pain provocation, and resulting in changes in movement patterns[36][37]. Scientific data show that patients with LBP adopt a stiffer lower spine position that is compensated by ankle or hip movements[41]. Apart from that, the intensity of pain will also interfere with the proprioceptive response of the lumbar muscles in patients with LBP[42].

This study shows that the addition of tVNS to exercise therapy can provide significant improvements in a short period of time (2 weeks), compared to other studies that provided exercise alone on balance function. The improvements obtained also exceeded the MDC, so it can be concluded that the improvements obtained were not due to measurement error, but due to improvements in dynamic balance resulting from the intervention effect. This study has limitations. First, the length of follow-up carried out in this study was relatively short, namely 2 weeks, so it was not possible to compare the long-term benefits of adding tVNS to exercise therapy compared to exercise therapy alone. Second, this study did not evaluate psychological factors such as fear avoidance or kinesiophobia.

Conclusions

This study found that either adding tVNS to exercise therapy or exercise therapy alone could have an improvement effect on dynamic balance. However, the addition of tVNS to exercise therapy provided a greater effect on improving dynamic balance compared to exercise therapy alone.

Ethical Approval and Consent to participate

This paper is an original article and therefore Bioethics Committee consent was required. The study protocol was approved by the Dr. Soetomo General Academic Hospital Surabaya of Medicine Ethics Committee.

Consent for publication

The patients were informed that the research will be published. A written consent for publication is given by the patients.

Availability of data and materials

Authors declare possibility to provide data if required.

Conflict of interests

Authors declare no possible conflict of interests

Funding

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Authors' contributions

YDA prepared the conceptualization, design, resources, data collection/processing, literature search, and writing. I.S., D.P., M.A., P.S., S.M., L.K. supervision, data analysis/data interpretation, critical reading, and materials. All authors contributed equally to the final version of the publication, have read, and approved the manuscript.

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