

Efficacy Of High Transcutaneous Electrical Nerve Stimulation (Tens) Application With Relaxation Breathing In Primary Dysmenorrhea

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DOI: 10.29322/IJSRP.12.06.2022.p12604

<http://dx.doi.org/10.29322/IJSRP.12.06.2022.p12604>

Paper Received Date: 11th May 2022

Paper Acceptance Date: 28th May 2022

Paper Publication Date: 6th June 2022

Abstract- Background and Objective: Primary dysmenorrhea are normal menstrual pain that have been of hindrance to majority of young adult female. Previous studies involving application of high transcutaneous electrical nerve stimulation (TENS) for pain relief in primary dysmenorrhea has shown to be inconclusive. Relaxation breathing as a way to calm the mind and body has proven to significantly increase pain threshold of an individual. Objective of the study are: (1) to determine the efficacy of high TENS in combination with relaxation breathing. (2) to compare between the efficacy of high TENS and relaxation breathing with placebo TENS and relaxation breathing.

Methods: A randomized controlled trial involving 30 participants were recruited by convenient sampling method and were randomized into Group A (high TENS with relaxation breathing) and Group B (placebo TENS with relaxation breathing). Both groups performed *Nadi Shodhan* and electrodes were applied at para spinal area of T10 to L1 region and S2 to S4 region. Parameters of TENS application were given according to the groups that participants were assigned to. VAS score was taken as pre-test and post test measurements.

Results: Data was analyzed with the exclusion of drop outs. Total mean age was 20.71 ± 0.94 years and mean age at menarche was 12.17 ± 1.36 years. There was significant difference for both groups ($p=0.000$). When comparing between both groups, post-test results and mean difference between pre and post-test was also significantly different ($p=0.000$).

Conclusion: High TENS application with relaxation breathing and placebo TENS application with relaxation breathing both showed effective pain relief in primary dysmenorrhea. However, the group with high TENS was more superior in pain management for primary dysmenorrhea.

Index Terms- TENS; Relaxation Breathing; Primary Dysmenorrhea

I. INTRODUCTION

Background

Overview of Dysmenorrhea

Dysmenorrhea is defined as pain associated with menstruation are classified into two type which are primary dysmenorrhea and secondary dysmenorrhea (Ju, Jones & Mishra, 2013). Primary dysmenorrhea is the common menstrual pain felt from uterine contractions without any underlying pelvic conditions while secondary dysmenorrhea is caused by disorders in the female reproductive systems such as endometriosis, uterine fibroids, adenomyosis or infection (Kural et al., 2015). In a study by Aziato, Dedey and Clegg-Lampsey (2014), it is stated that dysmenorrhea reduces quality of life (QoL) of a female during menstruation by altering their sleep pattern, decreases their activity tolerance, absenteeism and inattentiveness. Dizziness, nervousness and fainting are also common in dysmenorrhea (Calls et al., 2017).

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<http://dx.doi.org/10.29322/IJSRP.12.06.2022.p12604>

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Cause of primary dysmenorrhea are from excess production of prostaglandin F_{2a} (PGF_{2a}) in the uterus which is normally increased with progesterone influences where it will reach or reached a peak at the onset of menstruation (Beckmann et al., 2014). The shedding of the endometrium during onset of menstruation causes the release of formed prostaglandin which leads to intense uterine contraction due to the hormone's potent smooth muscle stimulants. Beckmann et al., (2014) stated that the necrosis of endometrial cells also increased prostaglandin synthesis by providing increased substrate arachidonic acid from the cell walls. Based on Bernardi et al. (2017), characteristics of pain felt in primary dysmenorrhea are usually intermittent, sharp and painful localizing at the lower abdomen, the suprapubic area and may radiate down the lower back and inner thigh and usually most prominent on the first 2 days of menstruation or prior to menstruation. Calls (2017), reported that nausea and vomiting (89%), diarrhea (60%), headaches (45%), fatigue (85%) are associated symptoms of primary dysmenorrhea. According to Beckmann et al. (2014), nausea, vomiting and diarrhea during menstruation are results from contractions of smooth muscles elsewhere in the body due to PGF_{2a} . According to Calls (2017), clinical features of primary dysmenorrhea are onset within 6 months of menarche and may last up to 48 to 72 hours.

In the case of secondary dysmenorrhea, the pain often lasts longer than normal menstrual cramps, may worsen during menstruation and may continue even after the end of menstrual period (The American College of Obstetrician and Gynecologist, 2015). Unlike primary dysmenorrhea, the onset of pain may be later in life and tend to worsen over time. Common signs and symptoms indicating of possible secondary dysmenorrhea are dysmenorrhea occurring after the age of 20 with relatively painless past menstrual cycle, pelvic pain during times other than menstruation, heavy menstrual flow or irregular cycles, infertility, dyspareunia, vaginal discharge and no significant response towards both therapies with nonsteroidal anti-inflammatory drugs (NSAIDs) and oral contraceptive (Calls, 2017). If dysmenorrhea occurs during the first or second cycles after menarche, this may indicate congenital outflow obstruction which also give rise to secondary dysmenorrhea (Calls, 2017).

According to The American College of Obstetrician and Gynecologist (2015), a female adolescent will start experiencing primary dysmenorrhea soon after having menstrual periods and will ease as they grow older or after giving birth. Normally, NSAIDs are proven effective in easing dysmenorrhea by blocking prostaglandins and thromboxane but these drugs may sometime carry side effects such as stomach problems, nausea, headaches or drowsiness (Institute for Quality and Efficiency in Health Care, 2016). Hormonal treatment such as oral contraceptive pill and progestin- only treatment are also commonly administered as they thin out the lining of the uterus thus lessening the flow of blood and cramping (Bernardi et al., 2017). However, just like NSAIDs, hormonal treatments are prevalent for side effects such as nausea, vaginal discharge and even missed periods. Other than that, it may also increase the risk of cardiovascular problem such as heart attack, blood clots, strokes, especially those with uncontrolled hypertension and family history of cardiovascular problems, and increased cancer risk such as breast cancer and cervical cancer (Smith, 2018).

1.1.1 Mechanism of High TENS in Providing Pain Relief

Griensven, Strong and Unruh (2014) stated that transcutaneous electrical nerve stimulation (TENS) provides rapid onset of effects that may occur within minutes for some patients and does not cause many of the drug's associated side effects like sedation, dizziness, disorientation and etcetera. It may also be given alone or with combination of other pain relief methods without the fear of overdosing as there is no potential for toxicity. According to Vance et al (2014), TENS has been known to be a noninvasive and non-pharmacological intervention in the treatment of both acute and chronic pain conditions. Conventional TENS or TENS with low intensity but high frequency of 80 Hz to 130 Hz provides pain relief through gate system where A beta sensory fibers are activated and this reduces the transmission of noxious stimulus by the 'c' fibers through the spinal cord and towards the higher centers (Watson, 2013). Preferential nerve fiber depolarization is achieved through sensory- level stimulation, motor- level stimulation and noxious- level stimulation based on appropriate settings of current amplitude and pulse duration (Bélanger, 2015). In the application of conventional TENS, electrical stimulation is said to be comfortable where sensation of tingling or pins and needles with no muscle contraction is felt. This is when it is confirmed that preferential sensory stimulation that depolarize large-diameter of A- delta fibers is achieved (Bélanger, 2015).

1.1.2 Relaxation Breathing in Providing Pain Relief

Pranayama, a yoga technique collectively defined as exercises in voluntary breath control, works by slowing down the breathing pattern to stimulate the response by the parasympathetic nervous system and a corresponding sense of calm (Weller, 2007). With this, it helps to cope with a wide variety of stressors like pain and anxiety. As stated by D'arcy (2011),

anxiety is common with acute pain and may show some sympathetic nervous system activity like increased in respiratory and heart rate. Busch et al. (2012) also stated that relaxed, deep and slow breathing had proven to significantly increase the participants' pain threshold.

Nadi Shodhan, is one of slow pranayama techniques in the field of yoga which in was believed to provide relaxation through restoration or maintenance of the body's natural biological rhythm. This in particular is achieved through the regular alteration of air flow from one nostril to the other. (Weller, 2007). As Weller (2007) continued to explain, the skeletal muscle in our body are almost never in complete resting state and always retain a degree of tension known as basal tension which sometime when increased may exert pressure on the underlying nerve. By learning to control the rhythms of pranic energy, one may be able to achieve a healthy mind and body (Ganesh, Donde and Hedge, 2015). Weller (2007) also stated that the pranayama technique was widely used to relax the mind and break the anxiety-tension- pain cycle

1.2 Objectives of the Study

1. To determine the efficacy of high TENS application in combination with relaxation breathing in producing pain relief for primary dysmenorrhea.
2. To compare the efficacy of high TENS application with relaxation breathing and placebo TENS with relaxation breathing in producing pain relief for primary dysmenorrhea.

1.3 Research Question

Does high TENS application in combination with relaxation breathing reduces pain in primary dysmenorrhea among female students aged 17 to 23 studying at Universiti Tunku Abdul Rahman?

1.4 Hypothesis

Null Hypothesis: There is no significant improvement in pain from primary dysmenorrhea with the addition of high TENS application along with relaxation breathing among female students of Universiti Tunku Abdul Rahman.

Alternate Hypothesis: There is significant improvement in pain from primary dysmenorrhea with the addition of high TENS application along with relaxation breathing among female students of Universiti Tunku Abdul Rahman.

1.5 Operational Definition

Menarche - The first onset of menstrual cycle in a female's life.

Menstruation - Normal vaginal bleeding of blood and tissue from the uterus if no fertilization occurred.

Primary Dysmenorrhea - Normal menstrual cramp felt commonly in the lower abdomen or lower back without any reproductive disorder or underlying pelvic disorder.

High TENS - Uses mild electrical current at a frequency of 100 Hz to provide short term pain relief through activation of pain gate mechanism.

Placebo TENS - Acts as a control where all parameters will be set the same as in high frequency TENS but intensity level remain 0.

Relaxation breathing - Breathing pattern that promotes relaxation.

VAS Score - A score rated by an individual's own perception of pain felt at a time with the help of a visual analogue scale.

1.6 Rationale of the Study

Despite primary dysmenorrhea being very common and impact quality of life (QoL) such as affecting sleep, decreased activity tolerance, absenteeism from work or school and inattentiveness in performing task, it is often not diagnosed and many preferred not to receive medical help and advices. Based on previous studies done on the prevalence of primary dysmenorrhea in Malaysia, it is noticeable that there were reports of high prevalence in Malaysian University students (Jaiprakash et al., 2016; Sulkalingam and Ganesan, 2016; Joseph,2013). Studies done in Malaysia and other countries also showed that the pain due to primary dysmenorrhea are root causes for absenteeism from classes and works

(Orhan et al., 2018; Sulkalingam and Ganesan, 2016). This is a major concern as this could lead to poor academic or work performances. For this reason, the data will be collected from female students aged 17 to 23 within a university from Malaysia. Moreover, this research is the first to be conducted with Malaysian population where high TENS is applied along with relaxation breathing techniques.

Although previous studies regarding the effects of high TENS application in relieving pain from primary dysmenorrhea had been conducted in other countries but the studies showed inconsistency of data (Kannan and Claydon, 2014; Proctor et al., 2010). The reason for inconsistency of results could be due to confounding factors mentioned by Sluka et al. (2013) and the time effect which was often not taken into consideration (Parsa and Bashirian, 2013; Tugay et al., 2007). Hence, this will be taken into consideration in the construction of methodology.

Investigation of a non- pharmacological intervention for the female population suffering from primary dysmenorrhea is important as this provide choices to manage it in a safe and effective way. High TENS application and relaxation breathing technique are easily applicable and highly feasible techniques where it reduces pain and promotes relaxation. Data from this study will also aid in giving a more precise estimates of average effect of non- invasive intervention for primary dysmenorrhea that are more easily applied and more feasible without fearing the side effects from pain management drugs.

1.7 Scope of the Study

The study focuses on the efficacy of high frequency TENS with relaxation breathing in the relief of acute pain in primary dysmenorrhea among female students ranging from aged 17 to 23 studying at UTAR.

II. REVIEW OF LITERATURE

Primary Dysmenorrhea

Epidemiology of Primary Dysmenorrhea

Sanctis et al. (2017), conducted a review in different countries in regards to the prevalence of dysmenorrhea and reported that the main gynecological complained by adolescents and young adults were dysmenorrhea with prevalence varying from 34% in Egypt and 94% in Oman with very severe pain varying from 0.9% in Korea and 59.8% in Bangladesh. Based on the same study by Sanctis et al. (2017), morbidity due to dysmenorrhea was also reported to be a substantial public health burden which leads to absenteeism from school and work thus significantly reducing quality of life. However, even with its high prevalence and associated negative effects, most of the population tend not to seek proper medical care.

In the population of 215 medical students among a Malaysian University, prevalence of dysmenorrhea was found to be high (78%) with a mean age of 21.4 ± 2.2 years in students with dysmenorrhea where Indians were found to have the highest prevalence of dysmenorrhea (59.3%) when compared to other races (Malays 19.2%, Chinese 15%, others 6.5%) (Jaiprakash et al., 2016). It was discussed by Jaiprakash et al. (2016), that the highest prevalence of age group to suffer from primary dysmenorrhea was thought to be between 20 to 24 years old and shows progressive decrease in older age groups. Out of the 215 participants, 52% of the participants complained that the pain felt from dysmenorrhea was a severity of moderate pain. Their results of severity differed from other studies and was explained that the difference in ethnicity and difference in the students' pain threshold could be hold accounted for. It was also reported by Jaiprakash et al. (2016) that the most common symptom felt were fatigue, back aches and mood swings.

Sulkalingam and Ganesan (2016) reported that in a population of 210 medical students with mean age of 22 ± 0.9 years old and mean age at menarche of 13 ± 0.8 years old residing in Shah Alam, Malaysia were reported to have a prevalence of dysmenorrhea of 61.9%. A high percentage of students reported that dysmenorrhea had an effect on their educational, sports and societal behavior. Majority of the population (73.8%) resolved to medication in easing menstrual cramps. Various other method such as rest (68.5%), consumption of herbal drinks (67%), using of heating pad (60%), consumption of hot tea (34.6%) and exercising (24.6%) were commonly reported as a way to manage pain and symptoms of dysmenorrhea. It was also stated that out of the participants taking medication, 73% of the participants were reported to consume over-the-counter drugs for pain relief without the prescription of a medical professional.

In another cross-sectional study regarding prevalence of primary dysmenorrhea and its association with the QoL among medical students in Universiti Sains Malaysia (USM) conducted by Joseph (2013) stated that overall prevalence of dysmenorrhea from 188 medical year one and year two medical students with mean age of 20.69 ± 1.56 years was 77.9%. The prevalence of mild, moderate and severe dysmenorrhea were 30.2%, 36.6% and 11.0% respectively. Joseph (2013) also reported that female students with dysmenorrhea had a significantly lower quality of life both mentally and physically.

Lacovides, Avidon and Baker (2015), commented in their systematic review regarding the recent knowledge of dysmenorrhea, prevalence is estimated to be in the range of 45% to 95% in menstruating women and roughly 10% to 25% of them reported to suffer from severe primary dysmenorrhea. Risk factors for dysmenorrhea was also reported to

be smoking, alcohol consumption, earlier age at menarche, higher BMI, longer and heavier menstrual flow, age, nulliparity and family history of dysmenorrhea.

In conclusion, the studies all showed that the prevalence of dysmenorrhea varies from country to country which could be due to numerous factors such as family history of dysmenorrhea, ethnicity difference and difference in pain threshold. The three studies by Joseph (2013), Jaiprakash et al. (2016) and Sulkalingam & Ganesan (2016) showed high prevalence in Malaysia's medical university students with similar mean ages. QoL was also affected as reported by Sanctis et al. (2017), Joseph (2013) and Sulkalingam & Ganesan (2016). Some of the most common practice in providing pain relief were medication, rest, drinking herbal drinks and applying heat pack (Sulkalingam & Ganesan, 2016).

Primary Dysmenorrhea and Its Association with Quality of Life (QoL) Among Students

University students tends to show negative effect on academic performances participation in sports and social activities as supported by Orhan et al. (2018) and Sulkalingam and Ganesan (2016). In a study by Kanwal et al. (2017), pain and severity of associated symptoms from primary dysmenorrhea shows significant association with depression that can cause hindrance in work, task performance and getting along with others. In another study by Joshi et al. (2014), it was reported that participant with dysmenorrhea are 4.9 times more likely to be absent from classes, 3.2 times more likely to loss concentration in workplace, 2.2 times more likely to have lower confidence during work, 2.4 times more likely to have poorer work satisfaction and 2.2 times more likely to have poorer social relationships compared to females without dysmenorrhea.

Jaiprakash et al. (2016) conducted a study which consisted of 215 participants with a prevalent rate of 78% discussed that the results from the study shows a significant level of social life interference by 2.55 times than usual. However, the result yielded a paradoxical result from other studies where it had been commonly reported high absenteeism as a common problem due to primary dysmenorrhea. Jaiprakash et al. (2016) explained that this may be due to the fact that participants recruited were medical students and were quite knowledgeable in the management of dysmenorrhea.

As reported by Bajalan et al. (2018), where they conducted a systemic review on mental health and primary dysmenorrhea, several factors such as demographic, lifestyle, reproductive, social and psychological factors may have an effect on the severity and incidence of primary dysmenorrhea. Bajalan et al. (2018) concluded that there was significant relationship between several component of mental health like depression, stress, anxiety, alcohol abuse and somatic disorders. Coping of primary dysmenorrhea involved both pharmacological and non- pharmacological methods such as exercise, warm compress, water and diet therapy, planning of activities before onset of pain, receiving support socially and spiritually and bearing the pain (Aziato, Dedey and Clegg-Lamptey, 2015).

In conclusion, most of the studies concluded that primary dysmenorrhea along with its associating symptoms decreases QoL in those suffering from it. Students are more likely to be absent from classes, shows a poorer performance in academic, sport and social activities, and lowered self esteem. Research also showed that several factors have a role in altering the incidence and severity of primary dysmenorrhea.

Diagnosis and Its Management

Osayande and Mehulic (2014) explained that primary dysmenorrhea usually shows characteristic symptoms such as lower abdominal or pelvic pain which may or may not radiate to the back or leg and the pain is common to last 8 to 72 hours typically from the onset of menstruation. Its initial onset usually is 6 to 12 months after menarche. Other associating symptoms commonly reported are headaches, diarrhea, fatigue, low back pain, nausea or vomiting. Osayande and Mahulic (2014) also explained that in the presence of abnormal uterine bleeding, noncyclic pain, changes in duration and intensity of pain, painful or difficult sexual intercourse (dyspareunia) and abnormal pelvic examination might lead one to suspect the presence of an underlying pathology which is called secondary dysmenorrhea and are commonly case by endometriosis. If heavy or abnormal menstrual flow are noticed, adenomyosis or leiomyomata are usually suggested to be suspected. Pelvic inflammatory diseases (PID) are also suspected if a female report of having a history of sexually transmitted infection or vaginal discharge with association to dyspareunia (Osayande and Mahulic, 2014). Usually, diagnosis of primary dysmenorrhea is based on clinical history taking and physical examination whereby laparoscopy is indicated if there are still uncertainty in the etiology after the completion of appropriate non- invasive evaluation (Osayande and Mahulic, 2014).

As discussed in a critical review regarding the recent knowledge of primary dysmenorrhea by Lacovides, Avidon and Fiona (2015), the most commonly used pharmacological treatment for primary dysmenorrhea are NSAIDs which are classified as prostaglandin synthetase inhibitors. Lacovides, Avidon and Fiona (2015), continued to state that for

roughly 15% of woman that are irresponsive to NSAIDs often optioned for oral contraceptives as they work by suppressing ovulation thus reduces the thickness of endometrial lining and therefore decreases PG synthesis and dysmenorrhea. However, with the long term usage of oral contraceptive it has been confirmed that the risk for development of venous thromboembolism is evident (Manzoli et al., 2012). Several other therapeutic approaches are gaining interest in the management of dysmenorrhea such as transcutaneous electrical nerve stimulation (TENS), acupuncture or acupressure, transdermal nitroglycerin patches and surgical interventions (Lacovides, Avidon and Fiona, 2015). However, these techniques were considered not effective enough for them to be widely use in clinical practice as lesser studies are done on them to showcase their efficacy (Khan and Lathe, 2012). Many had also reported that they manage their menstrual pain through non- pharmacological methods such as heating pads, increase resting periods, meditation, physical exercise, aromatherapy and diet therapy but usually results in ineffectiveness (Lacovides, Avidon and Fiona, 2015).

In conclusion, diagnosis of primary dysmenorrhea is usually based on clinical assessment which look into detail mainly in the aspect of their menstrual history, characteristic of the pain, presence of characteristic symptoms and associated symptoms of primary dysmenorrhea. Usually if a female is suspected to show signs of secondary dysmenorrhea, clinical tests such as laparoscopy and ultrasonography are indicated. It is also conclusive that a vast population of female with dysmenorrhea resorted to pharmacological management for primary dysmenorrhea as currently pharmacological drugs are considered more superior to non- pharmacological methods. Furthermore, majority of the people suffering from primary dysmenorrhea shows coping methods that does not involve advices or help from medical professionals which includes those who choose to self administer over- the- counter drugs such as NSAIDs or oral contraceptives. Investigating new non- pharmacological methods in management of primary dysmenorrhea is important as this can provide an alternative strategy in managing primary dysmenorrhea without the adverse drugs effect.

Previous Studies of TENS on Primary Dysmenorrhea

Results from Previous Studies

According to Kannan and Claydon (2014), a systematic review of some physiotherapy treatments that may relief menstrual pain in women with primary dysmenorrhea reported that when comparing the effect of analgesic of acupuncture- like TENS with placebo pill, the trial yield significant effect of TENS in reducing pain immediately after intervention with a mean difference of 2.3 (95% CI 0.03 to 4.6). In another study done by Smith and Younan (2011), they concluded that TENS may be an effective treatment modality in treating primary dysmenorrhea with only the feeling of uncomfortable sensation being the most serious side effects but the participants that had uncomfortable sensations stated that they were willing to undergo treatment despite the discomfort. However, the review by Kannan and Claydon (2014) included only one trial with 20 participants, reported to have a high risk of bias, the confidence interval did not exclude the possibility that the effect was clinically trivial and the quality of the trial was also low.

As mentioned by Kannan and Claydon (2014), the results of Proctor et al. (2010) contradicts their results where they had pooled three results of studies and concluded that low- frequency TENS shows no statistically significant effect. As stated by Smith and Younan (2011), high frequency TENS seem to be a more effective agent for pain relief in comparison to placebo TENS and low frequency TENS. Smith & Younan (2011) also suggested that low frequency TENS may even not be more effective than placebo TENS.

In conclusion, the magnitude of the effect of TENS in providing analgesic for primary dysmenorrhea may or may not be clinically worthwhile but with it being more feasible and easily applied with no adverse effects that are usually seen in pharmacotherapy, it has started to be in consideration for clinical usage.

Possible Factors for Inconsistency of Data

Numerous systematic review has shown that the efficacy of TENS is inconsistent and inconclusive in providing pain relief in people with primary dysmenorrhea and thus can be concluded that a number of variables related to TENS application that were not considered. According to Sluka et al. (2013), factors including dosing of TENS, population and outcome assessed, negative interactions with long- term opioid use, comparison group and timing of outcome measurement should be taken into consideration in an assessment of efficacy even if the trial were designed with the highest of standards.

In another study by Lacovides, Avidon and Fiona (2015), they discussed that the efficacy of non- pharmacological methods in providing pain relief in primary dysmenorrhea differs as each method are personal. This means that some methods may provide significant pain reduction in one adolescent but may not achieve the same outcome in another adolescent.

Most of the studies did not consider the time effect where it is said to be important when considering the nature of menstrual pain. This limitation was listed in studies such as Parsa and Bashirian (2013) and Tugay et al. (2007) and was not taken into consideration in the study by Mistry et al. (2015). Although all the studies provided TENS application on the participants' first day of menstruation but the probability of the participants being assessed after several hours from menstruation onset still exist.

In conclusion, results from previous study indicate TENS as a possible intervention for pain management in primary dysmenorrhea however, most studies showed that they did not take into consideration regarding confounding factors that can contribute to inaccuracy of results like the time effect in primary dysmenorrhea. Moreover, as the methods are personal, the type of population may have an influence on the efficacy of TENS.

TENS Parameters and Electrodes Placements.

Although high TENS and placebo TENS were both able to be effective pain modulation of primary dysmenorrhea, it is concluded that the group where high TENS with frequency of 0 to 100 Hz was applied showed a significant pain relief compared to the placebo group. The above statement was proven by Parsa and Bashirian (2013) where they conducted a study of comparing between high TENS and placebo TENS with 64 female adolescent having a mean age of 16.8 ± 0.97 . However, as reported in a study by Smith and Younan (2011), a study involving high TENS, low TENS and placebo TENS concluded that there was no significant difference between high TENS and low TENS. Placebo TENS was also able to provide significant relief in primary dysmenorrhea although being less superior to high TENS (Parsa and Bashirian, 2013; Smith and Younan, 2011; Wang and Lee and Hwa, 2009). As explained by Wiech, Ploner and Tracey (2008), the effect of placebo TENS in providing pain reduction involves cognitive pain modulation.

In a research when comparing between the efficacy of conventional TENS, or also known as high TENS, with spinal mobilization at the level of T10 to L1 vertebra, the results showed both methods were able to significantly reduce the pain in primary dysmenorrhea (Mistry et al, 2015). The electrode placements were placed at para spinal regions of T10 to L2 where most of the parasympathetic and sympathetic pelvic nerve pathways arises. Mistry et al (2015) further discussed that when stimulation is provided at the level of T10 to L1, mechanoreceptors and large diameters fibers may be able to block sensation of pain at the spinal level. Another study conducted by Patel, Sheth and Vyas (2016) where they placed electrodes at the level of L5 to S1 were acupuncture points for bladder and uterus are present.

In conclusion, high TENS seem to provide better and more significant pain reduction in primary dysmenorrhea when compare to low TENS and placebo TENS. However, evidence showed that low TENS and placebo TENS seem to also provide significant pain relief in primary dysmenorrhea but Smith and Younan (2011) suggested that placebo TENS may be more superior to low TENS application. It is also noticeable that electrode placement at the para spinal area at level between T10 to S1 provided pain relief by blocking the pain sensation at the spinal level.

Previous Studies of Relaxation Breathing On Primary Dysmenorrhea

Jafari et al (2017), in its systematic review on pain and respiration discussed that although the evidence failed to elucidate the exact physiological mechanism that occur for respiration techniques provided for pain management, the authors theorize that the cardiovascular system may potentially have a role in the respiratory modulation of pain. Sharma et al (2017) also provided evidence that pain tolerance after slow and deep breathing was more effective in increasing the pain tolerance level when compared to those who only did spontaneous breathing. Sharma et al (2017) continued to conclude that increased in pain tolerance after slow and deep breathing may show possibility that the autonomic nervous system along with underlying other factors are responsible for pain modulation.

In a study where 20 healthy volunteers were administered with painful electric shocks delivering to the sural nerve before the end of inspiration and expiration phase was conducted with the intention of trying to understand how the breathing phase and frequency have an association with perceived pain (Arsenault et al, 2013). Arsenault et al (2013) required the 20 participants to perform 3 cued- breathing conditions which are slow breathing with slow inspiration, slow breathing with fast inspiration and normal breathing with fast inspiration and it was concluded that pain and pain-related brain activity show possible reduction in phases of inspiration but the relationship between the changes and spinal nociceptive transmission are dissociated. Relaxation and meditation techniques in providing pain relief through analgesic effect may be due to other factors apart from respiration modulation (Arsenault et al, 2013).

In a study conducted investigating the effect of slow and deep breathing techniques on pain perception, autonomic activity and mood processing by Busch et al (2012), the authors state that deep and slow breathing had been proven effective in promoting relaxation and alleviating pain. In the study, the pain threshold of the group that performed relaxed

deep and slow breathing showed a significant increase compared to the group that did attentive deep and slow breathing. Sympathetic activity in the group that performed relaxing deep and slow breathing was also found to be significantly decreased and did not share similar results to that of attentive deep and slow breathing. Busch et al (2012) concluded that by performing relaxed deep breathing, sympathetic arousal and pain perception are modulated.

According to Subhash, Krishnamoorthi and Thomas (2017) where they had conducted a randomized controlled trial consisting of 151 female students aged 18 to 25 years old with primary dysmenorrhea splitting into intervention group (n= 75) and control group (n= 76) stated that anuloma viloma pranayama which is a relaxation breathing yoga technique that focuses on breathing through alternating nostril shows reduction of pain from primary dysmenorrhea. The study also reported that 1% of the intervention group reported that they experience complete pain relief and there was also a decreased number of people reporting that they experience severe pain from 8 to 1 after the intervention. With this result, Subhash, Krishnamoorthi and Thomas (2017) recommended that the pranayama technique should be carried out at school level and regularly used at home in managing primary dysmenorrhea.

Another research by Ganesh, Donde and Hegde (2015), shows that both slow pranayama and fast pranayama prove to be effective in relieving pain in primary dysmenorrhea but the slow pranayama which is *Nadi Shodhan* seems to be more effective. The study consisted a total of 90 unmarried females in the age group of 18 to 25 years old suffering from primary dysmenorrhea which was then randomly assigned to Group A (n= 45) and Group B (n= 45). Group A was required to perform slow pranayama which was *Nadi Shodhan* and Group B was subjected to fast pranayama which was *Kapalbhati*. Both groups were required to perform pranayama every morning with empty stomach for 10 minutes and was assessed on the next menstruation. Not only did *Nadi Shodhan*, the slow pranayama technique, showed better results in managing pain from primary dysmenorrhea, it also significantly improved the quality of participants' life, reduced absenteeism and reduced stress (Ganesh, Donde and Hedge, 2015). No adverse effect was reported and was recommended to be implemented by college students suffering from primary dysmenorrhea in an attempt to improve their menstrual well being (Ganesh, Donde and Hedge, 2015).

In conclusion, relaxed, slow and deep breathing are methods that had been widely used to help cope with pain and had been supported by several studies that when performing it, it shows significant effect in pain management (Hassan et al, 2017; Sharma et al, 2017; Arsenault et al, 2013; Busch et al, 2012). Specifically, slow and deep breathing that is relaxed seem to be better in providing management in pain (Busch et al, 2012). *Anuloma Viloma Pranayama*, also known as *Nadi Shodhan*, is a yogic technique whereby one performed slow breathing and alternated between each nostril was shown to have a significant effect and was more superior to fast pranayama techniques in the management of primary dysmenorrhea. (Subhash, Krishnamoorthi and Thomas, 2017; Ganesh, Donde and Hedge, 2015).

III. METHODOLOGY

Study Design

The study was conducted as a pilot study with the design of a randomized controlled trial to investigate the efficacy of high TENS application alongside with relaxation breathing in providing pain relief in people with primary dysmenorrhea.

Study Settings and Study Duration

The study took place at Physiotherapy Centre, 3rd Floor KA block, Universiti Tunku Abdul Rahman, Sungai Long Campus. The participants were required to attend a session of 30 minutes. A total of 7 weeks were used for the completion of the whole research project with 4 weeks of data collection starting from 1 November and ending at 30 November.

Study Participants

Female students studying in UTAR were recruited and were to notify the researcher during the first day of their menstruation to arrange a suitable time for a session. The participants must not consume any type of pain relief medication on the day itself and was required to attend a session within the first four hours of menstrual onset. A questionnaire which consisted of two segments consisting of demographic data and menstrual history for the past 3 months were given to them to act as a record and an assessment for primary dysmenorrhea. They were also given a consent form (as shown in APPENDIX B) to sign as proof that they had agreed to join in the research voluntarily.

Selection Criteria

Inclusion Criteria

- i. Single female aged between 17 to 23 years old.
- ii. Students in Universiti Tunku Abdul Rahman (Sungai Long campus).
- iii. Females with ongoing regular menses.
- iv. Females who experiences moderate to severe abdominal pain during their menstruation.

Exclusion Criteria

- v. Females with any known underlying pelvic disorder, female reproductive system disorder or neurological disorder.
- vi. Females under gynecology follow ups.
- vii. Females taking oral contraceptive pills or analgesics regularly.

Sampling Method

Convenient sampling techniques was used for participants' recruitment due to the limited time of data collection. This provide easier and faster recruitment of participants.

Randomization

Block randomization was used when allocating participants into experimental or control groups. Participants were divided into blocks based on their severity of their pain due to primary dysmenorrhea reported from the last 3 months. Each blocks are then randomized into either experimental group or control group by picking from a set amount of papers labeled either 'A', for experimental group, or 'B', for control group. This method guaranteed equal numbers of participants in each group.

Blinding

No blinding was done due to the nature of intervention.

Instruments and Equipment Used in the Study

Portable TENS unit

A portable TENS unit (APEX COM- TENS III, model no. GM3A10T) was used to provide intervention for primary dysmenorrhea in both groups. Self adhesive electrodes of size 40 x 40mm square with resistance less than 200 Ω was used for both groups. Contraindication for TENS was ruled out and precautions was taken note of. Before placements of electrodes, the area of electrode placement which was the lower back was ensured dried and clear of any substances application.



(This image is taken personally, 2018)

Figure 3.1 Front and back view of TENS device used

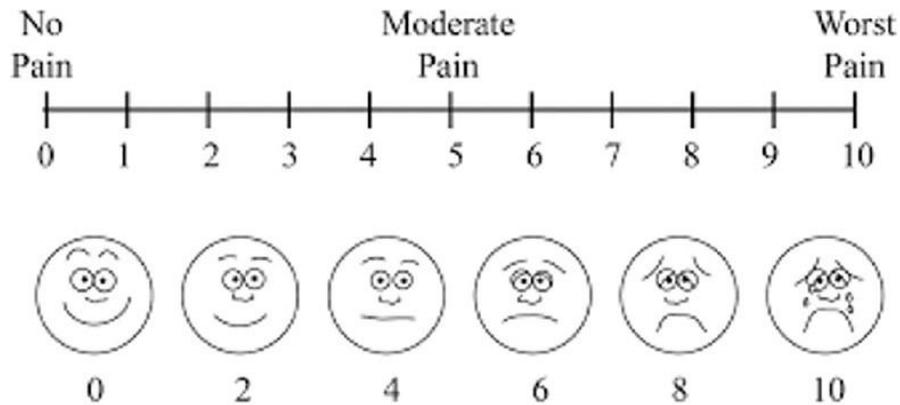


(This image is taken personally, 2018)

Figure 3.2 Self- Adhesive electrode (size 40 x 40mm square with resistance less than 200 \square)

Visual Analogue Scale (VAS)

VAS was used to score the participant’s perceived pain due to primary dysmenorrhea. The figure below was shown to the participant to rate their pain between a score of 0 to 10 where 0 represent no pain and 10 as the most unbearable pain.



(Visual Analogue Scale, n.d.)

Figure 3.3 A visual analogue scale used as a tool for outcome measure

Procedures

Approval was given by the Scientific and Ethical Review Committee (SERC) of Universiti Tunku Abdul Rahman (UTAR) before proceeding for any data collections (as shown in APPENDIX A). Participants then undergo a simple assessment to rule out the possibility of primary dysmenorrhea and their responses and data are recorded in the assessment form. The assessment included three segments which are the demographic data, menstrual history for the past 3 months and associated menstrual symptoms. The assessment form act as a guide to rule out any suspected cases of secondary dysmenorrhea and also as a record. Below shows a flow chart on assessing and ruling out of suspected cases of secondary dysmenorrhea.

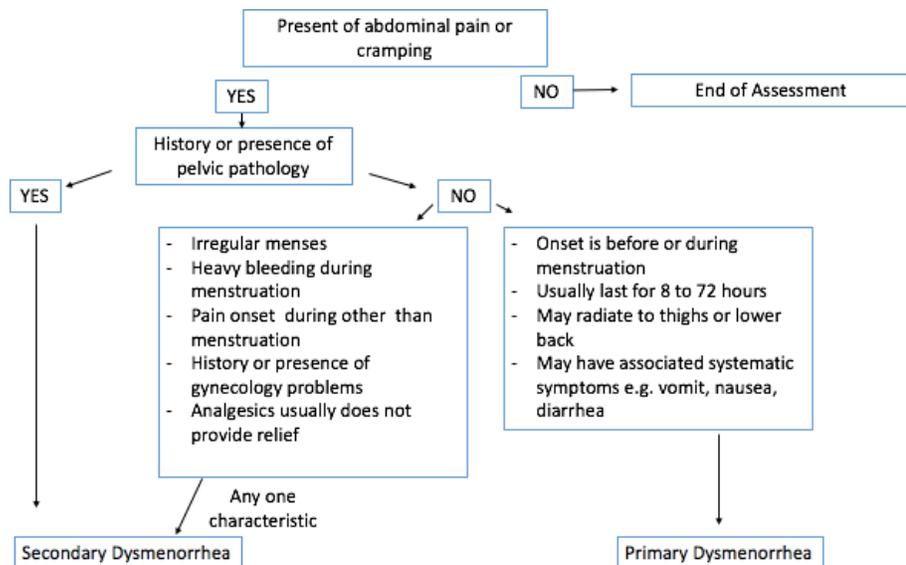


Figure 3.4 Flowchart of assessing for primary dysmenorrhea

Participants were notified to attend a session of 30 minutes within the first 4 hours from their onset of menstruation and to not take any form of pain relief medication on the day itself as this would influence the VAS. Those who failed to do so or request to stop the intervention anytime during the process will be considered as drop-outs. Qualified participants were required to give their consent after being notified of the purpose and brief about the procedure of the intervention. The participants were asked to expose their lower back for electrode placement after ruling out all the contraindication for TENS application. The contraindications and precautions of TENS application is stated as below.

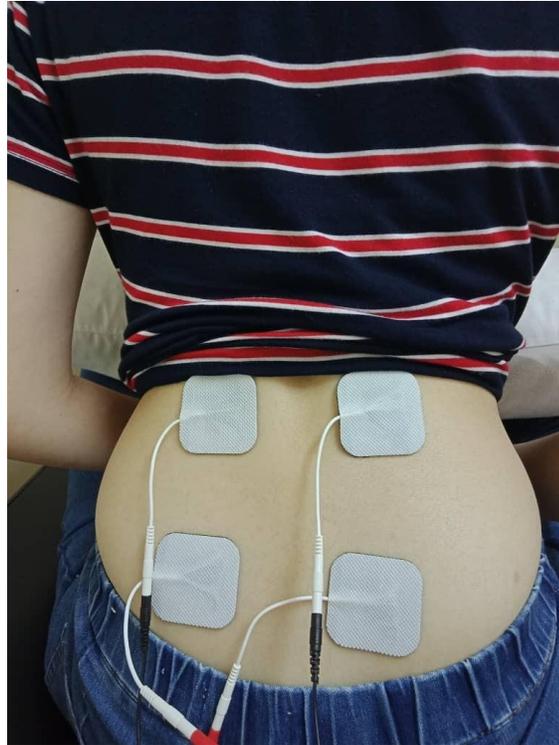
Contraindication

- i. Skin allergies in response to the electrodes.
- ii. Dermatological lesions like dermatitis or eczema over the area of electrode placements.
- iii. Presence of malignancy on area of electrode placements
- iv. Presence of active implants such as cardiac pacemaker

Precautions

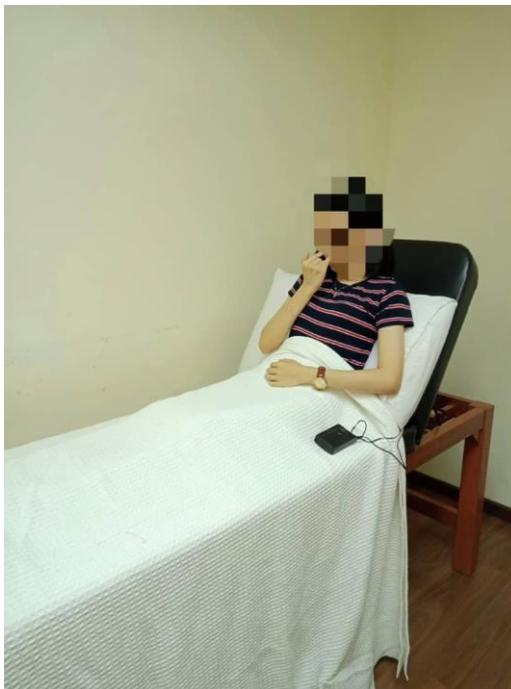
- i. Abnormal skin sensation over area of electrode placements.
- ii. Devitalised tissue
- iii. Local circulatory insufficiency

For both intervention group, VAS score was recorded and proceeded with placement of electrodes. Electrodes were placed along the dermatomes for female reproductive system where two electrodes were placed at both lateral sides between T10 to L1 region and the other two were placed at both lateral sides between S2 to S4 region (Patel, Sheth and Vyas, 2016; Mistry et al, 2015; Parsa and Bashirian, 2013).



(This image was taken and used with consent during a session with a participant, 2018)
Figure 3.5 Electrode placement at regions in between T10 to L1 and in between S2 to S4

Participants were then positioned in half lying position while ensuring the electrodes were still intact and had their lower bodies draped with a towel for their privacy and comfort. Interventions were given based on the set protocol of the respective groups.



(This image was taken and used with consent during a session with a participant, 2018)
Figure 3.6 Participant performing *Nadi Shodhan* with TENS application

During 15 minute into the session and immediately after the cessation of TENS, VAS score was noted and recorded for both of the interval. After the completion of a 30 minutes session, the participant was dismissed of and was required to update the researcher on their VAS score after 4 hours from the cessation of TENS. All VAS score was recorded in a data collection sheet (as shown in APPENDIX E) and average post- test score was calculated to be used to compare with the pre- test later in data analysis and statistical tests. Below shows a flowchart summarizing the procedure for data collection.

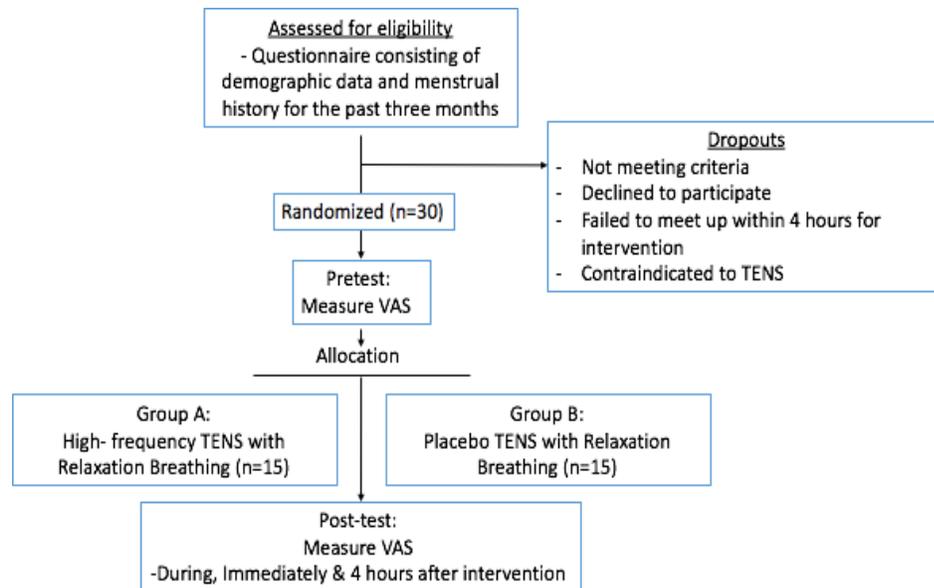


Figure 3.7 Flow chart of summarized procedure for data collection

Protocol for Each Group

Experimental Group (Group A)

High TENS were applied and relaxation breathing were taught based on the following parameters and steps

viii. Parameters of TENS (Foster & Palastanga, n.d.) Frequency: 100 Hz

Pulse width: 40 ms

Intensity: Each individual's tolerable level* within 0- 30mA Mode: Modulation**

Duration: 30 minutes

*The intensity was provided high enough until the participants could feel a felt by the participant should be comfortable and does not experience any muscle contracting.

** Modulation is given to minimize the accommodation effect as TENS stimulation are given in a less regular pattern

ix. Relaxation Breathing (*Nadi Shodhan*), (Weller, 2007)

1. Eyes are closed and the jaw is relaxed.
2. The right hand is raised with folded index and middle finger while the left hand is resting on the lap.
3. Inhale slowly and deeply through the left nostril with the thumb blocking the right nostril.
4. Close the left nostril with the ring or pinky finger while releasing closure of the right nostril and exhale slowly.
5. Inhale through the right nostril.

6. Repeat this for 3 -5 times per cycle
7. Proceed freely to complete 5 cycle for 30 minutes.

3.1.2 Control Group (Group B)

Relaxation breathing were taught and performed the same way as in intervention group. However, there was a slight amendment in parameters for placebo TENS compare to that of intervention group. Frequency, pulse width and duration remained the same but applied intensity remained as 0.

Frequency: 100 Hz Pulse width: 40 ms

Intensity: 0mA Duration: 30 minutes

Outcome Measurements

Pre-test measurement

VAS was given to the participant to identify their current pain score within the first 4 hour of onset of menstruation right before any intervention was given (VAS1). The score was then recorded in a data collection sheet (shown in APPENDIX D).

Post-test Measurements

Pain score were taken 3 times in total and the mean for all three score were used as post-test results. Pain score was taken during the intervention after 15 minute of TENS application (VAS2), immediately after cessation of TENS application (VAS3) and lastly 4 hours after cessation of TENS application (VAS4). The same VAS as in pre-test was used for all three measurements.

Data Analysis and Statistical Test

All data were analyzed using SPSS 22.0 software. All charts and tabulation of data were done using Microsoft Excel. The dropouts were excluded from the data analysis and statistical tests. The characteristic of participants such as age and age of menarche were shown through bar charts and normality between groups were analyzed by using descriptive analysis. Independent t test was used to compare the means of pre-test, post-test and differences in VAS score between both groups. Paired sample t- test was used to determine the significant difference between pre- test and post-test in each groups. $p < 0.05$ was set as the level of significance with confidence interval at 95%.

IV. RESULTS

Characteristic of Participants

	Groups	n	M (SD)	p value
Current Age	A	15	20.80± 0.86	0.001*
	B	13	20.62± 1.04	0.009*
	Total	28	20.71± 0.94	0.000*
Age at Menarche	A	15	12.13± 1.51	0.005*
	B	13	12.23± 1.24	0.037*
	Total	28	12.17± 1.36	0.009*

Note: A = Experimental group; B = Control group; M= mean; SD= standard deviation; n= number of participants; Sig.= significance difference; * indicates Sig. is $p < 0.05$

Table 4.1 Mean of participants' current age and age at menarche

The above Table 4.1 shows two data analysis of characteristic of the participants which are their current age and their age at menarche. The combined mean age of participants is 20.71 ± 0.94 years with mean age of 20.80 ± 0.86 years in Group A and mean age of 20.62 ± 1.04 years in Group B. Age at menarche in Group A shows a mean of 12.13 ± 1.51 years, mean of 12.17 ± 1.36 years in Group B and a combined mean of 12.17 ± 1.36 years. Results from Shapiro-Wilk, test for normality showed significant difference ($p < 0.05$) in both the characteristics which shows that it were not normally distributed between the groups.

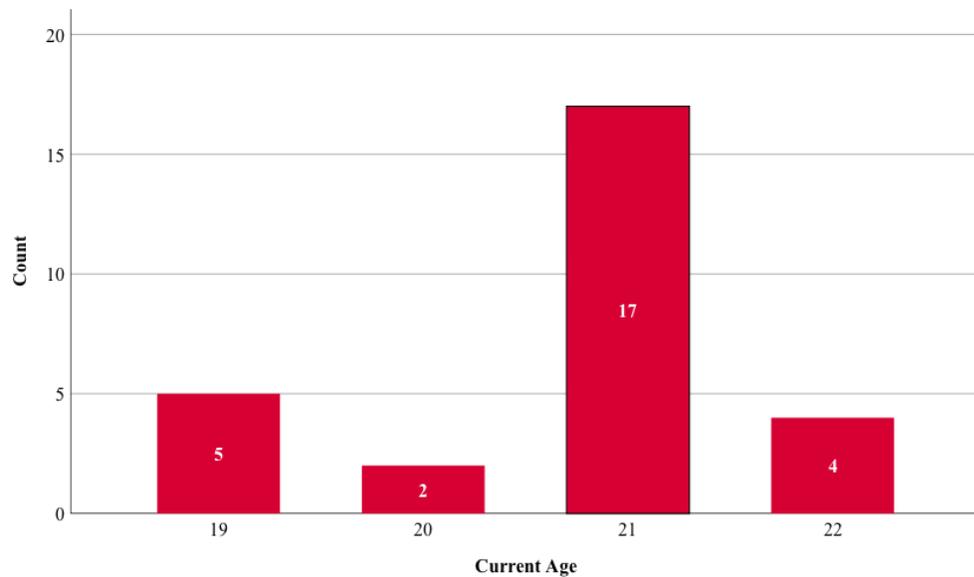


Figure 4.1 Bar chart showing current age of participants

The above bar chart in Figure 4.1 shows the current age of the participants. The youngest in the group was 19 years old and the oldest in the group was 22 years old. Most of the participants were in the age of 21.

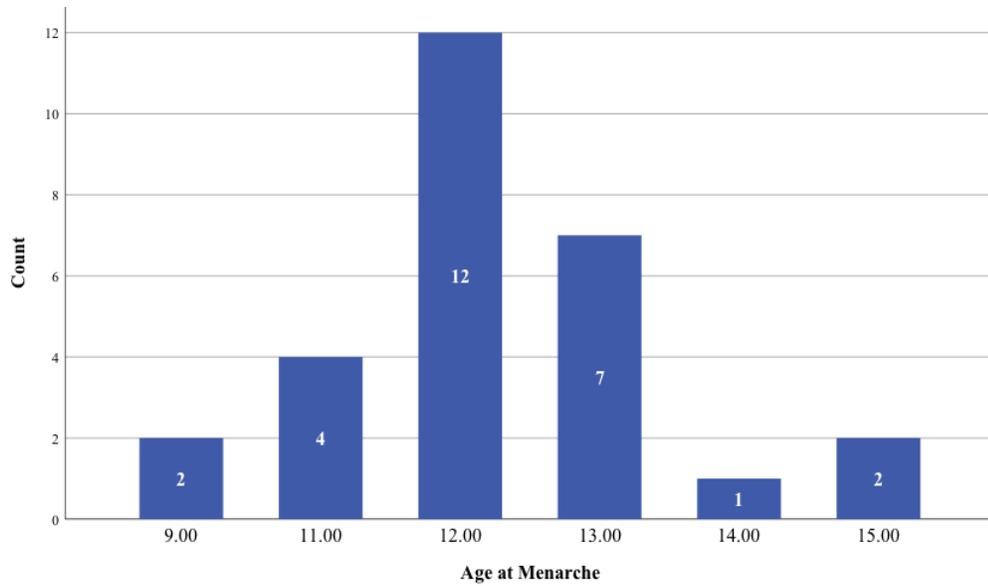


Figure 4.2 Bar chart showing age at menarche of participants

The above bar chart in Figure 4.2 show the participants' age at menarche where most of the participants experience their first menstrual cycle at the age of 12. The youngest age for menarche from the participants was 9 years old while the oldest stands at 15 years old.

Post-test Results

Groups	Post-test VAS Score	Average VAS Score
VAS2	VAS3	VAS4

A

(n=15) $m \pm SD$

3.27± 1.22 1.47± 1.46 0.87± 1.25 1.87± 0.97

B (n=13) m± SD

4.23± 1.36 3.77± 1.48 3.00± 1.53 3.67± 1.25

Note: A= Experimental group; B= Control group; M= mean; SD= standard deviation; n= number of participants

Table 4.2 Post- test results

The above Table 4.2 shows the average score from the three VAS score recorded at different time interval (VAS2, VAS3 and VAS4) as the value of post-test. The experimental group shows an average VAS score of 1.87 ± 0.97 and the control group shows an average pain score of 3.67 ± 1.25 .

Comparison of Pre-test and Post-test within Experimental and Control Groups

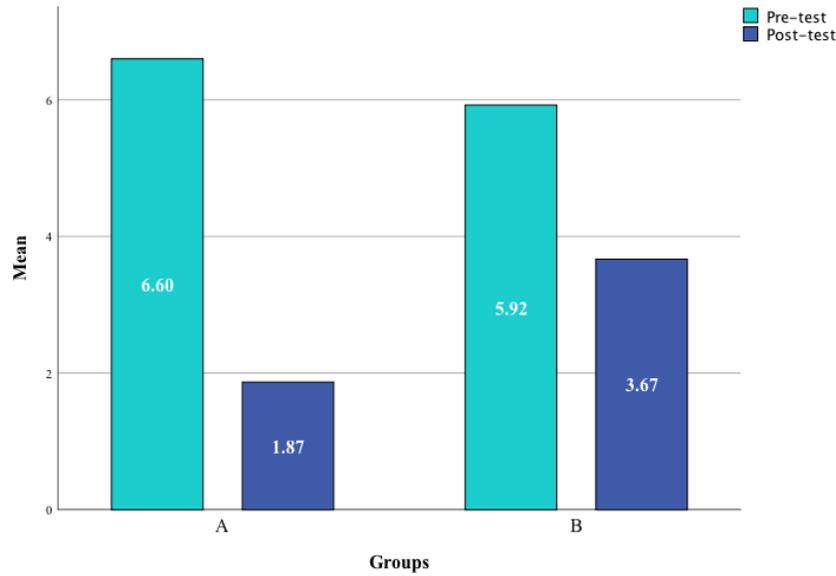


Figure 4.3 Bar chart showing the mean of pre-test and post-test within groups

The above bar chart in Figure 4.3 displays the mean pre-test and post-test of each group. In Group A, the mean VAS score in pre-test ($m= 6.60$) shows a decreased mean of score when compared to the mean VAS score in post-test ($m= 1.87$). Group B also shows a decreased in VAS score when the pre-test result ($m= 5.92$) is compared to the post-test result ($m= 3.67$). From the data collected, 75% of the participants (21 participants) reported that they suffered from moderate pain and the other 15% (7 participants) reported that they suffered from severe pain due to primary dysmenorrhea.

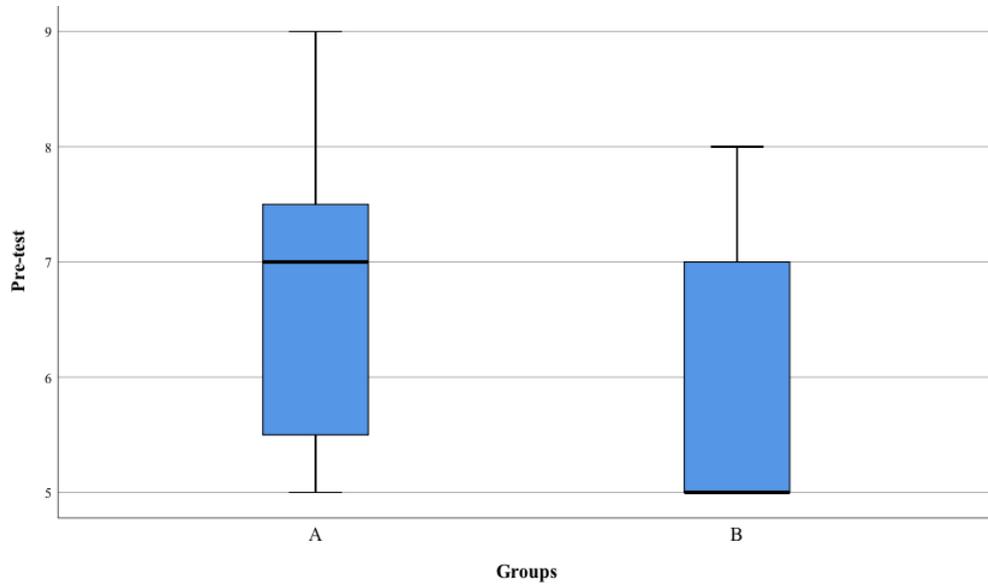


Figure 4.4 Boxplot of pre- test pain score

The above boxplot in Figure 4.4 shows the mean of the pre- test VAS score is 6.60 ± 1.30 in Group A and 5.92 ± 1.32 in Group B. Most of the participants in Group A reported having a pain score of 5 and 7 while most participants of Group B reported having pain score of 5. The median pre- test results for Group A and Group B are 7 and 5 respectively. The boxplot shows that the pre-test results were normally distributed within the groups.

Pain score	A (n=15) m± SD	B (n=13) m± SD
Pre-test	6.60± 1.30	5.92± 1.32
Post- test	1.87± 0.97	3.70± 1.25
Difference	4.73± 1.74	2.26± 0.56
Sig.	0.000*	0.000*

Note: A = Experimental group; B = Control group; m= mean; SD= standard deviation; n= number of participants; Sig.= significance difference; * indicates Sig. is p <0.05

Table 4.3 Comparison of Pre-test and Post-test within Experimental and Control Groups

The above Table 4.3 displays the comparison of pre- test and post-test of each groups. Paired- samples T test was used to compare means of pre-test and post-test to find the level of significance within groups of A and B. The p value of both Group A and Group B show significant p value (p<0.05) where p value is 0.000 for both groups. This can be interpreted that both groups showed significant difference in pre- test mean and post- test mean.

Comparison of Pre-test and Post-test between Experimental and Control Groups

VAS Score (m±SD)	P
Pre-test	
A (n=15) 6.60± 1.30	0.184
B(n=13) 5.92± 1.32	
Post- test	
A (n=15) 1.87± 0.97	0.000*
B(n=13) 3.70± 1.25	
Mean Difference	
(Difference of pre- test and post- test within each groups)	

A (n=15) 4.73± 1.74 0.000*

B(n=13) 2.26± 0.56

Note: A= Experimental group; B = Control group; M= mean; SD= standard deviation; n= number of participants; Sig.= significance difference; * indicates Sig. is $p < 0.05$

Table 4.4 Comparison of Pre-test and Post-test mean between Experimental and Control Groups

The above Table 4.4 compares the mean of pre- test and post- test between the two groups. Independent- samples T test was used to compare the pre- test mean, post- test mean, and mean difference, based on pre- test and post- test, between both groups. Pre- test between A and B groups shows no significant difference with p value of 0.184, two-tailed ($p > 0.05$). In the comparison of post- test mean, significant difference between both groups are seen with p value at 0.000, two-tailed ($p < 0.05$). Moreover, the mean of difference between pre-test and post- test results shows significant difference where p value is also at 0.000, two-tailed ($p < 0.05$). Where p value is less than 0.05, it can be interpreted that we fail to accept the null hypothesis. Group A shows more significant improvement of acute pain from primary dysmenorrhea with the addition of high TENS application along with relaxation breathing among the female students of Universiti Tunku Abdul Rahman when compare to Group B.

V. DISCUSSION

TENS and Relaxation Breathing in Primary Dysmenorrhea

The data analyzed from a total of 28 female students, excluding 2 dropouts, having a mean age of 20.71 ± 0.94 years old and mean age at menarche of 12.17 ± 1.36 years. The mean age and mean age at menarche are similar to previous studies that showed high prevalence in these age group and age at menarche (Joseph, 2013; Sulkalingam and Ganesan, 2016; Jaiprakash et al., 2016).

In the study conducted, pain from primary dysmenorrhea were significantly improved within both groups. However, the group with application of high TENS along with relaxation breathing showed more significant result in providing pain relief for primary dysmenorrhea as compared to the group administered with placebo TENS and relaxation breathing with a p value of less than 0.05 ($p = 0.000$) when comparing the mean difference between both groups. Its can be said that with the addition of high TENS application, the study shows an added effect of pain relief in primary dysmenorrhea. None adverse effects were observed from the participants and starts to show signs of pain reduction within 15 minutes of high TENS application. This is also supported by a study conducted by Dawood and Ramos (1990) where they concluded that TENS provide an added effect of pain relief when in combination of another pain relief method which High TENS in providing pain relief in individuals suffering from primary dysmenorrhea were also supported by previously conducted studies such as in Wang, Lee and Hwa (2009), Parsa and Bashirian (2013) and Patel, Sheth and Vyas (2016). In the study by Wang, Lee and Hwa, (2009) where they concluded that out of 22 participants at childbearing aged, the group with TENS administration provided immediate pain relief and showed significant changes in the degree of autonomic symptoms. Parsa and Bashirian (2013) conducted a study with adolescent having a mean age of 16.18 ± 0.97 proved that both high TENS and placebo TENS application was effective in relieving pain due to primary dysmenorrhea although it was provided through different mechanisms. However, when compared between groups, high TENS provided more significant effect compared to placebo TENS. Study conducted by Patel, Sheth and Vyas (2016) which involved 30 also stated that application of TENS during menstruation provided pain relief but was inferior to the other groups where TENS was administered 3 days prior to menstruation.

Pain modulation was provided through pain gate mechanism in Group A where high TENS blocks the pain signal through stimulation of the large diameter A beta fibers. This in turn produces pain relief at spinal cords level (Mistry et al., 2015). According to Mistry et al. (2015), the study supported that providing TENS with electrode placements at the back region (T10 to L1), it had a 70% reduction in pain and was found to be more effective. When placed at the lower back level L5 to S1, TENS application provided pain relief by stimulating the acupuncture points of the bladder and the uterus (Patel, Sheth and Vyas, 2016). This study showed similarity of significant pain reduction when compared to the previous studies when electrodes of TENS were placed between the region of T10 to S4. The present study theorizes that by placing electrodes at the T10 to S4 region, pain modulation was achieved at the spinal level as it blocks transmission of pelvic viscera pain which is innervated by the inferior hypogastric plexus (T10 to L1) and pelvic splenic nerves (S2 to S4) (Origoni et al., 2014)

In addition, the group that was administered with placebo TENS and relaxation breathing also showed significant decreased in pain score when comparing between pre- test and post- test within the group. Previous study (Ganesh, Donde and Hegde, 2015) also provided evidence that when technique of *Nadi Shodhan*, a slowed phased pranayama, was used on physiotherapy girls with primary dysmenorrhea, quality of life and perceived pain was significantly improved. However, when comparing their methodology which included 10 minutes of daily intervention up to their menstruation, our study's showed that *Nadi Shodhan* was possible in providing immediate effect of pain relief. A systematic review Jafari et al. (2017), the study summarizes a total of 31 publications between the year 1984 to 2015 focusing the association between respiration and pain. Jafari et al. (2017) then concluded that some studies showed that

paced slowed breathing is associated with improvement of pain. The mechanism of relaxation breathing techniques in pain modulation were mentioned to increase pain tolerance by altering the nervous system into parasympathetic state when the stretching of lung tissues inhibits the hyperpolarization and slowly adapting stretch receptors through fibroblasts. (Sharma et al., 2017; Jerath et al. 2006)

In support with several studies, it is also suggested that placebo may also have a role in providing pain relief (Parsa and Bashirian, 2013; Smith and Younan, 2011; Wiech, Ploner and Tracey, 2008). According to Parsa and Bashirian, (2013), the study theorize that placebo TENS provided pain relief by releasing endorphine as supported by a study Petrovic et al. (2002) where it showed similarity of reaction over the cortex and area and brainstem by comparing placebo stimulation and endorphin injection. Wiech, Ploner and Tracey (2008) also explained that the placebo effect is involved in cognitive pain modulation and further elaborated that the placebo effect might take place in reappraisal mechanisms which causes the pain to be perceived as less threatening and in controlled due to the expectation that it will reduce the pain effectively. Although placebo TENS is able to significantly reduce pain in primary dysmenorrhea but it is still not superior to high TENS.

Reasons for Dropouts

There were two drop outs from the total participants of 30 people. One of the reasons for drop out were being unable to attend a session of 30 minute within the first four hour of menstruation due to class schedules. The participant who failed to attend a session within the first four hour of menstrual onset was excluded to avoid confusion in the result on whether the pain reduction was directly from the application of TENS or was it due to time effect. This had been previously discussed by a Tugay et al. (2007), as an important factor to take into consideration when assessing menstrual pain.

The other drop out reported that she no longer suffer from any menstrual pain after consuming hot food and beverages prior to the session. As the participant reported, she did not experience any menstrual cramps anytime within the first four hour of menstrual onset and thus was excluded from the study.

Limitations of the Study

The study faced some limitation and one of it being that the study was not blinded. As the study included physiotherapist students that are familiar with the electrotherapy techniques and they would be able to tell if placebo TENS was admitted to them. Furthermore, following their dismissal from the session, we were unable to monitor the participant's daily activities. This come into consideration when some factors such as exercising or consumption of herbal products and dietary supplements may have also provided pain relief to the participants (Proctor and Farquhar, 2006).

Due to the possible time effect in menstrual pain, we were unable to fully investigate and understand the carry over effect of high TENS and relaxation breathing in pain management of primary dysmenorrhea. As the study was only performed on population of university students with primary dysmenorrhea, the finding could not be addressed to those with secondary dysmenorrhea as the etiology behind both dysmenorrhea are different.

Suggestions for Future Studies

Future studies should try looking into the efficacy of these pain relief methods in people experiencing secondary dysmenorrhea and its carry over effect. As mentioned, since the etiology of primary and secondary dysmenorrhea differs, the research in this field may provide better pain management to those suffering from it.

Beside that, more studies are needed to identify the actual time needed for pain relief to take place after application of TENS or after the performance of relaxation breathing.

Furthermore, future studies are also recommended to look into depth of the applicability and practicality of these techniques in clinical settings.

VI. CONCLUSION

In conclusion, high TENS application was able to give an added effect of pain relief when used alongside relaxation breathing. The effect was proved to be immediate after attending 30 minute of a session of high TENS application and performing relaxation breathing. The study also showed that the placebo group along with relaxation breathing was also significant in providing pain relief in primary dysmenorrhea but was inferior to the effect of high

TENS application along relaxation breathing. As both interventions are safe and free from any adverse effects that are usually seen associated with drugs and medication used for pain management in primary dysmenorrhea, it is advisable to consider the use of high TENS application with relaxation breathing in clinical settings. Moreover, since TENS are portable, safe and relatively inexpensive, those suffering from primary dysmenorrhea are may gain benefit in its usage without having to distract them from their daily activities.

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“Efficacy of High Transcutaneous Electrical Nerve Stimulation (TENS) Application with Relaxation Breathing in Primary Dysmenorrhea”

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<http://dx.doi.org/10.29322/IJSRP.12.06.2022.p12604>

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DEMOGRAPHIC DATA

1. Name: _____

2. Age: _____

3. Contact number: _____

4. Course of Study: _____

5. Age at menarche: _____

6. Are you currently suffering from any known pelvic or reproductive disorder?

Yes No

If "yes", please specify: _____

7. Have you been treated anytime in the past for any known pelvic or reproductive disorder?

Yes No

MENSTRUAL HISTORY (FOR THE LAST 3 MONTHS)

1. Last menstrual date: _____(Date)_____ (Month)

2. Length of cycle: _____(days)

3. Duration per cycle: _____(days)

4. Blood loss per cycle (no. of pads used daily):

Day of cycle	1	2	3	4	5	6	7
No. of pads used							

5. Are your periods regular? (± 7 days in between length of cycles)

Yes No

6. Does your menstrual blood contain clot?

Often

Sometimes

Rarely

Never

7. Do you suffer from stomach/ abdominal pain (menstrual cramps) during menses?

Often

Sometimes

Rarely

Never

8. Onset of menstrual pain every month:

2 days before period

1 day before period

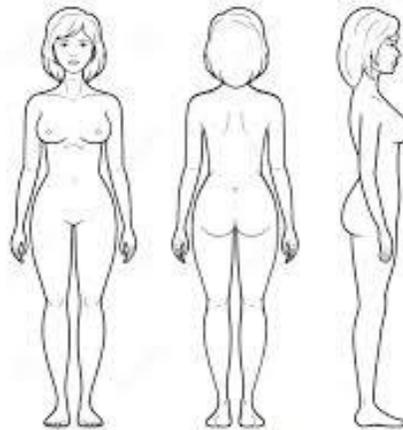
On the day of period

Others: _____

9. Duration of menstrual pain lasting from the day of onset

- 1 day
- 2 days
- 3 days
- More than 3 days

10. Please mark the areas of pain you feel during your menstruation



11. Please tick (✓) the following symptoms that you feel during your menses :

A) PHYSICAL SYMPTOMS

Sweating	
Giddiness	
Sleeplessness	
Headaches	
Abdominal pain	
Low back pain	
Leg cramps	
Swollen or tender breast	
Easily tired	

B) BLADDER AND BOWEL SYMPTOMS

Constipation	
Diarrhea	
Increased frequency of urination	

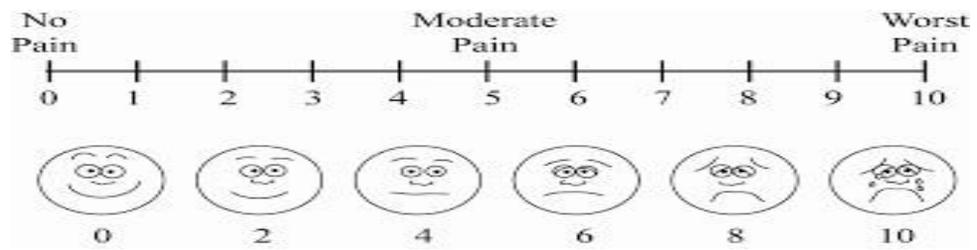
C) GASTROINTESTINAL SYMPTOMS

D) PSYCHOLOGICAL SYMPTOMS

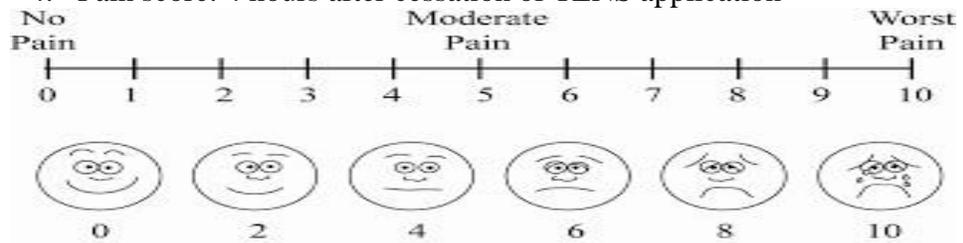
Nausea/ Vomiting	
Upset stomach	
Abdominal bloating	
Increased in appetite	
Loss in appetite	

Anxiety	
Mood swings	
Irritability	
Inability to concentrate	
Nervousness	
Feeling emotional	

[] Others: _____



4. Pain score: 4 hours after cessation of TENS application



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