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Gender response to 10 weeks acupuncture-TENS application on patients who presented with post-injection sciatic pain

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Abstract

Background: Studies to determine gender response to transcutaneous electrical nerve stimulation (TENS) application on individuals who presented with post-injection sciatic pain (PISP) following gluteal injection is not common. A total of 40 subjects comprising 20 males and 20 females who were purposively recruited and conveniently assigned to group A (male) and group B (female) completed the study. Acupuncture-like TENS (AL-TENS) was applied on the 20 male and 20 female subjects, 1 h per session, 3 times per week for the 10 weeks the study lasted.

Result: The pre-intervention baseline scores for the two groups were 8.80 ± 1.05 (Female) and 8.60 ± 1.27 (Male). The result revealed that after 10 weeks of intervention the VAS scores were 2.60± 3.28 ($p < 0.001$) and 2.40 ± 3.28 ($p < 0.001$) for the female and male subjects, respectively. The mean comparison of the female mean VAS scores (2.60 ± 3.28) and male VAS scores 2.40 ± 3.25 after 10 weeks of AL-TENS intervention shows no statistically significant difference ($p > 0.85$) in pain intensity (pain perception).

Conclusions: There was no gender variation in pain perception in subjects with post-injection sciatic pain (PISP) following gluteal muscle injection after 10 weeks of AL-TENS application. Therefore, gender-based variation should not be considered when applying AL-TENS as an instrument of intervention in subjects with PISP.

Trial registration: PACTR2018050034082

Keywords: Gender, Post-injection sciatic pain, Acupuncture TENS

Introduction

Post-injection sciatic pain is a peculiar type of pain that stems from an injury to the sciatic nerve, and its clinical presentations mimic that of sciatica only that its pain stems inferiorly and dorsally from the injection site downward [1]. Due to its sensitive anatomical location and its supply of most of the muscles of the lower limbs, the sciatic nerve is oftentimes traumatized during the gluteal injection. The sciatic nerve could also be irritated by some other medical problems such as herniated disc [2]. Post-injection sciatic pain (PISP) has an intriguing nature and could present with the symptoms of pain, weakness, numbness, and other discomforts along the sciatic nerve from the injection site. One of the tremendous advances in pain management research is the transcutaneous electrical nerve stimulation (TENS) which achieves pain relief via gate control theory. TENS is a non-invasive and inexpensive pain management approach that has been widely used for the treatment of

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chronic and intractable pain that is otherwise non-responsive to analgesics and surgical treatments. TENS is highly advantageous over pain medications in the aspect that it does not have the problem of drug interactions and toxicity. Many other invasive and non-invasive electrical stimulation techniques are useful in various chronic pain conditions like arthritic pain, diabetic neuropathy, fibromyalgia, etc.. The theory has also been extensively studied in the treatment of chronic back pain and cancer pain. Interestingly, results are not attained in some conditions, and the long-term efficacy of the techniques based on the theory is under question. However, a significant and growing body of evidence supports the use of TENS as a valid and effective intervention in acute pain conditions [3–7]. Interestingly, there are so many studies that dealt with the issue of gender differences in pain mechanisms, control, and treatments that had sufficed in the last decades [8]. There is also varying literature that refers to a broad range of topics, including preclinical studies on mechanisms underlying male and female differences in nociception and its control, clinical research on gender differences in pain perception and modulation, epidemiological investigations of sex differences in pain prevalence, and a growing number of studies examining sex differences in response to pain therapies [8–13]. Regarding sex differences in non-pharmacological pain interventions, when patients were asked to focus on the sensory components of pain, men reported less pain than women, whereas when they focused on affective components of pain, women reported more pain than men [14].

Literature data strongly suggest that men and women differ in their responses to pain: they are more variable in women than men, with increased pain sensitivity and many more painful diseases commonly reported among women. Gender differences in pharmacological therapy and non-pharmacological pain interventions have also been reported, but these effects appear to depend on the treatment type and characteristics. It is becoming very evident that gender differences in pain and its relief arise from an interaction of genetic, anatomical, physiological, neuronal, hormonal, psychological, and social factors which modulate pain differently in the sexes. Experimental data indicate that both different modulation of the endogenous opioid system and sex hormones are factors influencing pain sensitivity in males and females. However, the specific mechanisms underlying the observed disparity are not yet clear, and it has been suggested that interaction of biological, psychological, and sociocultural factors probably contributes to these differences. Androgens and estrogens are essential for the development and maintenance of the reproductive system [15]. The previous study by Okonkwo et al. (2019) demonstrated that TENS significantly relieved pain in patients who presented with post-injection sciatic pain (PISP); however, the study did not study gender response to TENS application [1]. The current study, therefore, aims to assess gender variation in pain perception after 10 weeks of AL-TENS application in patients who presented with PISP. It is therefore hypothesized that there will be no statistically significant difference in pain perception between the male and female subjects after 10 weeks of AL-TENS application.

Participants and methods

Participants

The 40 participants met the under listed criteria before participation in the study: age between 15 and 60 years, not obese, sciatic pain that resulted from intramuscular (gluteal) injection with unilateral involvement of lower limb; post-injection sciatic pain that has not existed for more than 1 year; subjects with no muscular wasting; and those who agreed to stop all forms of analgesic medications for 1 week before the study up until the end of the data collation. Those subjects that were obese, with unilateral or bilateral hip or knee osteoarthritis, degenerative spine or disc changes (as revealed from radiological reports), metal implant, elderly, and diabetic neuropathy were excluded from the study [1].

Methods

The study is an experimental design involving 40 subjects—20 males and 20 females. The purposive sampling technique was applied in the recruitment since all the subjects were required to have met a certain selection criterion before being allowed to participate in the study (Fig. 1). The criteria were spelled out to the prospective subjects before the selection to determine those who were qualified for participation. Ethical approval was obtained from the Institutional Review Committee of the Nnamdi Azikiwe University Teaching Hospital EthicCommittee, Nnewi. Participants were recruitedfrom the Department of Physiotherapy, Nnamdi Azikiwe University Teaching Hospital, Nnewi and Landmark Physiotherapy Services, Nnewi. Written consent was obtained from study participants before the intervention and data collation began. Participants were recruited from the (BLINDED FOR PEER REVIEW), (BLINDED FOR PEER REVIEW), and (BLINDED FOR PEER REVIEW).

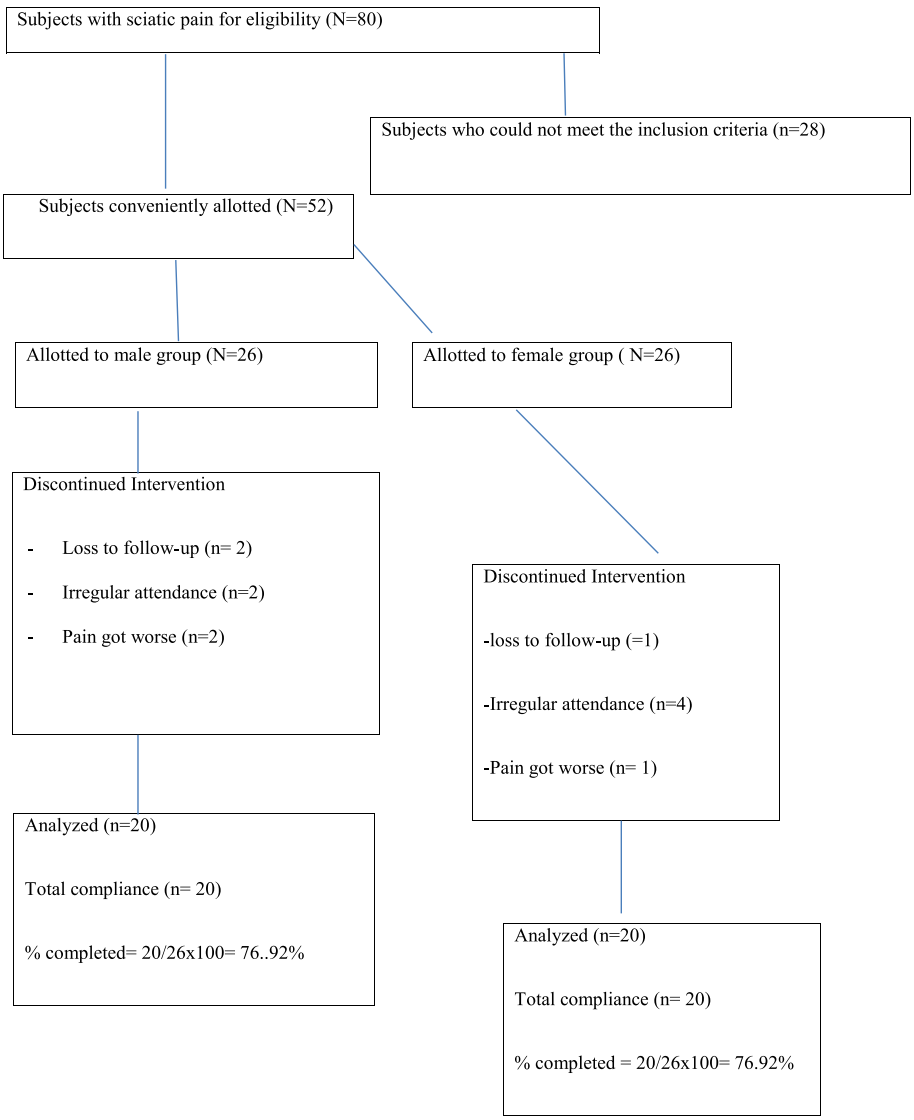

Fig. 1 Recruitment flow diagram. Eighty subjects were recruited; 28 subjects did not meet the inclusion criteria and hence were excluded. Fifty-two subjects met the inclusion criteria and were conveniently allotted to the two groups according to their gender. Twelve subjects, 6 from each group discontinued intervention because of loss to follow-up, irregular attendance, and worsening of pain. Forty subjects, 20 each from each group, completed the study

Instruments

The instrument used to measure the baseline characteristics of subjects include a dual-channel TENS (EZ 105 Model) with a variable pulse frequency of 2–250 Hz, the variable pulse width of 50–250 μs, and variable pulse intensity (amplitude) of 0–80 mA produced by Avionix Medical Devices, TX, USA; cotton and pin for skin sensation test; measuring tape for muscle bulk measurement; toilet soap, distilled water, and hand towel for skin toileting; a Seca model weighing scale calibrated in kilograms for weight measurement, and a Seca model stadiometer calibrated in centimeters and inches for height measurement [1]. The visual analogue scale (VAS) developed by Ali et al. (1983) was used in determining the pre and post-intervention VAS scores across the 10 weeks the study lasted [16]. It is calibrated from 0 to 10 cm; 10 cm represents the highest level of pain, while 0 cm represents no pain. The measuring instrument was presented and described to the subjects who were instructed to describe their level of pain by signifying a number on the VAS. The baseline pretreatment VAS scores were taken and recorded for all the subjects because they constituted the basis of comparison with post-VAS score readings.

Sample size determination

A sample size of 42 has an 80% power of detecting an effect size of 0.9 at an alpha level of 0.05. The sample size was calculated using G* Power 3.0.10 [17].

Intervention procedures

Each subject was made to lie on the available treatment plinth in a position (prone lying) that was comfortable and suitable for TENS application. A pair of adhesive electrodes from the dual-channel TENS machine were placed along the route or course of the presenting sciatic pain as maximum pain relief is obtained when the electrodes are placed on the painful area [18]. Subjects' education on the workings of TENS and skin toileting preceded both the electrode placement and TENS applications [1]. A lower-frequency stimulation (2–5 Hz) and a wider (longer) pulse width (200–250 μs) with intensity greater than that of the traditional TENS reflected the AL-TENS parameter chosen because of its "carry-over effect". With all settings on 0, the TENS machine was switched on and the output increased until the patient perceives a fairly strong buzzing or pulsating sensation. The pulse frequency, pulse width, and pulse amplitude were varied (because each patient/subject felt and experienced each of these parameters differently) until the level that was most comfortable to the subject and which did not produce motor contraction was found. When the subject ceased to feel the stimulus after a few minutes because of nervous accommodation, the output intensity was turned up until some strong sensation was felt again [1]. The subjects received a total of 1 h of AL-TENS per treatment session, three times per week for the 10 weeks the study lasted [1]. The mean VAS scores were collated for data analysis after the 1st, 2nd, 3rd, 4th, 5th, 6th, 7th, 8th, 9th, and 10th weeks of ALT intervention.

Statistical analysis

The Stata 13 statistical software (College Station, TX Stata Corp LP, 2017) was used for data analysis. The student *t* test was used to analyze the baseline mean VAS scores and post mean VAS scores for the male (Group A) and female (Group B) subjects across the 10 weeks of study, while the independent student *t* test was used to compare the two groups. Statistical level of significance was set at $p < 0.05$.

Results

The data used for this study were collected from forty (40) patients who completed the study to determine gender response to 10 weeks of AL-TENS application on patients who presented with PISP.

Table 1 The baseline characteristics of the participants

Variable	Mean ± STD
Sex	Males = 20, Females = 20
Age (years)	29.72 ± 15.22
Duration of symptoms (months)	3.95 ± 1.72
Weight (kg)	55.7 ± 17.63
Height (m)	1.41 ± 1.14
Baseline VAS scores	M = 8.80 ± 1.05, F = 8.60 ± 1.27

The results of the data analysis are shown in Tables 1, 2, 3, 4, and 5 below.

Results obtained show that of the 40 subjects, 20 were males, while 20 were females. Their mean age was 29.72 ± 15.22 years, and the mean duration of symptoms was 3.95 ± 1.72 months. The mean body weight and height were 55.7 ± 17.63 kg and 1.41 ± 1.14 m respectively. The mean baseline VAS scores for the two groups were 8.80 ± 1.05 and 8.60 ± 1.27 for the male and female groups, respectively.

The results from Table 2 show that the mean ages for the female and male groups were 30.6 ± 18.0 and 28.85 ± 12.26 ($p > 0.001$), respectively, and the mean duration of symptoms for the female and male groups were 3.35 ± 1.26 and 4.55 ± 1.93 months ($p < 0.001$), respectively. Also, the mean weight between the female and male groups were 56.15 ± 17.37 and 55.25 ± 18.33 kg ($p > 0.001$), respectively, and the mean height among the female and male groups was 1.41 ± 0.13 and 1.41 ± 0.16 m ($p > 0.001$), respectively.

There was no statistically significant difference ($p > 0.001$) between the female and male groups for age, weight, height, and baseline VAS scores. In contrast, there was a statistical difference between female and male groups for the duration of symptoms ($p < 0.025$).

In Table 3, the female baseline mean VAS scores were 8.80 + 1.05, and the post-intervention mean VAS scores were 2.60 $\pm$ 3.28. There was a statistically significant difference ($p < 0.001$) across each week (week 1–week 10) of post mean VAS scores and the baseline for the female participants.

In Table 4, the male baseline mean intervention score was 8.60 $\pm$ 1.27 and the post-intervention mean VAS score was 2.46 + 3.25. There was a statistically significant difference ($p < 0.001$) across each week (week 1–week 10) of post mean VAS scores and the baseline for the male participants.

In Table 5, a comparison of mean VAS scores of female subjects (2.60 + 3.28) and male subjects (2.40 + 3.25) after 10 weeks of ALT intervention shows no statistically significant difference ($p > 0.001$).

Table 2 The mean comparison of age, duration of symptom, weight, height, and baseline VAS scores between males and females

Variable	Female (n = 20) Mean ± STD	Male (n = 20) Mean ± STD	Mean differences	t value	p value
Age (years)	30.6 ± 18.0	28.85 ± 12.26	− 1.750	0.359	0.721
Duration of symptoms (months)	3.35 ± 1.26	4.55 ± 1.93	1.200	− 2.321	0.025*
Weight (kg)	56.15 ± 17.37	55.25 ± 18.33	− 0.900	0.159	0.874
Height (m)	1.41 ± 0.13	1.41 ± 0.16	0.000	0.000	1.000
Baseline score	8.80 ± 1.05	8.60 ± 1.27	0.20	0.541	0.592

*Significant *p value < 0.05*

Discussions

This study compared gender variation in pain perception after 10 weeks of application of AL-TENS in the management of post-injection sciatic pain. This was in line with a significant and growing body of evidence that supports the use of TENS as a valid and effective intervention in acute pain conditions [1, 3–7]. In carrying out this study, it was noted that literature on previous studies comparing gender variation to TENS application in the management of PISP was sparse. However, the authors applied the findings of other related studies (pharmacological and non-pharmacological) comparing gender perception of pain to explain the outcome of the present study. The pre-intervention characteristics of age, weight, height, and the baseline VAS scores were matched and were not statistically significant ($p > 0.001$) at baseline hence may not have influenced the outcome of the study. In contrast, there was a statistically significant difference ($p < 0.001$) for the duration of symptoms between the male and female groups at the baseline. The mean weight of the subjects shows that the obese people were not part of the study; hence, the effect of adipose tissue could not have influenced the transmission of the electrical impulses from the AL-TENS application which helps to trigger endogenous substances that bring about pain relief [19]. The previous study has shown that the amount of subcutaneous fat between the muscle and the electrode is well known to influence sEMG amplitude [19, 20]. Also, the mean duration of symptoms has shown that the subjects were all having chronic pains at the time of presentation; hence, the difference in the duration of symptoms might not have influenced the outcome of the study as TENS is effective in the management of chronic pain [21].

Table 3 demonstrated the effectiveness of ALT in the management of post-injection sciatic pain among the female subjects who participated in the experimental study. Across the 10 weeks of the study, there were decreases in the pain perception by the female subjects across the 10 weeks of study as demonstrated from the post-intervention VAS scores. The female subjects showed recorded maximum benefit at the 10th week of AL-TENS application statistically. Similarly, in Table 4, the male subjects who presented with PISP had a steady decline in pain perception from the baseline to the 10th week

Table 3 The mean comparison of pain levels (post visual analogue scale scores) in females across 10 weeks compared with the baseline (after the intervention)

Time	PVA scores (Mean ± Standard deviation)		Mean differences	t value[a]	p value
	At baseline	Weeks			
Week 1	8.80 ± 1.05	4.40 ± 2.68	4.40	7.228	< 0.001*
Week 2	8.80 ± 1.05	4.90 ± 3.22	3.90	5.669	< 0.001*
Week 3	8.80 ± 1.05	3.95 ± 2.74	4.85	7.282	< 0.001*
Week 4	8.80 ± 1.05	3.80 ± 3.38	5.00	6.426	< 0.001*
Week 5	8.80 ± 1.05	2.95 ± 3.10	5.85	7.785	< 0.001*
Week 6	8.80 ± 1.05	2.85 ± 3.03	5.95	8.182	< 0.001*
Week 7	8.80 ± 1.05	3.40 ± 3.23	5.40	6.959	< 0.001*
Week 8	8.80 ± 1.05	2.80 ± 3.27	6.00	7.814	< 0.001*
Week 9	8.80 ± 1.05	2.75 ± 3.33	6.05	7.597	< 0.001*
Week 10	8.80 ± 1.05	2.60 ± 3.28	6.35	8.152	< 0.001*

*Significant p value < 0.05; [a]paired sample t test value

Table 4 The mean comparison of pain levels (post visual analogue scale scores) in males across 10 weeks compared with the baseline (after the intervention)

Time	PVA scores (Mean ±Standard deviation)		Mean differences	*t* value[a]	*p* value
	At baseline	Weeks			
Week 1	8.60 ± 1.27	4.15 ± 2.73	4.45	7.014	< 0.001*
Week 2	8.60 ± 1.27	4.10 ± 2.93	4.50	6.281	< 0.001*
Week 3	8.60 ± 1.27	3.85 ± 2.94	4.75	7.467	< 0.001*
Week 4	8.60 ± 1.27	3.45 ± 3.57	5.15	6.760	< 0.001*
Week 5	8.60 ± 1.27	2.75 ± 3.20	5.85	8.052	< 0.001*
Week 6	8.60 ± 1.27	3.0 ± 3.34	5.60	7.380	< 0.001*
Week 7	8.60 ± 1.27	2.8 ± 3.42	5.80	7.403	< 0.001*
Week 8	8.60 ± 1.27	2.65 ± 3.37	5.95	7.985	< 0.001*
Week 9	8.60 ± 1.27	2.65 ± 3.16	5.95	8.622	< 0.001*
Week 10	8.60 ± 1.27	2.40 ± 3.25	6.20	8.881	< 0.001*

Significant p value < 0.05; [a]paired sample t test value

of study. The male subjects had a maximum benefit at the 10th week because that is where they experience a maximum decline in their level of pain as seen from the post-VAS scores across the 10 weeks of AL-TENS intervention. Interestingly, in between the pain perception decreases recorded in the two groups, there were minor spikes in pain level in the 2nd and 7th weeks for the female subjects and the 6th and 7th weeks for the male subjects. It was also noted that in the female group, the highest level of pain perception was felt at the 2nd week, while at the 8th and 9th weeks, the pain perception plateaus with a further decline in the pain level in the 10th week. Also, in the male subjects, there was a steady decline in pain level up until the 6th and 7th weeks where there were minor spikes in pain perception. The pain level plateaus at the 8th and 9th weeks and declined maximally at the 10th week. The authors, however, noticed that the spikes were not statistically significant to affect the outcome of the current study. It is, therefore, speculated that the spikes in pain level, as seen in both the tabular and graphical result presentations for the two experimental groups, could be attributed to an uncontrolled extraneous factor that might not have been factored during the study. These findings are consistent with the graphical illustration in Figs. 2 and 3 that represented the post-VAS pattern across the 10 weeks in the male and the female groups. In the two-line graphs, there was a slope (decrease in pain intensity level) from the first week the intervention started to the 10th week the intervention ended. However, the intervening spikes in post-intervention VAS scores during the 10 weeks TENS intervention are manifest in the line graph. These findings from the current study tend to agree with the previous studies which reported that TENS application was effective in the management of varying kinds of musculoskeletal and post-surgical pain [1, 22–34].

Table 5 The mean comparison of pain levels (post visual analogue scale scores) between males and females across 10 weeks (after the intervention)

TIME	Mean ±Standard deviation		Mean differences	t-value	*p*-value
	Female	Male			
Week 1	4.40±2.68	4.15±2.73	-0.250	0.291	0.772
Week 2	4.90±3.22	4.10±2.93	-0.800	0.820	0.417
Week 3	3.95±2.74	3.85±2.94	-0.100	0.111	0.912
Week 4	3.80±3.38	3.45±3.57	-0.350	0.318	0.752
Week 5	2.95±3.10	2.75±3.20	-0.200	0.200	0.842
Week 6	2.85±3.03	3.0±3.34	0.150	-0.148	0.882
Week 7	3.40±3.23	2.8±3.42	-0.600	0.569	0.572
Week 8	2.80±3.27	2.65±3.37	-0.150	0.142	0.887
Week 9	2.75±3.33	2.65±3.16	-0.100	0.097	0.923
Week 10	2.60±3.28	2.40±3.25	-0.200	0.193	0.847

The current study shows no difference in pain perception level between the male and female groups across the 10 weeks the study lasted as demonstrated in tabular form in Table 5 and graphically in Fig. 4. As can be deduced from the graph (Fig. 4), the females seem to feel higher pain at the 2nd, 4th, and 7th weeks, while at other weeks, the level of pain perception seems to be the same for the two groups. However, the pain perception plateaus at the 8th, 9th, and 10th weeks. This is an indication that the male subjects felt as much relief from the pain arising from the PISP after AL-TENS application as the female subjects after 10 weeks of AL-TENS. However, this relief or analgesia was not statistically significant across the weeks and at the end of the 10th week of

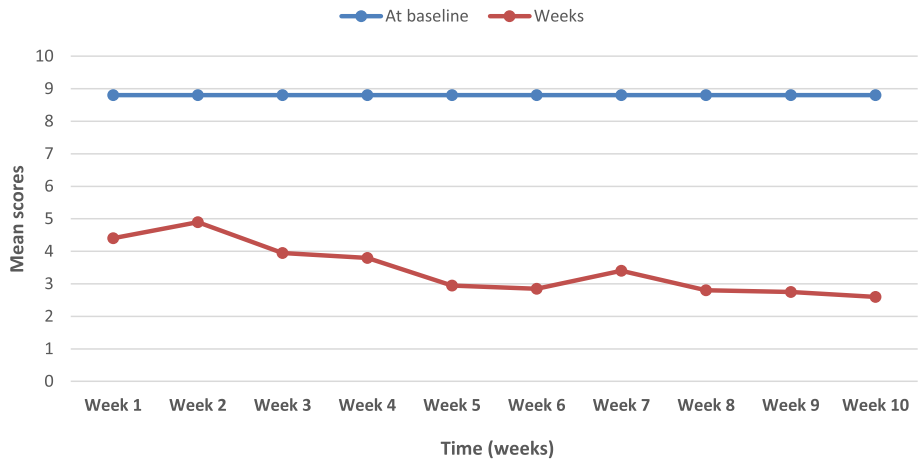

Fig. 2 Line graph showing the mean comparison of pain levels (post visual analogue scale scores) in females across 10 weeks compared with the baseline (after the intervention).This graph shows the baseline represented by the blue line. The blue line is constant throughout the study, the red line representing post-intervention VAS scores with spikes at the 2nd, 4th, and 7th weeks. The pain seems to plateau at the 8th, 9th, and 10th weeks

AL-TENS intervention. The null hypothesis has been proved right by this finding in the current study: there was no statistically significant difference in pain perception between the male and female subjects after the 10-week application of AL-TENS in subjects who presented with PISP. With regards to this finding, the authors noted a dearth of precedent studies to compare the outcome with but acknowledged that it differs with previous study findings on pain management, outside the TENS domain studies, which indicated that variability in sex differences affect pain perception and relief. Several studies based on pharmacological and non-pharmacological interventions seem to have documented variability in pain perception between the male and female subjects [9, 13, 14, 19]. The gender differences in pain perception after pharmacological and non-pharmacological interventions, from the previous studies, were linked to genetic, anatomical, physiological, neuronal, hormonal, psychological, and social factors. Also, experimental data indicate that both a different modulation of the endogenous opioid system and sex hormones are factors influencing pain sensitivity in males and females [15]. These findings were in variance with the current study which reports no statistically significant difference ($p < 0.05$) in pain perception between the male and female participants after 10 weeks (30 h) of AL-TENS application. The outcome of the current study

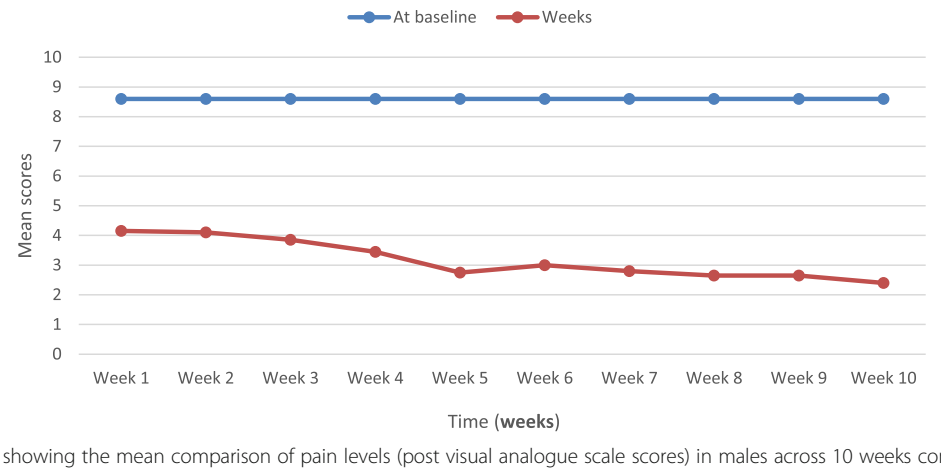

Fig. 3 Line graph showing the mean comparison of pain levels (post visual analogue scale scores) in males across 10 weeks compared with the baseline (after the intervention). The graph maintains a steady slope from the 1st week to the 5th week. It spikes at the 6th and 7th weeks then slopes to plateau at the 8th to 10th weeks

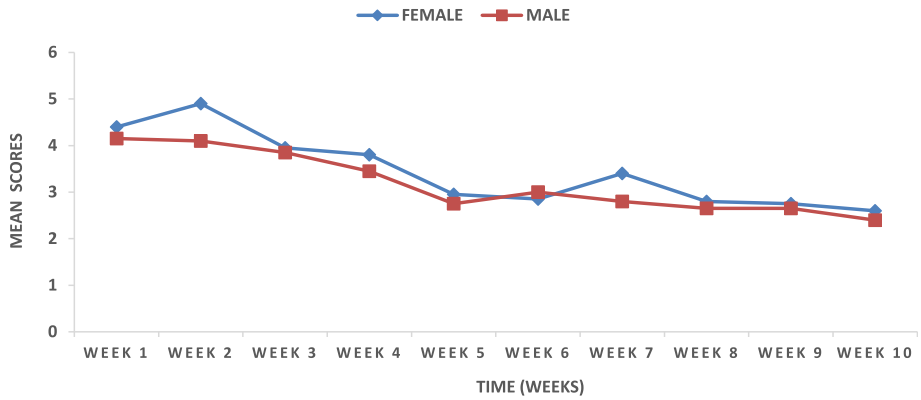

Fig. 4 Line graph showing the mean comparison of pain levels (post visual analogue scale scores) between males and females across 10 weeks (after the intervention). There were spikes in pain perception at the 2nd and 7th weeks in the female group, and 6th and 7th in the male group after acupuncture TENS application

shows that the mechanism of pain modulation in the female and the male subjects was the same. TENS works by triggering the generation of morphine-type (encephalin) substances via the pain gate theory to achieve pain relief, the current study finding shows that both male and female groups benefitted from the mechanism of AL-TENS modulation of pain via a morphine type effect on the C fibre system which results from encephalin produced by interneurons in the posterior horn which have been stimulated by A-δ pain receptor fibres. Consequently, the male patients presenting with PISP had as much relief as does the female who presented with PISP irrespective of the gender-based variability in subjects as previously reported by the other studies. The authors suggest that the TENS type (AL-TENS) applied in this study which is known to have a carry-over effect or longer analgesia unlike other TENS types might have contributed to the outcome of this current study. No previous studies specifically investigated and compared the gender variation in pain perception after AL-TENS application.

Conclusion

There was no gender variation in pain perception in subjects with post-injection sciatic pain after 10 weeks of ALT application. The implication to pain management is that ALT has equal beneficial therapeutic effects on both male and female subjects who presented with post-injection sciatic pain in the current study.

Abbreviations

PISP: Post-injection sciatic pain; PCA: Patient-controlled analgesia; TENS: Transcutaneous electrical nerve stimulation; AL-TENS: Acupuncture-like TENS; VAS: Visual analogue scale; Hz: Hertz; μs: Microsecond; mA: milliamps; *n*: Number; min: Minutes

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Authors' contributions

UPO and SCI were responsible for Conceptualization/Design; EFE and UNA did Acquisition, analysis; IUO and KUA did Interpretation of data; UPO and COO were responsible for Drafting and revision. The authors have read and approved the manuscript.

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Availability of data and materials

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Declarations

Ethics approval and consent to participate

Ethics approval was obtained from the Nnamdi Azikiwe University Teaching Hospital Ethics Committee (Ref: NAUTH/CS/66/VOL3/37). A written consent was obtained from study participants before the commencement of the study.

Consent for publication

Consent for publication is not applicable.

Competing interests

The authors have declared that no competing interest exists.

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