# **Research Papers**

# Relative Effectiveness of Transcutaneous Electrical Nerve Stimulation and Hot Packs in the Management of Hemiplegic Shoulder Pain

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#### ABSTRACT

Transcutaneous electrical nerve stimulation (TENS) and hot packs (HP) are among the common modalities used in the management of hemiplegic shoulder pain (HSP). The choice of either of the modalities is dependent on personal discretion rather than on proven relative effectiveness. This study examined the relative effectiveness of TENS and hot packs in the management of HSP in stroke patients.

Nineteen stroke patients with shoulder pain were randomized into two intervention groups. Both groups were treated with massage, passive and active mobilization of the shoulder joint twice a week with at least 24 hours interval for 6 consecutive weeks. In addition, each participant also received either TENS or hot packs for 30 minutes as adjuncts. Pain intensity and shoulder functional status were assessed on the Brief Pain Inventory Short Form Question-12 (BPI SF-12) and Action Research Arm Test (ARAT) at baseline and fortnightly by a blinded investigator. Data analysis included Friedman's mean rank and Mann-Whitney U tests for differences in the variables within and between groups respectively. P < 0.05(two-tailed) was considered statistically significant.

The study neither showed statistically significant (P > 0.05) reduction in pain nor did it meet the set minimal clinically important difference (MCID) for

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both groups. However, there was equal statistically significant improvement (P<0.05) and MCID in shoulder functions for both interventions.

It was concluded that both modalities modulated HSP in stroke survivors within six weeks of treatment without either being superior to the other. Thus either could be used to augment other forms of intervention.

**Key words:** Hemiplegic shoulder pain, relative effectiveness, transcutaneous electrical nerve stimulation, hot pack

#### **INTRODUCTION**

The ravaging health consequences of strokes are a source of concern to health care providers. Stroke has been rated as the third leading cause of death in the Western world and is emerging as a leading cause of preventable death and disability in developing countries.<sup>1,2</sup> It constitutes a major neurological load among hospital admissions in West Africa and accounts for major morbidity and mortality in the sub region.<sup>3</sup>

Hemiplegic shoulder pain (HSP) is inimical to functional upper limb recovery in stroke survivors. It is a common complication which is reported to affect 16 to 72 per cent of the patients.<sup>4</sup> Regardless of age and sex, HSP could occur as early as the second week after a stroke attack.<sup>5</sup> The cause of HSP is a subject of extensive debate and is probably multifactorial.<sup>6</sup> Shoulder pain can hinder rehabilitation and functional recuperation, owing to its debilitating effects, which may mask any improvement in motor function.<sup>7</sup> In spite of intense efforts to prevent shoulder pain, clinical experience shows that the total eradication of this complication still remains enigmatic and the optimal management for the pain is uncertain.<sup>8, 9</sup>

The evidence of TENS effectiveness in managing hemiplegic shoulder is equivocal. In a Cochrane review, Carroll and colleagues concluded that there is insufficient evidence to draw any conclusions about its (TENS) effectiveness for the treatment of chronic pain in adults.<sup>8</sup> High intensity TENS together with conventional rehabilitation were shown to be significantly effective in reducing shoulder pain and increasing the passive range of motion in stroke patients.9,10 In contrast, a review by Price and Pandyan found that TENS produced no significant change in pain intensity among patients with HSP, compared to the control group, although there was a clinically important treatment effect evidenced by the pain-free lateral rotation of the shoulder joints.<sup>11</sup> TENS also appears to be an effective adjunct in the regaining of motor functions and improving daily activities in hemiplegic patients.12, 13

The use of hot pack therapy in the reduction of pain and joint stiffness is well documented.<sup>14</sup> Anecdotal evidence shows that it is widely used in managing hemiplegic shoulder pain, however evidence for its relative efficacy is lacking.<sup>6</sup> The application of hot packs has been found to increase the range of movement by altering the properties of connective tissue that are affected in movement dysfunction.<sup>15</sup>

Based on personal observation, it appears that the preference for either of these modalities largely depends on personal choice and availability rather than on their relative effectiveness. Given that HSP is one of the major sequels of stroke; further exploration to find the best management strategy is worth pursuing. This study investigated the relative effectiveness of TENS and the use of hot packs in the management of stroke patients with HSP. We hypothesized that no significant difference would be found between the effectiveness of the two modalities.

#### **METHODS**

Nineteen participants comprising 6 men and 13 women were recruited into the randomized clinical trial. They were included if; the hemiplegia was as a result of stroke, pain in the hemiplegic shoulder was  $\geq$  4 on the Brief Pain Inventory Short Form Question-12 (BPI SF-12), the pain had lasted for at least 2 weeks and at most two months. Subjects with a history of pre-stroke shoulder pain, acute inflammation overlying skin infection, and impaired sensation were excluded.

## MATERIALS

The following materials were used for data collection:

- 1. Hot packs: These were heated by Packheater 451 (Enraf-Nonius, Holland) and maintained the temperature of water at about 70°C.
- 2. TENS unit: A dual channel digital portable TENS unit-Prom-350 (Promed, USA).
- The Brief Pain Inventory Short Form Question-12 (BPI SF-12): A self-reporting 11-point numeric rating scale (from 0 to 10) that assessed 'worst pain' in the last 7 days.
- Action Research Arm Test (ARAT): For assessing shoulder functions using the gross movement components. Each movement was scored from 0 to 3 as follows:
  - 3 Individual performs the test normally
  - 2 Individual completes the test but takes abnormally long time or has great difficulty
  - 1 Individual performs the test partially
  - 0 Individual cannot perform any part of the test
- 5. Soapy water and cotton wool: These were used to clean the anterior and posterior aspects of the affected shoulder joint.

The consenting patients were randomly allocated into two groups (10 in group I for TENS and 9 in group II for hot pack). This was conducted by an independent observer who was not responsible for determining their eligibility for the study. On the first day of appointment, participants were informed about the protocols involved and their age, sex, type of stroke, side of hemiplegia, duration of shoulder pain and pain aggravating factors were recorded. On each visit, patients in both groups were treated with massage and passive and active mobilization of the affected shoulder joint. Thereafter, the affected shoulder joint was cleaned with soap and water, prior to TENS application in group I. The application mode was low intensity TENS i.e., a frequency of 100Hz, a phase duration of  $60\mu$ s and 30 minutes treatment time. 9,14

Group II received hot pack therapy which was preceded by thermal sensation tests on the affected joint using two test tubes with each containing either warm or cold water. The hot pack, preheated to a temperature of about 70°C was covered with layers of Turkish towel and then wrapped round the painful shoulder joint for 30 minutes.<sup>14</sup> Participants in both groups were made to assume either lying or sitting positions depending on which position they found comfortable. An independent physiotherapist who was blinded to the subjects' treatment groups was involved to evaluate the treatment outcomes fortnightly throughout the study period. Each subject was treated twice a week for six consecutive weeks, with at least a 24 hour interval between the treatments. The study's protocol was approved by the ethical committee of the School of Allied Health Sciences, University of Ghana.

#### DATA ANALYSIS

Data were collected and analysed with the intentionto-treat (ITT) principle using the SPSS version 13.0 for Windows statistical software. The minimal clinically important differences (MCIDs) for the variables, in comparison to baseline scores, were defined as follows: pain reduction  $\ge 30\%$  on the BPI SF-12; shoulder function improvement  $\ge 10\%$  on the ARAT.<sup>16</sup>

Analysis involved both descriptive and inferential statistics. Differences in categorical data were analysed using Fisher's exact test. The mean and median were calculated for BPI SF-12 and ARAT scores respectively. The baseline values for the variables were compared using the independent t-test. The Mann-Whitney U-test compared the variables between the two groups whilst the Friedman mean rank test was used for within group analysis. P<0.05 (two-tailed) was considered significant for all the tests at 95% confident interval.

## RESULTS

The mean ages of the participants in the TENS and hot pack groups were  $56.6 \pm 6.6$  years and  $60.0 \pm$ 8.2 years respectively. The mean age of all the subjects was  $58.21 \pm 7.37$  years (table 1).

Table 1. Patients' clinical attributes and baseline measures

|                           | Treatme        | Between           |                                       |
|---------------------------|----------------|-------------------|---------------------------------------|
|                           | TENS<br>Group  | Hot pack<br>Group | - groups<br>differences<br>(P- value) |
|                           | (N = 10)       | (N = 9)           | 0.000+                                |
| Age (years) Mean $\pm$ SD | $56.6 \pm 6.6$ | $60.0 \pm 8.2$    | 0.329*                                |
| Gender                    |                |                   | 1.000*                                |
| Male n (%)                | 3 (30)         | 3 (33.3)          |                                       |
| Female n (%)              | 7 (70)         | 6 (66.7)          |                                       |
| Type of stroke            |                |                   | 0.459*                                |
| Ischaemic n (%)           | 6 (60)         | 4 (44.4)          |                                       |
| Haemorrhagic n (%)        | 0 (0)          | 2 (22.2)          |                                       |
| Unobtainable n (%)        | 4 (40)         | 3 (33.3)          |                                       |
| Duration of pain          |                |                   | 0.848*                                |
| Less than 2 weeks n (%)   | 3 (30)         | 3 (33.3)          |                                       |
| 2 weeks – 1 month n (%)   | 4 (40)         | 2 (22.2)          |                                       |
| 1 month – 2 months n (%)  | 3 (30)         | 4 (44.4)          |                                       |
| Side of hemiplegia        |                |                   | 0.628*                                |
| Right n (%)               | 4 (40)         | 2 (22.2)          |                                       |
| Left n (%)                | 6 (60)         | 7 (77.8)          |                                       |
| Situations with pain      |                |                   | 0.650*                                |
| Rest n (%)                | 3 (30)         | 4 (44.4)          |                                       |
| Movement n (%)            | 7 (70)         | 5 (55.6)          |                                       |
|                           |                |                   | ~ .                                   |

*Notes:* SD = Standard deviation; N= Group number; n= Subgroup number; \* =Non-significant.

The clinical attributes as shown in table 1 indicate that both groups were comparable in terms of sex, type of stroke, age, side of hemiplegia, duration of pain and situations which aggravated the pain, using Fisher's exact test at baseline.

The difference in pain level between the TENS and the hot pack groups on BPI SF-12 was not statistically significant (P > 0.05) at baseline. Within group analysis of change in pain level showed that neither group registered a statistically significant change in pain levels (P > 0.05) for both interventions (table 2). The minimal clinically important difference (MCID) in pain reduction was 16.9% and 11.8% after six weeks for the TENS and hot pack groups respectively.

| Table 2. | Changes | in | Mean | Scores | on | the | BPI | SF-12 | 2 |
|----------|---------|----|------|--------|----|-----|-----|-------|---|
|----------|---------|----|------|--------|----|-----|-----|-------|---|

|                               | Treatment Group  |                   |                               |
|-------------------------------|------------------|-------------------|-------------------------------|
|                               | TENS Group       | Hot pack<br>Group | Between groups<br>differences |
|                               | Mean $\pm$ SD    | Mean $\pm$ SD     | (P- value) <sup>a</sup>       |
| Baseline                      | $5.90\pm1.370$   | $5.67 \pm 1.414$  | 0.706                         |
| score                         |                  |                   | $(Z = -0.377)^*$              |
| Week 2                        | $5.70 \pm 1.160$ | $5.78\pm1.093$    | 0.847                         |
| score                         |                  |                   | $(Z = -0.256)^*$              |
| Week 4                        | $5.50\pm1.581$   | $5.67\pm1.936$    | 0.828                         |
| score                         |                  |                   | $(Z = -0.249)^*$              |
| Week 6                        | 4.9 ± 1.524      | $5.00\pm1.000$    | 0.769                         |
| score                         |                  |                   | $(Z = -0.294)^*$              |
| Within group                  |                  |                   |                               |
| (P-value) <sup>b</sup>        | 0.100*           | 0.136 *           |                               |
| analysis <sup>b</sup> $(x^2)$ | 6.23             | 5.53              |                               |
| df                            | 3                | 3                 |                               |

*Notes:* <sup>a</sup> = Between group analysis (Mann-Whitney U test);

<sup>b</sup> = Within group analysis (Friedman test);

SD = Standard deviation; \* = Non-significant;

 $\div^2$  = Chi-square; df = degree of freedom.

There was no significant difference (P > 0.05) in the baseline ARAT scores between the two groups. Both groups improved significantly (P<0.05) in ARAT scores after 6 weeks of treatment. The MCID was 34.1% for the TENS group and 21.7% for the 

 Table 3. Changes in Median Scores on the Action Research

 Arm Test (ARAT)

hot pack group when compared to the baseline.

However, there was no significant difference

(P>0.05) between the ARAT scores for the two

|                                       | Treatment Group                               |   | Between groups<br>differences |
|---------------------------------------|---|---|-------------------------------|
|                                       | TENS Group                                    | TENS Group Hot pack<br>Group                  |                               |
|                                       | Median (IQR)                                  | Median (IQR)                                  |                               |
| Baseline<br>score                     | 4.0 (2-7)                                     | 6.0 (3-7)                                     | 0.536<br>(Z = -0.619)*        |
| Week 2<br>score                       | 4.5 (2-8)                                     | 5.0 (3-7)                                     | 0.736<br>(Z = -0.370)*        |
| Week 4<br>score                       | 4.5 (3-8)                                     | 6.0 (4-8)                                     | 0.796<br>(Z = -0.288)*        |
| Week 6<br>score                       | 5.0 (4-9)                                     | 7.0 (5-8)                                     | 0.867<br>(Z = -0.167)*        |
| Within group<br>analysis <sup>b</sup> | $P = 0.005^{**},$<br>$x^2 = 12.99,$<br>df = 3 | $P = 0.007^{**},$<br>$x^2 = 12.99,$<br>df = 3 |                               |

*Notes:* \* = Between groups analysis (Mann-Whitney U test);<sup>b</sup> = Within group analysis (Friedman test); \*= Non-significant; \*\*=Significant; IQR= Interquartile range;  $x^2$ =chi-square; df= Degree of freedom.

## DISCUSSION

groups (table 3).

The randomized clinical trial showed that TENS and hot packs had comparable effects on the primary outcome measures. Changes in the scores on the Brief Pain Inventory Short Form Question-12 (BPI SF-12) did not indicate any statistical significant reduction in pain within and between the groups after six weeks of treatment. Pain reduced by 16.9% and 11.8% from the baseline for the TENS and hot pack groups respectively, which falls short of the targeted 30% minimal clinically important difference.<sup>16</sup> Indeed, there are diverse views on the effectiveness of TENS in the management of hemiplegic shoulder pain. The finding in this study is at variance with the reports of Leandri et al., and Ekim et al., who reported significant effects of TENS together with conventional rehabilitation in reducing shoulder pain in stroke patients.<sup>9,10</sup> It is however consistent with the review by Price and Pandyan who found that patients who received electrical stimulation along with TENS had no change in pain intensity, compared with the control group, although a significant treatment effect was reported.<sup>11</sup> In a Cochrane review, Carroll et al., concluded that there is insufficient evidence to draw any conclusions about the effectiveness of TENS for the treatment of chronic pain in adults.<sup>8</sup>

The disparity in these studies could be due to many factors among which are methodological designs (including the use of unspecified number of multiple blind testers), the frequency of treatment, and the outcome measures adopted. Previous researchers employed more treatment sessions per week as against the two treatment sessions adopted in the present study. Adoption of fewer sessions was informed by the need to conform to the participants' regular physiotherapy visits to the out-patient unit. Again, BPI SF-12 used in this study measures the 'worst' pain experienced in the last week as against the present pain intensity measured by the visual analogue scale (VAS) used in the previous studies. No previous research study that investigated the use of hot packs in the management of HSP was found though anecdotal evidence shows that it is widely used, though no comparison could be made with other studies.

Both modalities demonstrated significant improvement in motor function recovery on ARAT following the intervention. The finding was in tandem with the previous studies which had shown that stimulation by means of low-TENS could be a valuable complement to the usual training of arm and hand functions in the rehabilitation of stroke patients.<sup>12,13</sup> Also, the efficacy of hot packs is premised on its beneficial effects on the connective tissues that can cause movement dysfunction, thereby increasing the range of movement of the affected joints.<sup>15</sup>

The recruitment of participants in this study was slow owing to limited adherence to rehabilitation in our environment and it resulted in the failure to achieve a large sample size. This in turn informed the decision for the main short-term follow-up of six weeks. Perhaps, a larger sample size coupled with a longer period of evaluation could possibly generate proportionate wider outcomes.

#### CONCLUSION

In view of the aforementioned factors, we conclude that both TENS and hot pack therapies potentially contribute to the modulation of hemiplegic shoulder pain in stroke patients within six weeks of rehabilitation and both could become handy in augmenting other forms of management.

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