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ABSTRACT

Introduction: Whiplash associated disorders are currently a common musculoskeletal problem. Besides the high incidence in western countries, the costs derived from prolonged treatment and medicolegal compensation, make this entity a challenging problem for clinicians and insurance companies. To date, no conservative treatment has shown clear superiority in the management of acute cases.

Hypothesis: Percutaneous needle electrolysis (PNE) is an effective approach for the treatment of Quebec type II acute whiplash syndrome (AWS). PNE consists in the application of brief galvanic currents into a damaged structure, producing a local controlled inflammatory response, with subsequent tissue healing enhancement.

Materials and methods: One hundred AWS patients were randomized into: (a) standard physiotherapy intervention for AWS; (b) a standardized PNE protocol for AWS. Both groups were assessed for treatment outcome at the 5th week mark.

Results: Both groups showed a statistically significant improvement according to the Northwick Park Neck Questionnaire, visual analogic scale and pressure pain threshold. The improvement was similar in both groups, except for the pain pressure threshold, with a 56.6% reduction vs. 44.4% reduction in favour of the PNE group (P=0.035). In addition, the physio group consumed a mean treatment time of 20 hours, while the PNE intervention averaged less than 1 hour in total.

Discussion: PNE can be considered as an effective treatment option for AWS. Importantly, the technique is highly cost-effective, with limited equipment required and a notable treatment time reduction, compared to more comprehensive physiotherapy protocols.

Type of study: Randomized controlled trial.

Level of proof: 1b.

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1. Background

Whiplash associated disorders (WAD) are a common musculoskeletal disorder in recent times. This entity encompasses a range of injuries to the neck area, generally occurred in low-energy traffic collisions and sporting activities [1]. The forces involved in the collision result in a sudden passive extension of the neck, followed by a sudden flexion, in a whip-like fashion. Most patients suffer mild limited injuries, but in severe cases fractures and/or neurological damage can be identified, many times with subsequent Chronicity of the symptoms [2].

Despite the high incidence, the treatment of acute whiplash syndrome (AWS) remains controversial. In severe cases, where specific structures are damaged, they can be identified and individually treated (e.g.: treatment of cervical fractures or dislocations). Fortunately, in the vast majority of cases there are no major identifiable injuries, and symptoms prevail over physical examination signs or complementary test findings. In these cases, conservative treatment is generally indicated; here is where the consensus ends. There is a vast list of treatments and interventions for AWS, under the flag of “conservative measures”, and to date none of them has shown clear superiority [3].
There is little available evidence to recommend a certain conservative treatment for AWS cases. Several Cochrane Library systematic reviews have failed to find supportive evidence for the most common therapies; Gross concluded there is no evidence of effectiveness of patient education in WAD [4], while a wider review of all conservative modalities by Verhagen resolved: “clearly effective treatments are not supported at this time for the treatment of acute, subacute or chronic symptoms of whiplash-associated disorders” [3]. Other works found little or uncertain evidence of effectiveness for mobilisation-manipulation [5], electrotherapy [6] or acupuncture [7,8] in the treatment of acute neck pain. An additional review about physiotherapy for WAD by Michaleff showed similar conclusions, highlighting the unclear role of these interventions [9].

AWS is a demanding clinical problem, with cervical pain and often-associated brachialgia or vertiginous syndrome, which causes an important reduction in the functional level of the affected. Moreover, the legal implications commonly involved, make the treatment and evaluation of this syndrome specially challenging. Insurance companies spend millions of dollars every year to treat and compensate those affected by WAD [1,7]. Effective treatments, which could help patients to overcome the symptoms and resume their usual activities in the shortest time, are highly sought-after from both clinicians and insurance corporations, and due to the lack of clearly superior options, research on new alternatives is desirable.

Percutaneous needle electrolysis (PNE) is a relatively novel technique described by Sanchez Ibanez in Spain in the early 2000s [10], which is rapidly spreading in Western Europe. This technique consists in the application of a brief galvanic current into a desired musculoskeletal target structure, trough the placement of percutaneous acupuncture-like needles. The evidence supporting this technique is progressively growing; there is data of the histologic response generated by PNE [11], as well as data supporting good clinical outcomes in chronic and overuse injuries such as patellar tendinitis, tennis elbow or athletic pubalgia [12-15].

The clinical experience from the authors has lead to the impression that not only chronic conditions would have good response to PNE, and for that reason the present study was designed. We have been involved in the evaluation and treatment of AWS patients during the last 15 years. PNE has been a valuable tool for us in the treatment of other musculoskeletal pathologies, so we hypothesized it may be a useful for AWS cases. One of the most characteristic features of PNE is its short application time; most protocols for most conditions consist in 2-3 weekly sessions with a duration of 5 minutes approximately. The technique is not expensive (limited equipment required, our generator is priced 2700 €, with no additional costs for disposables rather than acupuncture needles) (Fig. 1), is easy to learn and teach (periodic formation courses offered by the Spanish Official Physiotherapists College, nationwide), and is generally well tolerated by the patient. This combination makes PNE a good candidate to become a first line option for the treatment of AWS, should its efficacy be proven.

The chosen target for this PNE study is levator scapulae muscle (LS). LS has been identified in many studies as one of the most commonly affected structures of the neck in WAD [16-19]. Our experience is that local treatment of the LS is generally indispensible to decrease pain in WAD affected patients, by means of massage, stretching, electrotherapy and/or topic analgesia. Thus, local application of PNE in this location was selected, with a specific position for needle placement in the scapular insertion of the muscle. To perform our study, the most painful side of the neck was determined and treated trough PNE currents.

In this paper, we present the results of a prospective randomized trial to assess the effectiveness of PNE versus a standard physiotherapy treatment in patients affected by AWS after a recent traffic accident.

2. Methods

The study was designed by the CHUMI Rehabilitation Department (Las Palmas de Gran Canaria, Gran Canaria Island, Spain) and developed in the Vecindario Rehabilitation Centre (Santa Lucia, Gran Canaria Island, Spain). Approval was obtained from the Regional Ethics Committee. Participants were recruited from over-18s patients presenting from 1st of March to 31st of May 2016 with neck pain secondary to AWS after a recent traffic accident, and classified as grade II in the Quebec classification (neck pain and stiffness, no neurological symptoms, no bony injuries). Patients with previous neck pathology or surgical interventions, psychiatric conditions or language barriers were excluded. In addition, patients with generic contraindications for PNE were also excluded: pacemaker, pregnancy, local infection or malignant tumours and local or systemic cutaneous disease. During the recruitment phase, 9 patients were excluded from the trial due to exclusion parameters, and 7 refused to participate in the trial.

Candidates matching the criteria were offered to voluntarily participate in the trial. They were informed that by participating, they would receive one of two different treatment options in the centre, but no further details were provided to avoid performance bias. Subsequently, 100 patients were randomized into group A, a standardized physiotherapy intervention for AWS and group B, a standardized PNE protocol. Patients chose one from 100 identical envelopes in a box, 50 with an A card inside and 50 with a B card, to determine their group.

All participating patients gave written consent to join the study, and filled in a data form with general data, basal visual analogue pain score (VAS) and basal Northwick Park Neck Questionnaire (NPQ), in its validated Spanish version [20]. In addition, algometric assessment of the LS insertion was recorded, in the most painful side of the neck. For this purpose a calibrated digital force-almometric gage (Wagner Instrument, Greenwich, US) was employed. The LS scapular insertion was located by means of palpation, and ultrasound confirmation of the proper location was granted. This was the place where the algometer was applied, with a constant increasing pressure, until the patient felt pain and gave a verbal order to stop the test. At that stage, the algometer was immediately cleared from the patient, and the maximum tolerated pressure registered by the device was recorded (Fig. 2). Three consecutive measurements were obtained, and the average value was defined as the pressure pain threshold (PPT). All patients underwent previous mock algometric assessments in their proximal tibia for training purposes.

2.1. Group A: standard physiotherapy protocol

Thirty females and twenty males formed this group. They received a standardized physiotherapy treatment, consisting of 20 sessions of:

- microwave thermotherapy: intensity from 100 to 150 mw, as tolerated, for 10 minutes;
- analgesic TENS currents. Individual setting according to tolerance, generally between 5 to 10 minutes;
- massage of the contractured muscles, including LS, for approximately 10 minutes;
- therapeutic ultrasounds, in pulsatile mode, 1 MHz to 1,5 W/cm², for 10 minutes;
- active exercises and stretching of scapulo-thoracic waist muscles and joints, approximately during 20 minutes.
2.2. Group B: PNE

Thirty-four females and sixteen males were assigned to the PNE group. The treatment consisted of three sessions of PNE performed by a trained physiotherapist (JGN). In our experience, almost universally, patients concentrate their pain in one side of the neck and upper body, depending on the direction of the forces involved in the collision mechanism; although pain is usually bilateral, a more sensitive side is generally identifiable. The PNE treatment was therefore applied in the most painful side of the neck.

The target point was the scapular insertion of the LS: entry point was selected by palpation, approximately 1 cm cranial and 1 cm medial to the medial edge of the scapular spine (Fig. 3). The depth and precise location of the needle was US-guided. In this trial, sterile 25 × 0.16 mm acupuncture needles were used.

Once the target tissue was aimed, the PNE probe (cathode) was connected to the needle, and a galvanic current deployed through it; the circuit was closed with a handle-like anode wielded by the patient. The starting intensity was 2 mAmp, and was increased on a 1 mAmp/sec speed to reach 4 mAmp. At that moment, the current was immediately stopped. This was repeated three times per session, with a resting interval of 1–2 minutes between shocks (Fig. 4).

Each patient received a weekly session for 3 weeks (3 sessions in total). They were requested to avoid taking anti-inflammatory drugs during the treatment, so that the desired inflammatory response would not be undermined. Pure analgesics such as paracetamol or light opioids were not restricted, equally to the standard treatment group. No other interventions such as massage, thermotherapy, electrotherapy or any other were indicated for group B patients.
Fig. 4. PNE session. Ultrasound guidance allows for accurate placement of the needle. The technique is generally well tolerated by most patients, and complications are extremely rare.

Table 1

<table>
<thead>
<tr>
<th></th>
<th>Standard physiotherapy</th>
<th>PNE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>35.3 ± 8.1</td>
<td>40.9 ± 9.2</td>
</tr>
<tr>
<td>Sex</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Male</td>
<td>Female</td>
</tr>
<tr>
<td>Days from injury</td>
<td>5.6 ± 1.6</td>
<td>6.1 ± 1.2</td>
</tr>
<tr>
<td>Pre VAS</td>
<td>6.6 ± 1.6</td>
<td>7.0 ± 1.4</td>
</tr>
<tr>
<td>Pre NQ</td>
<td>79.3 ± 15.6</td>
<td>73.5 ± 16.9</td>
</tr>
<tr>
<td>Pre PPT</td>
<td>3.2 ± 0.9</td>
<td>2.0 ± 1.1</td>
</tr>
</tbody>
</table>

Data is shown as mean ± SD.

2.3. Outcome assessment

Five weeks after treatment started, a blinded physiotherapist visited all patients. Current VAS, NPQ and PPT assessment were obtained. The same protocol and device was used for the algometry in both pre- and post-treatment measurements.

In addition, an evaluation of the costs for both groups is also presented in this report.

3. Results

Analysis of data was performed by an independent statistician (JML), who was blinded for the treatment received by each group. All statistical analysis was performed using SPSS v. 18.0 (IBM Corp., Armonk, NY, USA). Significant ($P < 0.05$) and trend values are shown. Numeric variables (VAS, NPQ and PPT) are presented as arithmetical mean values ± standard deviations. Comparison of values among treatment groups was performed by Student-t test.

The variation between pre- and post-treatment values for each score was calculated following the formulae:

\[
\text{VAS variation} = \frac{(\text{pre VAS} - \text{post VAS})}{\text{pre VAS}} \times 100
\]

\[
\text{NPQ variation} = \frac{(\text{pre NPQ} - \text{post NPQ})}{\text{pre NPQ}} \times 100
\]

\[
\text{PPT variation} = \frac{(\text{post PPT} - \text{pre PPT})}{\text{pre PPT}} \times 100
\]

Variation results are presented as percentages, and were calculated with non-parametric tests for paired samples.

One hundred patients participated on the study, 50 per group, and none of them was lost during follow-up. Both groups had a comparable distribution of demographics (Table 1). Although a significant difference was found for age, we considered the difference (≥ 5 years) as not clinically relevant, supported by the performance of an age-adjusted analysis that obtained similar conclusions (which has not been displayed to simplify data presentation and reading of the article).

When assessed individually, both techniques showed statistically significant improvement in the VAS scale, NPQ values and PPT tolerance (Table 2).

In regards to VAS variation, the standard group averaged a 49.1% improvement, while the PNE groups scored a mean value of 51.9%, this being a non-statistically significant difference. A similar result was obtained with the NPQ variation: 51.5% mean improvement for the physio group and 49.5% in the PNE group, with no statistically significant differences. A statistically significant difference was found in favour of the PNE group for the PPT variation; the average reached 56.6%, whilst the standard group mean was 44.4% (Fig. 5).

4. Discussion

AWS has become a challenging problem for clinicians and insurance companies. Large amounts of money are allocated to cover the expenses derived from medical care and sick-leave of the affected [1]. In consequence, the effectiveness and duration of the treatment options are crucial for patients, carers, and insurers.

The use of PNE has rapidly spread across Spain and other European countries. The technique, simple to learn and perform, is being used in the treatment of a number of musculoskeletal entities. It consists in the application of a brief galvanic current into a desired target structure; the placement of the needles is often ultrasound-assisted, when accurate deployment is required. The current generates local NaOH, which acts as a caustic agent, dissolving damaged collagen fibres and other tissue debris. Therefore, the therapeutic effect of PNE relies on a non-thermal ablation of the damaged area, producing a controlled local inflammatory response, with phagocytosis activation and favouring soft-tissue regeneration [10–12]. Further investigations have revealed the underlying molecular routes in the PNE technique [21]. In an animal model, the application of PNE resulted in an increased expression.
of Cytochrome, SMAC-DIABLO protein, VEGF, VEGFR-2 and PPAR-γ nuclear transcription factor. Cytochrome and SMAC-DIABLO are factors related to apoptosis, while endothelial factors stimulate angiogenesis and PPAR-γ is linked to anti-inflammatory mechanisms.

PNE has been especially popular as a treatment of overuse soft-tissue chronic injuries, particularly in the field of sports medicine. Several works claim the effectiveness of the technique in non-acute entities; Sanchez Iñáez communicated good results in the treatment of long-standing patellar tendinitis, both in the short [10] and long term [15]. Minaya concluded that a combination of PNE plus stretching in lateral epicondilalgia (more than 3 months from clinical onset) had a good cost-effectiveness [13]. Moreno reported good results in the treatment of subacute and chronic groin pain related to rectus abdominis in Italian professional soccer players, with rapid return to competition level [14]. All these evidences support the use of PNE for chronic injuries, and back the clinical impression of effectiveness of the intervention from those familiar with its use.

Less has been published about the effectiveness of PNE for acute musculoskeletal damage. To date, the only written reference in relation to acute injuries is a case report where a fresh pectoralis mayor muscular tear healing was assisted by PNE stimulation [22]. However, there is a theoretical frame that suggest acute harm may also benefit from PNE; the activation of phagocytes seen in chronic models could also led to tissular debris removal in acute injuries as well, promoting a faster healing and recovering of the insult. This has also been documented in recent animal models, where the technique enhanced new vascularization and reduced inflammatory mediators in acutely damaged muscular tissue [23].

A key factor of our study has been the selection of LS as our target for PNE. LS is a triangular bilateral muscle, with an origin in the transverse apophyses of C1 to C4 and a caudal insertion into the medial border of the scapula, extending from the superior angle to the junction of spine and medial border of scapula [24]. When the scapula is fixed, LS rotates and flexes the cervical spine laterally; a simultaneous bilateral contraction of both muscles produces straight flexion of the neck only. For decades, LS contracture has been identified as an isolated non-traumatic origin for neck pain [20], but has also been appointed as one of the most frequently damaged muscles in WAD; some studies have quantified this incidence as high as 80% of the affected [17]. Biomechanics studies suggest the muscle is more often injured when the subject experiences a lateral impact [18]; however Lange found a significantly increased prevalence of LE tenderness among fighter pilots frequently exposed to multidirectional whiplash-like forces [19].

Our study shows good clinical response of AWS to PNE, with similar results than in the conventional physiotherapy group for reported pain, pressure threshold and self-reported outcome. We found a statistically significant difference in favour of PNE for local pain threshold; we interpret this finding as a sign of effectiveness of the technique in healing and local pain control of the target structure (LS insertion). The LS was also locally treated in the physio group with conventional tools, showing a lower improvement rate in the PPT.

The fact that VAS and NPI values improved in a similar grade than in the standard treatment group enforces our previous observation that LS insertion local treatment is a paramount item in the treatment of this patients, probably the most important. A local action in the LS insertion (group B) obtains the same general response as in a more comprehensive approach involving more regional structures (group A), and this was obtained by PNE exclusively. We believe this finding leaves an open door for further research in this direction.

Although we did not perform an individual cost analysis, the estimations that could be inferred from the outcomes of this trial provide relevant conclusions in terms of cost-effectiveness. While the standard group received 20 sessions of treatment, averaging 20 hours of care time, the 3 PNE sessions consumed less than 1 hour in sum (approx. 15 minutes per session). This manifest difference is considered by the authors as a game-changing fact, as we believe avoiding daily attendance to a treatment centre is one of the most beneficial aspects of the PNE regimen. In our centre, the cost for a PNE or a standard physiotherapy session is the same: 30 € on average (small variations depending on the covering insurer). That makes the full individual cost of a PNE treatment approximately 90 €, while the cost for a standard treatment is close to 600 €: 6.6 times higher. The cost for the PNE generator, which ranges from 1000 € to 3000 € (according to manufacturer and/or model) and those derived from a relatively short formation period (courses provided nationwide by the Official Physiotherapy College) should not be concerning for centres with high volume of patients, and clearly not more relevant than those derived from any other physiotherapy technique involving any kind of electrical/electronic device. Even if we consider the technique to be equally as effective as standard procedures, the savings derived from reduced treatment time would make PNE a first line option for AWS. We believe that, if not as an only intervention, PNE should be at least part of any conservative protocol for neck pain treatment in a WAS context, as there are reasons to believe the treatment protocols would be shorter and less expensive.

The limitations of this study are those inherent to a first reported trial. We could not compare PNE versus a gold standard treatment, as none of the available has shown significant superiority; the election of a standard physiotherapy intervention was made as it can be considered the most common in Western countries. In addition, we designed the duration, intensity and frequency of the PNE applications based on previous reports [10,12–15], which were not specific for AWS disorders. Further trials will be required to evaluate alternative PNE settings and protocols for different injuries and locations. Another item open to discussion is the fact that we only applied the galvanic currents into the LS insertion. It is known that AWS affects several muscles in the neck and upper back; however in this study, we found that a confined LS local treatment with PNE showed similar clinical results than a more comprehensive treatment involving most regional muscles. The final PPT in the LS area was significantly lower in the PNE group; we interpret this as the effect of local anti-inflammatory routes activation by the PNE. Further research with different target muscles is desirable to postulate about the implications of this finding.

Additionally, we have not presented long-term results, nor data about time to return to work/sporting activities. Our centre is an affiliate treatment centre to UNESPA (Spanish Union of Insurance Companies, in Spanish); we receive patients from emergency/assessment centres, and we discharge them after treatment completion. We do not have a role in the assessment and follow-up of our patients after the physiotherapy phase, as they are required to attend to the associated assessment centres again; therefore, long-term follow-up was not possible for our team.

The randomized design of this prospective study allows our conclusions to be considered as reliable. Thus, we encourage other clinicians and research groups to use this evidence as a pillar to develop new trials about the effectiveness of PNE in the treatment of diverse musculoskeletal injuries. As any emerging technique, the recommendation as an elective therapy has to be evidence-based, despite the subjective impression it may cause among their advocates. The number of PNE trials is progressively increasing, and presumably we will be in a better position to objectively judge the role of PNE in the close future. As the technique is minimally invasive, well tolerated and with no relevant contraindications and costs, many groups are increasing the spectrum of pathologies to
treat, so we can expect a number of future publications in relation of PNE clinical appliances and its effectiveness in the upcoming years.

5. Conclusions

WAD are a challenging problem in Western countries. The costs derived from them urge clinicians and researchers to find cost-effective treatments for those affected. To date, there is little evidence to favour any of the multiple available conservative interventions.

In this trial, PNE has proven to be an effective option for the treatment of AWS. Patients receiving the therapy substantially decreased their pain, pressure-pain threshold and quality of life measures, equally to standardized physiotherapy programmes. Distinguishingly, PNE protocol consists in only 3 application sessions of 15 minutes each one, with no added interventions. The promising clinical results obtained, in addition to the associated cost reduction with the technique, suggest PNE should be considered, if not the only intervention, at least as a crucial part of any AWS conservative protocol.

Ethics and consent to participate

Approval was granted by the Ethics Committee of the CHUMI Hospital Complex, with protocol number Id:CEIm-CHUMI-2016/845. A copy of the approval notification has been presented to this journal with the supporting materials. Participants gave written consent to participate.

Author’s contribution

G.NJ. was responsible for the PNE application and physiotherapy team coordination. B.R.S. performed the literature review, wrote and translated into English the final manuscript and is the submitting author. L.F.J.F. was the main protocol designer. L.C.J.M. performed the statistic analysis. S.H.E. was the treating physician for most patients and coordinated the recruiting process. All authors read and approved the final manuscript.

Availability of data and materials

All data and materials generated in this study are available upon request to the submitting author.

Disclosure of interest

The authors declare that they have no competing interest.

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