Intramuscular NMES for Hemiplegic Shoulder Pain

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Abstract

The purpose of this study was to assess the effectiveness of intramuscular neuromuscular electrical stimulation (NMES) in reducing post-stroke shoulder pain. A multi-center, single-blinded, randomized clinical trial was conducted among 61 chronic stroke survivors with shoulder pain and subluxation. Treatment subjects received intramuscular NMES to the supraspinatus, posterior deltoid, middle deltoid and trapezius, 6-hrs per day for 6-wks. Control subjects were treated with a cuff-type sling for 6-wks. Outcomes were assessed with the Brief Pain Inventory question #12 (BPI #12), in a blinded manner at end of treatment (EOT), and at 3 and 6-months post-treatment. The NMES group exhibited significantly higher proportions of success based on the >3-point reduction in BPI #12 success criterion at EOT (65.6 vs. 24.1%, p<0.01), at 3-months (59.4 vs. 20.7%, p<0.01) and at 6-months (59.4 vs. 27.6%, p<0.05). Using the most stringent “no pain” criterion, the NMES group also exhibited significantly higher proportions of success at EOT (34.4 vs. 3.4%, p<0.01), at 3-months (34.4 vs. 0.0%, p<0.001), and at 6-months (34.4 vs. 10.3%, p<0.05). Intramuscular NMES reduces post-stroke shoulder pain among those with shoulder subluxation and the effect is maintained for at least 6-months post-treatment.

1 Introduction

Shoulder pain is a common complication following stroke [1]. To date, the only treatment option for post-stroke shoulder dysfunction supported by randomized clinical trials is surface neuromuscular electrical stimulation (NMES) [2]. However, surface NMES has not been adopted by the clinical community due to pain caused by stimulation, inability to focally stimulate deep muscles, need for skilled personnel and lack of third party payer reimbursement. In order to address the limitations of surface NMES systems and prior study designs, a multi-center, single-blinded randomized clinical trial of intramuscular NMES with clinically relevant shoulder pain as the primary outcome measure was carried out.

2 Methods

2.1 Subjects

Inclusion criteria included greater than 12-wks post-stroke, at least 18-yrs of age, shoulder pain rated as at least 2 on the Brief Pain Inventory [3] Question #12 (BPI #12) and at least ½ fingerbreadth of inferior glenohumeral separation by palpation. Exclusion criteria included history of cardiac arrhythmia with hemodynamic instability and any implantable stimulator or uncontrolled seizures. Subjects were allocated via computer-generated randomization in blocks of 4.

2.2 Stimulation System and Parameters

Both the percutaneous electrode and stimulator were previously described [4]. The stimulator “on” time of 20-secs consisted of 5-secs of ramp up, 10-secs of plateau and 5-secs of ramp down. The “off” time was 10-secs. The current amplitude was kept constant at 20mA. Adjusting the pulse width from 10 to 200µs regulated the stimulus intensity.

2.3 Treatment and Evaluation

NMES subjects were implanted with intramuscular electrodes via a percutaneous approach with subcutaneous tunneling under local anesthesia [4]. Specific muscles included the supraspinatus, posterior deltoid, middle deltoid and upper trapezius. NMES subjects were prescribed 6-hrs of stimulation per day for 6-wks. Control subjects were given a cuff-type hemisling with instructions to use the sling whenever the upper limb was unsupported. Concomitant therapies (medications and therapies) were monitored. Blinded evaluations
for both groups were performed at baseline, at EOT and at 3 and 6-months post-treatment.

The primary outcome measure was the BPI #12. Secondary outcome measures included the degree to which shoulder pain interfered with daily activities (BPI #23), radiographic shoulder subluxation, pain-free, passive external rotation ROM of the glenohumeral joint, Fugl-Meyer Motor Assessment, Ashworth, self-care portion of the Functional Independence Measure (FIM™) [5] and the Arm Motor Ability Test (AMAT) [6].

2.4 Analysis
BPI #12 was analyzed using an intent-to-treat approach. The primary success criterion was defined as ≥2-point reduction in pain. More stringent 3 and 4-point reduction and “no pain” criteria were also used. The differences in proportion of successes between groups at each evaluation point were assessed with the Fisher’s Exact test. A longitudinal analysis of BPI #12 using a General Estimating Equation (GEE) was also performed followed by post-hoc pairwise analyses. Secondary outcome measures were also assessed with the GEE longitudinal analysis, but using a per-protocol approach.

3 Results
3.1 Primary Outcome Measure
Table 1 shows the results of intent-to-treat analyses of the primary outcome measure BPI #12. Using 3 and 4-point reduction and “no pain” criteria, the NMES group exhibited significantly higher proportion of successes compared to controls at all evaluations. GEE analysis of BPI #12 revealed a significant main effect for treatment (Z=-5.38, p<0.001), and time by treatment interaction (Z=2.00, p=0.046) indicating a significant treatment effect.

3.2 Secondary Outcome Measures
GEE analysis of BPI #23 revealed non-significant main effects for time (Z=-1.25, p=0.213) and treatment assignment (Z=1.53, p=0.126). However, the interaction term involving treatment and time was highly significant (Z=-3.74, p < 0.001) indicating a significant treatment effect. GEE analyses of the remaining secondary measures did not demonstrate significant differences between groups. There were no significant differences in medication and therapy used between groups.

3.3 Safety
A total of 128 electrodes were implanted in 32 NMES subjects. During the treatment phase, all electrodes remained intact and free of infection. Granuloma formation was noted for 5 (3.9%) electrodes in 2 (6.3%) subjects. All granulomas resolved after electrode removal without additional intervention. The tips of 5 (3.9%) electrodes among 4 (12.5%) subjects broke during removal. Among the 4 subjects with retained electrode fragments, the fragments have remained for an average of 18.8 months (range 12 to 26- months) without evidence of granulomas or infections.

4 Discussion
Based on 3 and 4-point reduction in BPI #12 and “no pain” criteria, significantly greater proportions of NMES subjects were successfully treated for shoulder pain compared to controls at all evaluation points. Longitudinal analysis corroborated the results of success criteria based analyses with the NMES group exhibiting significant greater improvements in BPI #12 compared to controls.

While reduction in shoulder pain itself has high clinical significance, additional clinical relevance of intramuscular NMES is reflected by the significant improvement in BPI #23. In addition to assessing general activity and walking ability, BPI #23 assesses vocation, interpersonal relationships, mood, sleep and enjoyment of life. These latter domains are more typically elements of quality of life measures. Thus, data suggest that reduction in post-stroke shoulder pain mediated by

<table>
<thead>
<tr>
<th>Success Criterion</th>
<th>NMES (%)</th>
<th>Control (%)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>EOT</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>≥2</td>
<td>27/32 (84)</td>
<td>9/29 (31)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>≥3</td>
<td>21/32 (65)</td>
<td>7/29 (24)</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>≥4</td>
<td>19/32 (59)</td>
<td>5/29 (17)</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>“no pain”</td>
<td>11/32 (34)</td>
<td>1/29 (3)</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td><strong>3-mo</strong></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>≥2</td>
<td>21/32 (65)</td>
<td>9/29 (31)</td>
<td>&lt;0.05</td>
</tr>
<tr>
<td>≥3</td>
<td>19/32 (59)</td>
<td>6/29 (20)</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>≥4</td>
<td>17/32 (53)</td>
<td>3/29 (10)</td>
<td>&lt;0.001</td>
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<tr>
<td>“no pain”</td>
<td>11/32 (34)</td>
<td>0/29 (0)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td><strong>6-mo</strong></td>
<td></td>
<td></td>
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<tr>
<td>≥2</td>
<td>20/32 (62)</td>
<td>11/29 (37)</td>
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<tr>
<td>≥3</td>
<td>19/32 (59)</td>
<td>8/29 (27)</td>
<td>&lt;0.05</td>
</tr>
<tr>
<td>≥4</td>
<td>16/32 (50)</td>
<td>6/29 (20)</td>
<td>&lt;0.05</td>
</tr>
<tr>
<td>“no pain”</td>
<td>11/32 (34)</td>
<td>3/29 (10)</td>
<td>&lt;0.05</td>
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Table 1: Success Rate
intramuscular NMES is associated with improvements in quality of life.

Data indicate that percutaneous, intramuscular NMES as implemented in this study is safe for the treatment of post-stroke shoulder pain. The principal safety issue is retained electrode fragments. The distal tips of 5 electrodes (3.9%) fractured during electrode removal. Based on our experience with over 850 percutaneous electrodes implanted in humans in our laboratory since 1978, approximately 1.5% of retained electrode fragments may lead to one or both of these complications [7]. Thus, in the present application, the probability of electrode fracture during removal with subsequent development of medical complication is 0.039 x 0.015 or 0.0006 per electrode. The 4 subjects with retained electrode fragments have been followed for an average of more than 18-months without complications. In view of the demonstrated benefit on shoulder pain and daily activities, the minimal risk associated with intramuscular NMES, in our opinion, is clinically acceptable.

5 Conclusions
This multicenter, randomized clinical trial demonstrates that percutaneously placed intramuscular NMES is safe, and reduces post-stroke shoulder pain and the degree to which shoulder pain interferes with daily activities among chronic stroke survivors with shoulder subluxation and pain. The therapeutic effect is maintained for at least 6-mos post-treatment. NMES subjects were highly compliant with the treatment program, and subjects and their caretakers managed the system easily without the need for skilled personnel. Additional studies are needed to define optimal prescriptive parameters, elucidate the mechanism of action and further expand indications.

References

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