Experience exchange

Immediate effect of Fu's subcutaneous needling for low back pain

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Keywords: Fu's subcutaneous needling; minimal needling; low back pain; acupuncture

The traditional Chinese acupuncture has been reported to alleviate pain and is widely accepted as a complement therapy for pain relief in the world. In 1996, a novel acupuncture strategy, Fu's subcutaneous needling (FSN), was developed from the traditional Chinese acupuncture, but quite different from it. In FSN, needles are penetrated and swayed in the subcutaneous layer, but not the muscular layer. The choosing of its insertion points doesn't obey the principles of traditional Chinese medicine. To date, FSN has been widely used by clinicians in China for its good job in pain management though the systemic and rigorous studies are still lack.

About 70%-85% of the adult experience low back pain (LBP), which has become a social burden because it causes work incapability and early retirement. In this study we evaluated the immediate effects of a single treatment of FSN for LBP.

METHODS

Patients and groups
The following criteria must be fitted in participants with the diagnosed chronic benign back pain between the 12th rib and the gluteal fold: (1) no systemic disorders; (2) no history of disc or spine surgery, or psychiatric disease; (3) aged between 20-60 years; (4) no regular intake of analgesics or hormones; (5)patients gave written informed consent. From July 2004 to July 2005, sixty consecutive out-patients were enrolled in this study. A pre-intervention assessment was done to each participant by qualified physicians before they were randomly assigned to FSN group or minimal needling group through sealed envelopes. After treatment, patients were performed post-intervention assessment.

FSN needle
The main part of FSN needle, designed and patented in China (patent number: CN97114318, Nanjing FSN Medical Appliances Co.), looks like catheter IV. Though FSN needle is easier to manipulate and safer than catheter IV, we used catheter IV to replace the FSN needle in this study in order for others to easily repeat this study. Therefore, the FSN needle mentioned in this paper was a kind of single used catheter IV (SURFLO Flash IV catheter, TERUMO, Co., Japan).

The FSN needle (Fig.1A) consists of two parts: (1) stainless steel needle and its needlebed; (2) soft tube and its affiliated hard tube (Fig.1B). The steel needle is three millimeters longer than the soft tube in order to penetrate the skin.

Insertion point
The choosing of insertion points was based on our experience and some rules in Yellow Emperor's Internal Classic (a famous ancient Chinese medical book) for pain syndromes (also called Bi syndromes). There are multiple choices in selection of insertion points for FSN, however, this study we unified the
insertion points for each case to simplify the experiment. The insertion point was chosen at the same side with the suffered back. If both sides were afflicted, we only treated the severer one.

**Insertion and movement of the catheter needle**

Prior to insertion, patients were asked to lie on the stomach and be relaxed. Step 1: Quickly penetrate the needle obliquely through the skin. Make sure the needle tip is not too deep and stop when the needle tip just touches the muscular layer. Step 2: Draw back the needle a little to the subcutaneous layer. Step 3: In FSN group, push forward the needle parallel to the skin surface until the whole soft tube is under the skin and leave the needle in the subcutaneous layer. In minimal needling group, directly take out the steel needle and leave the soft tube in the subcutaneous layer. Step 4: In FSN group, draw the steel needle back 3 millimeters to make the steel tip wrapped in the soft tube in order not to hurt blood vessels or other organs during the following swaying, then swayed the needle smoothly and rhythmically from one side to another horizontally 200 times in 2 minutes (Fig.2A). In minimal needling group, moved the soft tube in the same way as in FSN group (Fig.2B).

**Therapy assessment**

**Motion-related pain (MRP)**

Patients rated the pain intensity for a certain movement using an 11-point visual analogue scale. For post-intervention assessment, the patients were asked to do the same movement as the movement for pre-intervention assessment and clearly instructed to rate the intensity of the motion-related pain to a certain point in the scale line.⁵

**Pain under pressure (PUP)**

It is important to measure the pain under pressure, because local tenderness is the top diagnostic feature of myofascial painful spots.⁶,⁷ We used a self-made algometry with the maximal pressure 20 newtons. The diameter of the metal end touching the patients' skin is 2 centimeters. When measuring, the algometer was put on the painful spot and 20 newtons pressure was implemented for 2 seconds with the metal rod perpendicular to the skin surface. Then the patients were asked to rate the PUP intensity in the same 11-point linear scale as in MRP.

**Lateral fingertip-to-ground distance (F-G)**

Lateral fingertip-to-ground distance in centimeters was measured according to the methods of Yip and Tse.⁸

**Statistical analysis**

All data in this study were expressed as mean ± standard deviation (SD) and analyzed by t test using software SPSS 11.5. A P value less than 0.05 was considered statistically significant.

**RESULTS**

**Patient information, pre-intervention assessment and side effects**

Patient information was shown in Table 1. Independent samples t tests regarding age, sex, duration of symptoms, pain location and pre-intervention MRP, PUP, and F-G did not show significant between-group differences. During this study, we found only one patient in minimal needling group fainted during the intervention. Seven patients in FSN group and 4 patients in minimal needling group
Table 1. Characteristics of the participants, pre-intervention assessment and side effects in FSN group and minimal needling group (mean ± SD)

<table>
<thead>
<tr>
<th></th>
<th>FSN group (n=32)</th>
<th>Minimal needling group (n=28)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>53.32±12.36</td>
<td>58.76±10.77</td>
</tr>
<tr>
<td>Sex</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Women</td>
<td>18</td>
<td>14</td>
</tr>
<tr>
<td>Men</td>
<td>14</td>
<td>14</td>
</tr>
<tr>
<td>Duration of symptoms (months)</td>
<td>5.43±7.45</td>
<td>5.56±6.54</td>
</tr>
<tr>
<td>Pain location</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Right side</td>
<td>17</td>
<td>13</td>
</tr>
<tr>
<td>Left side</td>
<td>15</td>
<td>15</td>
</tr>
<tr>
<td>Pre-intervention MRP</td>
<td>5.22±2.47</td>
<td>4.32±2.13</td>
</tr>
<tr>
<td>Pre-intervention PUP</td>
<td>5.28±2.22</td>
<td>4.07±2.19</td>
</tr>
<tr>
<td>Pre-intervention F-G</td>
<td>51.19±6.03</td>
<td>52.71±4.25</td>
</tr>
<tr>
<td>Faint during intervention</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Bleeding after intervention</td>
<td>7</td>
<td>4</td>
</tr>
<tr>
<td>Hurt feeling during needling manipulation</td>
<td>5</td>
<td>1</td>
</tr>
</tbody>
</table>

Table 2. Outcomes of post-intervention in FSN group and minimal needling group (mean ± SD)

<table>
<thead>
<tr>
<th>Groups</th>
<th>n</th>
<th>Post-intervention</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>MRP</td>
</tr>
<tr>
<td>FSN group</td>
<td>32</td>
<td>2.56±2.59*</td>
</tr>
<tr>
<td>Minimal needling group</td>
<td>28</td>
<td>3.79±2.33</td>
</tr>
</tbody>
</table>

MRP: motion-related pain; PUP: pain under pressure; F-G: Lateral fingertip-to-ground distance. *P<0.05, post-intervention vs pre-intervention.

Outcomes after intervention in FSN group and minimal needling group

In FSN group, MRP, PUP and F-G all significantly reduced after intervention (Table 2). Compared with the corresponding values before intervention (Table 1), the parameters were significantly reduced (P<0.05). In minimal needling group, values of these parameters after intervention were shown in Table 2, and these parameters were not changed significantly in minimal needling group after intervention (P>0.05). The differences after intervention of MRP, PUP and F-G in the two groups were shown in Table 3 respectively. Independent sample t tests showed that there were significant between-group differences.

Table 3. Comparison of the differences after intervention between the two groups (mean ± SD)

<table>
<thead>
<tr>
<th>Groups</th>
<th>n</th>
<th>△MRP</th>
<th>△PUP</th>
<th>△F-G</th>
</tr>
</thead>
<tbody>
<tr>
<td>FSN group</td>
<td>32</td>
<td>2.66±2.42</td>
<td>2.38±2.39</td>
<td>7.03±4.15</td>
</tr>
<tr>
<td>Minimal needling group</td>
<td>28</td>
<td>0.54±1.14</td>
<td>0.36±0.99</td>
<td>1.14±3.18</td>
</tr>
</tbody>
</table>

P value <0.05 <0.01 <0.05

△MRP/PUP/F-G: difference between pre-intervention MRP/PUP/F-G and post-intervention MRP/PUP/F-G. The comparison was conducted between FSN group and minimal needling group.

DISCUSSION

Acupuncture, dry needling and FSN are all needling therapies for pain relief. FSN is quite different from the other two in the following three aspects: (1) FSN needle is confined in the subcutaneous layer. (2) FSN needle is moved smoothly and rhythmically, but not performing “rotation and up-and-down” movement, characteristic needling strategy in acupuncture. In consideration of the more rapid and effective effects of FSN than the traditional acupuncture, we attributed the immediate effects of FSN to its larger influence on the loose connective tissue by mechanical forces. (3) FSN does not elicit Deqi (The patient feels soreness, numbness, heaviness, and distension around the acupuncture point, also called the arrival of Qi), while acupuncture and dry needling go deep into the muscular layer and elicit Deqi. The reason why Deqi wasn’t evoked in FSN was for only few free nerve endings and proprioceptive receptors in the subcutaneous layer, while they were abundant in epidermis and dermis or in the muscular layer.

The subcutaneous layer is the common layer involved in different needling therapies, and the main part of it (the loose connective tissue) can be
influenced by mechanical forces. In deed, collagen and elastic fibers were found to wind and tighten around the needle during needle rotation.\textsuperscript{13} Shape changes of fibroblast were also observed during needling manipulation.\textsuperscript{14} The preliminary investigation strongly hinted that the subcutaneous layer may play a crucial role in needling therapies. Thus FSN and acupuncture or dry needling may share the same mechanism.

Very interesting phenomena were found in FSN. For example, we found that needling directions were well correlated to the outcome. If the needling tips deviated away from the painful spots, the therapeutic effects were sharp decreased. During manipulation, we also found that the body part between the insertion point and the painful spot should keep relax in order to obtain good alleviation effects.

Needling therapies are difficult to establish placebo or sham controls that are both inert and indistinguishable. The use of minimal needling therapy as placebo has the following benefits: (1) the same insertion point as FSN group; (2) inserting the needle in the same way as in FSN group; (3) the patients couldn't distinguish between these two methods.

It was reported that acupuncture at distant points had better immediate effects than at 'ah shi' points (painful spot) in alleviating chronic neck pain and enhancing the neck mobility.\textsuperscript{15} Our results were in accordance with this phenomenon, as the FSN insertion points in this study were far away from the painful spot. Clinically, the distance between the painful spot and insertion point should vary with individuals. That is, the insertion points are chosen near to the painful point if the painful area is small. On the contrary, we select a distant point. In this trial, we chose a distant insertion point and used it for all the participants to simplify the study. This study suggested that FSN had immediate and safe effects on alleviating LBP.

REFERENCES


(Received December 28, 2005)
Edited by CHEN Li-min