Comparison between the effects of trigger point mesotherapy versus acupuncture points mesotherapy in the treatment of chronic low back pain: A short term randomized controlled trial

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KEYWORDS
Mesotherapy; Acupuncture; Trigger points; Low back pain

Summary
Objective: The goal of this study was to compare the effects of trigger point (TRP) mesotherapy and acupuncture (ACP) mesotherapy in the treatment of patients with chronic low back pain.

Design: Short term randomized controlled trial.

Setting: 62 subjects with chronic low back pain were recruited at outpatients Physical Medicine and Rehabilitation Clinic at the University of Rome "La Sapienza" in the period between July 2006 and May 2008.

Intervention: Study subjects were assigned to receive 4 weeks treatments with either trigger point mesotherapy (TRP mesotherapy, $n = 29$) or acupoints mesotherapy (ACP mesotherapy, $n = 33$).

Main outcome measures: Pain intensity with a pain visual analogic scale (VAS) and verbal rating scale (VRS) and pain disability with McGill Pain Questionnaire Short Form (SFMPQ), Roland Morris Disability Questionnaire (RMQ) and Oswestry Low Back Pain Disability Questionaire (ODQ).

Results: ACP mesotherapy shows a more effective results in VRS and VAS measures in the follow-up ($p_{VRS} = <.001$ and $p_{VAS} = <.001$). The SF-MPQ measure shows a better results for ACP instead of TRP with statistically significant differences between groups and time ($p = .035$). Participants reported a slight discomfort at the time of the inoculation, and 15% reported slight neck pain in ACP mesotherapy group.

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Introduction

Chronic low back pain (CLBP) is one of the most prevalent condition that affect modern society with increasing frequency. Approximately 70—80% of the population of industrialised countries suffers from low back pain (LBP) at least once in life. It is estimated that every year 5—10% of working age population is off work for a duration of approximately 7 days because of their LBP. Approximately 90% of subjects with acute LBP demonstrate a quick recovery even without therapy. However between 2% and 24% of cases last over three months. Many patients with CLBP request an unconventional therapy when treatment with non-steroidal anti-inflammatory drugs analgesics and myorelaxant, physiotherapy and exercise therapy is unsatisfactory. In 80—90% of cases the pain is of non-specific musculoskeletal origin with diagnostic tests (Rx, MRI) negative. Furthermore, there are many therapeutic strategies but the long term effect of single therapeutic approach remain limited.

Mesotherapy is one of the techniques that can be considered among the techniques proposed by the medical community in the treatment of LBP especially in Europe. The method dates back to 1952 in France with Doctor Michel Pistor and consists of a series of either single or simultaneous multiple, intradermal or superficial subcutaneous injections directly over the structures affected by inflammatory processes.

Mesotherapy is a specialized medical treatment that delivers approved medications like NSAIDS, analgesic, anesthetic under the surface of the skin to the mesoderm layer of the skin and it is recommended in the treatment of the painful musculoskeletal affections. Another widely complementary therapy is represented by acupuncture. Acupuncture has been frequently used in the treatment of CLBP. One of the techniques proposed by the medical community in the treatment of LBP especially in Europe is acupuncture. Acupuncture has been frequently used in the treatment of CLBP. Severe therapy is represented by acupuncture. Acupuncture has been frequently used in the treatment of CLBP.

Materials and methods

110 subjects with CLBP were examined at the outpatient Physical Medicine and Rehabilitation Clinic of the Locomotor Apparatus Sciences Department at the University of Rome “La Sapienza”, in the period between July 2006 and May 2008. After having met inclusion and exclusion criteria for the study, a sample of 62 subjects, were selected (Fig. 1a). The inclusion criteria were low back pain for at least 6 months, patient age above 45, no pharmacological therapy for other systemic pathologies, and no previous treatment with mesotherapy for CLBP. The exclusion criteria were the presence of neurological pathologies, concomitant severe rheumatic disease, systemic pathologies (e.g. diabetes), a surgical intervention within 3 months prior to the study, psychiatric pathologies or patients undergoing psychotherapeutic treatment or physical treatment within 5 weeks prior to the study. Patients did not receive any other medical intervention during the study. All patients who met the inclusion criteria and agreed to participate in the study received a general explanation of the trial, and gave written informed consent, approved by the University of Rome “La Sapienza” Institutional Review Board for Biomedical Research, were enrolled and randomly allocated to one of two groups by using 2 and 4 permuted block size randomization by employing a sequence of random numbers obtained from a statistics textbook. One of the investigators who was not involved in the clinical management of the patients prepared the results in sequentially numbered opaque envelopes. The sealed envelopes were then opened for each patient and patients were included in the study after taking a record of the allocation. Both groups were treated with drug injection. TRP mesotherapy group consisting of 29 subjects, treated according to the TRP mesotherapy and ACP mesotherapy group consisting of 33 patients treated according to ACP mesotherapy (Table 1).

At baseline all patients underwent complete evaluation including a detailed medical history, report of any allergic reactions to anesthetics, routine physical examination and a neurological investigation. The physical examination of the lumbar spine was conducted by a doctor who was unaware of the group allocation. All patients were asked to provide a standard radiography (anterior—posterior and lateral X-rays) of the lumbosacral tract. Primary outcome measures were pain intensity, quantified using a 10 cm VAS (visual analogic scale) where the patient is asked to mark on a millimetric scale from 0 (absence of pain) to 10 (the worst pain imaginable) the degree of intensity of LBP and VRS (verbal rating scale) graded on a six points scale (no pain, very slight, mild, moderate, severe, and intolerable pain); pain disability measured with the most used validated scales for patients with LBP: SFMPQ (McGill Pain Questionnaire Short Form) this scale consists in 15 descriptors (11 sensory, 4 affective) which are rated on an intensity scale as 0 = no pain, 1 = mild, 2 = moderate, 3 = severe, three pain scores are derived from the sum of intensity rank values of the words chosen for sensory, affective and total descriptors; RMQ (Roland Morris Disability Questionnaire) which consists of 24 questions answered yes or no response for each range 0—24 points. 

Conclusions: Our results suggest that the response to ACP mesotherapy may be greater than the response to TRP mesotherapy in the short term follow-up. This technique could be nevertheless a viable option as an adjunct treatment in an overall treatment planning of CLBP.

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Figure 1  (a) Participation flow in the study. (b) Design of the trial.

Pain Disability Questionaire) which consists of 10 items assessing the level of pain and interference with several physical activities, with six response options per item with an overall score 0–50. The evaluation scales were carried out by a blinded assessor before the first treatment (pre), at the end of the treatment after 4 weeks (post), and at a follow-up of 12 weeks after the last treatment (Fig. 1b).

Interventions

2 cc of local anesthetic lidocaine cloridrate 2% was used for injection. 18 injection points were stimulated in both groups. The main investigator (3 years of acupuncture training and 8 years of clinical experience) used a point by point injecting technique with specific needles (Luer needles, 30 G 0.4 mm × 4 mm) fully inserted. In this technique a 5 cc

Table 1  Baseline characteristics of TRP and ACP group mean values (standard deviation) at baseline, p-values.

<table>
<thead>
<tr>
<th></th>
<th>Group A TRP mesotherapy (n = 29)</th>
<th>Group B ACP mesotherapy (n = 33)</th>
<th>p-value</th>
</tr>
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<tbody>
<tr>
<td>Sex</td>
<td>16 female; 13 male</td>
<td>18 female; 15 male</td>
<td>0.923</td>
</tr>
<tr>
<td>Age (y)</td>
<td>52.5 ± 12.1</td>
<td>52.5 ± 12.9</td>
<td>0.544</td>
</tr>
<tr>
<td>Pain duration (months)</td>
<td>5 ± 0.2</td>
<td>4.7 ± 1.1</td>
<td>—</td>
</tr>
<tr>
<td>VRS</td>
<td>4.7 ± 0.9</td>
<td>5 ± 0.7</td>
<td>0.244</td>
</tr>
<tr>
<td>VAS</td>
<td>7.5 ± 1.6</td>
<td>7.3 ± 1.5</td>
<td>0.784</td>
</tr>
<tr>
<td>SF-MPQ</td>
<td>18.7 ± 8.2</td>
<td>16.3 ± 7.7</td>
<td>0.752</td>
</tr>
<tr>
<td>RMQ</td>
<td>12.8 ± 4.8</td>
<td>13.3 ± 4.1</td>
<td>0.856</td>
</tr>
<tr>
<td>ODQ</td>
<td>27.4 ± 13.9</td>
<td>24.5 ± 13.6</td>
<td>0.629</td>
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</table>
A syringe is held at a 45° angle from the skin and only a drop of anesthetic is introduced at each of the selected site. In TRP mesotherapy group 18 local superficial trigger points of the most important accessible muscles of the lumbar tract and the hip were examined and treated; the correct application of the technique requires experience in palpation and localization of tender points in taut bands of skeletal muscles; these were identified according to Travell and Simons’ trigger point manual. In particular, for the quadratus lumborum 2 bilateral trigger points were treated: one at the angle between the crest of the ilium and transverse processes of L4 and the other at the transverse processes of L1–L2; for the iliopsoas muscle two paravertebral bilateral points were treated: one on the D12 thoracic vertebrae and the other one on L2 lumbar vertebrae; for the gluteus maximus three bilateral trigger points were treated all on the medial superior portion of sacrum region; for the piriformis muscle 2 bilateral points were treated: one at the junction between the middle and the outer third of the piriformis line and the other one at medial end of piriformis line (Fig. 2). In ACP mesotherapy group after a literature review on acupuncture for the treatment of LBP, only widely accepted acupoints according to the traditional Chinese medicine were selected. We did not conduct a diagnostic procedure to determine individual acupoints. In particular, the following 18 fixed body acupoints were selected and treated: gall bladder 30, bladder 31 and 52 bilateral, governor vessel (Du Mai) 3, dorsal (Ashi) and points at a distance: gall bladder 34 and 41, bladder 60, kidney 4 bilateral, triple energizer 5 (Fig. 3). All the subjects received one treatment per week for four weeks. The follow up evaluation was carried out 12 weeks after the last treatment (Fig. 1b). The same experienced acupuncturist performed all treatments. To keep to a minimum the interaction with the subjects the main investigator was not involved in any other procedure of the study.

**Statistical analysis**

Blinding was maintained until the end of the study. Demographic and baseline values of clinical data of all subjects were calculated as the mean values at the first visit. Comparative analysis was focused on the end of the treatment (after 4 weeks) and follow-up (12 weeks from the last treatment). An intention to treat approach in all the statistical analyses was adopted. However, a per-protocol analysis was also performed. We assigned a constant outcome based on the last observed response to the dropout patients. This involved assigning the baseline response at 4 and 12 weeks measurement for the dropout at 0 weeks in TRP group.
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Figure 4  Mean value VRS, VAS, SF-MPQ, RMQ, ODQ — pre, post and follow-up.

and the end of treatment (week 4) response for the 12 weeks measurement for the single dropout patient in ACP group.

A Student unpaired t-test was performed to determine whether the two groups were similar at baseline (for demographic and the five outcomes scores), while the analysis of covariance (ANCOVA) for each individual’s post and follow-up treatment means with baseline measurements as covariate was performed to determine differences at post and follow-up between the two groups. A p level of ≤ .05 was considered to be statistically significant. All data analyses were performed with SPSS 13.

Results

The average age of the patients and the standard deviation was calculated for all subjects (Table 1). No differences were found between the two groups regarding the evaluated variables at the baseline including sex, age and duration of pain. At baseline there were also no statistically significant differences (p > .01) between the groups regarding the outcome measures examined, pain intensity (VAS and VRS scales) and pain disability (SFMPQ, RMQ, ODQ scales). The appearance of a new systemic disease (diabetes) was the reason for

<table>
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<th>Table 2</th>
<th>Mean values, standard deviation, differences between groups, p-values of all outcomes scales (VRS, VAS, SF-MPQ, RMQ, ODQ) — means and differences adjust for baseline scores.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Week</td>
<td>TRP group Mean (SD)</td>
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<tr>
<td>-----------</td>
<td>---------------------</td>
</tr>
<tr>
<td>VSR</td>
<td>4</td>
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<tr>
<td></td>
<td>12</td>
</tr>
<tr>
<td>VAS</td>
<td>4</td>
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<td></td>
<td>12</td>
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<tr>
<td>SF-MPQ</td>
<td>4</td>
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<td></td>
<td>12</td>
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<tr>
<td>RMQ</td>
<td>4</td>
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<td></td>
<td>12</td>
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<tr>
<td>ODQ</td>
<td>4</td>
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a drop-out in TRP mesotherapy group, while inability to respond to the functional questionnaires for work-related problems, was the reason for the drop-out in ACP mesotherapy group. In our study none of the patients presented side effects except for a slight neck pain that was experienced by the 15% of the patients in ACP mesotherapy group between the first and the second session, which had the remission of symptoms at the end of the second week of treatment, without the use of any drugs. In Table 2 the results for the ANCOVA analysis are shown. The difference between the two groups at post-measure (4 weeks) adjusted for the baseline scores, do not show statistically significant differences between the two groups for all measures (\( p_{\text{VRS}} = 0.852 \), \( p_{\text{VAS}} = 0.625 \), \( p_{\text{SF-MPQ}} = 0.064 \), \( p_{\text{ODQ}} = 0.411 \), \( p_{\text{ODQ}} = 0.111 \)) (Table 2). However, the group difference between the follow-up measures adjusted for the baseline indicates that exists a statistically significant difference between the two groups for all the measure except for the SF-MPQ test (\( p > 0.05 \)). For VSR (\( p = 0.008 \)), VAS (\( p = 0.001 \)), SF-MPQ (\( p = 0.002 \)), and ODQ (\( p = 0.034 \)) the ACP group shows significant better outcomes at the follow-up than the ones observed in the TRP group, indicating a better efficacy of the acupoints option in the long term run (Fig. 4).

Discussion

CLBP is an important healthcare and socioeconomic problem and is associated with high medical expenses, disability and inability to work. It often shows only minor improvement when treated with conventional therapies and for this reason, there is an ongoing research for additional standard or alternative treatments.

Acupuncture and mesotherapy separately represent two of the proposed treatments by the medical community to alleviate symptoms in patients with CLBP. A recent meta-analysis showed that acupuncture is more effective than sham acupuncture and no additional treatment for providing short term relief of CLBP. This short term relief seems to be sustained over the longer term. In most of the studies stimulation site has been a traditional acupoint. However, Kazunori et al. recently demonstrated that treatment of trigger points may be more effective on LBP in elderly patients than at traditional acupuncture points.

Long before, mesotherapy became an acceptable treatment modality in cosmetic dermatology but it gained recognition primarily in pain management, sport medicine and rheumatology. Claiming that localized therapy avoids systemic adverse effects, mesotherapy originally conceived in Europe, has been used primarily for pain relief following dental procedures and to treat a broad spectrum of injuries and medical conditions such as tendinitis, tendon calcifications, cervicobrachialgia, arthritis, etc. However, information on mesotherapy in the English language medical literature is scant, the majority of scientific data on the use of mesotherapy in sport medicine and in the treatment of pain are currently written in French and consist of clinical case studies, all published in the journal of French Society of Mesotherapy, which has been published for 30 years. The major strength of our study lies in its scientific stringency. We were extremely careful in the randomisation process, the two groups showed no statistically difference at baseline regarding their demographic variables, and in the use, as outcome measures, of different subjective pain scales and validated disability questionnaires, designed by selecting items relevant to back pain. Our design was moreover important, in fact all patients received treatment for four weeks and the final evaluation was performed after 12 more weeks to ascertain whether improvements lasted over time. The data for the statistical analysis were processed by a statistician who was unaware of the treatment allocation.

In the present study TRP and ACP mesotherapy show similar patterns in the decrease of measures between pre and post, however some differences can be identified at the follow-up. Using ACP instead of TRP show a more effective results in VRS and VAS measures in the follow-up. For the former the change in VRS measure between the post and the follow shows a slight increase compared to the TRP. For the latter at the follow-up the ACP show a slight decrease versus an increase in the value observed for the TRP group. The SF-MPQ measure shows a better results for ACP instead of TRP with statistically significant differences between groups and time.

Our results suggest that the response to ACP mesotherapy may be greater than the response to TRP mesotherapy in the short term follow-up (12 weeks after the end of last treatment). Our results suggest, moreover that the stimulation site is important. We hypothesized that the long lasting effect of ACP mesotherapy could be due to the smoothing out blocked energy (Qi) that stuck in different areas of the body; our hypothesis is further on strengthened by the presence of neck pain as a distance side effect experienced by the 15% of patients in the ACP mesotherapy, as a result of a general activation. The proposed mechanism of action of mesotherapy is that solutions that are injected intracutaneously remain in the area longer that would if delivered via deeper injection, because they are cleared more slowly by the general circulation. In addition, it is felt that this superficially injected solutions continue to penetrate into the deeper tissue. Kaplan and Raincourt injected radioisotope-marked calcitonin and found, upon serial scans that the more superficial the injections the longer the solution remained in the area. The mesotherapy analgesic effect could be mediated by poly-modal type receptors that are ubiquitously distributed in the skin as well as the fascia and muscle and respond to chemical and mechanical stimulation. However, the underlying mechanism of pain reducing effect of mesotherapy remains a matter of debate. In addition it should be emphasised that during the treatment with mesotherapy no side effects occurred, except for a slight discomfort reported by the patients at the time of the inoculation, and the above mentioned 15% of slight neck pain in ACP group that spontaneously had the resolution of symptoms at the end of the second week of treatment.

The present study does present limitations and potential biases. First the limited number of participants, second we did not know whether the results obtained with ACP mesotherapy would be still applicable with a longer follow-up, therefore the conclusions of our study are valid only for mesotherapy at fixed acupoints and the outcome might be different with other individualized treatment; third we did not have the possibility to compare our results with those of other authors, because of lack of studies in literature.
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on mesotherapy in the treatment of musculoskeletal pain. All patients, furthermore, agreed to study protocol, so the participation’s expectations may have affected treatment response; the main investigator who performed the treatment had to know the group assignment of the patients. To exclude this potential bias, the interaction with participants was minimized, and the evaluation was done by an independent physician and by questionnaires. Despite these limitations, the preliminary findings of the present study showed evidence of the beneficial effects of ACP mesotherapy in patients affected by CLBP. It is our opinion that this technique could be nevertheless a viable option as an adjunct treatment in an overall treatment planning of CLBP patients; with an initial pain reduction in fact, other rehabilitation programs could be more likely to be accepted by these patients, thus resulting in an improved outcome. The science of mesotherapy can be advanced only by scientific and clinical research; the theory behind mesotherapy is virtually untested in randomized double blind studies. Further well conducted studies are needed to evaluate the efficacy and safety of mesotherapy in any form, particularly in the management of musculoskeletal pain.

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