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RESEARCH ARTICLE

Chronic low back pain, 20 years follow up after back school and shiatsu massage in a controlled, blind, perspective, randomized trial

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Abstract

Background: Lot of studies have been made to demonstrate effectiveness of therapy in acute and sub acute l.b.p. Less are the trials about therapies in chronic l.b.p. Many people have experienced subjective effectiveness of massage, reflex therapy, but there are really few studies evaluating their objective effectiveness.

Aims: Verify after 20 years follow up, the trend of the low back pain and the treatments used, in time, after the treatments carried out, in reducing pain and disability of people with chronic l.b.p.

Materials and Methods: A preliminary trial including patients with l.b.p. since three month. All the subjects hadn't sciatica, neurological signs, evident alteration on x-ray, they were randomised. An independent blind observatory evaluates the preliminary results on pain and disability with two item scales, Backill and Mcgill pain questionnaire. About 20 years after the end of treatment we made a recall with telephone interview about the trend of back pain in 20 years.

Results: All the participants recalled answered the brief questionnaire proposed, all of them had recurrent back pain.

Conclusion: Chronic low back pain it's a difficult trial for every physician. The role of education and self-care seems to be one of the important factors for the management of c.l.b.p.

Background:

Low back pain (LBP) remains a problem at epidemic proportion, a burden for the patient, the family, and the economy. Despite the multiplicity of treatments available, a clear choice of effective treatment has not emerged. Massage therapy has a long history, and is associated with various effects that, in the symptomatic treatment, are potentially beneficial. Ernst in his

systematic review analysed four trials comparing massage with other therapies. All of those trials are burdened with methodological flaws; however there is some evidence that massage is effective. Pope et al. compared spinal manipulation, with t.e.n.s., corset and massage in sub acute low back pain, but used massage like a placebo group and concluded that there are no significant differences between treatments. Also Gillan used in his trial, massage like a control group receiving non-specific back massage comparing to McKenzie protocol. Cherkin in his randomised trial, compared massage vs acupuncture and self-care in back pain persisting at least six weeks. He found that massage is clearly superior in back function and satisfaction, there were no significant differences in symptoms. Also acupuncture had better results in satisfaction. Before alternatives therapies such as massage and acupuncture, are incorporated into standard primary care practice, more scientifically rigorous studies are needed, to determine which treatments are consistently cost-effective for LBP.

Introduction

Shiatsu Reflex Massage (Figure 1) is a therapy of pressure with finger and hands on the back, along the meridians of traditional Chinese medicine. This pressure is gradually increasing according with breathe before the treatment starts, the therapist fills in energetic diagnosis card.

This treatment has been standardized:

1. For the patient position, lying down prone over two mattresses with a pillow under the abdomen.

2. The licensed shiatsu therapist that administer the treatment, and her position near the patient (lying on her knees).

3. The side from where the treatment starts, that's where is less pain.

4. The areas where to put the pressure along the body: bowel meridian, bladder meridian, and kidney meridian.

5. Pressure characteristics: perpendicular to the skin, gradual and during the expiration, without generating pain or muscles stiffening.

6. The duration of treatment: 60 minutes, twice a week, for 5 weeks.

Back School (Figure 2) it's an educational therapy group tested and validated in acute and sub-acute low back pain; a structured program of finalized intervention on four participants conducted in a course. It's indicated with evidence in the report of Quebec task force and in the Swedish guidelines on Spinal disorders. The course has eleven 60 minutes lessons, twice a week.

To avoid discordance depending on the different propositions of informations, different execution of exercises, or in ergonomics proves, during the course, we wrote and proceeded with the same consequential organization of the events that we administered each course. So the different courses are comparable.

The treatment has been standardized for: two lessons of informations about education and prophylaxis of low back pain, with slides support explained and commented with examples and references; six sessions of exercises for the back, worked out over a mattress on the ground. Exercises are explained in their execution at the beginning of the session, so the participant may see their developing. During the execution, the therapist supervises the participants and corrects the errors. Three lessons of ergonomics, postural education and recommended physical activities, developed with slides and examples followed by practical trials, every time with the same consecution.

Control group receive, without explain or examples, a paper with exercises to be worked out at home for a duration of 5 weeks (like the other groups). The operators in the three groups of therapy are always the same, so the treatment administered to the patient it's near to be homogeneous.

Follow up 1 month after the end of the treatment; 3 month after; 6 month after; 1 year after the end of the course. Each follow up, the patients will fill out the questionnaires, item scales backill and McGill pain questionnaire (the patients who don't fill out receive a phone interview); at the end of treatment and one year after there was a clinical test.

Drop Out Criteria During the treatment, participant: Mustn't take drugs or other therapies for pain; must not change activities of daily living or job; must not stop the treatment and follow-ups.

Aims of the trial This study attempted to determine the relative efficacy, in reducing pain and disability, of Shiatsu massage reflex therapy in treatment of chronic low back pain, as compared with Back school and control group.

Figure 1: Shiatsu Reflex Massage.

Figure 2: Back School.

Materials and Methods

The reference population is in the province of Palermo heterogeneous for age (25-65) and sex; al the patients presented to the hospital ambulatory.

Inclusion Criteria low back pain (referred in a region beneath the costal arch and the buttock), the pain mustn't radiate to the thigh or the leg.

The referred pain must be a chronic pain since three month, (at least three episodes of back pain for 1 month, during the last year). Anamnestic and clinical characteristics of non-specific back pain. Participants' subscription, of a consent form to the trial protocol.

Exclusion Criteria Anamnestic or clinical signs of specific back pain; positive ness of S.L.R.T. or Lasegue for sciatica; pain radiating to the upper thigh, signs of neurological deficit. Impossibility to keep, a protracted prone position, (not indicated for shiatsu). No previous back surgery. X-ray evidence of previous fracture, significant degenerative endangering, or rheumatic processes of the vertebral bodies, (evaluation by a skilled independent observer).

Drop Out Criteria During treatment participants; Must not take drugs or other therapies for pain; Must not change activities of daily living or job; Must not stop the treatment and follow-up.

Physical Examination conducted trough a point up card, to be proposed every time the same way and complete by one Physician (Dr. Mandalà), with a numeric index on Range of Motion and S.L.R. test. R.O.M. was assessed by the Schober test, while the patient stood ink skin marks were made at the midline at the level of L5 another 5 and 10 cm above the first. Then the patient was asked to bend forward and the distance between the skin marks was measured again. S.L.R.Test was assessed with the patient supine; the examiner raised the inferior limb with extended knee and the foot at right.

Then a blind skilled observer evaluated the X-ray, with the intent to avoid the exclusion criteria.

Assessment Procedures After the physical examination, the patients who met inclusion\exclusion criteria are invited to fill-in three cards.

1. The first card is concerning: personal data and general informations on studies, work and habits of daily living or hobbies; anamnestic informations about previous illness and the characteristics of back pain (duration and location, pain with rest or movement); drugs assumption; previous therapies; maintenance of work and activity; traumas and work dissatisfaction.
2. The second is the 11 items scale "Backill", a one-dimensional pain/ disability measure for l.b.p., tested and validated in its fit, reliability.
3. The third card is one of the most used item scale for pain measure: the 15 items McGill Pain Questionnaire (Italian validated version) a multidimensional pain measure, evaluating three dimensions of pain, sensorial, affective and estimative. We used the short 8 items form. The patient was assisted in the compilation of cards.

After filling-in the cards the participants were randomised with a computer game, giving three colours for treatment that we called A, B or C.

Interventions The same licensed therapists according to the standardized protocols always administered interventions; the duration of treatment was homogeneous for the three groups, 5/6 weeks, also the control group must work out home exercises for 5/6 weeks. At the end of treatment the patients wrote a formal opinion like: I feel better or I don't feel better and like I'm satisfied of the treatment or I'm not satisfied.

At the end of one year follow up, the cards, marked with treatment A, B, C, are evaluated by an independent blind observer for the data analysis, the results and the statistics calculation.

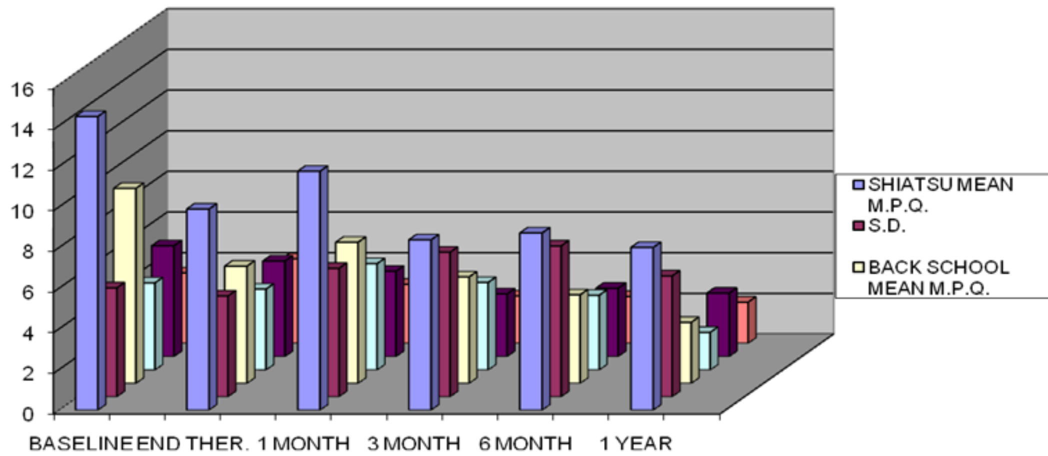
Subjects This clinical trial started in December 1999; and concluded in december 2001 with the enlisting of 60 patients, 30% (18) male and 70 % (42) female, the mean age of the sample was 44 year old (m. 41,4 – f. 44,9), the mean age in the group A was 45,6 in the group B was 43,2, in the group C was 45,1.

Results

The patients enlisted was 60 totally. Only 46 of the enlisted patients, concluded one year follow up.

Compliance 46 (77 %) of the enrolled patients completed treatments and follow-up; they are still full complying. 14 patients (23%) were drop out from the trial because not or partially complying. All the participants recalled, answered the brief questionnaire proposed, all of them had recurrent back pain and used different type of treatments to manage the pain.

Baseline Comparability since patients were randomly assigned to their treatment group, one would expect comparability between groups with regard to all the variables measured at baseline. There is a difference between the control group and the others in the M.P.Q. scale.


RESULTS OF MCGILL PAIN QUESTIONNAIRE
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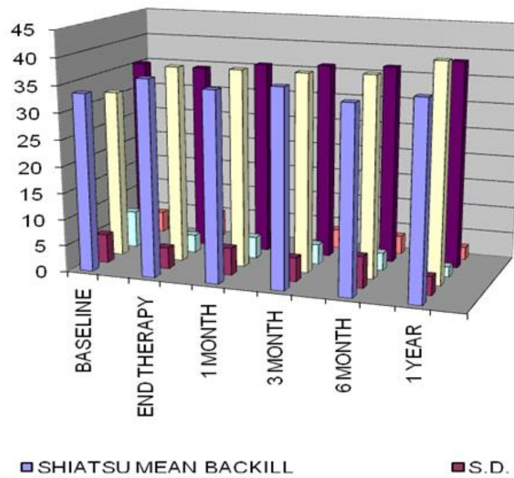
1 YEAR
SHIATSU MEAN M.P.Q.
S.D.
BACK SCHOOL MEAN M.P.Q.


RESULTS BACKILL
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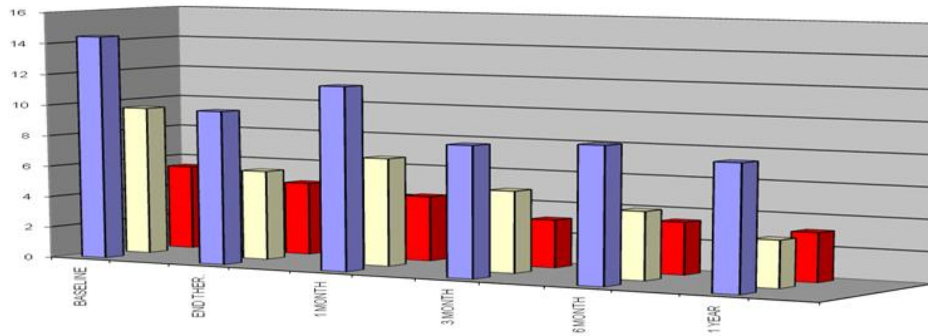
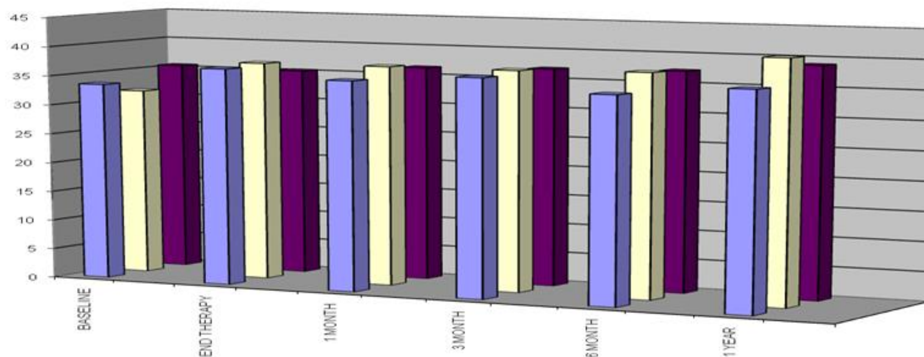


SHIATSU MEAN M.P.Q.
BACK SCHOOL MEAN M.P.Q.



SHIATSU MEAN BACKILL
BACK SCHOOL MEAN BACKILL
CONTROLS MEAN BACKILL

Back Pain Trend	Yes	Not	%
Have you had repeated episodes of back pain in the last 20 years?	45	1	97,8
If they were repeated, was the duration less than a week? or higher	35	11	76,1
Has the pain always been located in the back? or has also affected the lower limbs	32	14	69,6
Did you need to undergo a medical examination?	25	21	54,3
Did you need to take any medications?	33	23	71,7
Satisfaction and perceived effectiveness of the treatment performed			
Were you satisfied with the treatment provided?	44	2	95,7
Do you think the treatment was effective?	44	2	95,7
Do you think the benefits have been lost over time?	45	1	97,8
Do you think the treatment had to be repeated?	44	2	95,7
Would it have been worse if he hadn't done the treatment?	44	2	95,7
Other Treatments Performed Except Drugs			
Have you practiced manual or instrumental physiotherapy?	36	10	78,3
Have you practiced infiltrative therapy ?	12	34	26,1
Have you practiced other forms of unconventional medicine	16	30	34,8
Have you practiced minimally invasive surgery?	1	45	2,2
Have you had major surgery?	2	44	4,3

Back Pain Trend

Have you had repeated episodes of back pain in the last 20 years?
If they were repeated, was the duration less than a week? or higher
Has the pain always been located in the back? or has also affected the lower limbs
Did you need to undergo a medical examination?
Did you need to take any medications?

Satisfaction and Perceived Effectiveness of the Treatment Performed

Were you satisfied with the treatment provided?
Do you think the treatment was effective?
Do you think the benefits have been lost over time?
Do you think the treatment had to be repeated?
Would it have been worse if he hadn't done the treatment?

Other Treatments Performed Except Drugs

Have you practiced manual or instrumental physiotherapy?
Have you e practiced infiltrative therapy
Have you practiced other forms of unconventional medicine
Have you practiced minimally invasive surgery?
Have you had major surgery?

Preliminary differences at later visit one-year follow-up is available only for 21 patients. This number is a little sample to be significant, but the trial is going on and the enlisting growing up. Seems to be few, but significant differences between the two therapy group and the control group, in the results of the two item scales Backill and MPQ, little better for the back school group. Also the formal judgment on satisfaction and improving, find in the two therapy groups satisfied patients that refer to feel better. Back school seemed to be effective at the end of the treatment and in the short period, shiatsu demonstrate discordant results.

After 20 years we recalled the 46 patients who concluded the study, thus excluding the dropouts, to carry out a brief telephone interview on the progress of their back pain, on the satisfaction and perceived efficacy of the treatment performed and on any other treatments performed for the back pain from January 2002 to January 2022.

The questions in the questionnaire did not allow free answers, but it was a structured form with precise questions and standardized YES or NO answers with five questions in three different areas.

Discussion

Chronic back pain, as our study also demonstrates, is a pathology with a multifactorial genesis which, due to its complexity, cannot be resolved with single treatments with greater or lesser demonstrated efficacy. It is always preferable to intervene with combinations of traditional and unconventional treatments to try to alleviate the symptoms, improve the perceived quality of life and continue with one's daily activities. There is no doubt that the education and management of the disorder play a fundamental role, but a particular eye must be given to information and explanations from the doctor and to Waddel's illness behavior because often cognitive behavioral therapy, in addition to analgesic treatments and management courses can be decisive in improving the rehabilitation outcome.

It is necessary to continue scientific research with multicenter studies and enrollment of statistically more significant samples.

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Conflicts of Interest

None

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None

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