

FASCIAL MANIPULATION FOR CHRONIC LOW BACK PAIN – A RANDOMIZED CONTROLLED TRIAL

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Introduction

Chronic non specific low back pain (LBP) is one of the most common afflictions in modern society. Only 5% of subjects with LBP develop chronicity [1] but these subjects are responsible for 80% of total medical costs for LBP, including clinical examinations and treatment [2]. LBP disables subjects, limiting their work capacity and adversely influencing quality of life. Numerous international guidelines contain strong recommendations for a physiotherapy interventions for LBP. [3,4]

Many cochrane reviews show that there aren't strong indication towards a specific technique to get the best results, probably due to the difficult definition of the etiopathogenesis of chronic LBP. Many studies are focusing their attention on the correlation between LBP and the alteration in thickness and consistence of fascial tissue [6,7,8]

In this study we compared a physiotherapy intervention, based on the best practice (BP) that we have deduced from the national and international guidelines, with a specific manual therapy named Fascial Manipulation® (FM). FM is a manual intervention directed to deep muscular fascia, with the intention to restore natural fascia elasticity, the tissue involved in muscular coordination[9,10,11].

Recent studies about extra cellular matrix of connective tissue seem to confirm the utility to treat fascia because of its tixotropic properties[12]

Materials and Methods

We designed a monocentric, randomised, controlled and single blinded trial, that was approved by the Ethics Committee of S.Orsola-Malpighi Hospital, Bologna, Italy.

We enrolled 36 outpatients with chronic LBP, visited by a physiatrist or an orthopaedist of S.Orsola University Hospital. The doctors selected inclusion and exclusion criteria, then obtained informed consent from the patients. Afterwards they sent the patients to the head of the study for the assessment (T-0) of the outcome scores. We identified outcome score. For pain: Visual Analogic Scale (VAS); Brief Pain Inventory (BPI). For disability: Roland and Morris Disability Questionnaire (RMDQ). For health status: Health Survey, Short Form (SF-36).

Patients were randomized, following a random number sequence, in two groups. Both of these groups carried out 8 treatment sessions, two times a week. While patients in control group were treated with BP in each session, patients in study group were treated with one session of FM and one session of BP each week. Each patient was treated by the same physiotherapist. The physiotherapist who treated patients in study group was trained in FM. All physiotherapists involved in the study were students about to graduate, with the same educational background and clinical experience. VAS was also recorded before and after every treatment session in both group.

At the end of the 8th treatment (T-1), all patients were re-assessed by the head of the study with the same outcome. Same assessment was carried out in the 30 and 90 days follow up session (T-2 e T-3). The head of the study didn't know about the treatment group of the

patients. Data was analyzed with Wilcoxon-Mann Whitney test for non-parametric variables

Results

Only 24 subjects completed the study; 10 didn't begin the treatment because of organizational problems; 2 interrupted treatment for traumatic (n.1) and pulmonary (n.1) disease. 2 patients who completed all treatments were lost at both follow up. Results are presented for the 22 subjects who completed all the study sessions. 12 subjects were included in control group, 10 in study group. The pre-test analysis shows that groups didn't have significant difference about age and every outcome score, except for VAS score (see tab.1)

Outcome	Control (n.12) Mean (±S.D.)	Study (n.10) Mean (±S.D.)	Score
Age	49.4 [±11.05]	45.25 [±7.6]	p = 0.31
VAS	5.90 [±1.96]	2.83 [±1.81]	z = 0.003
BPI	9.26 [±3.67]	6.83 [±3.35]	z = 0.19
RMDQ	6.50 [±3.37]	7.17 [±3.92]	z = 0.55
SF-36	59.23 [±13.70]	50.61 [±17.50]	z = 1

Tab. 1: analisi pre-test

OUTCOME	Wilcoxon-Mann Whytney [ranksum-test]		
	Pre/Post	Pre/fu30	Pre/fu90
VAS	0.0009	0.0004	0.0008
RMDQ	0.022 (%Riduzione)	0.018 (%Riduzione)	0.11 (%Riduzione)
BPI	0.007	0.005	0.015
SF36	0.009	0.07	0.21

Tab. 2: analysis pre-post and at 30 and 90 days f.u.

Score recorded in T-1 shows a significant statistic difference of the study group compared to the control group, for every outcome.

Same relevant difference is maintained at T-2 and T-3 for VAS and BPI (in both intensity and interference score).

RMDQ maintain its significant difference at T-2, and SF-36 score is different at T-2 and T-3, but not statistically (see tab 2).

Pre-post treatment VAS analysis (particularly of the first four sessions) details that the mean difference between subjects was almost steady for control group, and different in study group, with higher values in FM session. Particularly, the first session has a significant statistic difference ($z < 0,03$) between groups (see tab. 3).

We calculated also the Minimal Clinical Important Difference (MCID) [13], representing for all patients in both groups very important clinical results for the outcome we had a clinical reference: VAS, BPI and RMDQ.

Study group got results really higher in every outcome (see tab. 4).

Discussion and Conclusions

Despite limited number of subjects (22), this study indicates that integrating Fascial Manipulation treatments with physiotherapy treatment sessions based on international guidelines could represent a valid modality for improving outcomes in subjects with LBP in the short e medium period.

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VAS	MEAN		Ranksum test z
	Pre-post	Control group	
1st treatment	0.98	2.92	0.02
2nd treatment	1.38	0.47	0.14
3rd treatment	1.21	1.68	0.97
4th treatment	1.25	1.19	0.88

Tab.3: VAS analysis pre-post first four treatment

Out Come	VAS		RMDQ		BPI Intensity		BPI Interference		BPI Total	
	Contr.	Study	Contr.	Study	Contr.	Study	Contr.	Study	Contr.	Study
MCID	1.5 (↔ 4)		30% less		1.5		1		1.5	
pre post	1.73	5.55	41.99	77.33	1.17	3.98	1.77	3.60	2.94	3.79
pre-Lu.30	0.67	5.30	39.89	80.01	1.19	4.08	1.75	3.93	2.94	4.00
pre-Lu.90	0.88	4.80	43.35	85.46	1.25	3.75	2.02	3.71	3.27	3.73
Subject /total	39%	100%	64%	100%	31%	90%	67%	80%	67%	90%

Tab.4: MCID value for VAS, RMDQ, and BPI in both groups