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Symptomatic efficacy of stabilizing treatment *versus* laser therapy for sub-acute low back pain with positive tests for sacroiliac dysfunction: a randomised clinical controlled trial with 1 year follow-up

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Aim. **Back pain is a highly frequent condition due to many causes, although most of them cannot be established with certainty. It is also the current clinical and scientific belief that sacroiliac joint syndrome can be a specific low back pain cause. Nonetheless the existence of clinical tests aimed at highlighting the responsibility for lumbar pain secondary to sacroiliac dysfunction, it is not easy to diagnose it with either manual or instrumental means. Moreover, uncertainty is diffuse when facing a correct treatment for patients involved. The aim of this study was to verify, in patients with acute or sub-acute low back pain and positive sacroiliac signs, the efficacy of a stabilising therapy (orthosis and exercises, with previous mesotherapy) directly targeted to sacroiliac dysfunction versus a symptomatic usual care such as He-Ne laser therapy.**

Methods. **Over a period of 14 months, we recruited 22 patients (10 females, mean age 44±11) with acute and sub-acute low back pain and symptoms and signs suggesting a sacroiliac dysfunction. They were randomised in a Group laser (GL), 11 patients treated with He-Ne laser therapy targeting the sacroiliac region, and a Group stabilisation (GS), 11 patients treated with mesotherapy, a specific dynamic sacroiliac support (ILSA) and specific exercises. Outcome criteria included VAS, and Mens and Laslett sacroiliac tests.**

Results. **Out of 449 acute and sub-acute low back pain outpatients, 22 (4.9%) had symptoms and signs suggesting a sacroiliac dysfunction. A reduction of pain was achieved only in the GS. All pain-provocation and stability tests were negative both after the end of treatment and at the follow-up only in the GS.**

Conclusion. **A targeted approach based on mesotherapy, a specific sacroiliac belt and specific stabilizing exercises proved its efficacy in acute and sub-acute low back pain patients with symptoms and signs suggesting a sacroiliac dysfunction. As soon as it will be possible to identify particular spine syndromes in the universe of non specific low back pain, there will also be the possibility to employ specific therapies.**

Key words: **Sacroiliac joint - Back pain - Mesotherapy - Orthosis - Rehabilitation.**

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Pain arising in the lumbar region of the spine can be due to many causes, and, in almost 80% of cases, these causes cannot be established with certainty.[1] Nearly 80% of the patients with pain in the low back seen by primary care practitioners are affected by simple, non-specific low back pain (LBP), which means a low back or leg pain not associated with an anatomical or functional abnormality, in the absence of an underlying malignant, neoplastic, infectious or inflammatory disease.[2] There is a high probability that the sacroiliac joint syndrome and sacroiliac dysfunction do exist, and cause LBP:[3, 4] when treating patients with acute or sub-acute back pain, the possibility of pathological involvement of the sacroiliac joints [5, 6] should

not be forgotten. However, sacroiliac syndrome has been the subject of several biomechanical and clinical controversies.[7, 8] As early as 1905, Goldthwaite *et al*.[9] introduced the concept of sacroiliac distraction responsible for LBP. Anyway, during the course of time, it was stated that most pain in the sacroiliac region was simply radiated pain. One significant example dates back to 1989, when Maigne first described the "thoraco-lumbar joint syndrome", correlated with a set of painful symptoms also in the lumbar and sacroiliac regions and a direct consequence of problems with the vertebral segments of the thoraco-lumbar joint.[10]

Sacroiliac dysfunction aetiology includes rheumatological, metabolic, infective, degenerative, peripartum and post-traumatic problems.[8] Sacroiliac joint can be the source and origin of painful symptoms, since it features the typical innervations of other synovial joints.[11] Pain may remain mostly localised, however it may sometimes shift and radiate distally, in view of the complexity of the innervations and of correlated anatomical structures. Sacroiliac pain increases during activities capable of inducing even very minor rotation or torsion: postural changes and walking (especially the initial phase of ambulation) are among the principal triggers of irritation and pain.[11, 12]

The awareness that it is quite difficult to diagnose on the basis of manual and instrumental findings discouraged spine researchers,[13] even if the number of clinical tests now available has increased progressively. Pain distribution and palpable tenderness near the posterior superior iliac spine are fairly reliable indicators that the sacroiliac joint is the pain source.[13] Traditional orthopaedic tests are not so reliable, as much as joint motion palpation tests are.[13] The commonest tests are therefore mainly related to manual therapy diagnostic techniques [14] having the purpose of highlighting the primary responsibility of the sacroiliac syndrome for LBP. While palpation tests have never had acceptable level of reliability, sacroiliac joint pain provocation tests should all be tested when facing a patient with LBP.[4] There are specific pain-provoking and sacroiliac joint stability tests that, not reliable if used alone, employed together can become predictive of sacroiliac dysfunction.[15] These tests aim to selectively stress the joint in an attempt to reproduce symptoms referred. Potter *et al*.[16] demonstrated a high inter-examiner agreement (superior to 70%) when distraction and compression tests were employed. On the contrary, McCombe [17] concluded that distraction, compression and Maitland tests were unreliable, pain on resisted hip external rotation was potentially reliable, and pain on hip flexion was reliable.[17] Laslett *et al*.[14] described 7 pain provocation tests which enable clinicians to identify selectively a sacroiliac problem. Through a high methodological and statistical trial, the authors proved the inter-reliability for distraction, compression, posterior glide and pelvic torsion (right posterior rotation and left posterior rotation) tests, while only potential reliability was achieved for sacral thrust and cranial glide tests.[14] Lee [18] described stability tests. Although the presence of non-definitive and contrasting conclusions, the author tried to differentiate between 2 typologies of sacroiliac dysfunction: hypo-mobility and hyper-mobility. In the first case only some directions of movement placed under stress are painful, while in the second there is no direction of preference and any movement will cause or increase the typical pain. A new stability test, the active straight leg-raising test, has been recently described by Mens.[19] This test was demonstrated to be useful to understand if the sacroiliac joint is unstable, but also as a post-treatment check. This test is positive when the patient cannot actively raise up the leg, a particular heaviness of the leg is felt, low level leg strength are discovered, significant ipsilateral trunk rotation. Moreover, improvement should be noted with manual compression around the pelvis, or with abdominal activation.[19] This test was also shown (test-retest reliability) to be associated with postpartum sacroiliac pain and dysfunction.[20, 21]

Unfortunately, clinical and diagnostic uncertainties remain and it is still difficult to identify a therapy able to meet patients' need for pain-relief, and above all biomechanical needs, by dealing with the possible origin of the complaint and its tendency to develop into chronic LBP.[18] Many treatments, with a symptomatic (antinflammatory) or a stabilising rationale, have been proposed,[22] including rest, systemic non steroidal antinflammatory drugs, injections, pelvic belts or specific exercises: the efficacy of none of these therapies have been proven through controlled studies. In particular, orthosis for sacroiliac dysfunction have been rarely employed in the literature,[20, 21, 23] mostly during peripartum pelvic instability.[24] On the other side, in everyday clinical practice in Italy, He-Ne laser is widely applied.

The aim of our study was to verify, in patients with acute or sub-acute LBP and positive sacroiliac signs,

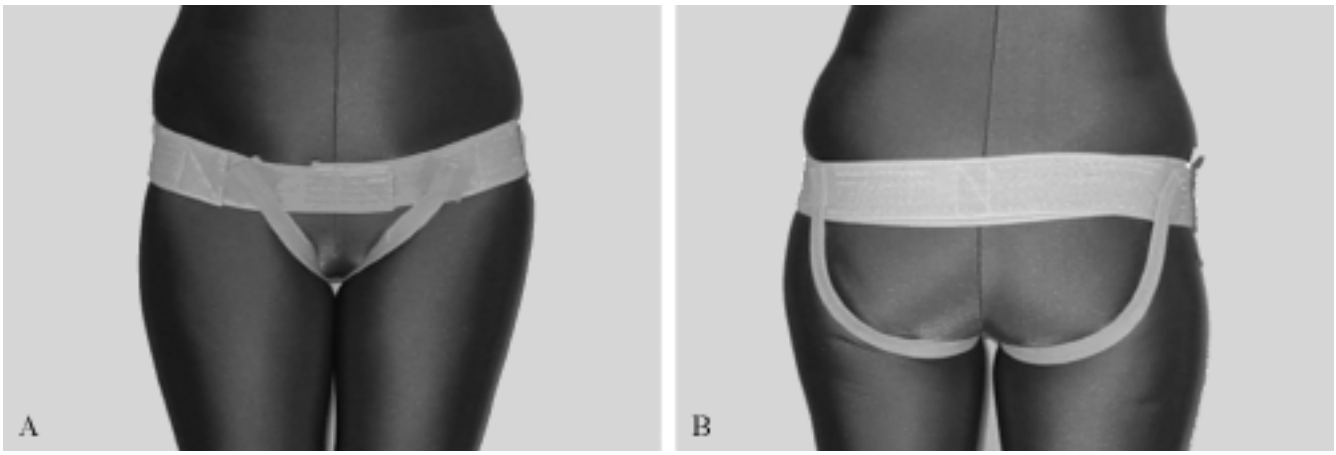

Figure 1. A) Sacro-iliac girdle (ILSA) anterior view. B) Sacro-iliac girdle (ILSA) posterior view.

the efficacy of a stabilising therapy directly targeted to sacroiliac dysfunction *versus* a symptomatic usual care such as He-Ne laser therapy. Thus, we developed a possibly specific approach to sacroiliac dysfunction, that combined a pharmacological local treatment to control pain and inflammation, with a biomechanical orthotic intervention through a sacroiliac belt, followed by specific stabilizing exercises and education. Secondary aim was to have some clues on the possible existence of sacroiliac dysfunction through this *ex-adjuvantibus* approach.

Materials and methods

Population

Four-hundred and forty-nine patients with LBP lasting 7 days to 3 months (acute and subacute [25]) were recruited during a 14 months period. All patients underwent a medical examination in order to highlight the following: case-history, presence and persistence of painful symptoms and their characteristic at rest, when changing posture and during walk, complete spine objective examination, legs peripheral neurological examination. Inclusion criteria were: LBP localised in one sacroiliac region; onset of pain in a period between 1 week and 3 months; clinical signs of sacroiliac dysfunction according to Laslett's pain-provocation tests,[14] and Mens's stability tests;[19] absence of clinical, radiographic and imaging evidence (CT or MRI scan) of any spinal or pelvic co-morbidity responsible for pain radiating through the sacroiliac region; no signs of cognitive deficiencies. Of the initial 449, 22 patients (12 males and 10 females, aged between 33 and 55, mean age 44) matched the inclusion criteria and were selected for the final study.

Therapy

After signing a consent form, patients were randomised, following the pair/unpair principle, into 2 groups.

Group laser (GL): 11 patients underwent an usual outpatient therapy with He-Ne laser therapy targeting the sacroiliac region. The 10 sessions were held daily, from Monday to Friday, for a total of 2 weeks.

Group stabilisation (GS): 11 patients underwent combined treatment with mesotherapy, specific dynamic sacroiliac support and exercises.

Mesotherapy

Mesotherapy sessions were held twice a week for a total of 8 sessions, ending the treatment after 4 weeks. Mesotherapy in-site drugs (NSAIDS) were used and administered through specific needles (Luer needles, 27 G and 0.4×4 mm).[26-28]

Sacroiliac girdle

Orthosis treatment was carried out on a daily basis, lasting for 4 weeks. The dynamic support (Figure 1) consisted of a special sacroiliac girdle (called ILSA) made of 5-cm high self-gripping elastic microfibre fabric. The sacroiliac girdle had an over-girdle applied at the centre and at the rear, of the same height and

TABLE I.—*Study of pain in the 2 groups of patients.*

		Group 1			Group 2		
		Median	Minimum	Maximum	Median	Minimum	Maximum
Pain at rest	Pre	7	5	9	7	5	9
	Post	7	6	8	2	0	4
	FU12	6	4	8	1	0	2
	p-value		<0.05			<0.05	
Pain during movement	Pre	9	8	10	9	8	10
	Post	5	4	6	2	1	3
	FU12	7	5	9	1	1	1
	p-value		<0.05			<0.05	
Pain on axial digitopressure	Pre	9	8	10	9	8	10
	Post	5	4	6	3	2	4
	FU12	7	6	8	2	1	3
	p-value		<0.05			<0.05	

made of the same material as the girdle, in order to enable it to be made tauter. The girdle also had 2 elastic thigh straps to prevent possible shifting of the dynamic support. All the closures and adjustable parts were designed with velcro strips.

EXERCISES AND EDUCATION

At the end of orthotic treatment, patients underwent 2 sessions to learn specific pelvic stabilizing exercises and receive postural education. We recommended all the patients to go on with daily exercises at least until follow-up were completed.

The patients were told how to activate and control their deep abdominal and lumbar multifidus (MF) muscles, explaining how these muscles act as stabilizers for the lumbar spine. The patients were taught how to activate the deep abdominal muscles together with relaxed breathing in different positions (supine, prone, four-point kneeling, sitting and standing). The activation of MF muscle together with the deep abdominal muscles was also trained. The physiotherapist controlled the patients by palpating the lower abdominal quadrant for deep tensioning of the abdominal muscles and, when requested, by palpating the MF. All the patients were finally instructed to use contraction of these muscles during daily living activities. They were encouraged to perform this training programme at home, every day.

Finally the patients received postural control advices.

Outcome criteria

Pain was evaluated before treatment, at the end, and at 6 and 12 month after treatment, as follow:

— pain at rest (visual-analogic scale, VAS);

— pain during movement (VAS);

— pain following axial pressure on the sacroiliac joint (VAS).

After treatment and at the 12 months follow-up, patients underwent a clinical complete re-assessment as that of the initial evaluation: in particular, we evaluated Laslett's pain-provocation tests,[14] and Mens's stability tests [19] as outcome criteria.

Analysis of data

Due to the distribution of the data, they were summarised and analysed using non parametric methods (median, range and Mann-Whitney test [29]). Software used included Excel 6.0 and Statgraphics 3.1.

Results

In our study 22 patients (4.9%), out of the original 449 acute and postacute LBP out-patients, matched the inclusion criteria suggesting a possible sacroiliac dysfunction. We found a statistically significant difference between the 2 groups in all parameters consid-

ered; a reduction of pain was achieved only in the GS (Table I). Laslett's pain-provocation tests, and Mens's stability tests were negative after the end of treatment as well as at the 12-month follow-up only in the GS, while remained positive at all assessments in all patients of GL. We did not have drop-out, nor we found problems both during patients selection and during trial development.

Discussion

Sacroiliac dysfunction can exist, even if today we have no definitive means to diagnose it. We identified a sub-group of patients with positive symptoms and signs for a possible sacroiliac joint dysfunction and proposed them a targeted treatment with positive results. This is a suggestion on the possibility that those patients really had a sacroiliac involvement. Data resulting from our trial demonstrate how sacroiliac joint syndrome is relatively significant (4.9%) when considering a wide population (449 subjects) of low back sub-acute patients: only the awareness of the principal sacroiliac tests described in literature helped us in the patients selection.

Today sacroiliac dysfunction management is mainly symptomatic: authors [22] advise relative rest, systemic non steroidal antinflammatory drugs, local steroid injections and pelvic belts. Conclusions drawn are inconclusive, and no elective therapy can be surely suggested to patients because of the absence of targeted controlled trials. Anyway, a correct approach should be advocated, when this disease is suspected. Unfortunately, there are several types of spine problems that can obscure and mime sacroiliac joint diseases: a misleading approach could lead to types of medical and rehabilitation treatments that differ radically from one another, not only in terms of medium and long-term therapeutic success, but also of prognosis. Furthermore, as already mentioned, sacroiliac dysfunction itself comprises several clinical tests, mostly reliable, that should not escape spine expert clinicians during their out-patient activities.

To our knowledge, this is the first randomized controlled trial on this topic, and this experience induced us to suggest that when diagnosing thoraco-lumbar and lumbar diseases, the possibility of an involvement of the sacroiliac joint should not be neglected. Clinical and statistical significance found was confirmed during follow-up sessions, proving how a correct intervention during acute and sub-acute phase is highly protective for chronic LBP onset and recurrences.

The usefulness of combining mesotherapy with an orthosis rely on the hypothesis of controlling pain and the possible underlying inflammatory process [30] together satisfying the biomechanical needs of pelvis and sacroiliac stability through the orthosis external support. This therapeutic approach was integrated with a specific rehabilitative programme, aimed at ensuring not only complete pain relief, but foremost the active stability of the elements possibly affected by the pathological process. Once pain phase has been overcome, patients took into consideration a specific rehabilitation treatment, with the goal of restoring the equilibrium of the structures responsible for maintaining the normal biomechanical situation. For these patients, it will be above all necessary to add specific exercises having the aim of stabilizing the lumbar-pelvic region in order to improve force closure:[31] exercises favouring vertebral stabilization claim to be introduced.[32] The last phase included education, helping patients also in terms of posture, ensuring early return to all daily and work activities.

Conclusions

A targeted approach based on mesotherapy, a specific sacroiliac belt and specific stabilizing exercises proved its efficacy in acute and sub-acute LBP patients with symptoms and signs suggesting a sacroiliac dysfunction. We suggest that, as soon as it will be possible to identify particular spine syndromes in the universe of non specific LBP, there will also be the possibility to employ specific therapies.

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