Journal of Back and Musculoskeletal Rehabilitation -1 (2022) 1–8 DOI 10.3233/BMR-210120 IOS Press

Effect of osteopathic manipulation of the sacroiliac joint vs electrotherapy on pain and functional disability in patients with low back pain: A pilot study

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Received 30 April 2021 Accepted 14 March 2022

Abstract.

BACKGROUND: One of the main problems faced by physiotherapists in primary care is low back pain with or without radiation to lower limbs. There are many different treatment approaches for the management of low back pain. Despite the large amount of published studies, the evidence remains contradictory.

OBJECTIVE: To evaluate the influence of the osteopathic manipulation of the sacroiliac joint on low back pain with or without radiation to lower limbs.

METHOD: Single-blind randomized clinical controlled trial. Participants with low back pain with or without lower limb radiation were randomized to osteopathic manipulation of the sacroiliac joint group (intervention, 6 sessions) or to an electrotherapy group (control, 15 sessions) for 3 weeks. Measures were taken at baseline (week 0) and post-intervention (week 4). The primary outcome measures were pain (Visual Analogue Scale), functional disability (Oswestry disability index and Roland Morris questionnaire). The secondary outcome measure was pain threshold at muscular tender points in the quadratus lumborum, pyramidal, mayor gluteus, and hamstrings.

RESULTS: In all, 37 participants completed the study. The results of the intragroup comparisons showed statistically significant improvements in both groups in the visual analogue scale (Osteopathic manipulation group, P = 0.000; Electrotherapy group, P = 0.005) and Oswestry disability index (Osteopathic manipulation group, P = 0.000; Electrotherapy group- P = 0.026) but not in the Roland Morris questionnaire (P = 0.121), which only improved in the intervention group (P = 0.012). The osteopathic manipulation was much more effective than electrotherapy improving to pain and functional disability.

CONCLUSION: Osteopathic manipulation of the sacroiliac joint improves pain and disability in patients with sacroiliac dysfunction after three weeks of treatment.

Keywords: Sacroiliac joint, low back pain, osteopathic manipulation of the sacroiliac joint, electrotherapy

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1. Introduction

One of the main problems faced by physiotherapists
in primary care is low back pain with or without radiation to lower limbs. It is estimated that 3–4% of the
primary care consultations of the Spanish health system
are due to low back pain, only surpassed in demand by
the common cold [1,2].

Between 80-85% of low back pain cases are of un-8 known origin [3,4]. The natural evolution of acute low 9 back pain is remission within six weeks in 75–90% 10 of the cases, regardless of the therapy approach used 11 for its management [5,6]. However, its high incidence 12 along with the low therapeutic effectiveness due to the 13 lack of knowledge of its cause means that the remaining 14 10-25% are at risk of developing chronic pain. This is a 15 serious health problem in todays' society, with great so-16 cial, occupational and economic repercussions as well 17 as professional, social and psychological consequences. 18 For instance, up to 29% of them end up diagnosed with 19 depression [7]. 20

It has been evidenced that many patients with acute
low back pain improve clinically without specific therapeutic treatment. In contrast, it is less clear why others
develop recurrent or chronic symptoms [5,7].

There are many different treatment approaches for 25 the management of low back pain. Despite the large 26 amount of published studies, the evidence remains con-27 tradictory [8]. Pharmacological treatments like NSAIDs 28 have shown positive results in acute low back pain 29 but not in chronic [9] pain. Conservative physiother-30 apy interventions (thermotherapy, laser, ultrasound, in-31 terferential currents, transcutaneous electrical nerve 32 stimulation-TENS, mechanical lumbar traction and 33 massage) have been studied and found to be ineffec-34 tive [10–12]. 35

In contrast, educational interventions, interdisci-36 plinary rehabilitation, cognitive-behavioral therapy, ex-37 ercise, manual therapy and spinal osteopathic manipula-38 tion [10,11,13] are among the recommended treatment 39 approaches. The systematic review conducted by Chou 40 et al. [13] showed evidence of the effectiveness of the 41 cognitive-behavioral therapy, the interdisciplinary reha-42 bilitation, the exercise and the spinal osteopathic ma-43 nipulation for the management of sub-acute or chronic 44 low back pain. In particular, spinal osteopathic manip-45 ulation is one of the techniques used to treat low back 46 pain [14] and is recommended by many clinical practice 47 guidelines [10–12]. 48 Researchers have suggested that alterations in the 49

⁵⁰ electrical activity of the muscle, the decrease of the

muscle inhibition, the reduction of reflex muscle spam and the increase of the joint range are some of the effects of spinal osteopathic manipulation that could explain the improvements achieved with this technique. These positive changes include the restoration of the range of movement of dysfunctional joints, the improvement of the muscle reflex responses, the reduction of the lower limb muscular inhibition and the improvement of movement symmetry [15–17].

In their clinical practice, physiotherapists find that the sacroiliac joint is one of the anatomical joints that most frequently need to be assessed in the objective evaluation of patients. This joint is recognised as a potential source of low back pain with or without radiation to lower limbs [18], between 15%-30% of the cases [19,20]. Sacroiliac joint syndrome has been described as pain and decreased mobility of the sacroiliac joint resulting from a mechanical disorder of the joint [17]. The sacro-iliac joint is considered a part of the lumbo-pelvic-hip complex which includes the fourth and fifth lumbar joints, the two hip joints and the symphysis pubis [17]. Thus, what one does affects the position and movement of the others [17]. In addition, studies that used fluoroscopically guided diagnostic intra-joint injections [21] indicate that the sacroiliac joint dysfunction has a prevalence of 13-30% in patients with chronic low back pain. Consequently, one of the treatment approaches within the current paradigm for the management of sacroiliac dysfunctions is the osteopathic manipulation of the sacroiliac joint [12].

The objective of this study was to assess the effectiveness of the sacroiliac joint osteopathic manipulation on low back pain with or without radiation to lower limbs, as well as to compare this treatment technique with an electrotherapy-based programme.

2. Materials and method

This was a single-blind randomized clinical controlled pilot study. Ethical approval was obtained from the Bioethical Commission of the University of Extremadura (Spain) and the National Health Service Bioethical Commission (Spain) (Registration number: 100/2016). All the ethical considerations and requirements of human clinical research mentioned in the Declaration of Helsinki were met. The trial was registered with the ClinicalTrials.gov registry (Study Identifier: NCT03794830). Written informed consent was obtained from all participants.

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98 2.1. Participants and procedures

A total of 151 patients with low back pain referred 99 to the Physiotherapy Unit of the Gévora Health Cen-100 tre (Extremadura, Spain) by a primary care physician. 101 The inclusion criteria were: patients aged between 18-102 70 years old diagnosed with low back pain with or 103 without radiation to lower limbs, sacroiliac joint dys-104 function or hypo mobility, to have stopped taking anti-105 inflammatory medicines or analgesics three days before 106 the commencement of the study. The exclusion criteria 107 were: to present any contraindication for osteopathic 108 manipulation of the sacroiliac joint such as the follow-109 ing medical conditions: spine and pelvis destructive in-110 juries, fractures, lumbar surgery, sacroiliac instability, 111 spondylolisthesis, pregnancy, cauda equina syndrome, 112 abdominal aneurysm, infection, inflammatory arthritis, 113 tumours or osteoporosis. 114

Measures were taken at baseline (week 0) and post 115 intervention (week 4). The evaluation was performed 116 the day after the end of the sessions to avoid immediate 117 post-intervention effects. As the last session was held 118 on the last day of week 3, the evaluation started in week 119 4. The primary outcome measures were pain measured 120 with the Visual Analogue Scale (VAS) [15] and func-121 tional disability assessed with the Oswestry disability 122 index [17] and Roland Morris questionnaire [10]. The 123 secondary outcome measure was pain threshold at mus-124 cular tender points [17] in the quadratus lumborum, 125 pyramidal, mayor gluteus and hamstrings which was 126 evaluated with the Wagner digital algometer, (FPIX 127 model). The sacroiliac dysfunction was assessed at the 128 baseline measurement. The assessor was independent 129 to the study and therefore, blinded to group allocation. 130

After the first assessment, the participants were ran-131 domly allocated to an osteopathic manipulation group 132 (intervention group) and to an electrotherapy group 133 (control group). A computer random number generator 134 was used to produce even allocation ratios by using the 135 IBM SPSS 23 statistical package. The randomisation 136 list was held by an independent researcher who was 137 unrelated to any aspect of the trial. 138

The osteopathic manipulation group patients were 139 treated with a semi-direct osteopathic manipulation of 140 the sacroiliac joint. The technique was performed with 141 the patient in side lying and with the pelvis in oblique 142 position. The physiotherapist hands were placed on the 143 patient's shoulder and on the posterior-superior iliac 144 spine (Fig. 2). The treatment sessions were carried out 145 twice a week every 3 to 4 days over a period of time 146 of 3 weeks (a total of 6 sessions). The electrotherapy 147

group patients followed the electrotherapy protocol of 148 the Physiotherapy Unit. This protocol included the ap-149 plication of microwaves (circular antenna in lumbar 150 area, pulsating-mode 120W for 12 minutes) followed by 151 the application of conventional analgesic TENS (80 Hz 152 frequency, 30 minutes). This method has been used for 153 two main reasons: the patient's high tolerance and the 154 rapidity in which analgesic effects appeared. The elec-155 trotherapy treatment was carried out 5 days per week 156 over a period of time of 3 weeks (15 sessions). 157

The participants did not receive any other treatment during the intervention. They stopped their medication (analgesics and anti-inflammatories) three days before the commencement of the study. Due to the nature of the treatment, neither the participants nor the therapist were blinded to the group assignment. Both treatments were performed by a qualified physiotherapist member of the Spanish Chartered Society of Physiotherapists, trained in joint osteopathic manipulation and electrotherapy and with extensive experience in the field.

2.2. Statistical analysis

The collected data was analysed with the SPSS 23.0 169 version (Statistical Package for the Social Sciences). 170 For the statistical analysis, intragroup comparisons were 171 carried out, i.e. within the same group and the time 172 factor (pre and post-intervention), and intergroup com-173 parisons, that is to say, between the participants of 174 both groups and the group factor. Normative distribu-175 tion was evaluated using the Shapiro-Wilk test. The 176 intragroup analysis was performed using the Wilcoxon 177 signed rank test for non-parametric related samples 178 and the intergroup analysis was calculated through the 179 Mann-Whitney U test (non-parametric test) for all the 180 outcome measures. In order to analyse if there were 181 variables that influenced pain reduction and disability 182 in the osteopathic manipulation group, the Spearman's 183 correlation coefficient between two ranked variables 184 was used for quantitative variables. 185

A value of P < 0.05 was considered for statistical significance for all tests. A 95% confidence interval was also established. The results were analysed by a different blinded researcher.

Accepting an alpha risk of 0.05 and a beta risk of 0.2 in a two-sided test, 12 subjects were necessary in the first group and 12 in the second to recognize as statistically significant a difference greater than or equal to 15 units [22]. The common standard deviation was assumed to be 10 and the correlation coefficient between the initial and final measurement as 0.35 [23].

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Fig. 1. CONSORT flowchart of the study.

3. Results 197

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Out of the 151 participants recruited, 41 met inclu-198 sion criteria and the final study sample consisted of 37 199 patients (Fig. 1). Participant characteristics were well 200 balanced between arms at baseline (Table 1). The par-201 ticipants had the following clinical presentation: 4 pa-202 tients had low back pain, 20 patients had lumbo-pelvic 203 or pelvic pain, 8 patients had lower limb irradiation 204 above the knee and 5 patients had lower limb irradiation 205 below the knee. 206



Table 2 shows the results obtained in relation to pain 208 and disability. The data suggest that osteopathic ma-209 nipulation is much more effective than electrotherapy 210 when it comes to pain relief and disability reduction in 211 patients with low back pain with or without radiation to 212 the lower limbs. 213

The results related to the muscle pain threshold as-214 sessment did not show statistically significant differ-215 ences between both groups for any of the evaluated 216 muscles (right quadratus lumborum: P = 0.273; left



Fig. 2. Osteopathic manipulation of the sacroiliac joint.

quadratus lumborum: P = 0.463; right pyramidal: P =0.782; left pyramidal: P = 0.732; right mayor gluteus: P = 0.386; left mayor gluteus: 0.0386; right hamstrings: P = 0.613; left hamstrings: P = 0.424).

In order to determine the existence of variables that could indicate when could be appropriate to apply an osteopathic manipulation of the sacroiliac joint and for which type of low back pain could be useful, the correlation of all the pain and disability outcome measures in both groups was analysed. The results of this analysis showed statistically significant changes in the os-

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Table 1 Baseline characteristics of the participants							
	Osteopathic manipulation group $(n = 20)$ Mean \pm SD	Electrotherapy group ($n = 17$) Mean \pm SD	p value				
Mean age (years)	37.89 ± 12.84	30.59 ± 11.20	0.682				
Height (cm)	170.42 ± 0.14	169.35 ± 0.20	0.223				
Weight (kg)	74.33 ± 5.12	72.23 ± 2.27	0.167				
Body mass index (kg/m ²)	25.95 ± 5.93	24.78 ± 2.23	0.214				
Pain (VAS)	5.41 ± 1.54	5.65 ± 1.61	0.53				
Disability (Oswestry disability Index)	28.15 ± 9.31	31.62 ± 12.20	0.50				
Disability (Roland Morris questionnaire)	8.39 ± 4.73	9.06 ± 5.36	0.71				
Muscle pain threshold (right lumbar quadratus)	3.12 ± 0.90	2.67 ± 1.02	0.18				
Muscle pain threshold (left lumbar quadratus)	3.12 ± 0.95	3.67 ± 0.80	0.61				
Muscle pain threshold (right pyramidal)	2.94 ± 0.91	2.85 ± 0.89	0.81				
Muscle pain threshold (left pyramidal)	3.21 ± 0.73	2.89 ± 0.80	0.15				
Muscle pain threshold (right upper gluteus maximus)	3.78 ± 0.41	3.61 ± 0.64	0.64				
Muscle pain threshold (left upper gluteus maximus)	3.75 ± 0.40	3.70 ± 0.43	0.66				
Muscle pain threshold (right hamstring)	3.49 ± 0.94	3.65 ± 0.42	0.55				
Muscle pain threshold (left hamstring)	3.57 ± 0.80	3.76 ± 0.32	1				

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cm: centimeters; Kg: kilograms; m: meters; SD: Standard Deviation; *p < 0.05: Statistical significance.

	Pa	Table 2 ain and disability intergr	oup assess	ment				
Post-intervention v	ariables	Osteopathic manipulation group $(n = 20)$ Mean \pm SD)) Electrotherapy g Mean ±	Electrotherapy group $(n = 17)$ Mean \pm SD		p value	
Final VAS		1.60 ± 1.59		$4.13 \pm$	4.13 ± 2.02		*	
Final Oswestry disabili	ity index	10.50 ± 8.19		$27.91 \pm$	27.91 ± 13.93		0.000^{*}	
Final Roland Morris qu	al Roland Morris questionnaire 3.78 ± 3		$8.24 \pm$	8.24 ± 4.96		0.005*		
	Pa	Table 3 ain and disability intragr	oup assess	ment				
	Osteopathic m	anipulation group ($n =$	Electrothe	Electrotherapy group ($n = 17$) Mean \pm SD				
	Preint. Mean \pm SD	Postint. Mean \pm SD	p value	Preint. Mean \pm SD	Postint. Mean	\pm SD	p value	
AS	5.41 ± 1.54	1.60 ± 1.59	0.000*	5.65 ± 1.61	4.13 ± 2.0)2	0.005*	
swestry disability index	28.14 ± 9.30	10.50 ± 8.19	0.000^{*}	31.62 ± 12.20	27.91 ± 13.0	.93	0.026*	
oland Morris questionnaire	8.39 ± 4.73	3.78 ± 3	0.01*	9.06 ± 5.35	8.24 ± 4.9	96	0.121*	

Note. Preint = preintervention; Postint = postintervention; SD = standard deviation; *p < 0.05 = statistical significance.

teopathic manipulation group: the pain threshold in-229 creased when applying pressure in the right quadratus 230 lumborum (P = 0.010) and the right pyramidal (P =231 0.013) for the variable VAS. On the other hand, disabil-232 ity decreased in the Roland Morris questionnaire (right 233 quadratus lumborum P = 0.012; right pyramidal P =234 0.014).

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3.2. Intragroup analysis 236

The analysis of pain and disability is shown in Ta-237 ble 3. Statistically significant results were obtained in 238 both groups for all variables except for the Roland Mor-239 ris questionnaire that was only significant in the osteo-240 pathic manipulation group. 241

The data also indicated that, at the end of the in-242

tervention (post-intervention), the pain threshold at all 243 the muscular tender point assessed was significantly 244 increased in the osteopathic manipulation group (right 245 quadratus lumborum: P = 0.006; left quadratus lum-246 borum: P = 0.028; right pyramidal: P = 0.002; left 247 pyramidal: P = 0.002; right mayor glute: P = 0.043; 248 left mayor glute: P = 0.028; right hamstrings: P =249 0.028; left hamstrings: P = 0.028). In the electrother-250 apy group, there was a quantitative increase of the mus-251 cle pain threshold which was statistically significant 252 for the right pyramidal (P = 0.008), the left pyramidal 253 (P = 0.033) and the left mayor gluteus (P = 0.028). 254

4. Discussion

The results of our study showed that, according to 256

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the changes obtained in the Oswestry disability index, 257 both treatment techniques used, osteopathic manipula-258 tion and electrotherapy, improved significantly pain and 259 disability. However, on the Roland Morris question-260 naire, only the positive changes related to osteopathic 261 manipulation were significant. In addition, the inter-262 group analysis revealed that osteopathic manipulation 263 was more effective for pain and functional disability 264 than electrotherapy treatment. The Oswestry disability 265 index is considered the best option for patients with 266 greater impairment (moderate-intense disability), as it 267 discriminates better the differences in functional dis-268 ability in the most affected patients, while the Roland 269 Morris questionnaire is recommended in patients with 270 less functional limitation, with the manipulation be-271 ing effective in patients with greater or lesser impair-272 ment [17]. In contrast, electrotherapy only proved to 273 be effective on the Oswestry disability index, i.e. when 274 patients are more affected. Given these results, in the 275 case of patients with little functional limitation, the use 276 of osteopathic manipulations would be more indicated. 277 To date, no study that specifically compares osteopathic sacroiliac joint manipulation with electrotherapy 279 in the management of low back pain has been found 280 in the literature. However, osteopathic sacroiliac joint 281 manipulation has been studied and compared with other 282 treatment techniques. Wreje et al. [24] conducted an 283 intervention in primary care with 39 patients with acute 284 low back pain. They compared osteopathic sacroiliac 285

joint manipulation with different manual interventions 286 with placebo consisting of transverse massages on glu-287 teus medius for 3 minutes. The therapist in charge in the 288 patient's clinic could decide whether to apply a sacroil-289 iac manipulation (the same technique used in our study), 290 or to apply joint mobilisations combined with stretch-291 ing. Pain was measured using the VAS. Regarding the 292 medication, the use of paracetamol was recommended 293 in both groups. The results obtained showed that os-294 teopathic manipulation reduced pain and medication 295 intake as compared to the control group. 296

There are other studies carried out in a primary care 297 health setting that have shown the benefits of apply-298 ing osteopathic manipulation in patients with low back 299 pain. Fritz et al. [25] conducted a clinical trial based on 300 postural education and hygiene and found significant 301 improvements in pain after at the measurements per-302 formed at week 4 and 12. A clinical trial carried out in 303 the United Kingdom [26] compared two study groups. 304 One group received osteopathic manipulation combined 305 with exercise and the other group performed only ex-306 ercise. Both groups improved on the Roland Morris 307

questionnaire scores at 3 and 12 months, whereas the exercise-only group just had a small benefit at 3 months.

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In the systematic review conducted by Licciardone 310 et al. [27], the effectiveness of acute and chronic low 311 back pain osteopathic manipulation was assessed. The 312 analysis of the included studies evidenced its effective-313 ness on pain relief in the short (1 month), medium (3 314 months) and long term (12 months) versus the placebo 315 control groups. The manipulation decreased the drug 316 intake or led to drug withdrawal in some of the clinical 317 trials [27]. 318

There are important differences between our research and those clinical trials conducted in primary care, as well as with Licciardone et al. [27] systematic review clinical trials: in most of the studies drug intake was allowed and the rest was not specified. We consider that drug intake could influence the results of the interventions. In this respect, we were very strict in the selection criteria of our study to avoid the possibility that the benefits obtained from the manipulation may be due to the medication, as scientific evidence has demonstrated [10].

Additionally, we only chose one possible technique 330 to treat sacroiliac joint dysfunction based on osteo-331 pathic manipulation. The approach of some clinical tri-332 als to use different techniques with different biomechanics and neurophysiological effects made difficult 334 the comparison of results. Molins-Cubero et al. [28] 335 investigated the effect of global bilateral osteopathic manipulation on both sacroiliac joints versus placebo (osteopathic manipulation simulating position held for 338 2 minutes) on low pelvic and lumbar pain in women 339 with dysmenorrhea. The manipulation was effective and achieved a significant improvement in pain and sensi-341 tivity in both sacroiliac joints measured with algometry 342 pressure, as it is shown in our study. One of the limits of their study was that anti-inflammatory medication intake was not controlled.

There is some controversy with regards to the effectiveness of the manipulation versus electrotherapy. The review carried out by Chou et al. [13] found good evi-348 dence that supported the effectiveness of manipulation 349 in the treatment of acute and chronic low back pain, 350 in comparison to microwaves and TENS. In contrast, Anderson et al. [29] did not find difference between 352 osteopathic manipulation and standard allopathic treatment with medication and physiotherapy (diathermy, TENS and ultrasound among others). According to their criteria, the physical therapist may decide which area 356 should be treated and which osteopathic manipulation 357 technique should be used. These techniques could be

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a thrust, a muscle energy technique or a myofascial 359 release. As previously mentioned, the use of different 360 biomechanics and neurophysiological techniques which 361 have different effects may alter the result. Furthermore, 362 if the treated areas differ, the results will also differ. This 363 was revealed by Chiradejnant et al. [30] who achieved 364 different results in their study results depending on 365 whether they treated the upper or lower back. There-366 fore, in our study, the intervention involved the use of 367 the same osteopathic manipulation technique only in 368 the sacro-iliac joint for treatment of all participants. 369

The results obtained indicate that the spinal mobilisa-370 tion applied to the lower lumbar spine levels was asso-371 ciated with greater pain relief than when applied to the 372 upper lumbar spine levels on five outcome measures: 373 current pain intensity was reduced by 0.5 units more 374 on the 0–10 Scale (p = 0.01), pain intensity at most 375 painful movements was reduced by 0.5 units more on 376 the 0 to 10 scale (p = 0.01), the percentage of current 377 pain intensity was reduced by 15% more (p < 0.001), 378 the percentage of pain intensity at the subject's worst 379 movement was reduced by 14% more (p < 0.001), and 380 the overall perceived effect improved by 0.4 units more 381 on the -5 to 5 scale (p = 0.04). We consider that the re-382 sults of the present study support the use of osteopathic 383 manipulation of the sacroiliac joint in patients with low 384 back pain and sacroiliac joint dysfunction as this treat-385 ment technique has shown a better effect on pain and 386 disability than electrotherapy. In addition, osteopathic 387 manipulation required less treatment sessions to achieve 388 pain the improvements (6 sessions maximum) as com-389 pared to the electrotherapy group (15 sessions) with im-390 plies a lower cost and sanitary expenditure. Therefore, 391 the results of our study have important implications 392 in the rehabilitation field and we consider that osteo-393 pathic manipulation should be included in the treatment 394 protocols for the management of low back pain in the 395 Physiotherapy units as recommended in diverse clinical 396 guidelines [10,13]. 397

4.1. Limitations 398

One of the limitations of the study is the use of pal-399 pation tests as they can have a low reliability. However, 400 in order to minimise this limitation, we used a battery 401 of tests proposed and used by most researchers [31–33]. 402 Future research should focus on prospective long-403 term studies in order to observe how long the effects 404 of osteopathic manipulation of the sacroiliac joint last 405 in the patients during the first post-treatment trimester. 406 This would allow to reach more solid conclusions. 407

5. Conclusion

Based on the results of the present study, both osteo-409 pathic manipulation and electrotherapy treatments are 410 effective in reducing pain and disability in patients with 411 low back pain with or without radiation to lower limb 412 in the presence of sacroiliac dysfunction. However, the 413 results showed greater effectiveness in the osteopathic 414 manipulation group. It would be advisable for treatment 415 protocols for low back pain with or without lower limb 416 irradiation to include osteopathic manipulation of the 417 sacroiliac joint if the patients present sacroiliac joint dysfunction.

Conflict of interest

None to report.

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